

RÉPUBLIQUE ALGÉRIENNE DÉMOCRATIQUE ET POPULAIRE
MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR ET DE LA
RECHERCHE SCIENTIFIQUE
ÈCOLE NATIONALE POLYTECHNIQUE



المدرسة الوطنية المتعددة التقنيات
Ecole Nationale Polytechnique

sanofi

**Département de Maîtrise des Risques Industriels et Environnementaux
Specialty: QHSE-GRI**

**End of Studies Project Thesis
In fulfillment of the requirements for: QHSE-GRI Engineer's Degree**

**Chemical Risk Assessment using the NIOSH Method
at Sanofi Sidi Abdellah Site**

MERIEM Hiba & NOUARA Hind

Directed By:

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**Presented and defended publicly on 8-07-2024 in front of the jury composed
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ENP 2024

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**Département de Maîtrise des Risques Industriels et Environnementaux
Spécialité : QHSE-GRI**

**Mémoire de Projet de fin d'Études
Pour l'obtention du Diplôme d'Ingénieur d'État en QHSE-GRI**

**Évaluation des Risques Chimiques selon la Méthode
NIOSH sur le Site de Sanofi Sidi Abdellah**

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ملخص

يواجه الموظفون في سانوفي سيدي عبد الله مخاطر صحية كبيرة بسبب التعرض للمواد الكيميائية الخطرة مثل المكونات الدوائية الفعالة (API) والمواد المسرطنة والمطفرة والسامة للتكاثر (CMRs). تفتقر ممارسات تقييم المخاطر الحالية إلى نهج منهجي لتحديد أولويات المخاطر الكيميائية، مما يؤدي إلى عدم الكفاءة في تنفيذ تدابير التحكم وتوحيد إجراءات التشغيل القياسية.

يهدف العمل الحالي إلى إجراء تقييم NIOSH للمخاطر الكيميائية ذات الطابع النوعي في موقع سانوفي سيدي عبد الله لتحديد وتحديد أولويات وإدارة المخاطر الكيميائية المرتبطة بالتعرض للجلد والتنفس. سيوجه هذا التقييم تطوير خطة عمل تشمل التقييمات الكمية ذات الأولوية، وتدابير التحكم، وإجراءات التشغيل القياسية الموحدة.

الكلمات المفتاحية: تقييم المخاطر الكيميائية، APIs، CMRs، NIOSH، SOPs.

Résumé

Les employés de Sanofi Sidi Abdellah sont exposés à des risques significatifs pour la santé en raison de l'exposition à des produits chimiques dangereux tels que les Ingrédients Pharmaceutiques Actifs (APIs) et les agents Cancérigènes, Mutagènes et Reprotoxiques (CMRs). Les pratiques actuelles d'évaluation des risques manquent d'une approche systématique pour hiérarchiser les dangers chimiques, ce qui entraîne des inefficacités dans la mise en œuvre des mesures de contrôle et la standardisation des procédures opérationnelles.

Le présent travail vise à mener une évaluation qualitative NIOSH des risques chimiques au site de Sanofi Sidi Abdellah pour identifier, prioriser et gérer les risques chimiques liés à l'exposition par inhalation et cutanée. Cette évaluation orientera l'élaboration d'un plan d'action comprenant des évaluations quantitatives prioritaires, des mesures de contrôle et des SOPs standardisés.

Mots-clés: évaluation des risques chimiques, NIOSH, APIs, CMRs, SOPs.

Abstract

Sanofi Sidi Abdellah employees face significant health risks due to exposure to hazardous chemicals such as Active Pharmaceutical Ingredients (APIs) and Carcinogenic, Mutagenic, and Reproductive toxicants (CMRs). Current risk assessment practices lack a systematic approach for prioritizing chemical hazards, leading to inefficiencies in implementing control measures and standardizing operating procedures.

The present work aims to conduct a NIOSH qualitative chemical risk assessment at Sanofi's Sidi Abdellah site to identify, prioritize, and manage chemical risks associated with inhalation and dermal exposure. This assessment will guide the development of an action plan, including prioritized quantitative assessments, control measures, and standardized SOPs.

Keywords: chemical risk assessment, NIOSH, APIs, CMRs, SOPs.

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A special thought is addressed to all the professors of the MRIE Department of the National Polytechnic School and to the students we interacted with daily during our years of study, who provided moral and intellectual support throughout our thesis.

Finally, may everyone who contributed, directly or indirectly, to the completion of this work find here the expression of our sincere gratitude

Dedications

*To all those who believed in me, even for just a day,
Your support means more than words can express.
With deepest gratitude.*

Hind

To my beloved parents, whose boundless love, sacrifices, and unwavering belief in my dreams have shaped the person I am today.

To my dear brother and sister, your encouragement, support, and endless belief in me have been my pillars of strength.

To my cherished friends, your companionship, laughter, and faith in my abilities have lifted me through every challenge.

And to all those who have believed in me, whether near or far, your encouragement has been a beacon of hope and inspiration.

This thesis is dedicated to each of you with deepest gratitude and love, without your presence in my life, this journey would not have been as meaningful or fulfilling.

Hiba

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List of Acronyms

| | |
|--------------|---|
| API | Active Pharmaceutical Ingredient |
| CAS | Chemical Abstracts Service |
| CMR | Carcinogenic, Mutagenic, or Reprotoxic |
| FY18 | fiscal year 2018 |
| DRAM | Dermal Risk Assessment Model |
| EDA | Environmental Protection Agency |
| HEG | Homogeneous Exposure Group |
| HSE | Health, Safety, and Environment |
| IH | Industrial hygiene |
| LEV | Local Exhaust Ventilation |
| LOTO | Lockout/Tagout |
| NIOSH | National Institute for Occupational Safety and Health |
| OEB | Occupational Exposure Band |
| OEL | Occupational Exposure Limit |
| OSHA | Occupational Safety and Health Administration |
| PPE | Personal Protective Equipment |
| PTW | Permit to Work |
| QRA | Qualitative Risk assessment |
| RM | Raw Material |
| SAA | Sanofi Aventis Algeria |
| SDS | Safety Data Sheet |
| SOP | Standard Operating Procedure |
| WHO | World Health Organization |

General introduction

The pharmaceutical industry is a complex and dynamic sector involving various chemicals essential for producing life-saving medications. However, these chemicals also pose significant risks to workers if proper safety measures are not in place. Chemical exposure within pharmaceutical operations can lead to immediate health concerns such as respiratory issues or skin irritations, and long-term implications like chronic illnesses or carcinogenic effects .[1]

Identifying chemical risks in a pharmaceutical plant is crucial for several reasons. Firstly, it significantly improves employee safety and well-being by reducing the likelihood of accidents or exposure to hazardous chemicals, thereby increasing productivity. Secondly, minimizing chemical risks helps reduce potential environmental contamination, which is crucial for preserving the natural environment and public health. Lastly, it ensures that pharmaceutical products are of high quality and meet regulatory requirements, essential for maintaining consumer trust and preventing costly recalls or legal issues .[1]

Statistics on occupational diseases underscore the urgency of this endeavor. According to the World Health Organization (WHO), occupational health problems contribute to significant economic losses, accounting for 4-6% of GDP in many countries[2] . These numbers highlight the significant impact of chemical exposures on employee health and well-being, emphasizing the critical importance of effective risk management practices.

The safe handling of hazardous drugs includes using appropriate personal protective equipment (PPE), proper training for staff, and implementing engineering controls. These measures are essential to prevent occupational exposure and ensure the safety of healthcare workers handling toxic drugs.

To address these risks effectively, our thesis emphasizes the importance of conducting comprehensive chemical risk assessments tailored to the Sanofi Sidi Abdellah site. Through qualitative analyses, we aim to gain a nuanced understanding of the chemicals used, their properties, and potential routes of exposure for employees. By identifying and prioritizing mitigation strategies based on these assessments, we seek to minimize the likelihood of chemical-related occupational illnesses. Our thesis will be divided into five chapters:

In the first chapter, we introduce Sanofi, Sanofi Algeria, and specifically Sanofi Sidi Abdellah. We detail the medications manufactured and the processes involved. Additionally, we define the problem statement, outline the methodology used, and specify the objectives of the thesis.

In the second chapter, we conduct a comprehensive literature review on chemical risks, focusing on current research and practices. We also delve into the NIOSH qra for assessing chemical hazards.

In the third chapter, we present the tools utilized in conducting the qualitative risk assessment. Detailed findings from the assessment are provided in annexes, and an in-depth analysis of these results is included.

In the fourth chapter, we outline the action plan derived from the qualitative assessment. This plan discusses the implementation of the hierarchy of control to mitigate identified risks.

In the fifth chapter, the focus is on the updated Standard Operating Procedures (SOPs). We present the revised SOPs, highlighting the objectives behind the updates and discussing the specific elements that have been revised to enhance chemical safety and operational efficiency. Finally, a general conclusion summarizing the results will conclude this work.

Chapter 1

The Company Presentation

In this chapter, we will introduce Sanofi Algeria, detailing the production of medications in solid, liquid, and sachet forms, as well as the processes involved in their manufacturing. Following this introduction, we will outline the problematic addressed in our project, state our objectives, and explain the methodology we have employed.

1.1 Presentation of Sanofi

Sanofi is one of the largest healthcare companies worldwide, ranking ninth in 2024 according to Pharm Exec's latest listing [3]. This French-based multinational biopharmaceutical company specializes in researching, developing, manufacturing, and selling medical products such as drugs and vaccines. With a global presence in more than 110 countries and boasting over 105,000 employees. Sanofi operates across five key areas of care:

1. **General Medicine and Emerging Markets:** This segment comprises mature products, generics, and pharmaceuticals in emerging markets. It contributed approximately \$12 billion, accounting for 38% of Sanofi's revenues in 2018 alone.[4]
2. **Specialty Medicine (Sanofi Genzyme):** This division focuses on medications used to treat rare diseases, generating \$6.6 billion, or 21% of the company's revenue during the same year.[4]
3. **Vaccines (Sanofi Pasteur):** Responsible for managing all vaccine-related activities, Sanofi Pasteur represents approximately \$4.7 billion, or 15% of the total revenues earned by Sanofi in FY18.[4]
4. **Diabetes and Cardiovascular Diseases:** This area includes diabetes treatments and cardiovascular medications valued at approximately \$4 billion, equivalent to 13% of Sanofi's sales recorded during the twelve months ending December 31st, 2018.[4]
5. **Consumer Healthcare:** Generating around \$3.9 billion, equivalent to 13% of the firm's sales recorded during the twelve months ending December 31st, 2018.[4]

1.1.1 Historical Background

Sanofi was founded in 1973, a branch of ELF Aquitaine known as Omnium Financier Aquitaine for Hygiene and Health. In 2004 it merged with Franco-German pharmaceutical company Aventis to become Sanofi-Aventis. The following year, in 2011, Genzyme was purchased by Sanofi and the company's name changed again.[5] We illustrate the history of Sanofi in the following Figure 1.1.

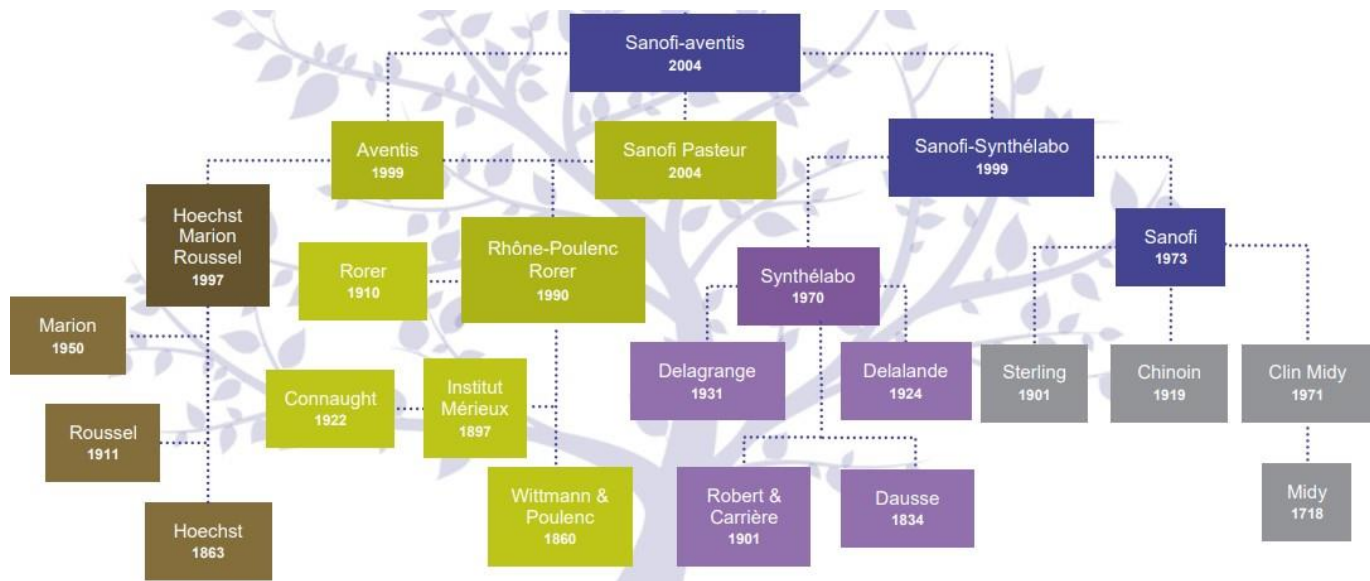


Figure 1.1: The history of Sanofi[6]

1.2 Sanofi HSE Management System

1.2.1 Overview of the HSE Management System

The Sanofi HSE Management System is a set of requirements arranged into a pyramid to reflect the ownership and maintenance of the various documents as well as the level of detail and coverage of the document.[6]

The global HSE Manual, including the HSE Key Requirements, are the full set of applicable and auditable requirements for all sites. Applicability of the specific requirements is context-dependent. The global HSE standards are mandatory and auditable in each site/affiliate where the topic is applicable. They usually require a local SOP for implementation. Supporting Documents may be attached to Standards and to Operational Procedures. It is specified in the main document if such a supporting document is mandatory or informational. Other types of informational documents are published (Global HSE Guides, Toolboxes, Practices). They either explain methodologies or give more details on a specific topic.[6]

The HSE Management System encompass:

- **the organization (who is doing what)[6].**
- **the processes (what, when and how).[6]**
- **the structure (the set of documents).[6]**

1.2.2 Sanofi HSE Policy

The HSE Policy establishes a framework for the actions that the Group implements for both employees and external partners. This policy is represented in the following Figure 1.2.



Figure 1.2: Sanofi HSE Policy[6]

1.2.3 Structure of Sanofi HSE Management System

The structure of the HSE Management System is based on the international standards management systems principles and designed with a Plan – Operate – Monitor – Improve structure (this is equivalent to the improvement management approach known as Plan- Do-Check-Act or PDCA cycle).[7]

The Sanofi HSE Management System is divided into the following elements:

1. Leadership & Governance

Management demonstrates visible leadership in HSE and supports HSE strategies, policies, and plans as well as defining HSE roles & responsibilities for all employees.[7]

2. Plan

A risk-based approach is developed to enable the establishment of comprehensive objectives and plans to improve risk management and to ensure compliance with applicable regulations and conformance to internal requirements.[7]

3. Operate

Operational controls, procedures, and processes are implemented to ensure safe work practices and effective control of risks.[7]

4. Monitor

HSE results are monitored on an ongoing basis to measure the performance against objectives and targets. Audits are performed to evaluate the system's effectiveness.[7]

5. Improve

Regular management reviews are performed to ensure the achievement of targets. Corrective and preventive actions are implemented to drive continual HSE performance improvement. A Learning Experience process is in place to ensure continuous improvements following events.[7]

6. Support

Processes and programs are in place to ensure adequate document management, employee competencies, and communication of progress towards achieving the desired level of HSE performance.[7]

1.3 Presentation of Sanofi Algeria

Sanofi Algeria, a subsidiary of the global pharmaceutical company Sanofi Group, has been actively operating in Algeria's pharmaceutical sector since 1991. The company employs more than 900 personnel across its multiple subsidiaries, providing a diverse range of over 135 pharmaceutical products tailored to meet the healthcare needs of patients and stakeholders in Algeria.[8]

Sanofi Algérie operates two significant production units:

- Sanofi Winthrop Pharma Sidal Oued S'Mar (WPS).
- Sanofi Aventis Sidi Abdellah.

1.3.1 Overview of the Sidi Abdellah Site

The Sidi Abdallah site is dedicated to manufacturing and packaging solid, liquid, and suppository pharmaceutical forms, as well as distributing pharmaceutical products for the Algerian market. Spanning 66,000 m², with 33,000 m² of built-up area.[8] represented in Figure 1.3.

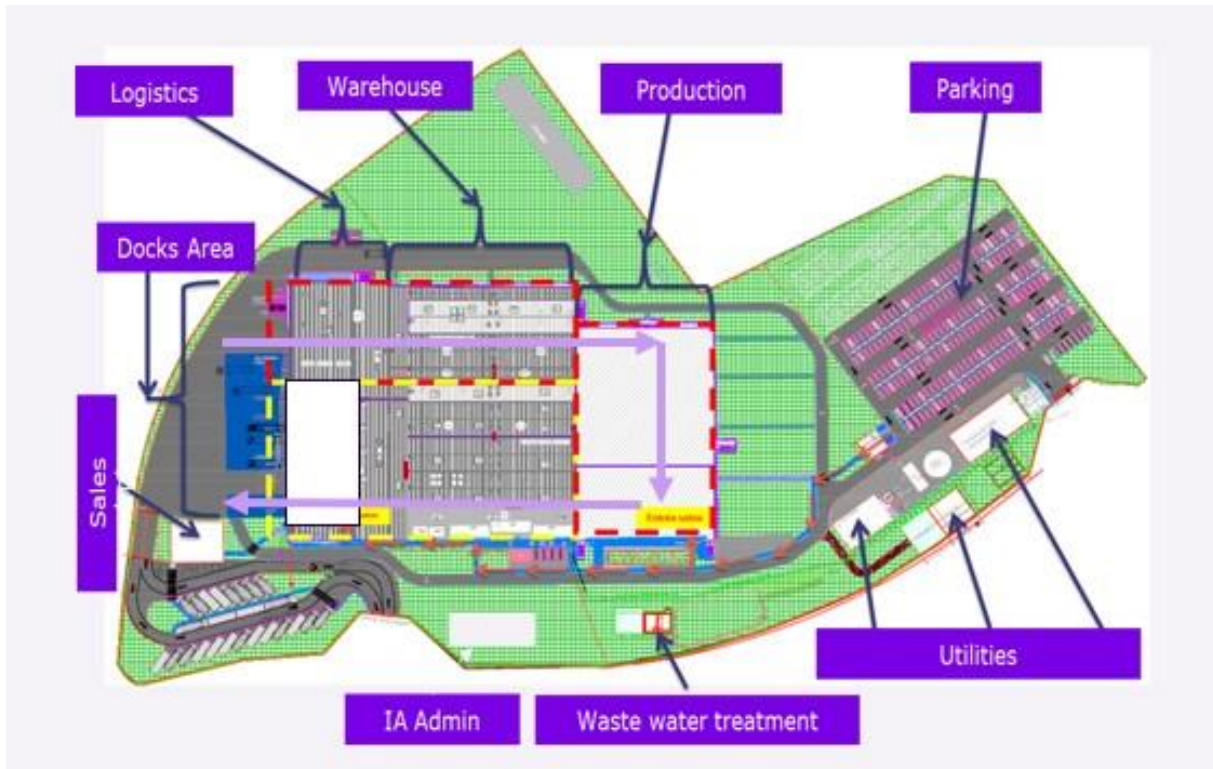


Figure 1.3: Site Plan of Sanofi Sidi Abdellah, Algeria[6]

1.3.2 Site Operations and Objectives

The site commenced operations in December 2017 for distribution and initiated production validation in November 2019. The storage facilities can hold 5,000 pallets for raw materials and packaging articles, along with a distribution warehouse with a capacity of 10,000 pallets for finished products in Algeria. The site is projected to produce approximately 75 million boxes annually.[6]

The entire framework of SA's strategy can be translated into a set of objectives and priorities for the Sidi Abdellah site, including:

- Cultivating a performance-driven mindset by implementing Key Performance Indicators (KPIs).[6]
- Completing the construction of the site and fully utilizing its operations.[6]
- Expanding the product portfolio and initiating the insulin production project.[6]
- Establishing a performance tracking system within the Profit & Loss .[6]
- Strengthening the culture of Hygiene, Safety, and Environment (HSE), quality, and SMS.[6]

1.3.3 List of Produced Medications

Sanofi provides over 135 different medications to Algerian patients, including treatments for diabetes, hypertension, cardiology, oncology, and vaccines through Sanofi Pasteur.

The following table 1.1 represents the list of medications in tablet form produced by Sanofi at the Sidi Abdellah site.

Table 1.1: Medication Table in tablet [6]

| No | Medication | Form | Strength/Concentration |
|----|------------|--------|------------------------|
| 1 | Doliprane | Tablet | 1000 mg |
| 2 | Doliprane | Tablet | 500 mg |
| 3 | TRIA TEC | Tablet | 1.25 mg |
| 4 | TRIA TEC | Tablet | 5 mg |
| 5 | TRIA TEC | Tablet | 2.5 mg |
| 6 | TRIA TEC | Tablet | 10 mg |
| 7 | PROFENID | Tablet | 100 mg |
| 8 | TRITAZIDE | Tablet | 10-12.5 mg |
| 9 | TRITAZIDE | Tablet | 10-25 mg |
| 10 | TRITAZIDE | Tablet | 5-12.5 mg |
| 11 | TELF AST | Tablet | 120 mg |
| 12 | TELF AST | Tablet | 180 mg |
| 13 | COAPROVEL | Tablet | 300-12.5 mg |
| 14 | COAPROVEL | Tablet | 300-25 mg |
| 15 | COAPROVEL | Tablet | 150-12.5 mg |
| 16 | APROVEL | Tablet | 300 mg, 150 mg |
| 17 | PLAVIX | Tablet | 75 mg |
| 18 | APROVASC | Tablet | 300/5 mg |
| 19 | AMAREL | Tablet | 1 mg, 2 mg, 3 mg, 4 mg |
| 20 | SOLIAN | Tablet | 200 mg |
| 21 | ZEMIGLO | Tablet | 50 mg |
| 22 | TRITAZIDE | Tablet | 10-12.5 mg |

1.3.4 Sanofi SAA organization chart

The organizational chart of Sanofi is provided in the figure 1.1 below:

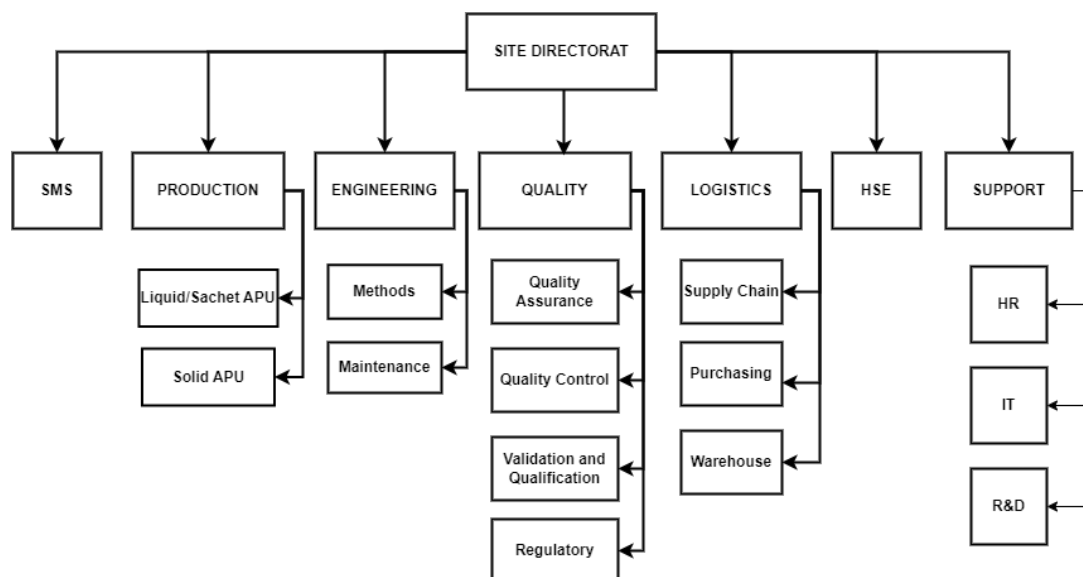


Figure 1.4: map of Sanofi SAA site[6]

1.3.5 The production processes at sanofi Sidi Abdellah

1.3.5.1 Production of solid form medications process

The phases of this process proceed sequentially as follows:

- **Weighing of raw materials (RM):** The first actual production phase is the weighing of excipients and active ingredients according to the measurements provided in the batch file.
- **Mixing:** During this phase, the different powders (active ingredient and excipients) are mixed in a Bin for a predefined duration using a mixer.
- **Granulation:** Following the mixing of the raw materials, this phase comprises several steps:
 1. Wetting the powder.
 2. Drying and calibrating.
 3. Lubricating the powder.
- **Compression:** The compression phase is carried out by compression machines where the powder is transformed into raw tablets through the following cycle:
 1. Filling the mold.
 2. Dosing the granulate.
 3. Compression.
 4. Ejecting the tablet.
- **Coating:** This phase involves coating the tablets and is only performed for certain products to obtain a semi-finished product.

- **Packaging:** The final phase is packaging, subdivided into two parts:
 1. **Primary packaging:** Placing the tablets in blisters using dedicated machines.
 2. **Secondary packaging:** Placing the blisters and leaflets into labeled boxes, and then placing the boxes into cartons.[6]

Figure 1.5 illustrates the production process of solid form medication.

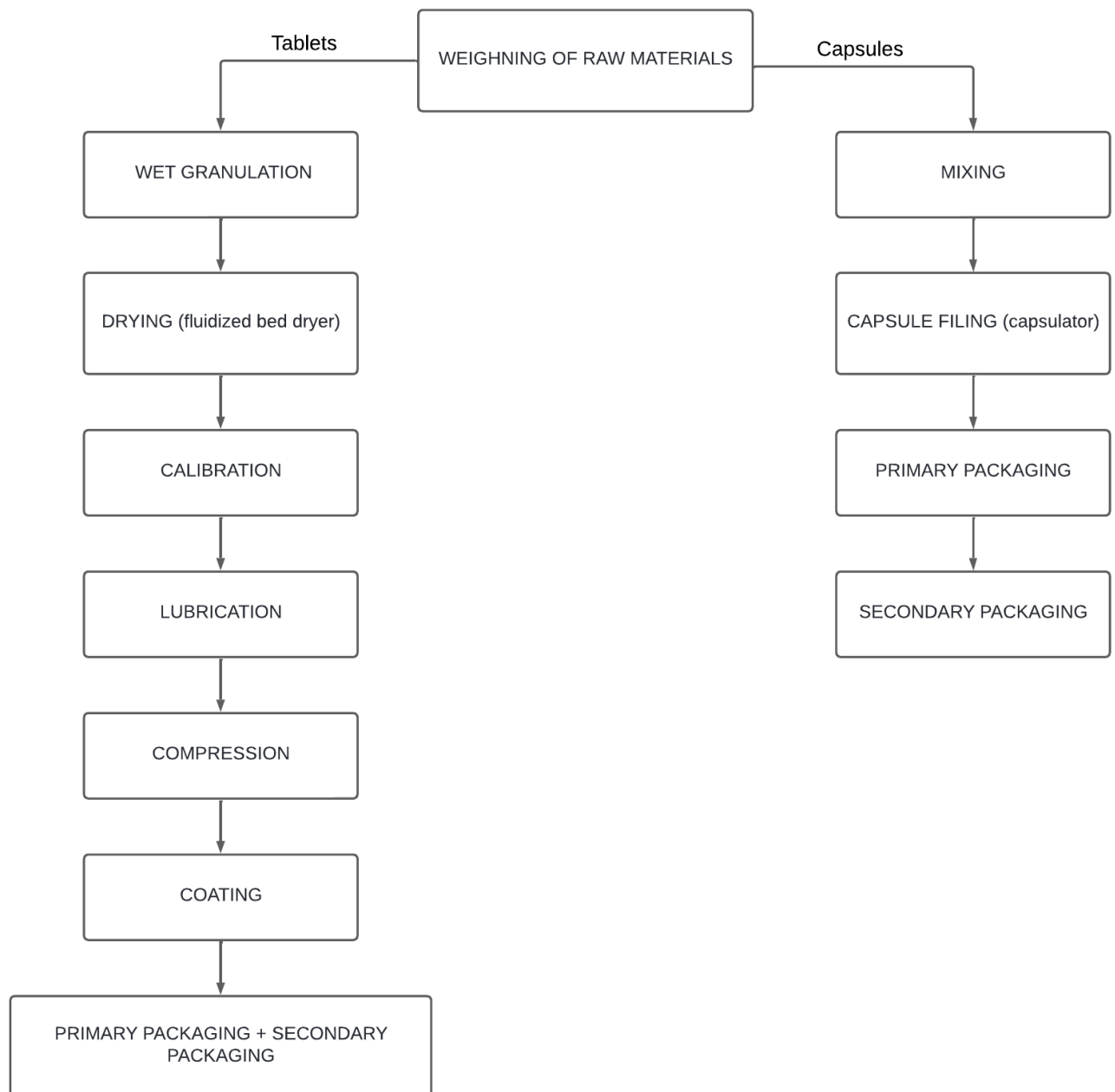


Figure 1.5: Solid Form Manufacturing Process[6]

1.3.5.2 Production of Liquid Form Medications process

The phases of this process proceed sequentially as follows:

- **Weighing of Raw Materials (RM):**

After this verification operation, the first production phase can begin, which is the weighing of excipients and active ingredients according to the measurements provided in the batch file.

- **Manufacturing:**

The raw materials are then transferred to another workshop for the manufacturing phase after the necessary preliminary checks on the workshop. Manufacturing is done by mixing the raw materials in a heated tank at a temperature T for a duration t . After achieving the final solution, it is filtered and transferred to a holding tank to begin the packaging phase

- **Packaging:**

The final phase is packaging, subdivided into two parts:

1. **Primary packaging:** lacing the tablets in blisters using dedicated machines.
2. **Secondary packaging:** Placing the blisters and leaflets into labeled boxes, and then placing the boxes into cartons.[6]

Figure 1.6 illustrates the production process of liquid form medication.

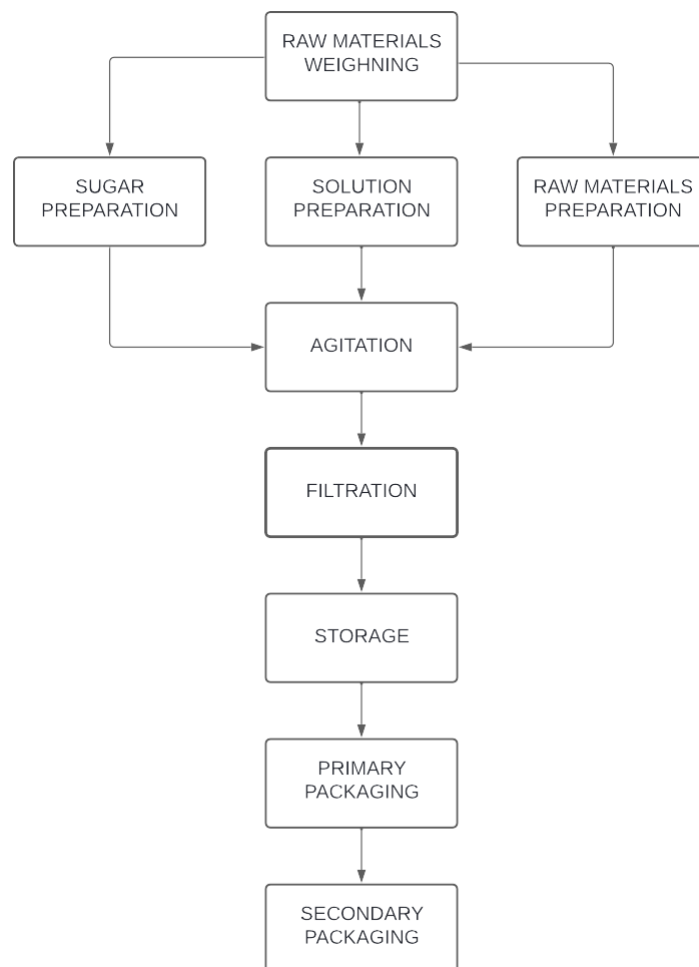


Figure 1.6: Liquid Form Manufacturing Process[6]

1.3.5.3 Production of Sachet Form Medications Process

Production Process of Medications in Sachet Form The production process for medications in sachet form follows several sequential phases:

- **Weighing and Transferring the Granulate:** the first phase of production begins with weighing the Big Bags transferred from the warehouse to the production unit. The contents of these Big Bags are then loaded onto a bin for transfer to the mixing workshop. The bin containing the raw materials is then transferred to a mixer after performing the necessary checks.
- **Mixing and Transferring the Granulate:** The mixing operation involves setting the mixer to a specific rotation speed and duration, defined by the nature of the product being manufactured. After mixing the raw materials, the bin is directed to a loading box to empty its contents into loading stands for the sacheting operation.
- **Packaging:** The final phase is packaging, subdivided into two parts:
 1. **Primary packaging:** Placing the tablets in blisters using dedicated machines.
 2. **Secondary packaging:** Placing the blisters and leaflets into labeled boxes, and then placing the boxes into cartons.[6]

Figure 1.7 illustrates the production process of liquid form medication.

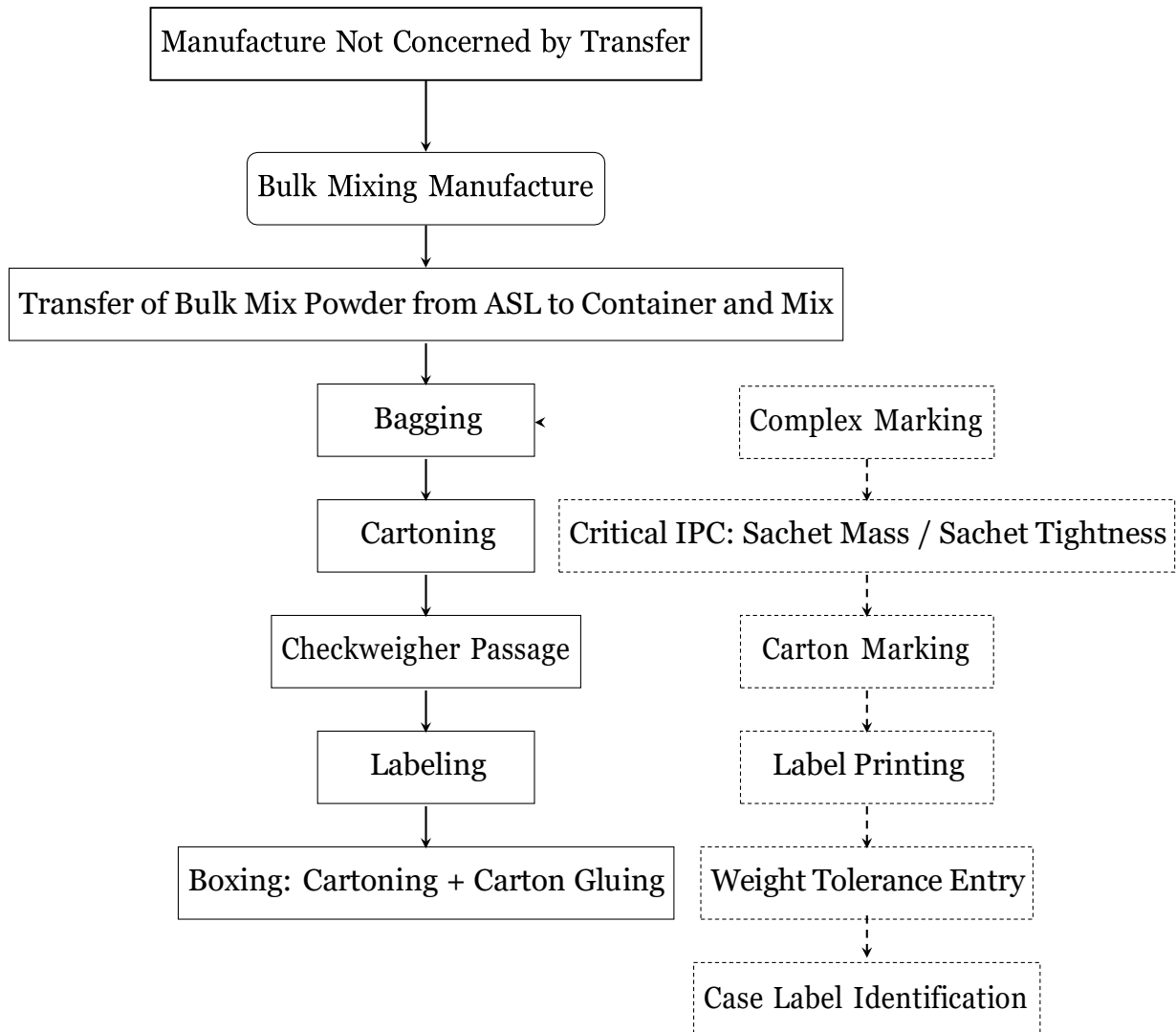


Figure 1.7: Medication Sachet Manufacturing Process[6]

1.3.6 Sanofi Sidi Abdellah 2023 Risk Map

The risk mapping process at Sanofi Sidi Abdellah begins with compiling a comprehensive checklist encompassing risk identification criteria such as Risk Number, Name, Description, and relevant Scenarios. Risks are categorized and assessed for their impact on various aspects, followed by documenting existing control measures and validating information sources. Each risk undergoes evaluation based on Likelihood, Severity, and Criticality to prioritize mitigation efforts. This systematic approach aligns with Sanofi's risk management methodology, aiming to proactively address potential threats and ensure operational continuity through structured action planning and continuous evaluation.

figure 1.8 illustrate sanofi sidi abdeallah 2023 risk map.

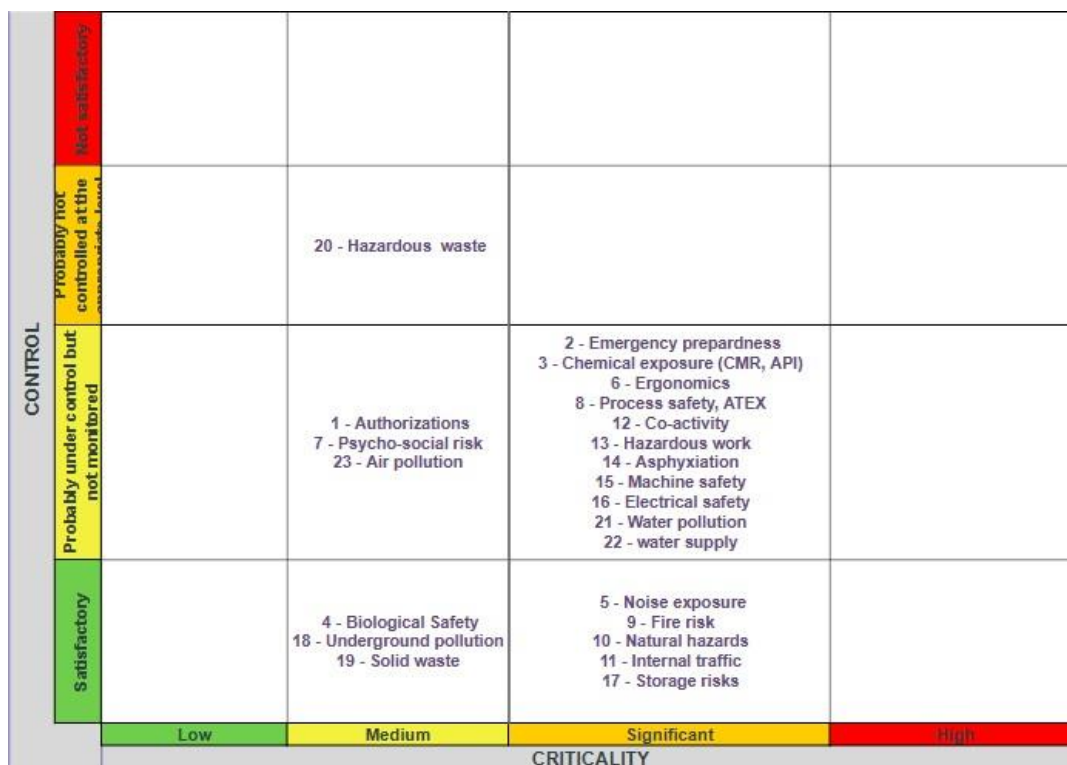


Figure 1.8: Sanofi Sidi Abdellah 2023 Risk Map [6]

1.4 Problematic

The Sanofi Sidi Abdellah 2023 risk map indicates that the criticality of chemical exposure is significant, with controls in place but not adequately monitored. It is evident that chemical exposure to hazardous materials such as Active Pharmaceutical Ingredients (APIs) and Carcinogenic, Mutagenic, and Reproductive toxicants (CMRs) poses significant health risks to employees. Effective chemical risk assessment and management are essential to ensure workplace safety and regulatory compliance. However, current risk assessment practices may lack a systematic approach for prioritizing chemical hazards based on their inherent risks, leading to inefficiencies in implementing control measures and standardizing operating procedures (SOPs).

1.5 The methodology

Conduct NIOSH qualitative chemical risk assessment at Sanofi’s Sidi Abdellah site. This assessment aims to identify, prioritize, and manage chemical risks associated with inhalation and dermal exposure. The findings will be used to develop an action plan that includes prioritized quantitative assessments, control measures, and standardized SOPs to effectively mitigate chemical risks.

The NIOSH QRA provides a structured and scientifically grounded approach to chemical risk assessment, integrating data from epidemiological and toxicological studies

to evaluate health risks posed by workplace chemicals. This systematic framework not only facilitates the identification of hazards but also guides the implementation of practical control measures such as engineering controls, administrative controls, and personal protective equipment (PPE). By applying the NIOSH QRA, organizations can systematically prioritize and mitigate chemical risks, ensuring a safer working environment and compliance with regulatory standards.

It will detail the following steps:

1. **Literature Review:** Review existing literature on chemical risk assessment, with a particular focus on the NIOSH qra. Additionally, study industry-specific guidelines for handling APIs, CMRs, and chemicals with defined Occupational Exposure Limits (OELs).
2. **Data Collection:** Identify and list all chemicals used in Sanofi's manufacturing and laboratory processes, including cleaning products. Collect data on chemical properties, for example Hazard Phrases (H-phrases) and exposure limits (OELs), from safety data sheets (SDSs). Gather workplace exposure data, including quantity and duration of exposure.
3. **Qualitative Risk Assessment:** Apply the NIOSH qualitative risk assessment to evaluate potential health risks associated with each chemical. Assess inhalation and dermal exposure risks separately, considering factors like volatility and dustiness. Categorize chemicals based on their risk levels using a risk matrix. Prioritize chemicals for quantitative assessment based on the results.
4. **quantitative risk assessment :** Conduct a quantitative risk assessment for the prioritized list of chemicals identified in the qualitative assessment. This assessment should include both inhalation and dermal exposure risks, providing a comprehensive evaluation of potential health hazards.
5. **Development of Action Plan:** Propose control measures for high-risk chemicals, such as engineering controls, administrative controls, and personal protective equipment (PPE). Develop standardized SOPs for safe handling, management, storage, and disposal of hazardous chemicals.

1.6 Objectives

- A comprehensive qualitative risk assessment of chemicals used at Sanofi's Sidi Abdellah site.
- A prioritized list of chemicals requiring immediate risk mitigation.
- A detailed action plan for implementing control measures and conducting quantitative risk assessments.
- Standardized SOPs for safe handling and management of hazardous chemicals.

In this chapter, we have introduced Sanofi Algeria, providing an overview of their medication production processes across solid, liquid, and sachet forms. Moving forward, we have identified the specific issues addressed in our project, outlined our objectives, and detailed the methodology employed for our assessment. The subsequent chapter will delve deeper into the literature review, and introduce the NIOSH QRA as a foundational approach for assessing chemical risks in occupational settings.

Chapter 2

chemical risk assessemnt

In this chapter, we will provide a comprehensive overview of chemical risks in occupational settings and the methodologies used for their assessment. We will begin by defining chemical risks and their sources, then explore the health impacts and factors influencing these risks. We will delve into various occupational health assessment methods, with a particular focus on the NIOSH Chemical Risk Assessment Methodology, highlighting both qualitative and quantitative approaches. Additionally, we will discuss emerging trends, regulatory frameworks, and the interdisciplinary nature of chemical risk assessment.

2.1 Chemical Hazards

Chemical hazards refer to the inherent properties of chemical substances that have the potential to cause harm. These properties can include being flammable, explosive, corrosive, toxic, or reactive. Exposure to these hazardous chemicals can occur in various settings, particularly in workplaces where substances like solvents, biological extracts, disinfectants, detergents, paints, and welding fumes are commonly found.[9]

The transition from recognizing chemical hazards to understanding chemical risks is crucial. Chemical risks refer to the potential for harm or adverse effects resulting from exposure to hazardous chemicals. These risks are a function of the inherent hazards of the chemical substances and the likelihood of exposure to them.[9]

Exposure to hazardous chemicals can occur through inhalation, skin absorption, or ingestion, leading to acute health effects like burns, poisoning, and asphyxiation, as well as chronic conditions like cancer, organ damage, and developmental disorders.[9] Understanding the risks associated with chemicals is particularly important in environments where medications, Active Pharmaceutical Ingredients (APIs), and Carcinogenic, Mutagenic, or toxic to Reproduction (CMR) substances are handled. These substances require specific protocols to ensure safety and mitigate potential health hazards.

2.1.1 Active Pharmaceutical Ingredients (APIs)

An active pharmaceutical ingredient (API) is defined as "any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body".[10] APIs are the main biologically active components of a drug product that produce the intended therapeutic effects. They are the chemical-based compounds that have pharmacological activity and are used to diagnose, cure, mitigate, treat or prevent disease.[11]

2.1.2 Carcinogenic, Mutagenic, or toxic to Reproduction (CMR) Substances

CMR refers to substances that are carcinogenic (C), mutagenic (M), or reprotoxic (R). Carcinogenic substances and mixtures can cause cancer or increase its frequency when inhaled, ingested, or absorbed through the skin. Mutagenic substances and mixtures can

produce heritable genetic defects or increase their frequency under the same conditions. Reprotoxic substances and mixtures can produce or increase the frequency of non-heritable adverse effects on sexual function and fertility in adult males and females, as well as adverse effects on the development of the offspring, when inhaled, ingested, or absorbed through the skin.[12]

2.1.3 Health Impacts

Exposure to hazardous chemicals can lead to various health effects:

- Acute symptoms: headaches, skin irritation[13]
- Chronic conditions: effects on nervous, hematopoietic, or reproductive systems[13]
- Potential contribution to cancer development[13]

2.1.4 Factors Influencing Chemical Risks

The level of risk associated with chemical exposure depends on several factors:

- Toxicity of the chemical.[14]
- Frequency of exposure.[14]
- Duration of exposure.[14]
- Intensity of exposure.[14]
- Individual susceptibility.[14]
- Routes of exposure

2.2 Occupational Health Assessment Methods

Several methods have been developed to assess occupational health risks in chemical processes, including:

- Inherent Occupational Health Index (IOHI).[15]
- Health Quotient Index (HQI).[15]
- Occupational Health Index (OHI).[15]

2.3 Risk Assessment

Risk assessment is a crucial component of managing chemical risks effectively. It involves:

- Identifying hazardous chemicals present in the workplace.[16]
- Evaluating the likelihood and severity of potential consequences.[16]

Risk assessment methods can be categorized as qualitative, semi-quantitative, or quantitative.

2.4 Regulatory Framework

Chemical risk assessment and management are governed by various regulatory bodies and standards. In the United States, key agencies include:

- Occupational Safety and Health Administration (OSHA)
- Environmental Protection Agency (EPA)
- National Institute for Occupational Safety and Health (NIOSH)

These agencies set standards, provide guidelines, and enforce regulations to ensure workplace safety and environmental protection.

2.5 NIOSH Chemical Risk Assessment

The NIOSH QRA provides a structured framework for assessing chemical risks in occupational settings. It involves several interrelated steps:

1. **Hazard Identification:** Systematic evaluation of epidemiological and toxicological data to identify chemical hazards.[17]
2. **Dose-Response Assessment:** Analyzing the relationship between exposure levels and health effects.[17]
3. **Exposure Assessment:** Measuring or estimating chemical concentrations in the workplace.[17]
4. **Risk Characterization:** Integrating hazard identification and exposure assessment to quantify risks.[17]

2.5.1 NIOSH Qualitative Risk Assessment

The NIOSH QRA incorporates qualitative risk assessment parameters, including:

2.5.1.1 Exposure Potential

$$ES = qi + di + du + f + c \tag{2.1}$$

Where:

- *qi*: Quantity
- *du*: Duration
- *di*: Dispersion
- *f*: Frequency
- *c*: Controls

The exposure score (ES) is used to determine the exposure potential (EP). The relationship between the ES and EP is illustrated in the following table 2.1.[18]

| Exposure Score (ES) | Exposure Potential (EP) |
|---------------------|------------------------------------|
| 1-5 | EP-1: Low exposure potential |
| 6-10 | EP-2: Moderate exposure potential |
| 11-15 | EP-3: High exposure potential |
| 16-20 | EP-4: Very high exposure potential |

Table 2.1: Relationship between Exposure Score and Exposure Potential

For API substances, the exposure potential is determined using a matrix that considers the **dustiness/volatility** potential, **the quantity** handled, and **the task duration**. The matrix is shown below in the figure 2.1

| | | Dustiness/Volatility Potential | | | | |
|--|-------------|--|---|--|-------------|---------------|
| | | LOW (uncoated tablets, coated tablets, non-volatile liquid/solutes) | MEDIUM (Granular, cakes, volatile <80C BP) | HIGH (Powder/<35C BP volatile liquid/solutes) | | |
| Quantity Handled (in 100% active equivalent) | Small (g) | EP-1 | EP-1 | EP-2 | Short (min) | Task duration |
| | | EP-1 | EP-2 | EP-3 | Long (hr) | |
| | Medium (kg) | EP-1 | EP-2 | EP-3 | Short (min) | |
| | | EP-2 | EP-3 | EP-3/4 | Long (hr) | |
| | High (ton) | EP-2 | EP-3 | EP-3 | Short (min) | |
| | | EP-3 | EP-4 | EP-4 | Long (hr) | |

Figure 2.1: EP matrix for APIs

A detailed table providing the description and rating criteria for each term in the equation is provided in the Appendix B

2.5.1.2 Health risk Hazard Ratings

$$\text{Health risk Rating} = \text{Hazard Rating} \times \text{Exposure Potential} \quad (2.2)$$

The health hazard rating is determined by the figure 1.a in the appendix A .

The resulting Health Risk Rating is then compared against a predefined matrix to determine whether the exposure is acceptable, uncertain, or unacceptable.[18]
 The health risk calculation matrix is represented in the following figure 2.2

| | | | | | |
|--------------------|---------------|--------------|--------------|--------------|--------------|
| Hazard Rating | 5 – Very High | | | | Unacceptable |
| | 4 – High | | | | |
| | 3 – Moderate | | | Uncertain | |
| | 2 – Low | | | | |
| | 1 – Very Low | Acceptable | | | |
| | | 1 – unlikely | 2 – possible | 3 – probable | 4 – likely |
| Exposure Potential | | | | | |

Figure 2.2: Health Risk Matrix[18]

- **Acceptable Exposure:** No further control actions. Review risk assessment periodically or in event of change.
- **Uncertain Exposure:** Apply good practice control measures. Determine and complete the strategy for quantitative exposure assessment.
- **Unacceptable Exposure:** Take immediate action to control exposure. Conduct quantitative exposure assessment after additional controls are implemented.

For substances with a skin hazard rating, the dermal hazard rating is calculated by combining the skin hazard rating with the skin exposure potential, which is determined using the tables in Annex C. Figure 2.3 below can be used to determine if a quantitative risk assessment is recommended.

| Skin Hazard Rating | | | |
|--------------------|-----|--------|------|
| Exposure Potential | 1 | 2 | 3 |
| 1 | Low | | |
| 2 | | Medium | |
| 3 | | | High |

Figure 2.3: Dermal Risk Rating Matrix [18]

- **Low:** Acceptable control. Review risk assessment periodically or in event of change.
- **Medium:** Apply best practice control measures.
- **High:** Take immediate action to control skin exposure.

2.5.1.3 containment strategy

For API components, the containment strategy level is assigned based on the matrix above. This matrix considers the occupational exposure band (OEB) and the exposure potential (EP) to determine the appropriate containment strategy.[19]

| Containment Strategy Determination | | | | | |
|------------------------------------|-------|--------------------|------|------|------|
| | | Exposure Potential | | | |
| Occupational Exposure Band | | EP-1 | EP-2 | EP-3 | EP-4 |
| | OEB 1 | 1 | 1 | 1 | 1 |
| | OEB 2 | 1 | 1 | 2 | 2 |
| | OEB 3 | 2/3 | 2/3 | 3 | 3/4 |
| | OEB 4 | 3 | 3 | 3/4 | 4 |
| | OEB 5 | 3 | 3/4 | 4 | 4 |

Figure 2.4: Containment Strategy Determination[19]

For non-API components, the focus is solely on the existing containment strategies in place. The required containment strategy is not considered for non-API components.

2.5.2 Quantitative Risk Assessment

2.5.2.1 Methodology

A quantitative exposure assessment consists of three stages:

1. data collection

the process of data collection involves the development of a sampling strategy determined from the outcome of the qualitative exposure assessment and other sources, includes the type of sampling to conduct, number of measurements to be taken and from whom. The primary goal is to obtain valid and representative measurements of worker exposure using personal samples within the worker's breathing zone for OEL compliance and area samples to characterize emission sources.

- **Sampling Strategy:** A minimum of three samples per exposure scenario is required, with six samples often needed for statistical analysis. Sampling duration should cover the entire applicable OEL period, with calibration of personal sampling pumps and passive diffusive air sampling being essential methods.
- **Sample Methods and Analysis:** Field sampling data sheets must document key details such as dates, sample identification, location, tasks, and calibration information. Each chemical requires a specific IH sampling method, with field blanks

included in the plan. Samples must be stored, shipped properly, and sent to accredited laboratories.

2. data analysis

Exposure measurements may have significant uncertainty, and compliance with the OEL can be assessed using decision statistics, particularly Bayesian Decision Analysis. This method determines the likelihood of the 95th percentile of exposure being within certain OEL categories.

Guidelines for statistical analysis include:

- For 3 samples < 0.1 OEL: considered low health risk.
- For fewer than 6 samples:
 - Geometric means < 0.5 OEL: low health risk.
 - Geometric means \geq 0.5 OEL: high health risk.
- For 6 samples or more:
 - CMR compounds: 99.9% percentile should indicate $\text{Pr}[\text{CI } 95\%] < 0.1\%$ for low risk.
 - Non-CMR compounds: 95%percentile should indicate $\text{Pr}[\text{CI } 95\%] < 5\%$ for low risk[18]

Below i figure 2.4 the tree illustrating the Occupational Exposure Limit (OEL) Health Risk Decision Tree

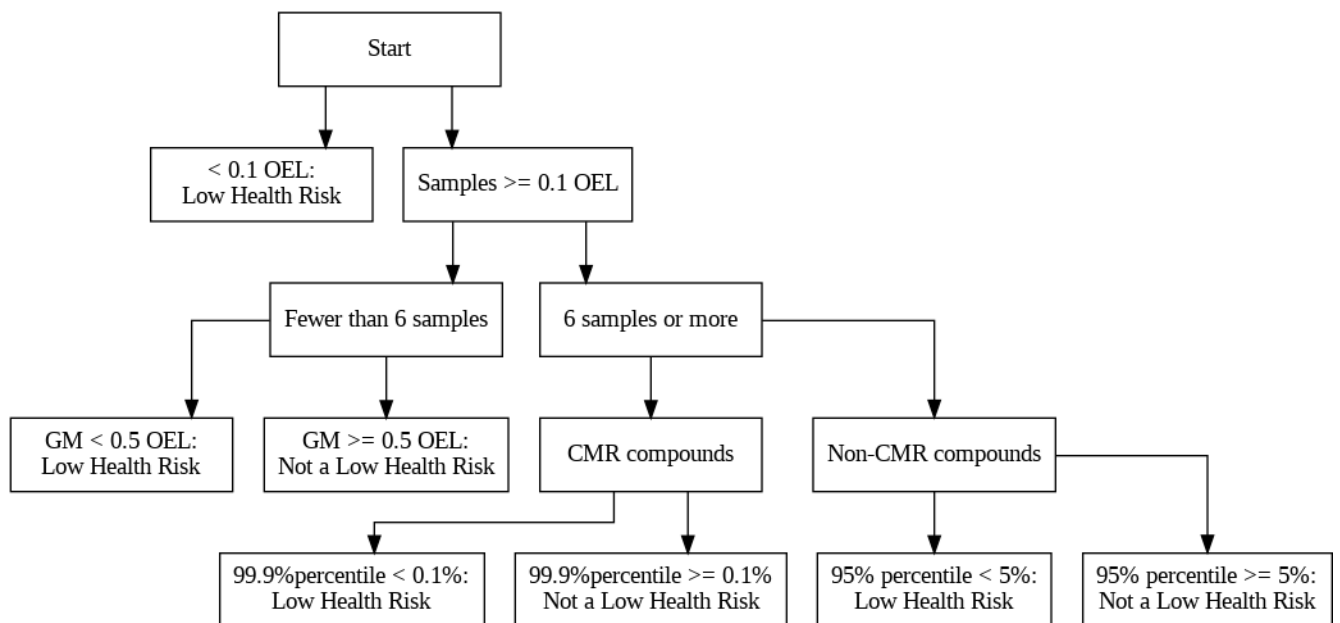


Figure 2.5: OEL Health Risk Decision Tree

Statistical tools like AIHA’s IHSTAT and Expostats Bayesian calculator can be used for calculating exposure statistics and interpreting industrial hygiene data.

3. data interpretation:

Table 2.2 should be used to determine actions based on exposure measurement outcomes and data analysis:

| Measured Exposure | Recommended Action |
|--------------------------|--|
| < 10% OEL | No further action. |
| 10 – 50% OEL | Apply best practice control measures where applicable. Continue periodic qualitative reassessment. |
| 50 – 100% OEL | Apply best practice control measures utilizing the hierarchy of controls and reassess once control is implemented. |
| > 100% OEL | Take immediate action to control exposure and reassess once control is implemented. |

Table 2.2: Exposure Outcome Compared to OEL

2.5.2.2 Dermal Assessment**• Modeling Tools**

- The AIHA’s Dermal Risk Assessment Model (DRAM) is used for systematic screening of dermal exposure risks.
- It evaluates factors such as dermal toxicity, contact area, frequency, retention time, concentration/loading, and penetration potential.
- The tool estimates risk and plots it on a risk grid.

• Dermal Sampling

- Dermal dosimeters (patches) are the most common method for dermal sampling.
- Indirect methods like skin or surface wipe sampling are also used but less common due to limited research and established methods.

• Record Retention

- Records of IH Assessments, evaluations, notes, reports, calibration documentation, chain of custody, employee notifications, final reports, and photos must be retained per country-specific regulations and the Sanofi Record Retention Schedule.
- An electronic file of the final report and associated documentation should be provided to the Global Occupational Hygiene Expert for additional record retention.[18]

2.5.2.3 Importance of Quantitative Risk Assessment

Quantitative risk assessments are mandatory to:

- provide precise and trustworthy data on exposure levels
- Verify and supplement the findings of qualitative assessments
- Ensure compliance with regulatory standards.

In this chapter, we have provided a comprehensive overview of chemical risks in occupational settings and the methodologies employed for their assessment. Beginning with the definition of chemical risks and their sources, we explored the health impacts and influencing factors. Our discussion encompassed various occupational health assessment methods, focusing prominently on the NIOSH Chemical Risk Assessment , which includes both qualitative and quantitative approaches. Additionally, we examined emerging trends, regulatory frameworks, and the interdisciplinary nature inherent in chemical risk assessment. The subsequent chapter will delve into practical applications, presenting detailed results and analyses.

Chapter 3

Practical Application and Results interpretation

We introduce the qualitative risk assessment tool in this chapter, explaining the inventory and risk assessment phases. We present the results of risk rankings for various activities in both laboratory and manufacturing environments, particularly for active pharmaceutical ingredients (APIs) and other hazardous substances. Additionally, we describe the process of prioritizing products for quantitative assessments, focusing on both dermal and inhalation exposure. After the analysis and prioritization, we will provide an action plan to address the identified risks and ensure the implementation of appropriate safety measures.

3.1 Qualitative Risk Assessment

3.1.1 introduction to the tool used

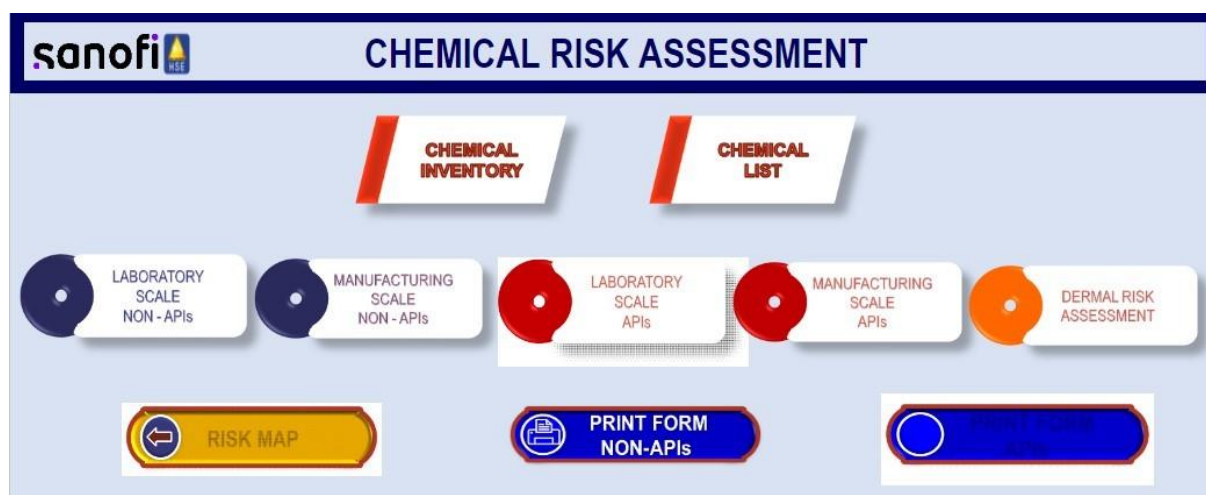


Figure 3.1: Qualitative Risk Assessment Tool[18]

3.1.2 Inventory Phase: Hazard Identification and Dose-Response

3.1.2.1 Hazard Identification

We initiated the hazard identification by compiling a list of chemical substances used in both laboratory and manufacturing environments. This included active pharmaceutical ingredients (APIs) and CMR substances.

We used the SEDDA web interface to access Safety Data Sheets (SDS) for each chemical. The hazard identification criteria included the CAS numbers, physical state, and nature of solids or boiling point interval.

3.1.2.2 Dose-Response Assessment

Our dose-response assessment incorporates Occupational Exposure Limits (OELs) derived from critical toxicological data, alongside Occupational Exposure Bands (OEBs)

that classify chemicals according to their potential health hazards, ranging from OEB1 indicating low health hazard to OEB5 for high health hazard substances. Additionally, suffixes unique to Sanofi's SDS provide supplemental hazard information essential for accurate risk assessment.

The chemical inventory resulting from the hazard identification and Dose-Response Assessment can be found in Annex D.

3.1.3 Risk Assessment Phase: Exposure Potential

We selected substances identified as having significant health risks, specifically those categorized under Occupational Exposure Bands (OEB) 3 and OEB 4, as well as substances classified as Carcinogenic, Mutagenic, or toxic to Reproduction (CMRs) from the inventory results. These substances were chosen due to their potential to pose substantial health hazards within our operational environments.

Substances were categorized into distinct groups: Manufacturing API, Laboratory API, and Laboratory Non-API, allowing us to tailor our risk assessment approach to specific operational settings. Manufacturing Non-API activities were excluded from the risk assessment due to the predominantly non-hazardous and inert nature of the substances involved.

We gathered pertinent data necessary for comprehensive risk assessment, including documenting the number of employees exposed (HEG), assessing the frequency and duration of exposure, quantifying the volume of substance handled, evaluating the effectiveness of containment strategies, and reviewing both administrative controls and personal protective equipment (PPE) measures in place.

The inhalation risk assessment for the laboratory in API can be found in Annex E, for the laboratory API in Annex F, and for manufacturing API in Annex G. The dermal risk assessment can be found in Annex H.

3.2 Analysis of the Risk Assessment Results

Laboratory NON-API Overall Risk Ranking

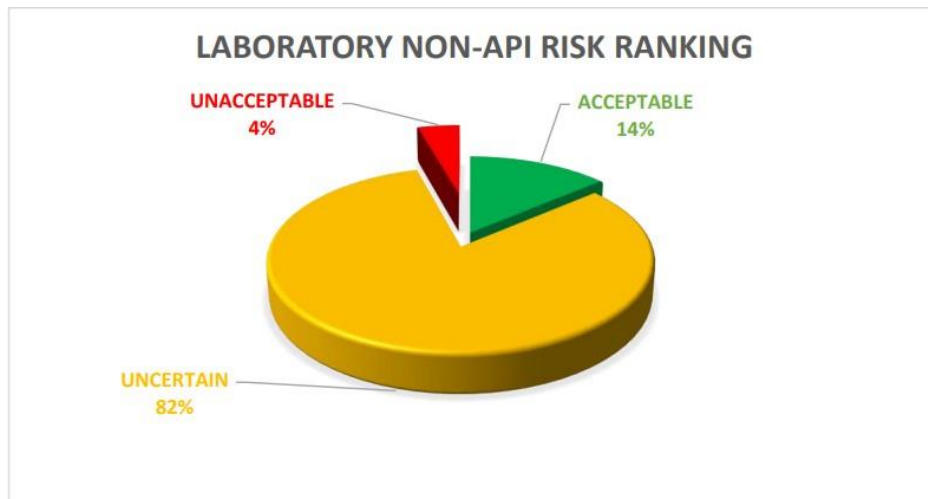


Figure 3.2: Laboratory NON-API Overall Risk Ranking

Laboratory NON-API Risk Ranking by Activity

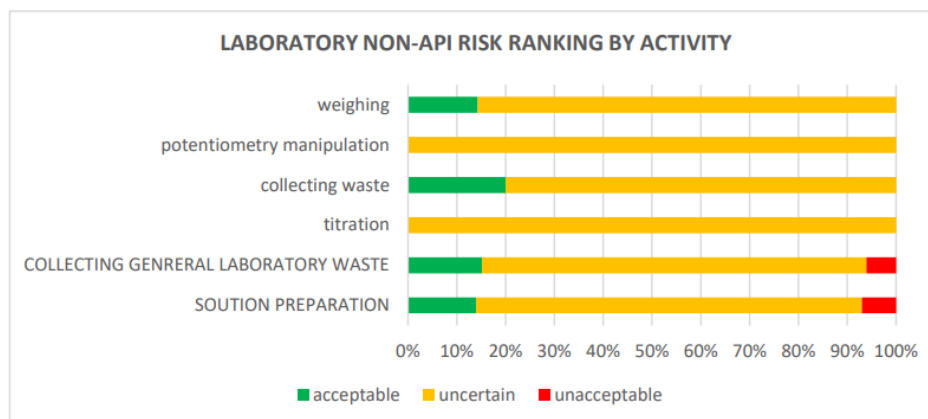


Figure 3.3: Laboratory NON-API Risk Ranking by Activity

Interpretation

- **Low Unacceptable Risk:**

- **Weighing:** This activity shows a significant portion of acceptable risk, indicating robust safety practices.

- **Moderate Unacceptable Risk:**

CHAPTER 3. PRACTICAL APPLICATION AND RESULTS INTERPRETATION

- **Potentiometry Manipulation:** While there is a notable percentage of unacceptable risk, it still has a significant portion of acceptable risk, indicating that some improvements are needed but the activity is relatively safer compared to others.
 - **Collecting Waste:** Similar to potentiometry manipulation, this activity has a moderate portion of acceptable risk. Safety practices are somewhat effective, but there is room for improvement to further reduce the risk.
 - **Titration:** This activity shows a combination of acceptable and uncertain risks, suggesting that some safety practices are effective, but additional measures are needed to ensure overall safety.
- **High Unacceptable Risk:**
 - **Collecting General Laboratory Waste:** This activity has a high percentage of unacceptable risk, indicating that the current safety measures are insufficient, and significant improvements are required.
 - **Solution Preparation:** The entire bar shows unacceptable risk, highlighting a critical need for review and enhancement of safety protocols in solution preparation activities.

Laboratory API Overall Risk Ranking

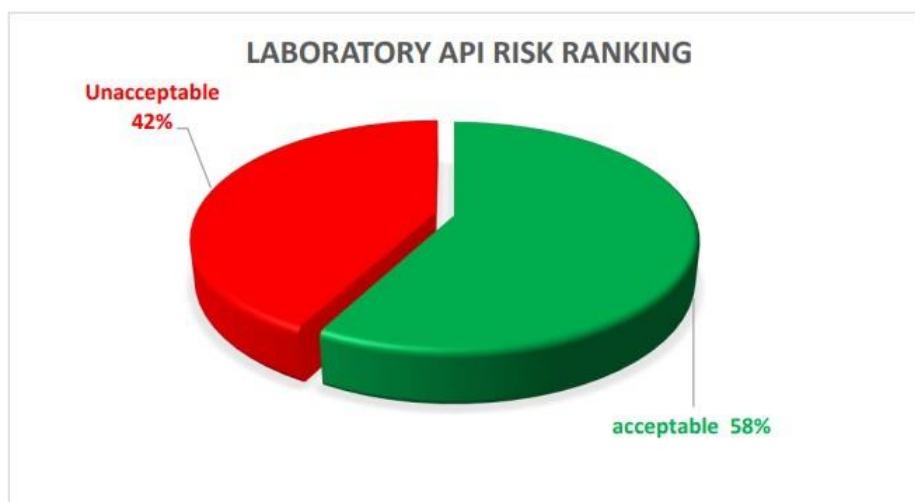


Figure 3.4: Laboratory API Overall Risk Ranking

Laboratory API Risk Ranking by Activity

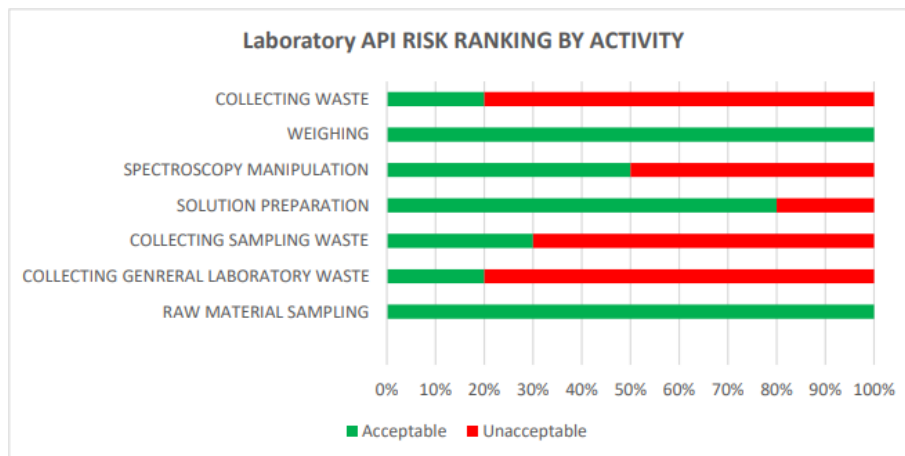


Figure 3.5: Laboratory API Risk Ranking by Activity

Interpretation

- **Low Unacceptable Risk:**

- **Raw Material Sampling:** This activity shows a significant portion of acceptable risk, indicating robust safety practices.
- **Weighing:** Similar to raw material sampling, weighing activities have a significant portion of acceptable risk, suggesting effective safety measures are in place.

- **Moderate Unacceptable Risk:**

- **Spectroscopy Manipulation:** While there is a notable percentage of unacceptable risk, it still has a significant portion of acceptable risk, indicating that some improvements are needed but the activity is relatively safer compared to others.
- **Solution Preparation:** This activity shows a combination of acceptable and unacceptable risks, suggesting that some safety practices are effective, but additional measures are needed to ensure overall safety.
- **Collecting Waste:** Similar to spectroscopy manipulation, this activity has a moderate portion of acceptable risk. Safety practices are somewhat effective, but there is room for improvement to further reduce the risk.

- **High Unacceptable Risk:**

- **Collecting Sampling Waste:** This activity has a high percentage of unacceptable risk, indicating that the current safety measures are insufficient, and significant improvements are required.

CHAPTER 3. PRACTICAL APPLICATION AND RESULTS INTERPRETATION

- **Collecting General Laboratory Waste:** Similar to collecting sampling waste, this activity also has a high percentage of unacceptable risk, highlighting a critical need for review and enhancement of safety protocols.

Manufacturing API Overall Risk Ranking

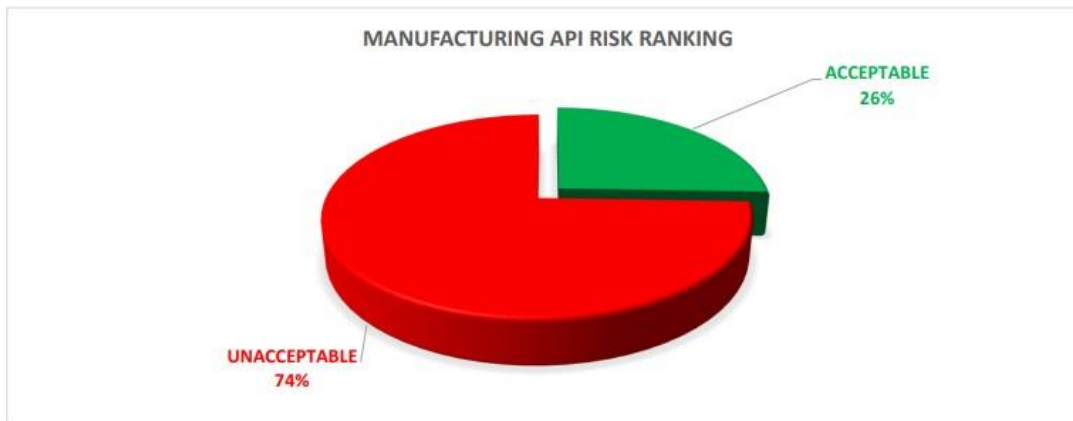


Figure 3.6: Manufacturing API Overall Risk Ranking

Laboratory API Risk Ranking by Activity

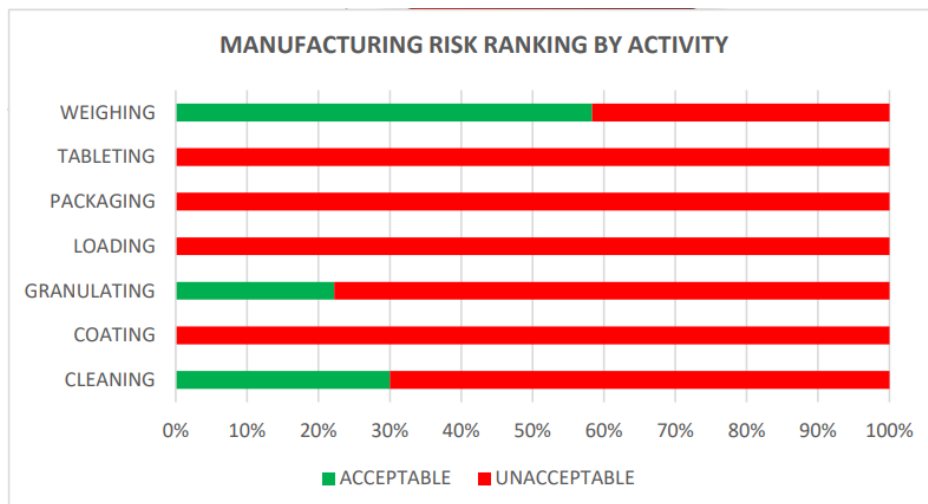


Figure 3.7: Laboratory API Risk Ranking by Activity

interpretation

- **Low Unacceptable Risk:**

- **Weighing:** This activity shows a significant portion of acceptable risk, indicating robust safety practices.
- **Moderate Unacceptable Risk:**
 - **Granulating:** While there is a notable percentage of unacceptable risk, it still has a significant portion of acceptable risk, indicating that some improvements are needed but the activity is relatively safer compared to others.
 - **Cleaning:** Similar to granulating, this activity has a moderate portion of acceptable risk. Safety practices are somewhat effective, but there is room for improvement to further reduce the risk.
- **High Unacceptable Risk:**
 - **Tableting:** This activity has a high percentage of unacceptable risk, indicating that the current safety measures are insufficient, and significant improvements are required.
 - **Packaging:** The entire bar shows unacceptable risk, highlighting a critical need for review and enhancement of safety protocols in packaging activities.
 - **Loading:** Similar to packaging, loading activities are entirely in the unacceptable risk category, necessitating urgent attention to safety measures.
 - **Coating:** This activity also shows a high percentage of unacceptable risk, suggesting that safety measures need to be thoroughly reviewed and improved.

DERMAL HAZARD Overall Risk Ranking

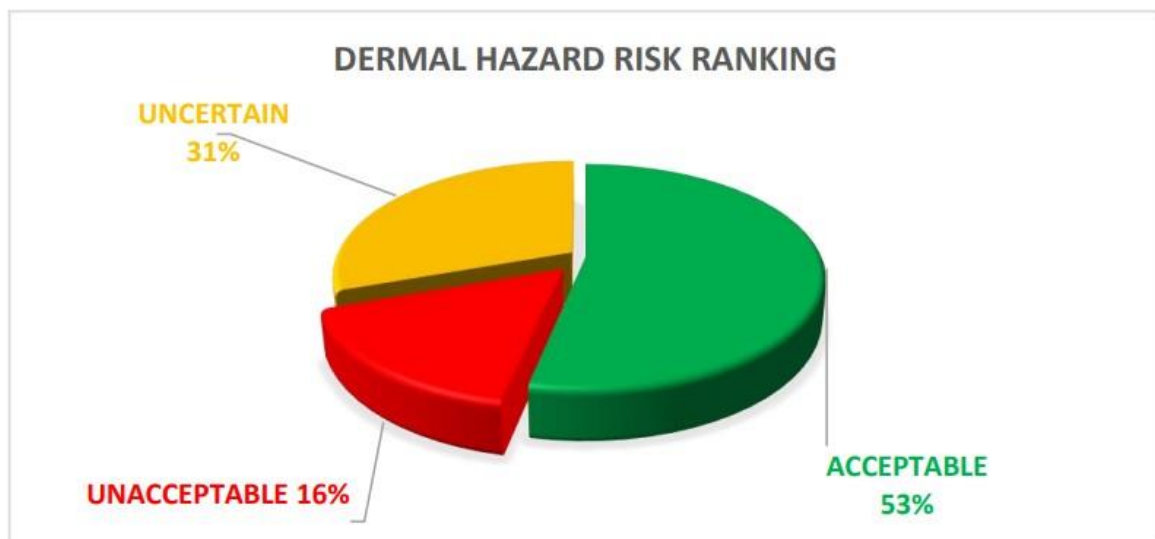


Figure 3.8: Overall Dermal Hazard Risk Ranking

Dermal Hazard Risk Ranking By Activity

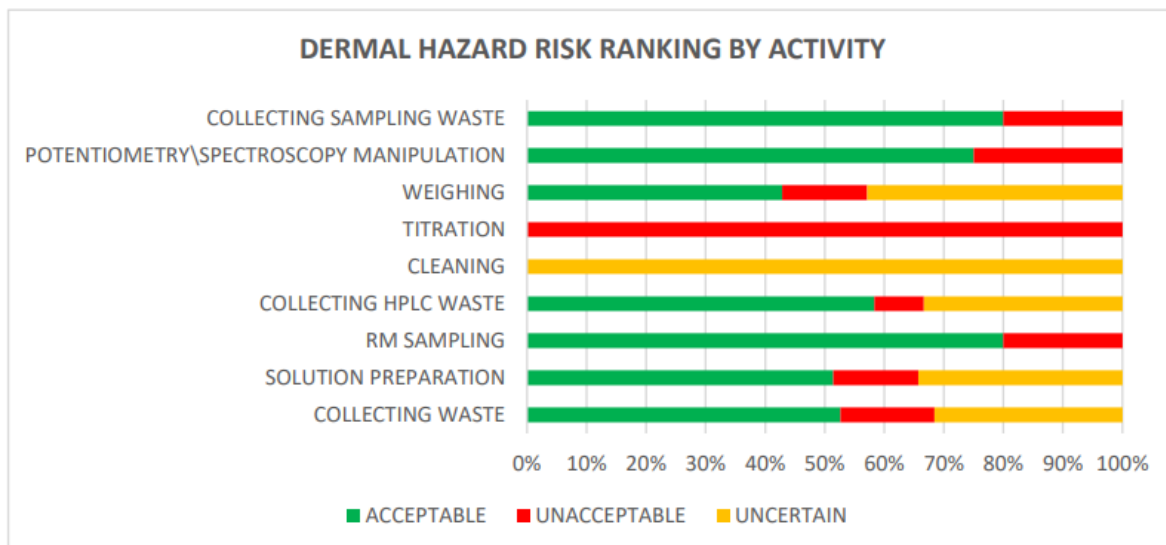


Figure 3.9: Dermal Hazard Risk Ranking by Activity

Interpretation

- **Low Unacceptable Risk:** Solution Preparation, RM Sampling, Titration, and Potentiometry/Spectroscopy Manipulation show very low unacceptable risk percentages, indicating effective safety practices.
- **Higher Unacceptable Risk:** Collecting Waste, Collecting HPLC Waste, and Collecting Sampling Waste require additional safety measures due to higher proportions of unacceptable risk.
- **Moderate Risk:** Cleaning and Weighing have low unacceptable risks, but continuous monitoring is advised given their significance in lab operations.

The comprehensive risk assessment conducted across both laboratory and manufacturing operations has provided critical insights into the safety landscape within our facility. In laboratories, the risk levels of many activities are uncertain, which means we need to assess and control them more strictly. While some processes are considered safe, many others are less clear and require closer attention to prevent potential hazards.

Manufacturing presents its own set of risks, especially with the complexities and exposure to hazardous substances.

Based on our findings, we will prioritize the substances deemed unacceptable for the quantitative risk assessment. and apply structured control measures across both lab and manufacturing settings.

3.3 Quantitative risk Assessment

Quantitative risk assessments will prioritize products with high health and dermal risk rankings resulting from the qualitative risk assessment. Each product will undergo both health and dermal risk rankings. By focusing on high-risk products for quantitative assessment, our goal is to achieve a thorough understanding of their specific risks and implement suitable mitigation .

3.4 hierarchy of controls

Upon completing the risk assessment, we developed and initiated an action plan guided by the hierarchy of controls. This structured approach is crucial for mitigating identified risks and ensuring workplace safety, we prioritized and implemented effective measures to manage risks systematically:

- **Elimination and Substitution:** While ideal, eliminating or substituting chemical hazards is often not feasible due to the essential nature of certain chemicals.
- **Engineering Controls:** Prioritized to isolate people from chemical hazards, these controls are selected smartly to balance effectiveness and cost.
- **Administrative Controls:** Modify work practices and procedures to reduce exposure to the chemical hazard.
- **Personal Protective Equipment (PPE):** Although PPE is necessary in certain situations, its effectiveness is limited based on our method of assessment.

In our corrective plan, we prioritized engineering controls because our assessment emphasizes the importance of containment strategy levels. We utilized the containment strategy matrix to choose the engineering controls, as shown in Appendix I. Similarly, administrative controls were prioritized as we plan to update procedures to ensure sustained safety improvements.

3.4.1 Key Points for Optimal Action Plan:

- **Unified Control Measures:** Engineering controls that meet the highest containment strategy level for each task.
- **Efficiency:** Streamlined control measures to cover multiple risks within the same task, reducing redundancy and administrative burden.
- **Cost-Effectiveness:** Robust engineering controls that provide comprehensive protection, proving more cost-effective in the long run.
- **Simplified Compliance:** Highest containment level met for all tasks, simplifying regulatory compliance and safety management.

PRODUCTION API ACTION PLAN

| Operation | Chemical Names | Containment Strategy Level | Conclusion of Risk | Containment Strategy Existing | Engineering Control Selected | Administrative Control |
|---------------|----------------------------|----------------------------|--------------------|---|--|---|
| Granulation | Amlodipine besylate | Prod Containment Level 3 | NOT ACCEPTABLE | Open bench (no LEV) | Powder Weighing Hood with HEPA Filter/Exhausted to the Outdoors (with glove port shield) | |
| | Glimepiride | Prod Containment Level 3 | | | | |
| | Oxomemazine | Prod Containment Level 3 | | | | |
| | Ramipril | Prod Containment Level 3 | | | Glovebox or Isolator with HEPA Filter/Exhausted to the Outdoors (with airlock and rapid transfer port) Closed Automated Systems | |
| | Sodium Valproate | Prod Containment Level 4 | | | | |
| Packaging 1 | Glimepiride | Prod Containment Level 4 | NOT ACCEPTABLE | Open bench (no LEV) | Glovebox/Isolator with HEPA Filter/Exhausted to Outdoors (with airlock and rapid transfer port) Automated Packaging Systems with Integrated Isolators | <ul style="list-style-type: none"> • Increase break frequency and duration, • install clean break areas • Increase the distance between people and the source of pollution • Delineate contaminated areas with visual markings and instructions • Restrict access to the risky areas • Write SOP or instruction detailing prevention and protection action to apply • Train and inform • Implement a sanitation program when appropriate (work suit, shower, locker room, cafeteria) • When applicable, review medical surveillance requirements • Develop and implement process for reporting hazardous and uncomfortable situations. |
| | Ramipril | Prod Containment Level 4 | | | | |
| | Sodium Valproate | Prod Containment Level 3 | | | | |
| Tableting | Glimepiride | Prod Containment Level 3 | NOT ACCEPTABLE | Open bench (no LEV) | Automated Tablet Presses with Glovebox Integration Glovebox/Isolator with HEPA Filter/Exhausted to Outdoors (with airlock and rapid transfer port) | |
| | Ramipril | Prod Containment Level 4 | | | | |
| Weighing Room | Alpha Amylase | Prod Containment Level 4 | NOT ACCEPTABLE | Powder Weighing Hood with HEPA Filter (Exhausted to the Outdoors) | Glovebox or Isolator with HEPA Filter/Exhausted to the outdoors (with airlock) Automated Weighing and Dispensing Systems within Glovebox | |
| | Fexofenadine Hydrochloride | Prod Containment Level 2 | | Open bench (no LEV) | Downflow Booth (with closed/dust-tight transfer and LEV) | |
| | Oxomemazine | Prod Containment Level 3 | | Open bench (no LEV) | Powder Weighing Hood with HEPA Filter/Exhausted to the Outdoors (with glove port shield) | |
| | Paracetamol | Prod Containment Level 3 | | Open bench (no LEV) | | |

| Operation | Chemical Names | Containment Strategy Level | Conclusion of Risk | Containment Strategy Existing | Engineering Control Selected | Administrative Control |
|-----------------------------------|------------------------|----------------------------|--------------------|--|--|---|
| Collection of bench waste | Mercuric Iodide | NA | NOT ACCEPTABLE | Open bench or bench top barrier or shield (no LEV) | Powder Weighing Hood with HEPA Filter - Recirculated | |
| | Formaldehyde | NA | | | | |
| | Glimepiride | Lab Containment Level 3 | | | | |
| | Irbesartan | Lab Containment Level 2 | | | | |
| | Sodium Valproate | Lab Containment Level 2 | | | | |
| | Paracetamol | Lab Containment Level 2 | | | | |
| | Ramipril | Lab Containment Level 2 | | | | |
| | Oxememazine | Lab Containment Level 3 | | | Class II Type A1/A2/B1/B2 Biosafety Cabinet recirculated | |
| Solution preparation | Potassium Bromate | NA | NOT ACCEPTABLE | Laminar flow hood (clean bench) (Transfer of gram solids only No solvent aerosol generating activities) | Laboratory Hood Exhausted to the Outdoors, | <ul style="list-style-type: none"> • Increase break frequency and duration, install clean break areas • Increase the distance between people and the source of pollution • Delineate contaminated areas with visual markings and instructions • Restrict access to the risky areas • Write SOP or instruction detailing prevention and protection action to apply • Train and inform • Implement a sanitation program when appropriate (work suit, shower, locker room, cafeteria) • When applicable, review medical surveillance requirements • Develop and implement process for reporting hazardous and uncomfortable situations. |
| | Potassium Permanganate | NA | | | | |
| | Glimepiride | LAB CONTAINEMNT LEVEL 3 | | | | |
| | Paracetamol | LAB CONTAINEMNT LEVEL 3 | | | | |
| | Vinyl-1-pyrrolidone | LAB CONTAINEMNT LEVEL 3 | | | Class II Type A1/A2/B1/B2 Biosafety Cabinet | |
| Collection of Bench or HPLC Waste | Amisulpride | Lab Containment Level 2 | NOT ACCEPTABLE | Open bench or bench top barrier or shield (no LEV) | Powder Weighing Hood | |
| | Glimepiride | | | | | |
| | Irbesartan | | | | | |
| | Sodium Valproate | | | | | |

| | | | | | |
|---|------------------|-------------------------|----------------|--|--|
| | Paracetamol | | | | |
| | Ramipril | | | | |
| | Oxememazine | Lab Containment Level 3 | | | Class II Type A1/A2/B1/B2 Biosafety Cabinet recirculated |
| Collection of Solid Waste (Sample Return) | Amisulpride | Lab Containment Level 2 | NOT ACCEPTABLE | Open bench or bench top barrier or shield (no LEV) | Powder Weighing Hood |
| | Irbesartan | | | | |
| | Sodium Valproate | | | | |
| | Paracetamol | | | | |
| | Ramipril | | | | |
| | Oxememazine | Lab Containment Level 3 | | | Class II Type A1/A2/B1/B2 Biosafety Cabinet recirculated |

CHAPTER 3. PRACTICAL APPLICATION AND RESULTS INTERPRETATION

After completing the qualitative risk assessment and developing an action plan to address identified risks using the hierarchy of controls, our focus now shifts to the standardization of Standard Operating Procedures (SOPs). Updating and standardizing SOPs are crucial administrative actions aimed at ensuring consistency and compliance with safety regulations. This transition not only enhances operational efficiency but also fosters a safer working environment for all employees, maintaining high safety standards throughout our operations. By integrating these efforts, we reinforce our commitment to proactive risk management and continuous improvement in safety practices.

Chapter 4

Standardization of SOPs

This chapter is a direct outcome of our action plan following the chemical risk assessment conducted at Sanofi Algeria's Sidi Abdellah DC site. Here, we will delve into the necessity and process of updating key safety procedures to ensure they remain effective and compliant with current standards. Specifically, we will focus on the procedures that were identified as needing updates due to the gaps between existing protocols and the latest safety standards, as well as insights gained from the chemical risk assessment. During our internship, we identified several critical procedures requiring updates, namely the Permit to Work (PTW) system, Extinguisher protocols, and Lockout/Tagout (LOTO) procedures

4.1 Definition of Standardization:

the process of establishing and consistently applying uniform procedures, guidelines, and practices to manage and mitigate risks effectively across an organization. This involves creating documented protocols that outline specific steps and measures to be taken in various scenarios to ensure safety and compliance with regulatory requirements. Standardization aims to eliminate variability in safety practices, ensuring that every individual in the organization follows the same procedures, thus reducing the likelihood of errors and enhancing overall safety.

4.2 Process of Standardization :

4.2.0.1 Review of Existing Procedures:

Conduct a comprehensive review of current safety procedures and practices related to chemical risk management. Identify gaps and areas for improvement based on the risk assessment and action plan.

4.2.0.2 Development of Standardized Procedures:

- Ensure procedures are clear, concise, and easy to follow.
- Include specific protocols for unusual activities such as permit to work (PTW), and the use of fire extinguishers and LOTO.
- Stakeholder Involvement: Involve key stakeholders, including safety officers, department heads, and frontline workers in the development process.
- Gather feedback to ensure the procedures are practical and comprehensive.
- Documentation and Communication: Create detailed documentation of all standardized procedures.
- Develop a communication plan to disseminate the updated procedures to all relevant personnel.

- Utilize various communication channels (e.g., meetings, emails, training sessions) to ensure widespread understanding and adoption.

4.3 Permit to Work (PTW)

4.3.1 Objective

The primary objective of the Permit to Work (PTW) system is to ensure that all necessary safety measures are in place before commencing any high-risk work activities. The PTW system is designed to:

- Control high-risk activities such as maintenance, confined space entry, hot work, and electrical work.
- Ensure that all hazards are identified, assessed, and mitigated before work begins.
- Provide a formal authorization process to manage and oversee work activities safely.
- Promote communication and coordination between all parties involved in the work.
- Ensure compliance with regulatory and organizational safety standards.

4.3.2 Purpose of Our Update

Our update of the PTW (Permit to Work) procedure aimed to enhance safety and operational efficiency in several key areas:

- Ensuring compliance with the latest industry regulations and standards.
- Simplifying the PTW process to improve user-friendliness for workers.
- Enhancing clarity and focus by separating the PTW procedure from external enterprise procedures.
- Specifically addressing chemical hazards associated with non-routine tasks such as welding and painting, implementing targeted precautions to effectively manage these risks.

The new permit to work SOP can be found in Annex J.

4.3.3 process of permit to work

Below is a figure illustrating the step-by-step process of PERMIT TO WORK

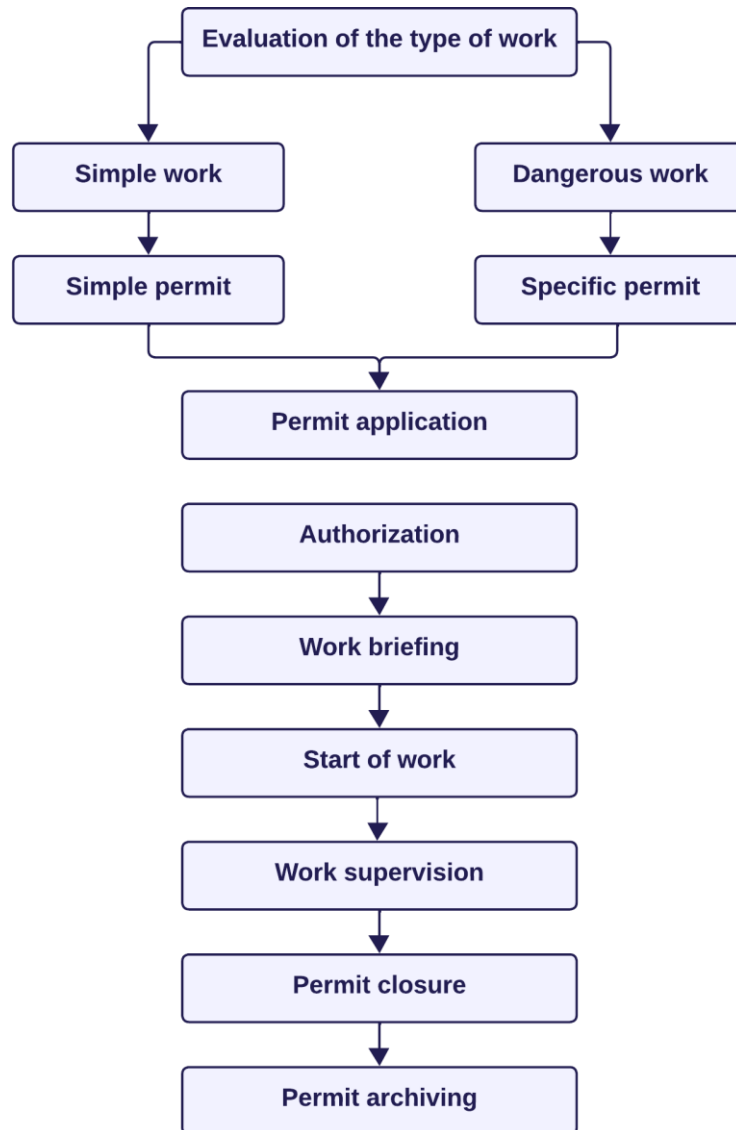


Figure 4.1: process of permit to work

The new permit to work can be found in Annex k.

A gap describing the differences between the new and old SOP can be found in Annex N.1 summarize the changes made.

4.3.4 Suggestions for Further Enhancements

- **Digital Transformation:** Fully integrate the PTW system with digital platforms, including mobile applications, to facilitate real-time updates and communication.

4.4 Use Of Extinguisher

4.4.1 Objective Of Fire Extinguisher Procedure

The objective of the Use of Extinguisher procedure is to ensure that all employees are knowledgeable and capable of using fire extinguishers effectively in the event of a fire emergency. This procedure aims to:

- Provide clear instructions on the types and use of fire extinguishers available in the workplace.
- Ensure that all fire extinguishers are easily accessible and properly maintained.
- Promote quick and effective response to small fires to prevent escalation.
- Ensure compliance with fire safety regulations and standards.

The Use Of Extinguisher SOP can be found in Annex J

4.4.2 Purpose of Our Update

The purpose of our update was twofold: to create a new, standalone Use of Extinguisher procedure, and to update the map of extinguisher placements to ensure adequacy. Previously, there was no specific procedure for the use of extinguishers, and the existing map did not accurately reflect the actual placement of extinguishers. Our updates aimed to:

- Establish a clear and comprehensive procedure for the use of fire extinguishers.
- Ensure that the map of extinguisher placements is accurate and corresponds to the actual locations of extinguishers.
- Improve the overall fire safety preparedness of the workplace.
- ensure readiness in handling chemical-related fires, aligning with identified risks to mitigate potential human and material damage.

4.4.3 Fire Extinguisher Management Cycle

The following figure illustrates the management cycle of fire extinguishers, detailing each critical step ;

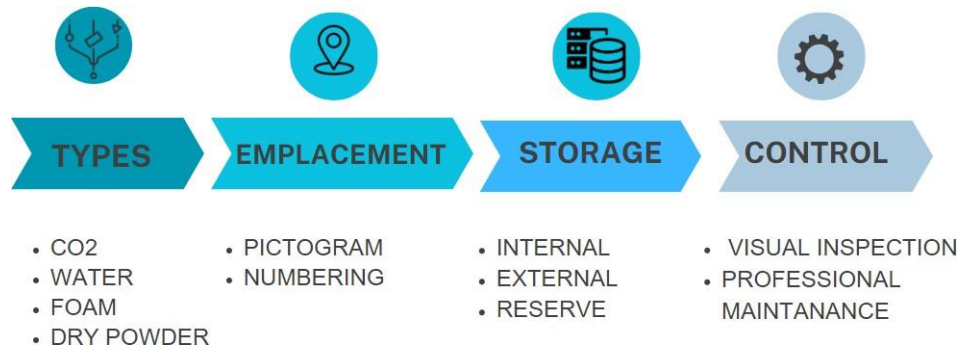


Figure 4.2: Fire Extinguisher Management Cycle

A gap describing the differences between the new and old SOP can be found in Annex N.2 summarize the changes made.

4.4.4 Suggestions for Further Enhancements

- **Advanced Training Modules:** Develop advanced training modules using simulations or virtual reality (VR) to provide hands-on experience in using fire extinguishers.
- **Feedback and Improvement:** Establish a feedback system for employees to provide suggestions and report issues related to fire extinguishers and their placements.
- **Regular Audits:** Conduct regular audits of extinguisher placements and conditions to ensure ongoing compliance with safety standards.
- **Enhanced Signage:** Improve signage around extinguisher placements to make them more visible and easily accessible in an emergency.

4.5 Lockout-Tagout

4.5.1 Objective of LOTO Procedure

The Lockout/Tagout (LOTO) procedure is designed to ensure the safety of workers during maintenance and servicing of machinery and equipment. The main objectives of the LOTO procedure are:

- Ensure that machinery and equipment are properly shut down, de-energized, and isolated from all energy sources before any maintenance or servicing work begins.
- Use standardized locks and tags to clearly communicate the status of equipment and the presence of maintenance work being performed, preventing unauthorized access and operation.

- Adhere to occupational safety and health regulations and standards (such as OSHA standards in the United States) to maintain a safe working environment and avoid legal and regulatory penalties.

4.5.2 Purpose of the Update

The recent updates to the Lockout/Tagout (LOTO) procedure were implemented to enhance clarity, compliance with best practices, and regulatory requirements. The key updates include:

Addition of Lockout Kit: A dedicated lockout kit has been incorporated into the LOTO procedure. This kit includes essential tools and devices necessary for effective lockout/tagout operations, ensuring secure isolation of all energy sources.

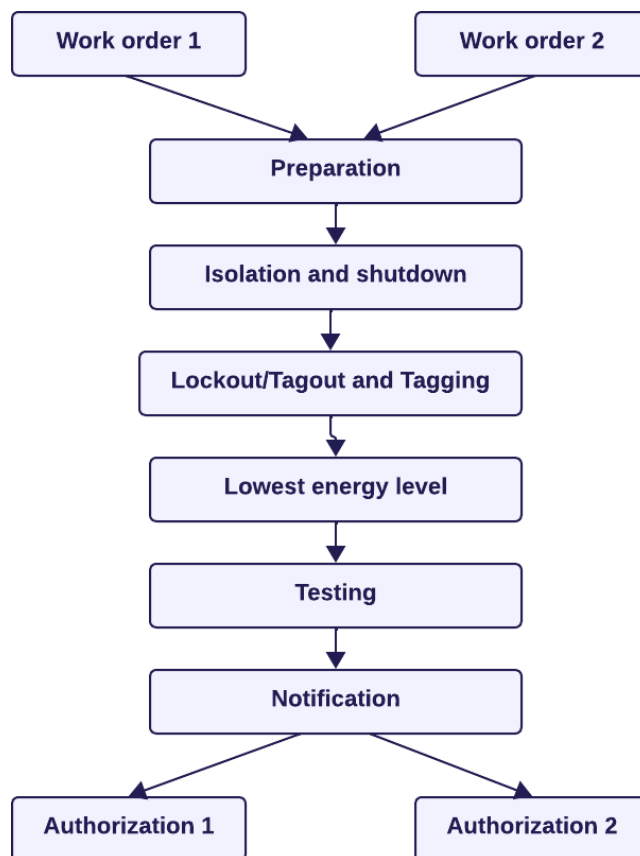
Identification of Energy Isolation Points: The updated procedure emphasizes the critical task of identifying and clearly labeling all energy isolation points. This includes disconnect switches, valves, and other isolation devices, which are vital for safely controlling hazardous energy during maintenance activities.

Detailed Procedure Steps: The updated procedure provides detailed steps for preparation, isolation, verification, and de-isolation of energy sources. It defines specific responsibilities and outlines mandatory training requirements for personnel involved in LOTO procedures. Regular audits are also mandated to ensure ongoing compliance.

Consideration of Chemical Risks: The updated LOTO procedure includes measures for dealing with expired or hard-to-treat chemical products. By locking out and tagging out storage areas with these hazardous substances, we can prevent accidental exposure and ensure personnel safety.

4.5.3 PROCESS OF LOTO

Below is a figure illustrating the step-by-step process of Lockout/Tagout (LOTO)



A gap describing the differences between the new and old SOP can be found in **Annex N.3** summarize the changes made.

By revising the Permit to Work (PTW), Extinguisher, and Lockout/Tagout (LOTO) procedures, we addressed the gaps identified in our chemical risk assessment, ensuring effective risk management. Involving stakeholders and thorough documentation were key to developing clear and compliant safety protocols.

conclusion

In the complex world of pharmaceuticals, ensuring employee safety and high-quality production is essential. This thesis has highlighted the importance of comprehensive chemical risk assessments at Sanofi Sidi Abdellah. By thoroughly examining potential chemical hazards and understanding their impact, we have developed effective strategies to reduce risks and improve workplace safety.

The comprehensive risk assessment conducted across both laboratory and manufacturing operations has provided critical insights into the safety landscape within our facility. In laboratories, the risk levels of many activities are uncertain, which means we need to assess and control them more strictly. While some processes are considered safe, many others are less clear and require closer attention to prevent potential hazards. Manufacturing presents its own set of risks, especially with the complexities and exposure to hazardous substances.

Analyzing the results found from this assessment allows us to better understand the specific areas of concern and the severity of the risks involved. This analysis is crucial in identifying the priorities and resources required to mitigate these risks effectively. After thoroughly analyzing the results and understanding the prioritization of risks, we will provide an action plan to address the identified risks and ensure the implementation of appropriate safety measures.

Our action plan, based on these assessments, prioritizes the most hazardous chemicals for further evaluation and implements key safety measures. The updated Standard Operating Procedures (SOPs) standardize safety practices and enhance operational efficiency, making the work environment safer for everyone.

By minimizing chemical exposure risks, Sanofi not only protects its employees but also ensures the quality and safety of its medications, maintaining consumer trust and meeting regulatory standards. Continuous training, proper use of personal protective equipment (PPE), and engineering controls are crucial for ongoing safety.

In summary, this thesis demonstrates that proactive risk management is vital in the pharmaceutical industry. By focusing on safety, compliance, and continuous improvement, Sanofi Sidi Abdellah can achieve excellence and create a safer, healthier workplace. With dedication and strategic investments, we can strive towards a minimal-risk environment for all employees.

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Appendices

Appendix **A**

health hazard rating table

APPENDIX A. HEALTH HAZARD RATING TABLE

| Table 1: Health Hazard Ratings | | | | | | |
|--|-------------------|--------------------------|-------------------------------|---|---|--|
| Health Hazard Ratings | | | | | | |
| Hazard Rating | | 1 | 2 | 3 | 4 | 5 |
| OEL Ranges | Particle/ Dust | >10 mg/m ³ | >1 to 10 mg/m ³ | >0.1 to 1 mg/m ³ (Relates to OEB 2) | >0.01 to 0.1mg/m ³ (Relates to OEB 3) | ≤ 0.01 mg/m ³ (Relates to OEB 4/5) |
| | Gas/Vapor | >100 ppm | >10 to 100 ppm | >1 to 10 ppm | >0.1 to 1 ppm | ≤ 0.1 ppm |
| Acute Toxicity | | | | H301 Category 3 | H300 Category 2 | H300 Category 1 |
| | | | | H302 Category 4 | | |
| | | | | H331 Category 3 | H330 Category 2 | H330 Category 1 |
| | | | | H332 Category 4 | | |
| | | | | H311 Category 3 | H310 Category 2 | H310 Category 1 |
| | | | | H312 Category 4 | | |
| Skin corrosion/ irritation | | | | H315 Category 2 | | H314 Category 1A, 1B, or 1C |
| Serious eye damage/eye irritation | | | | H319 Category 2A or H320 2B | | H318 Category 1 |
| Respiratory and skin sensitization | | | | H317 Category 1B (skin) | H317 Category 1A | |
| | | | | H335 Category 3 | H334 Category 1B | H334 Category 1 or 1A |
| Genotoxicity | | | | | H341 Category 2 | |
| Carcinogenicit y | | | | | | H350 Category 1A, or 1B |
| | | | | | | H351 Category 2 |
| Reproductive Toxicity | | | | H361 (all) Category 2 | H360 (all) Category 1B | H360 (all) Category 1 or 1A |
| Specific target organ toxicity | | | | H371 Category 2 | | H370 Category 1 |
| | | | | H373 Category 2 | | H372 Category 1 |

Figure A.1: health hazard rating

Appendix B

Inhalation exposure assessment parameters tables

APPENDIX B. INHALATION EXPOSURE ASSESSMENT
PARAMETERS TABLES

Table B.1: Dispersion Values

| Rating | Liquids | Solids |
|---------------|--|--|
| 1 | Low Volatility is a non-volatile liquid pellets | Low Dustiness materials are tablets or pellets |
| 2 | Medium Volatility is a volatile liquid (boiling point <80 degree C) static and uncoated fine powder tablets. | Medium Dustiness examples are granular materials or crystalline, low |
| 3 | High Volatility is a highly volatile liquid (boiling point <35 degree C) nanoparticles with low density/ high adhesion substances. | High Dustiness is for fine powder handling of active materials and |

Table B.2: Quantity of the material handled

| Rating | Lab | Industrial |
|---------------|-----------------------|-------------------|
| 1 | Up to 15 minutes | Up to 1 hour |
| 2 | 15 minutes to 4 hours | 1 to 4 hours |
| 3 | More than 2 hours | More than 4 hours |

Table B.3: the frequency

| Rating | Lab | Industrial |
|---------------|------------------|--------------------------------|
| 1 | < 10 g or 50 ml | < 10 kg or < 10 L |
| 2 | 10 g – 100 g | 10 kg – 100 kg 10 L – 100 L |
| 3 | > 100 g or > 1 L | > 100 kg or > 100 L |

APPENDIX B. INHALATION EXPOSURE ASSESSMENT
 PARAMETERS TABLES

Table B.4: the duration

| Rating | Lab | Industrial |
|---------------|-----------------------|-------------------|
| 1 | Up to 15 minutes | Up to 1 hour |
| 2 | 15 minutes to 4 hours | 1 to 4 hours |
| 3 | More than 2 hours | More than 4 hours |

Table B.5: Containment Strategy Manufacturing Scale

| Rating | Description |
|---------------|---|
| 0 | Open bench, general exhaust ventilation |
| -1 | Containment Strategy 1 and 2 - open system with limited engineering controls. Rely on PPE for protection of workers. |
| -2 | Containment Strategy 3- engineering controls in place at the source (downflow booth, laminar flow, closed transfers) |
| -3 | Containment Strategy 4- engineering controls to ensure closed system for transfers, handling utilizing technology such as isolators and closed vessels. |

APPENDIX B. INHALATION EXPOSURE ASSESSMENT
PARAMETERS TABLES

Table B.6: Containment Strategy Lab Scale

| Rating | Lab Scale Containment (Liquids, Vapors, Gases) | Lab Scale Containment (Powders) |
|---------------|---|--|
| 0 | Open bench, general exhaust ventilation | Open bench, general exhaust ventilation |
| -1 | Lab snorkel LEV (calibrated annually, near activity) | Lab snorkel LEV (calibrated annually, near activity) |
| -2 | Ventilated weight station(HEPA recirc. or fumehood) | Ducted Biosafety Cabinet Class II (certified annually) |
| -3 | Ventilated weight station(HEPA) | |
| -4 | Ventilated weight station(HEPA) | Fume Hood Class II (undocumented performance, cluttered) |
| -5 | Closed system (glove box, glove bag) | Fume Hood Class II (documented, good housekeeping) Fume Hood Class II (documented, good housekeeping, optimized design) |

Table B.7: control rating for respirator types

| Respirator Type | Rating | Mask Type | Rating |
|-------------------------|---------------|------------------|---------------|
| Supplied Air Respirator | -4 | N95, FFP1 | -1 |
| PAPR | -3 | N99, FFP2 | -1 |
| Full face respirator | -3 | N100, FFP3 | -1 |
| Half Face respirator | -2 | | |

Table B.8: GHS Dermal Hazard Codes

| Description | Code |
|--|-------------|
| Acute toxicity, dermal, Category 1 and 2 | H310 |
| Acute toxicity, dermal, Category 3 | H311 |
| Acute toxicity, dermal, Category 4 | H312 |
| Acute toxicity, dermal, Category 5 | H313 |
| Skin corrosion/irritation, Category 1A, 1B, 1C | H314 |
| Skin corrosion/irritation, Category 2 | H315 |
| Skin corrosion/irritation, Category 3 | H316 |
| Sensitization, Skin, Category 1, 1A or 1B | H317 |

Appendix C

dermal qualitative exposure assessment tables

APPENDIX C. DERMAL QUALITATIVE EXPOSURE ASSESSMENT
TABLES

| Dermal Hazard Rating | Skin Related GHS-statements |
|-----------------------------|------------------------------------|
| 1 | H312, H313, H316 |
| 2 | H311, H315 |
| 3 | H310, H314, H317 |

Table C.1: Dermal Hazard Ratings

Table C.2: Skin Exposure Potential

| Skin Exposure Potential | Description |
|--------------------------------|---|
| 1 | No direct contact, minor risk of indirect contact |
| 2 | Significant risk of indirect contact e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is plausible |
| 3 | Workers have direct contact, evidence of significant surface contamination. |

Appendix **D**

chemical inventory

| S. No | Chemical name | CAS number | API | Handled @ Manufacturing scale | Handled @ Laboratory scale | Physical State (Liquid = VaporGas) | Nature (BP °C/ powder) | OEL Unit (µg/m3 or PPM) | OEL (Sanofi approved/ Regulatory) | OEB (Default) (In case of NO OEL) | Suffix (As per Sanofi SDS) | H Phrases (Health) | Dispersion | Skin Hazard rating | CMR | Health Hazard Data Reference | List updated by | Date of updation (DD/MM/YYYY) | Remarks | |
|-------|--|------------|-----|-------------------------------|----------------------------|------------------------------------|------------------------|-------------------------|-----------------------------------|-----------------------------------|----------------------------|------------------------------------|---------------------|--------------------|-----------|------------------------------|-----------------|-------------------------------|------------|--|
| 1 | Chloroform | 67-66-3 | No | Yes | Yes | VaporGas | 80<BP>35 | PPM | 2 | --- | G1,Sk | H302,H315,H319,H331,H351,H361,H372 | Volatile liquid | 2 | CMR 2 | Very high | SEDDA | Hiba Meriem/ Hind Nouara | 13/06/2024 | |
| 2 | 2-BUTANONE | 78-93-3 | No | Yes | Yes | VaporGas | 80<BP>35 | PPM | 200 | --- | Sk | H319 | Volatile liquid | 1 | | Moderate | SEDDA | | | |
| 3 | ASPARTAM | 22839-47-0 | No | Yes | Yes | Powder | Granules | NA | NA | Not available | Not applicable | | Dusty solid | | | | SEDDA | | | |
| 4 | Benzoic acid | 65-85-0 | No | Yes | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H372,H318,H315 | Very dusty solid | 2 | | Very high | SEDDA | | | |
| 5 | Citric Acid | 77-92-9 | No | No | Yes | Powder | Micronized powder | µg/m3 | 5000 | OEB1 | Not applicable | H319 | Very dusty solid | | | Moderate | SEDDA | | | |
| 6 | DICHLOROMETHANE | 75-09-2 | No | Yes | No | VaporGas | 80<BP>35 | PPM | 50 | --- | Not applicable | H315,H319,H351 | Volatile liquid | 2 | CMR 2 | Very high | SEDDA | | | |
| 7 | DIETHYL AMINE | 109-89-7 | No | No | Yes | VaporGas | 80<BP>35 | PPM | 5 | --- | G1,Cor | H302,H311,H314,H332,H335 | Volatile liquid | 3 | | Very high | SEDDA | | | |
| 8 | DIISOPROPYL ETHER | 108-20-3 | No | No | Yes | VaporGas | 80<BP>35 | PPM | 250 | --- | Not applicable | | Volatile liquid | | | Very low | SEDDA | | | |
| 9 | DISODIUM TARTRATE Dihydrate | 6106-24-7 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB1 | Not applicable | | Very dusty solid | | | Very low | SEDDA | | | |
| 10 | PYRIDINE | 110-86-1 | No | No | Yes | VaporGas | BP >80 | PPM | 5 | --- | Sk | H302,H312,H332,H315,H319 | Non volatile liquid | 2 | | Moderate | SEDDA | | | |
| 11 | TOLUENE | 108-88-3 | No | No | Yes | VaporGas | BP >80 | PPM | 50 | --- | Not applicable | H315,H361,H373 | Non volatile liquid | 2 | CMR 2 | Moderate | SEDDA | | | |
| 12 | TRISODIUM PHOSPHATE DODECAHYDRATE | 10101-89-0 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB1 | Not applicable | H315,H319,H335 | Very dusty solid | 2 | | Moderate | SEDDA | | | |
| 13 | (+)-Lactic acid | 79-33-4 | No | Yes | Yes | VaporGas | | NA | NA | OEB2 | Not applicable | H315,H318 | | 2 | | Very high | SEDDA | | | |
| 14 | 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tétraméthyl-2-naphthyl)éthane-1-one | 54464-57-2 | No | Yes | Yes | VaporGas | | NA | NA | Not available | Not applicable | H315,H317Cat1B | | 2 | | Moderate | SEDDA | | | |
| 15 | 1-(2,6,6-trimethyl-3-cyclohexen-1-yl)-2-buten-1-one | 57378-68-4 | No | Yes | Yes | VaporGas | | NA | NA | Not available | Not applicable | H301,H311,H331,H314,H317Cat1A | | 3 | | Very high | SEDDA | | | |
| 16 | 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexaméthylindeno[5,6-c]pyran | 1222-05-5 | No | Yes | Yes | VaporGas | | NA | NA | Not available | Not applicable | | | | | | | SEDDA | | |
| 17 | 1,4-Dioxane | 123-91-1 | No | No | Yes | VaporGas | BP >80 | PPM | 20 | --- | Sk | H319,H335,H350 | Non volatile liquid | 1 | CMR 1A/1B | Very high | SEDDA | | | |
| 18 | 1,5-DIPHENYLCARBAZIDE | 140-22-7 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB4 | Not applicable | H315,H319,H335 | Very dusty solid | 2 | | High | SEDDA | | | |
| 19 | 1-Butanol | 71-36-3 | No | NO | Yes | VaporGas | BP >80 | PPM | 50 | --- | Not applicable | H302,H315,H318,H335 | Non volatile liquid | 2 | | Very high | SEDDA | | | |

| S. No | Chemical name | CAS number | API | Handled @ Manufacturing scale | Handled @ Laboratory scale | Physical State (Liquid = VaporGas) | Nature (BP °C/ powder) | OEL Unit (µg/m3 or PPM) | OEL (Sanofi approved/ Regulatory) | OEB (Default) (In case of NO OEL) | Suffix (As per Sanofi SDS) | H Phrases (Health) | Dispersion | Skin Hazard rating | CMR | Health Hazard Data Reference rating | SEDDA | List updated by | Date of updation (DD/MM/YYYY) | Remarks |
|-------|---|-------------|-----|-------------------------------|----------------------------|------------------------------------|------------------------|-------------------------|-----------------------------------|-----------------------------------|----------------------------|--------------------------|------------------------|--------------------|-------|-------------------------------------|-------|-----------------|-------------------------------|---------|
| 20 | 1-Methylimidazole | 616-47-7 | No | No | Yes | VaporGas | BP<35 | NA | NA | OEB3 | COR | H311,H314 | Highly volatile liquid | 3 | | Very high | SEDDA | | | |
| 21 | 1-Naphthol | 90-15-3 | No | No | Yes | Powder | Granules | NA | NA | OEB3 | Not applicable | H302,H312,H315,H318,H335 | Dusty solid | 2 | | Very high | SEDDA | | | |
| 22 | 1-OCTANESULFONIC ACID SODIUM SALT | 5324-84-5 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB3 | Cor | H314 | Very dusty solid | 3 | | Very high | SEDDA | | | |
| 23 | 1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-(C8-18 and C18-unsatd. acyl) derivs., inner salts | 147170-44-3 | No | Yes | Yes | VaporGas | | NA | NA | Not available | Not applicable | H318 | | | | Very high | SEDDA | | | |
| 24 | 1-PROPANOL | 71-23-8 | No | No | Yes | VaporGas | BP >80 | PPM | 200 | --- | Not applicable | H318 | Non volatile liquid | | | Very high | SEDDA | | | |
| 25 | 2,7-Dihydronaphthalene | 582-17-2 | No | No | Yes | VaporGas | BP >80 | NA | NA | OEB3 | Not applicable | H302,H319 | Non volatile liquid | | | Moderate | SEDDA | | | |
| 26 | 2-iodopropane | 75-30-9 | No | NO | Yes | VaporGas | BP >80 | NA | NA | OEB4 | Not applicable | H315,H319,H335 | Non volatile liquid | 2 | | High | SEDDA | | | |
| 27 | 2-Naphthol | 135-19-3 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H302,H332 | Very dusty solid | | | Moderate | SEDDA | | | |
| 28 | 2-PROPANOL | 67-63-0 | No | No | Yes | VaporGas | BP >80 | PPM | 200 | --- | Not applicable | H319 | Non volatile liquid | | | Moderate | SEDDA | | | |
| 29 | 3,5-Dinitrosalicylic acid | 609-99-4 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H302,H315,H319,H335 | Very dusty solid | 2 | | Moderate | SEDDA | | | |
| 30 | 4-Aminophenol | 123-30-8 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB4 | G1,Sk | H302,H332,H341 | Very dusty solid | 1 | CMR 2 | High | SEDDA | | | |
| 31 | 4-Heptanone | 123-19-3 | No | NO | Yes | VaporGas | BP >80 | NA | NA | Not available | Not applicable | H332 | Non volatile liquid | | | Moderate | SEDDA | | | |
| 32 | 4-Methoxyphenylacetic Acid | 104-01-8 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB3 | Not applicable | H302,H315,H318,H335 | Very dusty solid | 2 | | Very high | SEDDA | | | |
| 33 | 4-Methyl-2-Pentanone | 108-10-1 | No | NO | Yes | VaporGas | BP<35 | PPM | 20 | --- | Not applicable | H319,H332 | Highly volatile liquid | | | Moderate | SEDDA | | | |
| 34 | 4-Nitrophenol | 100-02-7 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H373,H332,H312,H302 | Very dusty solid | 1 | | Moderate | SEDDA | | | |
| 35 | 4-tert-butylcyclohexyl acetate | 32210-23-4 | No | Yes | Yes | VaporGas | | NA | NA | Not available | Not applicable | H317Cat1B | | | | Moderate | SEDDA | | | |
| 36 | 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2H-isothiazol-3-one | 55965-84-9 | No | Yes | Yes | VaporGas | | NA | NA | Not available | Sk | H315,H319,H317Cat1A | | 2 | | High | SEDDA | | | |
| 37 | Acetaldehyde | 75-07-0 | No | NO | Yes | VaporGas | BP<35 | PPM | 100 | --- | G1,Sk | H319,H335 | Highly volatile liquid | 1 | | Moderate | SEDDA | | | |
| 38 | ACETIC ACID | 64-19-7 | No | No | Yes | VaporGas | BP >80 | PPM | 10 | --- | Not applicable | H314,H318 | Non volatile liquid | 3 | | Very high | SEDDA | | | |

| S.No | Chemical name | CAS number | API | Handled @ Manufacturing scale | Handled @ Laboratory scale | Physical State (Liquid = VaporGas) | Nature (BP °C/ powder) | OEL Unit (µg/m3 or PPM) | OEL (Sanofi approved/ Regulatory) | OEB (Default) (In case of NO OEL) | Suffix (As per Sanofi SDS) | H Phrases (Health) | Dispersion | Skin Hazard rating | CMR | Health Hazard rating | Data Reference | List updated by | Date of updation (DD/MM/YYYY) | Remarks |
|------|---|-------------|-----|-------------------------------|----------------------------|------------------------------------|------------------------|-------------------------|-----------------------------------|-----------------------------------|----------------------------|--------------------------|------------------------|--------------------|-----|----------------------|----------------|-----------------|-------------------------------|---------|
| 39 | Acetic anhydride | 108-24-7 | No | No | Yes | VaporGas | BP >80 | PPM | 5 | --- | G1,Cor | H302,H314,H318,H330C at2 | Non volatile liquid | 3 | | Very high | SEDDA | | | |
| 40 | ACETONE | 67-64-1 | No | No | Yes | VaporGas | 80<BP>35 | PPM | 500 | --- | Not applicable | H319 | Volatile liquid | | | Moderate | SEDDA | | | |
| 41 | ACETONITRILE | 75-05-8 | No | No | Yes | VaporGas | BP >80 | PPM | 40 | --- | Sk | H302,H312,H319,H332 | Non volatile liquid | 1 | | Moderate | SEDDA | | | |
| 42 | Acide Stéarique | 57-11-4 | No | Yes | Yes | Powder | Granules | NA | NA | Not available | Not applicable | | Dusty solid | | | | SEDDA | | | |
| 43 | Activated carbon | 7440-44-0 | NO | No | Yes | Powder | Micronized powder | µg/m3 | 3500 | OEB1 | Not applicable | | Very dusty solid | | | Very low | SEDDA | | | |
| 44 | Adipic acid | 124-04-9 | No | No | Yes | Powder | Granules | NA | NA | OEB2 | Not applicable | H319 | Dusty solid | | | Moderate | SEDDA | | | |
| 45 | Alfuzosine Chlorhydrate | 81403-80-7 | Yes | Yes | Yes | Powder | Micronized powder | µg/m3 | 32 | OEB3 | G1 | H373 | Very dusty solid | | | Moderate | SEDDA | | | |
| 46 | ALPHA AMYLASE | 9000-90-2 | Yes | Yes | Yes | Powder | Micronized powder | µg/m3 | 3 | OEB4 | Sr,Sk | H334Cat1A | Very dusty solid | 1 | | Very high | SEDDA | | | |
| 47 | alpha-hexylcinnamaldehyde | 101-86-0 | No | Yes | Yes | VaporGas | | NA | NA | Not available | Not applicable | H317Cat1B | | | | Moderate | SEDDA | | | |
| 48 | ALUMINIUM HYDROXIDE | 21645-51-2 | Yes | Yes | Yes | Powder | Micronized powder | µg/m3 | 1500 | OEB1 | Not applicable | | Very dusty solid | | | Very low | SEDDA | | | |
| 49 | Aluminium Oxide | 1344-28-1 | No | No | Yes | Powder | Granules | NA | NA | OEB4 | Not applicable | H301 | Dusty solid | | | High | SEDDA | | | |
| 50 | ALUMINIUM POTASSIUM SULFATE DODECAHYDRATE | 7784-24-9 | No | No | Yes | Powder | Granules | µg/m3 | 2000 | OEB1 | Not applicable | | Dusty solid | | | Very low | SEDDA | | | |
| 51 | Aluminum Hydroxide | 21645-51-2 | No | Yes | Yes | Powder | Micronized powder | µg/m3 | 1500 | OEB1 | Not applicable | | Very dusty solid | | | Very low | SEDDA | | | |
| 52 | Amines, coco alkyldimethyl, N-oxides | 61788-90-7 | No | Yes | Yes | VaporGas | | NA | NA | Not available | Not applicable | H318,H315 | | 2 | | Very high | SEDDA | | | |
| 53 | AMISULPRIDE | 71675-85-9 | Yes | Yes | Yes | Powder | Micronized powder | µg/m3 | 100 | OEB2 | Sk | H302 | Very dusty solid | 1 | | Moderate | SEDDA | | | |
| 54 | Amlodipine besylate | 111470-99-6 | Yes | Yes | Yes | Powder | Micronized powder | µg/m3 | 15 | OEB3 | Not applicable | H302,H318 | Very dusty solid | | | Very high | SEDDA | | | |
| 55 | Ammonia (32%) | 7664-41-7 | No | No | Yes | VaporGas | BP<35 | PPM | 10 | --- | Cor | H314,H331 | Highly volatile liquid | 3 | | Very high | SEDDA | | | |
| 56 | Ammonium Acetate | 631-61-8 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB1 | Not applicable | | Very dusty solid | | | Very low | SEDDA | | | |
| 57 | Ammonium Carbonate | 506-87-6 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB2 | Not applicable | H302 | Very dusty solid | | | Moderate | SEDDA | | | |
| 58 | AMMONIUM CERIUM(IV) NITRATE | 16774-21-3 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB3 | Not applicable | H302,H318 | Very dusty solid | | | Very high | SEDDA | | | |
| 59 | Ammonium Chloride | 12125-02-9 | No | No | Yes | Powder | Micronized powder | µg/m3 | 1000 | OEB1 | Not applicable | H302,H319 | Very dusty solid | | | Moderate | SEDDA | | | |
| 60 | Ammonium Dihydrogen Orthophosphate | 7722-76-1 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | | Very dusty solid | | | | SEDDA | | | |
| 61 | Ammonium hydroxide | 1336-21-6 | No | Yes | Yes | VaporGas | 80<BP>35 | PPM | 10 | --- | Cor | H302,H332,H314,H335 | Volatile liquid | 3 | | Very high | SEDDA | | | |
| 62 | Ammonium iron(II) sulfate hexahydrate 7 H2O | 7783-85-9 | No | No | Yes | Powder | Granules | NA | NA | OEB2 | Not applicable | H315,H319,H335 | Dusty solid | 2 | | Moderate | SEDDA | | | |

| S. No | Chemical name | CAS number | API | Handled @ Manufacturing scale | Handled @ Laboratory scale | Physical State (Liquid = VaporGas) | Nature (BP °C/ powder) | OEL Unit (µg/m3 or PPM) | OEL (Sanofi approved/ Regulatory) | OEB (Default) (In case of NO OEL) | Suffix (As per Sanofi SDS) | H Phrases (Health) | Dispersion | Skin Hazard rating | CMR | Health Hazard rating | Data Reference | List updated by | Date of updation (DD/MM/YYYY) | Remarks |
|-------|--|------------|-----|-------------------------------|----------------------------|------------------------------------|------------------------|-------------------------|-----------------------------------|-----------------------------------|----------------------------|--|------------------------|--------------------|-----------|----------------------|----------------|-----------------|-------------------------------|---------|
| 63 | Ammonium Iron(III) Sulfate Dodecahydrate | 7783-83-7 | No | No | Yes | Powder | Granules | NA | NA | OEB2 | Not applicable | H315,H319 | Dusty solid | 2 | | Moderate | SEDDA | | | |
| 64 | Ammonium Molybdate Tetrahydrate | 12054-85-2 | No | No | Yes | Powder | Micronized powder | µg/m3 | 500 | OEB2 | Not applicable | | Very dusty solid | | | Low | SEDDA | | | |
| 65 | Ammonium nitrate | 6484-52-2 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB2 | Not applicable | H315,H319,H335 | Very dusty solid | 2 | | Moderate | SEDDA | | | |
| 66 | Ammonium phosphate dibasic | 7783-28-0 | No | No | Yes | Powder | Granules | µg/m3 | 6000 | OEB1 | Not applicable | | Dusty solid | | | Very low | SEDDA | | | |
| 67 | Ammonium Sulfamate | 7773-06-0 | No | No | Yes | Powder | Micronized powder | µg/m3 | 10000 | OEB1 | Not applicable | H302 | Very dusty solid | | | Moderate | SEDDA | | | |
| 68 | AMMONIUM SULFATE | 7783-20-2 | No | No | Yes | Powder | Granules | NA | NA | OEB1 | Not applicable | | Dusty solid | | | Very low | SEDDA | | | |
| 69 | Anhydrous dextrose (Glucose) | 50-99-7 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | | Very dusty solid | | | | SEDDA | | | |
| 70 | Anhydrous Potassium Dihydrogen Phosphate | 7778-77-0 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | | Very dusty solid | | | | SEDDA | | | |
| 71 | ANILINE | 62-53-3 | No | No | Yes | VaporGas | BP >80 | PPM | 2 | --- | Sk | H301,H311,H317Cat1B, H318,H331,H341,H351, H372 | Non volatile liquid | 2 | CMR 2 | Very high | SEDDA | | | |
| 72 | Anthrone | 90-44-8 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H319,H315 | Very dusty solid | 2 | | Moderate | SEDDA | | | |
| 73 | Arsenic trioxide | 1327-53-3 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H300Cat1,H314,H318,H350 | Very dusty solid | 3 | CMR 1A/1B | Very high | SEDDA | | | |
| 74 | Azorubine | 3567-69-9 | No | Yes | Yes | Powder | Micronized powder | NA | NA | OEB2 | | | Very dusty solid | | | Low | SEDDA | | | |
| 75 | Barium chloride | 10361-37-2 | No | No | Yes | Powder | Micronized powder | µg/m3 | 500 | OEB2 | Not applicable | H301,H319,H332 | Very dusty solid | | | Moderate | SEDDA | | | |
| 76 | Barium Chloride Dihydrate | 10326-27-9 | No | No | Yes | Powder | Granules | µg/m3 | 500 | OEB2 | Not applicable | H319,H332,H301 | Dusty solid | | | Moderate | SEDDA | | | |
| 77 | Barium Hydroxide Octahydrate | 12230-71-6 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Cor | H302,H314,H332 | Very dusty solid | 3 | | Very high | SEDDA | | | |
| 78 | Basic Fuchsin | 632-99-5 | No | No | Yes | Powder | Micronized powder | NA | NA | --- | Not applicable | | Very dusty solid | | | | SEDDA | | | |
| 79 | Benzaldehyde | 100-52-7 | No | NO | Yes | VaporGas | BP <35 | NA | NA | OEB3 | SK | H302,H315,H319,H332 | Highly volatile liquid | 2 | | Moderate | SEDDA | | | |
| 80 | Benzoic acid | 65-85-0 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H302,H315,H319 | Very dusty solid | 2 | | Moderate | SEDDA | | | |
| 81 | BENZYL ALCOHOL | 100-51-6 | No | No | Yes | VaporGas | BP >80 | NA | NA | OEB3 | Sk | H302,H319,H332 | Non volatile liquid | 1 | | Moderate | SEDDA | | | |
| 82 | Biuret | 108-19-0 | No | No | Yes | VaporGas | BP >80 | NA | NA | OEB3 | Not applicable | H315,H319,H335 | Non volatile liquid | 2 | | Moderate | SEDDA | | | |
| 83 | Boric Acid | 108-17-1 | No | No | Yes | Powder | Micronized powder | µg/m3 | 2000 | OEB1 | G1,Sk | H360Cat1B | Very dusty solid | 1 | CMR 1A/1B | High | SEDDA | | | |
| 84 | Bromocresol Green | 76-60-8 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | | Very dusty solid | | | | SEDDA | | | |
| 85 | Bromophenol blue | 115-39-9 | No | No | Yes | Powder | Granules | NA | NA | OEB2 | Not applicable | | Dusty solid | | | Low | SEDDA | | | |

| S. No | Chemical name | CAS number | API | Handled @ Manufacturing scale | Handled @ Laboratory scale | Physical State (Liquid = VaporGas) | Nature (BP °C/ powder) | OEL Unit (µg/m3 or PPM) | OEL (Sanofi approved/ Regulatory) | OEB (Default) (In case of NO OEL) | Suffix (As per Sanofi SDS) | H Phrases (Health) | Dispersion | Skin Hazard rating | CMR | Health Hazard Data Reference rating | | List updated by | Date of updation (DD/MM/YYYY) | Remarks |
|-------|---------------------------------------|-------------|-----|-------------------------------|----------------------------|------------------------------------|------------------------|-------------------------|-----------------------------------|-----------------------------------|----------------------------|--|---------------------|--------------------|-----------|-------------------------------------|-------|-----------------|-------------------------------|---------|
| 86 | Bromothymol Blue | 76-59-5 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB3 | Not applicable | | Very dusty solid | | | Moderate | SEDDA | | | |
| 87 | Butyric Acid | 107-92-6 | No | No | Yes | VaporGas | BP >80 | NA | NA | OEB3 | Cor | H314,H318 | Non volatile liquid | 3 | | Very high | SEDDA | | | |
| 88 | C.I. ACID RED 2 | 493-52-7 | No | No | Yes | VaporGas | | NA | NA | OEB3 | Not applicable | | | | | Moderate | SEDDA | | | |
| 89 | Caffeine | 58-08-2 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H302 | Very dusty solid | | | Moderate | SEDDA | | | |
| 90 | Calcium Carbonate | 471-34-1 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB1 | Not applicable | | Very dusty solid | | | Very low | SEDDA | | | |
| 91 | Calcium sulfate | 7778-18-9 | No | No | Yes | Powder | Granules | NA | NA | Not available | Not applicable | H341,H334Cat1A,H317 Cat1B,H360Cat1B,H350 | Dusty solid | | CMR 1A/1B | Very high | SEDDA | | | |
| 92 | Calcium Sulfate Dihydrate (Gypsum) | 10101-41-4 | No | No | Yes | Powder | Micronized powder | µg/m3 | 5000 | OEB1 | Not applicable | | Very dusty solid | | | Very low | SEDDA | | | |
| 93 | CARBOCISTEINE | 638-23-3 | Yes | Yes | Yes | Powder | Granules | µg/m3 | 2000 | OEB1 | Not applicable | | Dusty solid | | | Very low | SEDDA | | | |
| 94 | Cellulose Acetate Phthalate | 9004-38-0 | No | Yes | Yes | Powder | Micronized powder | NA | NA | OEB1 | Not applicable | | Very dusty solid | | | Very low | SEDDA | | | |
| 95 | Cerium(IV) sulfate | 13590-82-4 | No | NO | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H314,H318 | Very dusty solid | 3 | | Very high | SEDDA | | | |
| 96 | Cesium chloride | 7647-17-8 | No | NO | Yes | Powder | Micronized powder | NA | NA | OEB2 | G1 | H315,H319,H335,H361,H373 | Very dusty solid | 2 | CMR 2 | Moderate | SEDDA | | | |
| 97 | Chlorhexidine gluconate solution | 18472-51-0 | No | Yes | Yes | VaporGas | | NA | NA | OEB3 | Not applicable | H318 | | | | Very high | SEDDA | | | |
| 98 | Cire de Carnauba | 8015-86-9 | No | Yes | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | | Very dusty solid | | | | SEDDA | | | |
| 99 | CITRIC ACID MONOHYDRATE | 5949-29-1 | No | Yes | Yes | Powder | Micronized powder | NA | NA | OEB1 | Not applicable | H319,H335 | Very dusty solid | | | Moderate | SEDDA | | | |
| 100 | CLOPIDOGREL HYDROGENSULFATE (form II) | 120202-66-6 | Yes | Yes | Yes | Powder | Micronized powder | µg/m3 | 95 | OEB3 | Cor | H314,H318,H335 | Very dusty solid | 3 | | Very high | SEDDA | | | |
| 101 | Cobalt chloride | 7646-79-9 | No | No | Yes | Powder | Micronized powder | µg/m3 | 10 | OEB3 | Sr,Sk | H302,H317Cat1B,H318,H341,H350,H360Cat1B | Very dusty solid | 1 | CMR 1A/1B | Very high | SEDDA | | | |
| 102 | Cobalt(II) Chloride Hexahydrate | 7791-13-1 | No | NO | Yes | Powder | Micronized powder | µg/m3 | 20 | OEB3 | Sr,Sk | H302,H317Cat1A,H318,H334Cat1A,H341,H350,H360Cat1B | Very dusty solid | 1 | CMR 1A/1B | Very high | SEDDA | | | |
| 103 | Cobalt(II) Nitrate Hexahydrate | 10026-22-9 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H302,H317Cat1A,H318,H334Cat1A,H341,H350,H360Cat1/1A,H373 | Very dusty solid | | CMR 1A/1B | Very high | SEDDA | | | |
| 104 | Copper sulfate | 7758-98-7 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H302,H315,H319 | Very dusty solid | 2 | | Moderate | SEDDA | | | |
| 105 | Copper(II) Sulfate Pentahydrate | 7758-99-8 | No | Yes | Yes | Powder | Micronized powder | NA | NA | OEB3 | Not applicable | H302,H318 | Very dusty solid | | | Very high | SEDDA | | | |
| 106 | Crystal violet | 548-62-9 | No | No | Yes | Powder | Granules | NA | NA | OEB4 | Not applicable | H302,H318,H351 | Dusty solid | | CMR 2 | Very high | SEDDA | | | |
| 107 | D-(+)-Maltose monohydrate | 6363-53-7 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | | Very dusty solid | | | | SEDDA | | | |
| 108 | Decyl glucoside | 68515-73-1 | No | Yes | Yes | VaporGas | | NA | NA | Not available | Not applicable | H318 | | | | Very high | SEDDA | | | |

| S.No | Chemical name | CAS number | API | Handled @ Manufacturing scale | Handled @ Laboratory scale | Physical State (Liquid = VaporGas) | Nature (BP °C/ powder) | OEL Unit (µg/m3 or PPM) | OEL (Sanofi approved/ Regulatory) | OEB (Default) (In case of NO OEL) | Suffix (As per Sanofi SDS) | H Phrases (Health) | Dispersion | Skin Hazard rating | CMR | Health Hazard rating | Data Reference | List updated by | Date of updation (DD/MM/YYYY) | Remarks |
|------|---|------------|-----|-------------------------------|----------------------------|------------------------------------|------------------------|-------------------------|-----------------------------------|-----------------------------------|----------------------------|---------------------|------------------------|--------------------|-----------|----------------------|----------------|-----------------|-------------------------------|---------|
| 109 | D-fructose | 57-48-7 | No | No | Yes | Powder | Granules | NA | NA | OEB1 | Not applicable | | Dusty solid | | | Very low | SEDDA | | | |
| 110 | D-Fructose | 57-48-7 | No | Yes | Yes | Powder | Micronized powder | NA | NA | OEB1 | Not applicable | | Very dusty solid | | | Very low | SEDDA | | | |
| 111 | Diammonium Hydrogen Phosphate | 7783-28-0 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB1 | Not applicable | | Very dusty solid | | | Very low | SEDDA | | | |
| 112 | Dicarboxylic acid | 144-62-7 | No | No | Yes | Powder | Micronized powder | µg/m3 | 1000 | OEB1 | Not applicable | H302,H312,H318 | Very dusty solid | 1 | | Very high | SEDDA | | | |
| 113 | DIETHYL ETHER | 60-29-7 | No | No | Yes | VaporGas | BP<35 | PPM | 100 | --- | Not applicable | H302 | Highly volatile liquid | | | Moderate | SEDDA | | | |
| 114 | Diethylene Glycol | 111-46-6 | No | No | Yes | VaporGas | BP >80 | PPM | 10 | --- | Not applicable | H302 | Non volatile liquid | | | Moderate | SEDDA | | | |
| 115 | Dimethyl yellow | 60-11-7 | NO | NO | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H301,H351 | Very dusty solid | | CMR 2 | Very high | SEDDA | | | |
| 116 | DIPHENYL ETHER | 101-84-8 | No | Yes | Yes | Powder | Micronized powder | NA | NA | OEB2 | Not applicable | H319 | Very dusty solid | | | Moderate | SEDDA | | | |
| 117 | Disodium hydrogen phosphate anhydrous | 7558-79-4 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB1 | Not applicable | | Very dusty solid | | | Very low | SEDDA | | | |
| 118 | Disodium hydrogen phosphate dihydrate | 10028-24-7 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H319 | Very dusty solid | | | Moderate | SEDDA | | | |
| 119 | Disodium hydrogen phosphate dodecahydrate | 10039-32-4 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB1 | Not applicable | | Very dusty solid | | | Very low | SEDDA | | | |
| 120 | DISODIUM TARTRATE Dihydrate | 6106-24-7 | No | No | Yes | Powder | Granules | NA | NA | OEB1 | Not applicable | | Dusty solid | | | Very low | SEDDA | | | |
| 121 | Disodium tetraborate | 1330-43-4 | NO | NO | Yes | Powder | Micronized powder | µg/m3 | 1000 | OEB1 | G1 | H360Cat1B | Very dusty solid | | CMR 1A/1B | High | SEDDA | | | |
| 122 | DISODIUM TETRABORATE DECAHYDRATE | 1303-96-4 | No | No | Yes | Powder | Micronized powder | µg/m3 | 5000 | OEB1 | G1 | H360Cat1B | Very dusty solid | | CMR 1A/1B | High | SEDDA | | | |
| 123 | Dithizone | 60-10-6 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB4 | Not applicable | H315,H319,H335 | Very dusty solid | 2 | | High | SEDDA | | | |
| 124 | D-Limonene | 5989-27-5 | No | No | Yes | VaporGas | BP >80 | PPM | 20 | --- | G1,Sk | H315,H317Cat1A | Non volatile liquid | 2 | | High | SEDDA | | | |
| 125 | D-Maltose | 69-79-4 | No | No | Yes | VaporGas | | NA | NA | --- | Not applicable | | | | | | SEDDA | | | |
| 126 | D-MANNITOL | 69-65-8 | No | Yes | Yes | Powder | Micronized powder | NA | NA | OEB1 | Not applicable | | Very dusty solid | | | Very low | SEDDA | | | |
| 127 | DODECYLDIMETHYLAMINE OXIDE | 1643-20-5 | No | Yes | Yes | Powder | Micronized powder | NA | NA | OEB3 | Not applicable | H315,H302,H318 | Very dusty solid | 2 | | Very high | SEDDA | | | |
| 128 | D-Sorbitol | 50-70-4 | No | Yes | Yes | Powder | Micronized powder | NA | NA | OEB1 | Not applicable | | Very dusty solid | | | Very low | SEDDA | | | |
| 129 | EDTA disodium salt | 6381-92-6 | No | No | Yes | Powder | Granules | NA | NA | Not available | Not applicable | H332,H373 | Dusty solid | | | Moderate | SEDDA | | | |
| 130 | Epsilon-Caprolactam | 105-60-2 | No | No | Yes | Powder | Micronized powder | µg/m3 | 1000 | OEB1 | Not applicable | H302,H315,H319,H335 | Very dusty solid | 2 | | Moderate | SEDDA | | | |

| S.No | Chemical name | CAS number | API | Handled @ Manufacturing scale | Handled @ Laboratory scale | Physical State (Liquid = VaporGas) | Nature (BP °C/ powder) | OEL Unit (µg/m3 or PPM) | OEL (Sanofi approved/ Regulatory) | OEB (Default) (In case of NO OEL) | Suffix (As per Sanofi SDS) | H Phrases (Health) | Dispersion | Skin Hazard rating | CMR | Health Hazard rating | Data Reference | List updated by | Date of updation (DD/MM/YYYY) | Remarks |
|------|-----------------------------------|-------------|-----|-------------------------------|----------------------------|------------------------------------|------------------------|-------------------------|-----------------------------------|-----------------------------------|----------------------------|--|------------------------|--------------------|-----------|----------------------|----------------|-----------------|-------------------------------|---------|
| 131 | Eriochrome Black T | 1787-61-7 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB4 | Not applicable | H319 | Very dusty solid | | | High | SEDDA | | | |
| 132 | Ethanol | 64-17-5 | No | Yes | Yes | VaporGas | 80<BP>35 | PPM | 1000 | --- | Not applicable | H319 | Volatile liquid | | | Moderate | SEDDA | | | |
| 133 | Ethoxylated C10-16 alcohols | 68002-97-1 | No | Yes | Yes | VaporGas | | NA | NA | Not available | Not applicable | H302,H318,H315 | | 2 | | Very high | SEDDA | | | |
| 134 | ETHYL ACETATE | 141-78-6 | No | Yes | Yes | VaporGas | 80<BP>35 | PPM | 200 | --- | Not applicable | H319 | Volatile liquid | | | Moderate | SEDDA | | | |
| 135 | Ethyl acrylate | 140-88-5 | No | No | Yes | VaporGas | BP >80 | PPM | 5 | --- | Sk | H302,H312,H315,H317C at1A,H319,H331,H335 | Non volatile liquid | 2 | | High | SEDDA | | | |
| 136 | ETHYL PHTHALATE | 84-66-2 | No | Yes | Yes | VaporGas | BP >80 | NA | NA | OEB2 | G1 | | Non volatile liquid | | | Low | SEDDA | | | |
| 137 | Ethylene Glycol (Antifreeze) | 107-21-1 | No | No | Yes | VaporGas | BP >80 | PPM | 20 | --- | G1,Sk | H302,H373 | Non volatile liquid | 1 | | Moderate | SEDDA | | | |
| 138 | Ethylenediamine tetraacetic Acid | 60-00-4 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB2 | G1 | H319,H373,H332 | Very dusty solid | | | Moderate | SEDDA | | | |
| 139 | Etidronic acid | 2809-21-4 | No | Yes | Yes | VaporGas | BP >80 | NA | NA | Not available | Not applicable | H302,H318 | Non volatile liquid | | | Very high | SEDDA | | | |
| 140 | EUCALYPTOL | 470-82-6 | No | Yes | Yes | VaporGas | BP >80 | NA | NA | Not available | Not applicable | H317Cat1A | Non volatile liquid | | | High | SEDDA | | | |
| 141 | Fexofenadine Hydrochloride | 153439-40-8 | Yes | Yes | Yes | Powder | Granules | µg/m3 | 800 | OEB2 | Not applicable | | Dusty solid | | | Low | SEDDA | | | |
| 142 | Formaldehyde | 50-00-0 | No | No | Yes | VaporGas | BP >80 | PPM | 0.3 | --- | Sr,Cor | H314,H317Cat1A,H318,H301,H311,H335,H341,H315 | Non volatile liquid | 3 | CMR 2 | Very high | SEDDA | | | |
| 143 | FORMAMIDE | 75-12-7 | No | Yes | Yes | VaporGas | BP >80 | PPM | 20 | --- | G2,Sk | H351,H360Cat1B,H373 | Non volatile liquid | 1 | CMR 1A/1B | Very high | SEDDA | | | |
| 144 | Formic Acid | 64-18-6 | No | No | Yes | VaporGas | BP >80 | PPM | 5 | OEB1 | Cor | H302,H314,H331 | Non volatile liquid | 3 | | Very high | SEDDA | | | |
| 145 | Gemigliptin | 957054-30-7 | Yes | Yes | Yes | Powder | Micronized powder | µg/m3 | 90 | OEB3 | Sk | H302,H351 | Very dusty solid | 1 | CMR 2 | Very high | SEDDA | | | |
| 146 | Genapol LRO | 68891-38-3 | No | Yes | Yes | VaporGas | | NA | NA | Not available | Not applicable | | | | | | SEDDA | | | |
| 147 | GLIMEPIRIDE | 93479-97-1 | Yes | Yes | Yes | Powder | Micronized powder | µg/m3 | 10 | OEB3 | Not applicable | | Very dusty solid | | | High | SEDDA | | | |
| 148 | Glycolic acid | 79-14-1 | No | No | Yes | Powder | Granules | NA | NA | OEB3 | Cor | H302,H314 | Dusty solid | 3 | | Very high | SEDDA | | | |
| 149 | Gomme de Xanthane | 11138-66-2 | No | Yes | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | | Very dusty solid | | | | SEDDA | | | |
| 150 | Acetylsalicylic Acid | 50-78-2 | Yes | Yes | Yes | Powder | Micronized powder | µg/m3 | 150 | OEB2 | G1 | H302 | Very dusty solid | | | Moderate | SEDDA | | | |
| 151 | HEPTANE | 142-82-5 | NO | NO | Yes | VaporGas | BP >80 | PPM | 400 | --- | Not applicable | H315 | Non volatile liquid | 2 | | Moderate | SEDDA | | | |
| 152 | Hexamethylenetetramine (Hexamine) | 100-97-0 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB3 | Sk | H317Cat1A | Very dusty solid | 1 | | High | SEDDA | | | |
| 153 | HYDRAZINE SULFATE | 10034-93-2 | No | No | Yes | Powder | Micronized powder | µg/m3 | 1000 | OEB1 | G1,Sk | H301,H311,H331,H317C at1A,H350 | Very dusty solid | 2 | CMR 1A/1B | Very high | SEDDA | | | |
| 154 | HYDROCHLORIC ACID | 7647-01-0 | No | No | Yes | VaporGas | BP >80 | PPM | 5000 | --- | Cor | H314,H335 | Non volatile liquid | 3 | | Very high | SEDDA | | | |
| 155 | HYDROCHLOROTHAZIDE | 58-93-5 | Yes | Yes | Yes | Powder | Micronized powder | µg/m3 | 90 | OEB3 | Sk | H302,H351 | Very dusty solid | 1 | CMR 2 | Very high | SEDDA | | | |
| 156 | Hydrofluoric Acid | 7664-39-3 | No | No | Yes | VaporGas | BP<35 | PPM | 1.8 | --- | Sk | H300Cat2,H310Cat1,H314,H318,H330Cat2 | Highly volatile liquid | 3 | | Very high | SEDDA | | | |

| S. No | Chemical name | CAS number | API | Handled @ Manufacturing scale | Handled @ Laboratory scale | Physical State (Liquid = VaporGas) | Nature (BP °C/ powder) | OEL Unit (µg/m3 or PPM) | OEL (Sanofi approved/ Regulatory) | OEB (Default) (In case of NO OEL) | Suffix (As per Sanofi SDS) | H Phrases (Health) | Dispersion | Skin Hazard rating | CMR | Health Hazard rating | Data Reference | List updated by | Date of updation (DD/MM/YYYY) | Remarks |
|-------|---------------------------------------|-------------|-----|-------------------------------|----------------------------|------------------------------------|------------------------|-------------------------|-----------------------------------|-----------------------------------|----------------------------|--|------------------------|--------------------|-----------|----------------------|----------------|-----------------|-------------------------------|---------|
| 157 | HYDROGEN PEROXIDE SOLUTION >=20% <35% | 7722-84-1 | No | No | Yes | VaporGas | BP >80 | PPM | 1 | --- | COR | H302,H314,H332,H335 | Non volatile liquid | 3 | | Very high | SEDDA | | | |
| 158 | HYDROGENE IODIDE | 10034-85-2 | No | NO | Yes | VaporGas | BP >80 | NA | NA | OEB4 | COR | H314 | Non volatile liquid | 3 | | Very high | SEDDA | | | |
| 159 | Hydroxylamine hydrochloride | 1304222 | No | No | Yes | Powder | Granules | NA | NA | OEB4 | G1,Sk | H302,H312,H315,H319, H317Cat1A,H351,H373 | Dusty solid | 2 | CMR 2 | Very high | SEDDA | | | |
| 160 | Indigo Carmin Aluminum | 860-22-0 | No | Yes | Yes | Powder | Granules | NA | NA | Not available | Not applicable | | Dusty solid | | | | SEDDA | | | |
| 161 | Insulin Glulisine SKH | 207748-29-6 | Yes | Yes | Yes | Powder | Micronized powder | µg/m3 | 200 | OEB2 | Not applicable | | Very dusty solid | | | Low | SEDDA | | | |
| 162 | Iodine | 7553-56-2 | No | No | Yes | Powder | Micronized powder | µg/m3 | 1000 | OEB1 | G1,Sr | H302,H312,H332,H315, H319,H335 | Very dusty solid | 2 | | Moderate | SEDDA | | | |
| 163 | Irbesartan | 138402-11-6 | Yes | Yes | Yes | Powder | Micronized powder | µg/m3 | 100 | OEB2 | G1 | H361,H373 | Very dusty solid | | CMR 2 | Moderate | SEDDA | | | |
| 164 | IRON (III) NITRATE NONAHYDRATE | 7782-61-8 | No | No | Yes | Powder | Granules | µg/m3 | 1000 | OEB1 | Not applicable | H315,H319 | Dusty solid | 2 | | Moderate | SEDDA | | | |
| 165 | Iron(II) sulfate hexahydrate | 7782-63-0 | No | No | Yes | Powder | Granules | µg/m3 | 1000 | OEB1 | Not applicable | H302,H315,H319 | Dusty solid | 2 | | Moderate | SEDDA | | | |
| 166 | Iron(II) Sulfate Monohydrate | 13463-43-9 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H302,H315,H319 | Very dusty solid | 2 | | Moderate | SEDDA | | | |
| 167 | Iron(III) Chloride Hexahydrate | 10025-77-1 | No | No | Yes | Powder | Granules | µg/m3 | 1000 | OEB1 | Not applicable | H315,H318,H302 | Dusty solid | 2 | | Very high | SEDDA | | | |
| 168 | Iron(III) sulfate hexahydrate | 15244-10-7 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB3 | Not applicable | H302,H315,H319 | Very dusty solid | 2 | | Moderate | SEDDA | | | |
| 169 | Isoamyl Alcohol (Isopentanol) | 123-51-3 | No | No | Yes | VaporGas | BP >80 | PPM | 100 | --- | Not applicable | H315,H318,H332,H335 | Non volatile liquid | 2 | | Very high | SEDDA | | | |
| 170 | ISOBUTANE | 75-28-5 | No | Yes | Yes | VaporGas | BP <35 | NA | NA | OEB2 | Not applicable | | Highly volatile liquid | | | Low | SEDDA | | | |
| 171 | Ketoprofen | 22071-15-4 | Yes | Yes | Yes | Powder | Micronized powder | NA | NA | OEB2 | G1,Sk | H301,H315,H319,H335 | Very dusty solid | 2 | | Moderate | SEDDA | | | |
| 172 | L-(+)-Tartaric Acid | 87-69-4 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB1 | Not applicable | H318 | Very dusty solid | | | Very high | SEDDA | | | |
| 173 | Lead acetate | 6080-56-4 | No | No | Yes | Powder | Micronized powder | µg/m3 | 100 | OEB2 | G2 | H361,H373 | Very dusty solid | | CMR 2 | Moderate | SEDDA | | | |
| 174 | LEAD(II) NITRATE | 10099-74-8 | No | No | Yes | Powder | Micronized powder | µg/m3 | 100 | OEB2 | G2 | H302,H332,H360Cat1/1 A,H373 | Very dusty solid | | CMR 1A/1B | Very high | SEDDA | | | |
| 175 | Linalol | 78-70-6 | No | Yes | Yes | VaporGas | | NA | NA | Not available | Not applicable | H315,H317Cat1B,H319 | | 2 | | Moderate | SEDDA | | | |
| 176 | Liquid Paraffin | 8012-95-1 | No | NO | Yes | VaporGas | BP >80 | NA | NA | OEB1 | Not applicable | | Non volatile liquid | | | Very low | SEDDA | | | |
| 177 | L-Menthyl acetate | 2623-23-6 | No | No | Yes | VaporGas | BP >80 | NA | NA | Not available | Not applicable | | Non volatile liquid | | | | SEDDA | | | |
| 178 | L-Methionine | 63-68-3 | No | Yes | Yes | Powder | | NA | NA | Not available | Not applicable | | | | | | SEDDA | | | |
| 179 | Macrogol 6000 | 25322-68-3 | No | Yes | Yes | Powder | Pellets | NA | NA | Not available | Not applicable | | Non dusty solid | | | | SEDDA | | | |
| 180 | Magnesium Chloride Hexahydrate | 7791-18-6 | No | Yes | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | | Very dusty solid | | | | SEDDA | | | |

| S. No | Chemical name | CAS number | API | Handled @ Manufacturing scale | Handled @ Laboratory scale | Physical State (Liquid = VaporGas) | Nature (BP °C/ powder) | OEL Unit (µg/m3 or PPM) | OEL (Sanofi approved/ Regulatory) | OEB (Default) (In case of NO OEL) | Suffix (As per Sanofi SDS) | H Phrases (Health) | Dispersion | Skin Hazard rating | CMR | Health Hazard rating | Data Reference | List updated by | Date of update (DD/MM/YYYY) | Remarks |
|-------|---|-------------|-----|-------------------------------|----------------------------|------------------------------------|------------------------|-------------------------|-----------------------------------|-----------------------------------|----------------------------|---|------------------------|--------------------|-----------|----------------------|----------------|-----------------|-----------------------------|---------|
| 181 | MAGNESIUM HYDROXIDE | 1309-42-8 | No | No | Yes | Powder | Granules | NA | NA | Not available | Not applicable | | Dusty solid | | | | SEDDA | | | |
| 182 | Magnesium powder | 7439-95-4 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB2 | Not applicable | | Very dusty solid | | | Low | SEDDA | | | |
| 183 | Magnesium sulfate anhydrous | 7487-88-9 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | | Very dusty solid | | | | SEDDA | | | |
| 184 | Magnesium Sulfate Heptahydrate (Epsom Salt) | 10034-99-8 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | | Very dusty solid | | | | SEDDA | | | |
| 185 | Magnesium sulfate hydrate | 22189-08-8 | No | No | Yes | Powder | Granules | NA | NA | Not available | Not applicable | | Dusty solid | | | | SEDDA | | | |
| 186 | m-Cresol | 108-39-4 | No | Yes | Yes | VaporGas | BP >80 | PPM | 5000 | --- | Cor | | Non volatile liquid | 1 | | Very low | SEDDA | | | |
| 187 | Menthol | 89-78-1 | No | No | Yes | VaporGas | BP <35 | NA | NA | OEB2 | Not applicable | H315,H319 | Highly volatile liquid | 2 | | Moderate | SEDDA | | | |
| 188 | Mercuric iodide | 7774-29-0 | No | No | Yes | Powder | Micronized powder | µg/m3 | 20 | OEB3 | G1,Sk | H300Cat2,H310Cat1,H330Cat2,H373 | Very dusty solid | 1 | | Very high | SEDDA | | | |
| 189 | Mercury nitrate | 10045-94-0 | No | No | Yes | Powder | Micronized powder | µg/m3 | 20 | OEB3 | G1,Sk | H300Cat2,H310Cat1,H330Cat2,H373 | Very dusty solid | 1 | | Very high | SEDDA | | | |
| 190 | Mercury(II) Acetate | 1600-27-7 | No | No | Yes | Powder | Micronized powder | µg/m3 | 20 | OEB3 | G1,Sk | H300Cat2,H310Cat1,H330Cat2,H373 | Very dusty solid | 1 | | Very high | SEDDA | | | |
| 191 | Mercury(II) chloride | 7487-94-7 | No | No | Yes | Powder | Micronized powder | µg/m3 | 20 | OEB3 | G1,Cor | H300Cat2,H314,H341,H361,H372 | Very dusty solid | 3 | CMR 2 | Very high | SEDDA | | | |
| 192 | Metformin Hydrochloride | 1115-70-4 | Yes | Yes | Yes | Powder | Granules | µg/m3 | 1250 | OEB1 | Not applicable | H302,H315,H319 | Dusty solid | 2 | | Moderate | SEDDA | | | |
| 193 | METHANOL | 67-56-1 | No | No | Yes | VaporGas | 80 < BP > 35 | PPM | 200 | --- | Sk | H311,H301,H331,H370 | Volatile liquid | 2 | | Very high | SEDDA | | | |
| 194 | METHOXYMETHYLETHOXY)PROPANOL | 34590-94-8 | No | Yes | Yes | VaporGas | BP <35 | PPM | 50 | --- | Not applicable | | Highly volatile liquid | | | Low | SEDDA | | | |
| 195 | METHYL ACETATE | 72-20-9 | No | No | Yes | VaporGas | 80 < BP > 35 | PPM | 200 | --- | Not applicable | H319 | Volatile liquid | | | Moderate | SEDDA | | | |
| 196 | Methyl Methacrylate | 80-62-6 | No | No | Yes | VaporGas | BP >80 | PPM | 50 | --- | Not applicable | H335,H315,H317Cat1A | Non volatile liquid | 2 | | High | SEDDA | | | |
| 197 | Methyl Orange | 547-58-0 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB4 | Not applicable | | Very dusty solid | | | High | SEDDA | | | |
| 198 | Methyl tert-butyl ether | 1634-04-4 | No | No | Yes | VaporGas | 80 < BP > 35 | PPM | 50 | --- | Not applicable | H315 | Volatile liquid | 2 | | Moderate | SEDDA | | | |
| 199 | Methylene Blue Hydrate | 122965-43-9 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H302 | Very dusty solid | | | Moderate | SEDDA | | | |
| 200 | Molecular sieve | 1318-02-1 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | | Very dusty solid | | | | SEDDA | | | |
| 201 | N-HEXANE | 110-54-3 | No | No | Yes | VaporGas | 80 < BP > 35 | PPM | 20 | --- | G1,Sk | H315,H373 | Volatile liquid | 2 | | Moderate | SEDDA | | | |
| 202 | Nickel sulfate | 7786-81-4 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB4 | G2,Sr,Sk | H302,H317Cat1A,H332,H315,H341,H372,H350,H360Cat1B,H334Cat1A | Very dusty solid | 2 | CMR 1A/1B | Very high | SEDDA | | | |
| 203 | Ninhydrin | 485-47-2 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB3 | Not applicable | H302,H315,H319,H335 | Very dusty solid | 2 | | Moderate | SEDDA | | | |
| 204 | Nitric Acid | 7697-37-2 | No | No | Yes | VaporGas | BP >80 | PPM | 1 | OEB1 | Cor | H314,H331 | Non volatile liquid | 3 | | Very high | SEDDA | | | |

| S. No | Chemical name | CAS number | API | Handled @ Manufacturing scale | Handled @ Laboratory scale | Physical State (Liquid = VaporGas) | Nature (BP °C/ powder) | OEL Unit (µg/m3 or PPM) | OEL (Sanofi approved/ Regulatory) | OEB (Default) (In case of NO OEL) | Suffix (As per Sanofi SDS) | H Phrases (Health) | Dispersion | Skin Hazard rating | CMR | Health Hazard Data Reference rating | | List updated by | Date of updation (DD/MM/YYYY) | Remarks |
|-------|---|------------|-----|-------------------------------|----------------------------|------------------------------------|------------------------|-------------------------|-----------------------------------|-----------------------------------|----------------------------|---|------------------------|--------------------|-----------|-------------------------------------|-------|-----------------|-------------------------------|---------|
| 205 | Nitrotrimethylene phosphonic acid | 6419-19-8 | No | Yes | Yes | VaporGas | BP >80 | NA | NA | OEB2 | Cor | H319 | Non volatile liquid | 1 | | Moderate | SEDDA | | | |
| 206 | N-NDIMETHYLFORMAMIDE | 68-12-2 | No | No | Yes | VaporGas | BP >80 | PPM | 5 | --- | Sk,G2 | H312,H319,H332,H360C at1B | Non volatile liquid | 1 | CMR 1A/1B | High | SEDDA | | | |
| 207 | O-Toluenesulfonamide | 88-19-7 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H319,H351 | Very dusty solid | | CMR 2 | Very high | SEDDA | | | |
| 208 | OXOMEMAZINE | 3689-50-7 | Yes | Yes | Yes | Powder | Micronized powder | µg/m3 | 10 | OEB3 | Sk | H301,H317Cat1A | Very dusty solid | 1 | | High | SEDDA | | | |
| 209 | O-Xylene | 95-47-6 | No | No | Yes | VaporGas | BP >80 | PPM | 50 | --- | G1,Sk | H312,H315,H319,H332,H335 | Non volatile liquid | 2 | | Moderate | SEDDA | | | |
| 210 | Paracetamol | 103-90-2 | Yes | Yes | Yes | Powder | Micronized powder | µg/m3 | 2500 | OEB1 | Not applicable | H302 | Very dusty solid | | | Moderate | SEDDA | | | |
| 211 | Paraffin Oil | 8012-95-1 | No | No | Yes | VaporGas | BP >80 | NA | NA | OEB1 | Not applicable | | Non volatile liquid | | | Very low | SEDDA | | | |
| 212 | Pararosaniline hydrochloride | 569-61-9 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB4 | Not applicable | H350 | Very dusty solid | | CMR 1A/1B | Very high | SEDDA | | | |
| 213 | Perchloric acid 70% | 7601-90-3 | No | No | Yes | VaporGas | BP >80 | NA | NA | OEB3 | COR | H302,H314,H373 | Non volatile liquid | 3 | | Very high | SEDDA | | | |
| 214 | Periodic acid | 10450-60-9 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB3 | Cor | H314 | Very dusty solid | 3 | | Very high | SEDDA | | | |
| 215 | Petroleum Ether | 8032-32-4 | No | No | Yes | VaporGas | BP <35 | PPM | 300 | --- | G1 | H315,H340,H350 | Highly volatile liquid | 2 | CMR 1A/1B | Very high | SEDDA | | | |
| 216 | Phenol | 108-95-2 | No | No | Yes | Powder | Granules | µg/m3 | 7800 | --- | Sk,Cor | H301,H311,H314,H331,H341,H373 | Dusty solid | 3 | CMR 2 | Very high | SEDDA | | | |
| 217 | Phenolphthalein | 77-09-8 | No | No | Yes | Powder | Micronized powder | µg/m3 | 3 | OEB4 | | H341,H350,H360Cat1B | Very dusty solid | | CMR 1A/1B | Very high | SEDDA | | | |
| 218 | Phenylhydrazine Hydrochloride | 59-88-1 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB4 | SK | H301,H311,H331,H315,H317Cat1A,H319,H341,H350,H373 | Very dusty solid | 2 | CMR 1A/1B | Very high | SEDDA | | | |
| 219 | Phosphoric Acid | 7664-38-2 | No | Yes | Yes | Powder | Micronized powder | µg/m3 | 1000 | OEB1 | Cor | H302,H314 | Very dusty solid | 3 | | Very high | SEDDA | | | |
| 220 | Phosphorus Pentoxide | 1314-56-3 | No | No | Yes | Powder | Micronized powder | µg/m3 | 1000 | OEB1 | Not applicable | H314 | Very dusty solid | 3 | | Very high | SEDDA | | | |
| 221 | Phthalic Anhydride | 85-44-9 | No | No | Yes | Powder | Micronized powder | µg/m3 | 6000 | --- | Sr,Sk | H302,H315,H318,H334C at1A,H317Cat1A | Very dusty solid | 2 | | Very high | SEDDA | | | |
| 222 | POLYSORBATE 20 | 9005-64-5 | No | Yes | Yes | VaporGas | BP >80 | NA | NA | OEB1 | Not applicable | | Non volatile liquid | | | Very low | SEDDA | | | |
| 223 | Potassium acid Phthalate | 877-24-7 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB2 | Not applicable | | Very dusty solid | | | Low | SEDDA | | | |
| 224 | Potassium Antimonyl Tartrate Trihydrate | 28300-74-5 | No | No | Yes | Powder | Micronized powder | µg/m3 | 500 | OEB2 | Not applicable | H301,H332,H315,H317C at1B | Very dusty solid | 2 | | Moderate | SEDDA | | | |
| 225 | Potassium Bisulfate | 7646-93-7 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB3 | Cor | H314,H335 | Very dusty solid | 3 | | Very high | SEDDA | | | |
| 226 | Potassium Bromate | 2139594 | No | No | Yes | Powder | Micronized powder | µg/m3 | 100 | OEB2 | Not applicable | H301,H350 | Very dusty solid | | CMR 1A/1B | Very high | SEDDA | | | |

| S. No | Chemical name | CAS number | API | Handled @ Manufacturing scale | Handled @ Laboratory scale | Physical State (Liquid = VaporGas) | Nature (BP °C/ powder) | OEL Unit (µg/m3 or PPM) | OEL (Sanofi approved/ Regulatory) | OEB (Default) (In case of NO OEL) | Suffix (As per Sanofi SDS) | H Phrases (Health) | Dispersion | Skin Hazard rating | CMR | Health Hazard rating | Data Reference | List updated by | Date of updation (DD/MM/YYYY) | Remarks |
|-------|--|------------|-----|-------------------------------|----------------------------|------------------------------------|------------------------|-------------------------|-----------------------------------|-----------------------------------|----------------------------|--|------------------------|--------------------|-----------|----------------------|----------------|-----------------|-------------------------------|---------|
| 227 | Potassium bromide | 2139626 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB2 | Not applicable | H319 | Very dusty solid | | | Moderate | SEDDA | | | |
| 228 | Potassium Carbonate | 584-08-7 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB1 | Not applicable | H315,H319,H335 | Very dusty solid | 2 | | Moderate | SEDDA | | | |
| 229 | Potassium chloride | 7447-40-7 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB1 | Not applicable | | Very dusty solid | | | Very low | SEDDA | | | |
| 230 | Potassium chromate | 7789-00-6 | No | No | Yes | Powder | Granules | µg/m3 | 1 | OEB4 | G1,Sk | H315,H317Cat1A,H319,H335,H340,H350 | Dusty solid | 2 | CMR 1A/1B | Very high | SEDDA | | | |
| 231 | Potassium dichromate | 7778-50-9 | No | No | Yes | Powder | Granules | µg/m3 | 1 | OEB4 | G2,Sr,Cor | H301,H312,H330Cat2,H314,H334Cat1A,H317Cat1A,H340,H350,H360Cat1B,H372 | Dusty solid | 3 | CMR 1A/1B | Very high | SEDDA | | | |
| 232 | Potassium ferricyanide | 13746-66-2 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB3 | Not applicable | | Very dusty solid | | | Moderate | SEDDA | | | |
| 233 | POTASSIUM HEXACYANOFER RATE(II) | 13943-58-3 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB3 | Not applicable | | Very dusty solid | | | Moderate | SEDDA | | | |
| 234 | Potassium hexacyanoferrate(II) | 13746-66-2 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB3 | Not applicable | | Very dusty solid | | | Moderate | SEDDA | | | |
| 235 | POTASSIUM HYDROGEN CARBONAT | 298-14-6 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB1 | Not applicable | | Very dusty solid | | | Very low | SEDDA | | | |
| 236 | POTASSIUM HYDROXIDE | 1310-58-3 | No | No | Yes | Powder | Granules | µg/m3 | 2000 | OEB1 | Cor | H302,H314,H318 | Dusty solid | 3 | | Very high | SEDDA | | | |
| 237 | Potassium Iodide | 7681-11-0 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H372 | Very dusty solid | | | Very high | SEDDA | | | |
| 238 | Potassium nitrate | 7757-79-1 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB1 | Not applicable | | Very dusty solid | | | Very low | SEDDA | | | |
| 239 | Potassium Permanganate | 7722-64-7 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB3 | G1 | H302,H314,H361,H373 | Very dusty solid | 3 | CMR 2 | Very high | SEDDA | | | |
| 240 | Potassium Phosphate Monobasic | 7778-77-0 | No | No | Yes | Powder | Micronized powder | µg/m3 | 3000 | OEB1 | Not applicable | | Very dusty solid | | | Very low | SEDDA | | | |
| 241 | Potassium sodium tartrate tetrahydrate | 6381-59-5 | No | No | Yes | Powder | Granules | NA | NA | Not available | Not applicable | H319 | Dusty solid | | | Moderate | SEDDA | | | |
| 242 | Potassium Sorbate | 24634-61-5 | No | Yes | Yes | Powder | Granules | NA | NA | Not available | Not applicable | | Dusty solid | | | | SEDDA | | | |
| 243 | Potassium Sulfate | 7778-80-5 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB1 | Not applicable | | Very dusty solid | | | Very low | SEDDA | | | |
| 244 | Potassium Thiocyanate | 333-20-0 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB3 | G1,Sk | H302,H312,H332 | Very dusty solid | 1 | | Moderate | SEDDA | | | |
| 245 | Potato Starch | 9005-25-8 | No | No | Yes | Powder | Micronized powder | µg/m3 | 10000 | --- | Not applicable | | Very dusty solid | | | Very low | SEDDA | | | |
| 246 | Povidone | 9003-39-8 | No | Yes | Yes | Powder | Granules | NA | NA | Not available | Not applicable | | Dusty solid | | | | SEDDA | | | |
| 247 | propane | 74-98-6 | No | Yes | Yes | VaporGas | BP<35 | NA | NA | OEB2 | Not applicable | | Highly volatile liquid | | | Low | SEDDA | | | |
| 248 | Propylene Glycol | 56-81-5 | No | Yes | Yes | VaporGas | | NA | NA | OEB1 | Not applicable | | | | | Very low | SEDDA | | | |
| 249 | PSEUDOEPHEDRINE HYDROCHLORIDE | 345-78-8 | Yes | Yes | Yes | Powder | Micronized powder | NA | NA | OEB2 | G1,Sk | H302,H317Cat1A,H335 | Very dusty solid | 1 | | High | SEDDA | | | |

| S. No | Chemical name | CAS number | API | Handled @ Manufacturing scale | Handled @ Laboratory scale | Physical State (Liquid = Vapor/Gas) | Nature (BP °C/ powder) | OEL Unit (µg/m3 or PPM) | OEL (Sanofi approved/ Regulatory) | OEB (Default) (In case of NO OEL) | Suffix (As per Sanofi SDS) | H Phrases (Health) | Dispersion | Skin Hazard rating | CMR | Health Hazard Data Reference | List updated by | Date of updation (DD/MM/YYYY) | Remarks |
|-------|--------------------------------------|-------------|-----|-------------------------------|----------------------------|-------------------------------------|------------------------|-------------------------|-----------------------------------|-----------------------------------|----------------------------|---|------------------|--------------------|-----------|------------------------------|-----------------|-------------------------------|---------|
| 250 | Pulegone | 89-82-7 | No | No | Yes | Vapor/Gas | | NA | NA | Not available | Not applicable | H301,H311,H331 | | 2 | | Moderate | SEDDA | | |
| 251 | Quinine sulfate dihydrate | 6119-70-6 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB3 | G1,Sk | H315,H317Cat1A,H319,H335 | Very dusty solid | 2 | | High | SEDDA | | |
| 252 | Ramipril | 87333-19-5 | Yes | Yes | Yes | Powder | Micronized powder | µg/m3 | 11.2 | OEB3 | G1 | H360Cat1/1A | Very dusty solid | | CMR 1A/1B | Very high | SEDDA | | |
| 253 | Resorcinol | 108-46-0 | No | No | Yes | Powder | Micronized powder | µg/m3 | 45000 | --- | Not applicable | | Very dusty solid | | | Very low | SEDDA | | |
| 254 | Rhodamine | 81-88-9 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H318 | Very dusty solid | | | Very high | SEDDA | | |
| 255 | RON(III) CHLORIDE Anhydrous | 7705-08-0 | No | No | Yes | Powder | Micronized powder | µg/m3 | 1000 | OEB1 | Not applicable | H302,H315,H318 | Very dusty solid | 2 | | Very high | SEDDA | | |
| 256 | Saccharose (Sucrose) | 57-50-1 | No | Yes | Yes | Powder | Granules | µg/m3 | 10000 | --- | Not applicable | | Dusty solid | | | Very low | SEDDA | | |
| 257 | Salicylic Acid | 69-72-5 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H302,H318 | Very dusty solid | | | Very high | SEDDA | | |
| 258 | Selenium | 7782-49-2 | No | No | Yes | Powder | Granules | µg/m3 | 20 | OEB3 | G1 | H301,H331,H373 | Dusty solid | | | Moderate | SEDDA | | |
| 259 | SILICON DIOXIDE | 7631-86-9 | No | Yes | Yes | Powder | Micronized powder | NA | NA | OEB2 | Not applicable | | Very dusty solid | | | Low | SEDDA | | |
| 260 | Silver Nitrate | 7761-88-8 | Yes | No | Yes | Powder | Micronized powder | µg/m3 | 10 | OEB3 | Cor | H314 | Very dusty solid | 3 | | Very high | SEDDA | | |
| 261 | Sodium 1-heptane sulfonate | 22767-50-6 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB2 | Not applicable | | Very dusty solid | | | Low | SEDDA | | |
| 262 | Sodium 1-Octanesulfonate Monohydrate | 207596-29-0 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H319,H314,H335 | Very dusty solid | 3 | | Very high | SEDDA | | |
| 263 | Sodium Acetate | 127-09-3 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB1 | Not applicable | | Very dusty solid | | | Very low | SEDDA | | |
| 264 | Sodium acetate trihydrate | 6131-90-4 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H319,H315,H335 | Very dusty solid | 2 | | Moderate | SEDDA | | |
| 265 | Sodium Benzoate | 532-32-1 | No | Yes | Yes | Powder | Micronized powder | NA | NA | OEB2 | Not applicable | H319 | Very dusty solid | | | Moderate | SEDDA | | |
| 266 | Sodium Bicarbonate | 144-55-8 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB1 | Not applicable | | Very dusty solid | | | Very low | SEDDA | | |
| 267 | Sodium Bisulfate Monohydrate | 10034-88-5 | No | No | Yes | Powder | Micronized powder | µg/m3 | 5000 | OEB1 | Not applicable | H318 | Very dusty solid | | | Very high | SEDDA | | |
| 268 | Sodium carbonate | 497-19-8 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB1 | Not applicable | H319 | Very dusty solid | | | Moderate | SEDDA | | |
| 269 | Sodium cyanure | 143-33-9 | No | No | Yes | Powder | Micronized powder | µg/m3 | 1000 | OEB1 | Not applicable | H300Cat1,H310Cat1,H314,H318,H330Cat1,H370 | Very dusty solid | 3 | | Very high | SEDDA | | |
| 270 | Sodium DL-Tartrate (Sodium Tartrate) | 868-18-8 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H315,H319,H335 | Very dusty solid | 2 | | Moderate | SEDDA | | |
| 271 | Sodium Dodecyl Sulfate | 151-21-3 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB3 | Sr,Sk | H302,H332,H315,H318,H335 | Very dusty solid | 2 | | Very high | SEDDA | | |
| 272 | Sodium dodecylbenzenesulfonate | 25155-30-0 | No | Yes | Yes | Vapor/Gas | | NA | NA | Not available | Not applicable | H302,H312,H319 | | 1 | | Moderate | SEDDA | | |
| 273 | SODIUM HEXANESULFONATE | 2832-45-3 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB2 | Not applicable | | Very dusty solid | | | Low | SEDDA | | |

| S. No | Chemical name | CAS number | API | Handled @ Manufacturing scale | Handled @ Laboratory scale | Physical State (Liquid = VaporGas) | Nature (BP °C/ powder) | OEL Unit (µg/m3 or PPM) | OEL (Sanofi approved/ Regulatory) | OEB (Default) (In case of NO OEL) | Suffix (As per Sanofi SDS) | H Phrases (Health) | Dispersion | Skin Hazard rating | CMR | Health Hazard rating | Data Reference | List updated by | Date of updation (DD/MM/YYYY) | Remarks |
|-------|--|-------------|-----|-------------------------------|----------------------------|------------------------------------|------------------------|-------------------------|-----------------------------------|-----------------------------------|----------------------------|------------------------------|---------------------|--------------------|-----------|----------------------|----------------|-----------------|-------------------------------|---------|
| 274 | Sodium Hydroxide | 1310-73-2 | No | Yes | Yes | VaporGas | BP >80 | NA | NA | Not available | Not applicable | H314,H318 | Non volatile liquid | 3 | | Very high | SEDDA | | | |
| 275 | Sodium laureth sulfate | 68891-38-3 | No | Yes | Yes | VaporGas | BP >80 | NA | NA | Not available | Not applicable | H302,H315,H319 | Non volatile liquid | 2 | | Moderate | SEDDA | | | |
| 276 | SODIUM META PERIODATE | 7790-28-5 | No | No | Yes | Powder | Granules | NA | NA | OEB3 | Cor | H314,H372 | Dusty solid | 3 | | Very high | SEDDA | | | |
| 277 | Sodium metabisulfite | 7681-57-4 | No | No | Yes | Powder | Micronized powder | µg/m3 | 5000 | OEB1 | Sr,Sk | H302,H318 | Very dusty solid | 1 | | Very high | SEDDA | | | |
| 278 | Sodium nitrate | 7631-99-4 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB1 | Not applicable | H319 | Very dusty solid | | | Moderate | SEDDA | | | |
| 279 | Sodium Nitrite | 7632-00-0 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB3 | Not applicable | H301,H319 | Very dusty solid | | | Moderate | SEDDA | | | |
| 280 | Sodium nitroprusside | 13755-38-9 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB3 | Not applicable | H301 | Very dusty solid | | | Moderate | SEDDA | | | |
| 281 | Sodium perchlorate | 7601-89-0 | No | No | Yes | Powder | Granules | NA | NA | OEB3 | Not applicable | H302,H373,H319 | Dusty solid | | | Moderate | SEDDA | | | |
| 282 | Sodium perchlorate monohydrate | 2151829 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB3 | Not applicable | H302,H319,H373 | Very dusty solid | | | Moderate | SEDDA | | | |
| 283 | Sodium phosphate monobasic | 7558-80-7 | No | No | Yes | Powder | Granules | NA | NA | Not available | Not applicable | | Dusty solid | | | | SEDDA | | | |
| 284 | Sodium Phosphate Monobasic Dihydrate | 113472-35-0 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | | Very dusty solid | | | | SEDDA | | | |
| 285 | Sodium Phosphate Monobasic Monohydrate | 7558-80-7 | No | NO | Yes | Powder | Granules | NA | NA | Not available | Not applicable | | Dusty solid | | | | SEDDA | | | |
| 286 | Sodium polyacrylate | 2594415 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB2 | Not applicable | H319 | Very dusty solid | | | Moderate | SEDDA | | | |
| 287 | Sodium salicylate | 54-21-7 | No | No | Yes | Powder | Granules | NA | NA | OEB2 | G1 | H302,H319,H360Cat1B | Dusty solid | | CMR 1A/1B | High | SEDDA | | | |
| 288 | Sodium sulfamate | 13845-18-6 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H302,H315,H319 | Very dusty solid | 2 | | Moderate | SEDDA | | | |
| 289 | Sodium sulfate | 7757-82-6 | No | No | Yes | Powder | Granules | µg/m3 | 20000 | --- | Not applicable | | Dusty solid | | | Very low | SEDDA | | | |
| 290 | Sodium sulfide nonahydrate | 1313-84-4 | No | No | Yes | Powder | Granules | NA | NA | OEB3 | Cor | H311,H302,H314 | Dusty solid | 3 | | Very high | SEDDA | | | |
| 291 | Sodium sulfite | 7757-83-7 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB3 | Sr,Sk | | Very dusty solid | 1 | | Moderate | SEDDA | | | |
| 292 | Sodium tetraphenylborate | 143-66-8 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB3 | Not applicable | H301 | Very dusty solid | | | Moderate | SEDDA | | | |
| 293 | Sodium thiosulfate | 7772-98-7 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB2 | Sk | | Very dusty solid | 1 | | Low | SEDDA | | | |
| 294 | SODIUM THIOSULFATE Pentahydrate | 10102-17-7 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB2 | Sk | | Very dusty solid | 1 | | Low | SEDDA | | | |
| 295 | SODIUM VALPROATE | 1069-66-5 | Yes | Yes | Yes | Powder | Micronized powder | µg/m3 | 100 | --- | G1 | H302,H315,H318,H360C at 1/1A | Very dusty solid | 2 | CMR 1A/1B | Very high | SEDDA | | | |

| S. No | Chemical name | CAS number | API | Handled @ Manufacturing scale | Handled @ Laboratory scale | Physical State (Liquid = VaporGas) | Nature (BP °C/ powder) | OEL Unit (µg/m3 or PPM) | OEL (Sanofi approved/ Regulatory) | OEB (Default) (In case of NO OEL) | Suffix (As per Sanofi SDS) | H Phrases (Health) | Dispersion | Skin Hazard rating | CMR | Health Hazard Data Reference | List updated by | Date of update (DD/MM/YYYY) | Remarks |
|-------|--|------------|-----|-------------------------------|----------------------------|------------------------------------|------------------------|-------------------------|-----------------------------------|-----------------------------------|----------------------------|---------------------|---------------------|--------------------|-----------|------------------------------|-----------------|-----------------------------|---------|
| 296 | Soluble Starch | 9005-84-9 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | | Very dusty solid | | | SEDDA | | | |
| 297 | Sudan IV | 85-83-6 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H317Cat1A | Very dusty solid | | | High | SEDDA | | |
| 298 | Sulfamic acid | 5329-14-6 | No | No | Yes | Powder | Granules | NA | NA | OEB3 | Cor | H315,H319 | Dusty solid | 2 | | Moderate | SEDDA | | |
| 299 | Sulfanilic acid | 121-57-3 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H315,H319,H317Cat1A | Very dusty solid | 2 | | High | SEDDA | | |
| 300 | SULFATE DE BARYUM HYDRODISPERSIBLE | 7727-43-7 | No | No | Yes | Powder | Granules | NA | NA | OEB2 | Not applicable | | Dusty solid | | | Low | SEDDA | | |
| 301 | Sulfuric Acid | 7664-93-9 | No | No | Yes | VaporGas | BP >80 | NA | NA | OEB3 | Cor | H314 | Non volatile liquid | 3 | | Very high | SEDDA | | |
| 302 | SUNSET YELLOW FCF | 2783-94-0 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | | Very dusty solid | | | | SEDDA | | |
| 303 | Talc | 14807-96-6 | No | Yes | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | | Very dusty solid | | | | SEDDA | | |
| 304 | Tartaric acid | 147-71-7 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB1 | Not applicable | H318 | Very dusty solid | | | Very high | SEDDA | | |
| 305 | Tert-Butanol | 75-65-0 | No | NO | Yes | Powder | Micronized powder | µg/m3 | 300000 | --- | Not applicable | H319,H332,H335 | Very dusty solid | | | Moderate | SEDDA | | |
| 306 | Tetrabutyl ammonium hydrogen sulfate | 32503-27-8 | No | No | Yes | Powder | Granules | NA | NA | OEB3 | Sk | H315,H319,H335 | Dusty solid | 2 | | Moderate | SEDDA | | |
| 307 | Tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)imidazo[4,5-d]imidazole-2,5(1H,3H)-dione | 5395-50-6 | No | Yes | Yes | VaporGas | | NA | NA | Not available | Not applicable | H317Cat1A | | | | High | SEDDA | | |
| 308 | Tetrahydrofuran | 109-99-9 | NO | NO | Yes | VaporGas | 80<BP>35 | PPM | 50 | --- | Not applicable | H302,H319,H335,H351 | Volatile liquid | | CMR 2 | Very high | SEDDA | | |
| 309 | Thioacetamide | 62-55-5 | No | No | Yes | Powder | Granules | NA | NA | OEB4 | G1 | H302,H315,H319,H350 | Dusty solid | 2 | CMR 1A/1B | Very high | SEDDA | | |
| 310 | Thymol | 89-83-8 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H302,H314 | Very dusty solid | 3 | | Very high | SEDDA | | |
| 311 | Thymol blue | 76-61-9 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB4 | Not applicable | | Very dusty solid | | | High | SEDDA | | |
| 312 | TRIETHANOLAMINE | 102-71-6 | No | No | Yes | VaporGas | BP >80 | NA | NA | OEB3 | Sk | H315,H319,H335 | Non volatile liquid | 2 | | Moderate | SEDDA | | |
| 313 | Trifluoroacetic Acid | 76-05-1 | No | No | Yes | VaporGas | BP >80 | NA | NA | OEB3 | Cor | H314 | Non volatile liquid | 3 | | Very high | SEDDA | | |
| 314 | TRISODIUM CITRATE | 68-04-2 | No | Yes | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | | Very dusty solid | | | | SEDDA | | |
| 315 | Trisodium citrate dihydrate | 1545801 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB1 | Not applicable | | Very dusty solid | | | Very low | SEDDA | | |
| 316 | Tromethamine (Tris) | 77-86-1 | No | Yes | Yes | Powder | Granules | NA | NA | OEB2 | Not applicable | | Dusty solid | | | Low | SEDDA | | |
| 317 | Urea | 57-13-6 | No | Yes | Yes | Powder | Micronized powder | µg/m3 | 10000 | --- | G1 | | Very dusty solid | | | Very low | SEDDA | | |
| 318 | Vanillin | 121-33-5 | No | Yes | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H319 | Very dusty solid | | | Moderate | SEDDA | | |

| S. No | Chemical name | CAS number | API | Handled @ Manufacturing scale | Handled @ Laboratory scale | Physical State (Liquid = Vapor/Gas) | Nature (BP °C/ powder) | OEL Unit (µg/m3 or PPM) | OEL (Sanofi approved/ Regulatory) | OEB (Default) (In case of NO OEL) | Suffix (As per Sanofi SDS) | H Phrases (Health) | Dispersion | Skin Hazard rating | CMR | Health Hazard Data Reference rating | | List updated by | Date of updation (DD/MM/YYYY) | Remarks |
|-------|-------------------------------|-------------|-----|-------------------------------|----------------------------|-------------------------------------|------------------------|-------------------------|-----------------------------------|-----------------------------------|----------------------------|------------------------------------|---------------------|--------------------|-----------|-------------------------------------|-------|-----------------|-------------------------------|---------|
| 319 | Vinyl-1-pyrrolidone | 88-12-0 | NO | No | Yes | Powder | Micronized powder | NA | NA | OEB3 | Not applicable | H302,H312,H318,H332,H335,H351,H373 | Verv dustv solid | 1 | CMR 2 | Very high | SEDDA | | | |
| 320 | Zinc Chloride | 7646-85-7 | No | Yes | Yes | Powder | Micronized powder | NA | NA | OEB3 | G1, Cor | H302,H314 | Very dusty solid | 3 | | Very high | SEDDA | | | |
| 321 | Zinc Metal | 7440-66-6 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB1 | Not applicable | | Very dusty solid | | | Very low | SEDDA | | | |
| 322 | Zinc Sulfate Heptahydrate | 7733-02-0 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB3 | G1 | H302,H318 | Very dusty solid | | | Very high | SEDDA | | | |
| 323 | α-Naphtholbenzein | 145-50-6 | NO | Yes | Yes | Powder | Micronized powder | NA | NA | OEB4 | Not applicable | H315,H319,H335 | Very dusty solid | 2 | | High | SEDDA | | | |
| 324 | Glimepiride | 93479-97-1 | Yes | No | Yes | Powder | Micronized powder | µg/m3 | 10 | OEB3 | Not applicable | | Very dusty solid | | | High | SEDDA | | | |
| 325 | Amlodipine besilate | 111470-99-6 | Yes | No | Yes | Powder | Granules | µg/m3 | 15 | OEB3 | Not applicable | H302.H318 | Dustv solid | | | Very high | SEDDA | | | |
| 326 | Fexofenadine HCl | 153439-40-8 | Yes | No | Yes | Powder | Granules | µg/m3 | 800 | OEB2 | Not applicable | | Dusty solid | | | Low | SEDDA | | | |
| 327 | Pseudoephedrine | 90-82-4 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB2 | G1 | H302 | Very dusty solid | | | Moderate | SEDDA | | | |
| 328 | Lysine hydrochloride | 657-27-2 | No | No | Yes | Powder | Micronized powder | NA | NA | --- | Not applicable | H315,H319 | Very dusty solid | 2 | | Moderate | SEDDA | | | |
| 329 | Acetylsalicylic acid | 50-78-2 | Yes | No | Yes | Powder | Micronized powder | µg/m3 | 150 | OEB2 | G1 | H302 | Very dusty solid | | | Moderate | SEDDA | | | |
| 330 | Valproic acid | 99-66-1 | Yes | No | Yes | VaporGas | BP >80 | PPM | 100 | --- | G1 | H302,H315,H318,H360C at1/1A | Non volatile liquid | 2 | CMR 1A/1B | Very high | SEDDA | | | |
| 331 | Spiramycin | 8025-81-8 | Yes | No | Yes | Powder | Micronized powder | µg/m3 | 3 | OEB4 | Sr,Sk | H317Cat1A,H319,H334 Cat1A | Verv dustv solid | 1 | | Very high | SEDDA | | | |
| 332 | Chloroacetanilide | 539-03-7 | No | No | Yes | Powder | Micronized powder | NA | NA | Not available | Not applicable | H315,H319,H335 | Very dusty solid | 2 | | Moderate | SEDDA | | | |
| 333 | Dimethicone | 63148-62-9 | No | No | Yes | VaporGas | 80<BP>35 | NA | NA | OEB1 | Not applicable | | Volatile liquid | | | Very low | SEDDA | | | |
| 334 | CLOPIDOGREL HYDROGENSULP HATE | 120202-66-6 | Yes | No | Yes | Powder | Micronized powder | µg/m3 | 75 | OEB3 | Cor | H314,H335 | Very dusty solid | 3 | | Very high | SEDDA | | | |
| 335 | CARBOCISTEINE | 638-23-3 | Yes | No | Yes | Powder | Granules | µg/m3 | 2000 | OEB1 | Not applicable | | Dusty solid | | | Very low | SEDDA | | | |
| 336 | Arginine Chlorhydrate | 1119-34-2 | No | No | Yes | Powder | Micronized powder | NA | NA | OEB1 | Not applicable | | Very dusty solid | | | Very low | SEDDA | | | |

Appendix **E**

Laboratory NON API qualitative risk assessment

| Lab ID | Chemical name | Lot number | Phase | Where the area of chemical handled is used | Description of the activity (what/when/how/why) | HEP (no. of workers involved) | Frequency | Duration | Quantity | Preparation | Containment Strategy | Exposure level | Risk/Health rating | Risk Ranking with Engineering controls | Administrative controls in place | Personal protective controls in place | Risk rating after PPE controls | Qualitative Risk Assessment done by | Qualitative Risk Assessment date (DDMMYY) | Status of Quantitative Risk Assessment | Date of last Quantitative Risk Assessment (DDMMYY) | Final Conclusion | Remarks |
|--------|---------------|------------|----------|--|--|-------------------------------|---------------|---------------------|--------------------------------|---------------------|---|----------------|--------------------|--|---|---------------------------------------|---|-------------------------------------|---|--|--|--|---------|
| L.C-1 | TOLUENE | 108-88-3 | VaporGas | Solution Preparation Area | Manual solution preparation involves: -Opening the bottle. -Transferring a small quantity into a beaker. -Adding the necessary amount of solvent from the beaker for solution preparation. -Introducing the prepared quantity into a volumetric flask and diluting. -Transferring the solution into a labeled brown bottle. | 15 | <1Month | 15Min ex x2 Hourly | 10 x x 100 g or 50 ml ex x 1 l | Non volatile liquid | Open bench, general exhaust ventilation | Possible | Moderate | Unacceptable Exposure | Specific skills and hand-on training | Full Face Respirator | Acceptable Exposure Due to low Exposure potential and low hazard chemical. Continue the existing measures to maintain low Exposure potential. No further actions required since this is Acceptable risk due to low Exposure potential/hazard nature of the chemical and controls in place. | HERREN Nilsa | 13/06/2024 | Quantitative Assessment not conducted | | Acceptable (Low risk to health) | |
| L.C-2 | TOLUENE | 108-88-3 | VaporGas | Waste Collection Station | Collection of bench or HPLC waste | 15 | <1Month | 15Min ex x2 Hourly | 10 x x 100 g or 50 ml ex x 1 l | Non volatile liquid | Open bench, general exhaust ventilation | Possible | Moderate | Unacceptable Exposure | Specific skills and hand-on training | Full Face Respirator | Acceptable Exposure Due to low Exposure potential and low hazard chemical. Continue the existing measures to maintain low Exposure potential. No further actions required since this is Acceptable risk due to low Exposure potential/hazard nature of the chemical and controls in place. | | | Quantitative Assessment not conducted | | Acceptable (Low risk to health) | |
| L.C-3 | 1,4-Dioxane | 123-91-1 | VaporGas | Reagent Preparation Area | Manual preparation of a reagent involves: -Opening the reagent bottle. -Transferring a specified quantity into a graduated cylinder. -Pouring the measured reagent into a labeled brown bottle. | 15 | 1month - 1day | 15Min ex x2 Hourly | 10 x x 100 g or 50 ml ex x 1 l | Non volatile liquid | Fume hood performance undocumented, cluttered | Unlikely | Very High | Unacceptable Exposure | Specific skills and hand-on training | Full Face Respirator | Unacceptable Exposure Continue to maintain the existing control measures. Additional control measures need to be adopted to reduce the Exposure potential (examples based on priority - engineering controls, work practices, PPE). Quantitative exposure monitoring required for validation of actual exposure. | | | Quantitative Assessment not conducted | | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status. | |
| L.C-4 | 1,4-Dioxane | 123-91-1 | VaporGas | General Laboratory Waste Collection Area | collection of bench waste | 15 | 1month - 1day | 15Min ex x2 Hourly | 10 x x 100 g or 50 ml ex x 1 l | Non volatile liquid | Open bench, general exhaust ventilation | Possible | Very High | Unacceptable Exposure | Specific skills and hand-on training | Full Face Respirator | Unacceptable Exposure Continue to maintain the existing control measures. Additional control measures need to be adopted to reduce the Exposure potential (examples based on priority - engineering controls, work practices, PPE). Quantitative exposure monitoring required for validation of actual exposure. | | | Quantitative Assessment not conducted | | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status. | |
| L.C-5 | 4-Aminophenol | 123-30-8 | Powder | Weighing room | Weighing of Reagents and SCR | 15 | 1month - 1day | < 15 Min x 1 Hourly | < 10 g or < 50 ml | Very dusty solid | Ventilated weight station with HEPA recirculated or fume hood | Unlikely | High | Unacceptable Exposure | Specific skills and hand-on training | | Unacceptable Exposure Continue to maintain the existing control measures. Additional control measures need to be adopted to reduce the Exposure potential (examples based on priority - engineering controls, work practices, PPE). Quantitative exposure monitoring required for validation of actual exposure. | | | Quantitative Assessment not conducted | | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status. | |
| L.C-6 | 4-Aminophenol | 123-30-8 | Powder | Solution Preparation Area | solution preparation | 15 | 1month - 1day | 15Min ex x2 Hourly | < 10 g or < 50 ml | Very dusty solid | Ventilated weight station with HEPA recirculated or fume hood | Possible | High | Unacceptable Exposure | Specific skills and hand-on training | | Unacceptable Exposure Continue to maintain the existing control measures. Additional control measures need to be adopted to reduce the Exposure potential (examples based on priority - engineering controls, work practices, PPE). Quantitative exposure monitoring required for validation of actual exposure. | | | Quantitative Assessment not conducted | | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status. | |
| L.C-7 | 4-Aminophenol | 123-30-8 | Powder | Waste Collection Station | Collection of HPLC waste | 15 | 1month - 1day | < 15 Min x 1 Hourly | 10 x x 100 g or 50 ml ex x 1 l | Very dusty solid | Open bench, general exhaust ventilation | Probable | High | Unacceptable Exposure | Specific skills and hand-on training | Full Face Respirator | Unacceptable Exposure Continue to maintain the existing control measures. Additional control measures need to be adopted to reduce the Exposure potential (examples based on priority - engineering controls, work practices, PPE). Quantitative exposure monitoring required for validation of actual exposure. | | | Quantitative Assessment not conducted | | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status. | |
| L.C-8 | 4-Aminophenol | 123-30-8 | Powder | General Laboratory Waste Collection Area | collection of bench waste | 15 | 1month - 1day | < 15 Min x 1 Hourly | 10 x x 100 g or 50 ml ex x 1 l | Very dusty solid | Open bench, general exhaust ventilation | Probable | High | Unacceptable Exposure | Specific skills and hand-on training | Full Face Respirator | Unacceptable Exposure Continue to maintain the existing control measures. Additional control measures need to be adopted to reduce the Exposure potential (examples based on priority - engineering controls, work practices, PPE). Quantitative exposure monitoring required for validation of actual exposure. | | | Quantitative Assessment not conducted | | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status. | |
| L.C-9 | ACETIC ACID | 64-19-7 | VaporGas | Manipulating procedures | | 15 | <1Month | 15Min ex x2 Hourly | 10 x x 100 g or 50 ml ex x 1 l | Non volatile liquid | Fume hood performance undocumented, cluttered | Unlikely | Very High | Unacceptable Exposure | Specific skills and hand-on training | | Unacceptable Exposure Continue to maintain the existing control measures. Additional control measures need to be adopted to reduce the Exposure potential (examples based on priority - engineering controls, work practices, PPE). Quantitative exposure monitoring required for validation of actual exposure. | | | Quantitative Assessment not conducted | | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status. | |
| L.C-10 | ACETONITRILE | 75-05-4 | VaporGas | Weighing room | Weighing of Reagents and SCR | 15 | > 1day | < 15 Min x 1 Hourly | > 100 g or > 1 l | Non volatile liquid | Open bench, general exhaust ventilation | Probable | Moderate | Unacceptable Exposure | Specific skills and hand-on training | Full Face Respirator | Acceptable Exposure Due to low Exposure potential and low hazard chemical. Continue the existing measures to maintain low Exposure potential. No further actions required since this is Acceptable risk due to low Exposure potential/hazard nature of the chemical and controls in place. | | | Quantitative Assessment not conducted | | Acceptable (Low risk to health) | |
| L.C-11 | ANILINE | 62-53-3 | VaporGas | Reagent Preparation Area | Manual preparation of a reagent involves: -Opening the reagent bottle. -Transferring a specified quantity into a graduated cylinder. -Pouring the measured reagent into a labeled brown bottle. | 15 | <1Month | 15Min ex x2 Hourly | 10 x x 100 g or 50 ml ex x 1 l | Non volatile liquid | Fume hood performance undocumented, cluttered | Unlikely | Very High | Unacceptable Exposure | Specific skills and hand-on training | | Unacceptable Exposure Continue to maintain the existing control measures. Additional control measures need to be adopted to reduce the Exposure potential (examples based on priority - engineering controls, work practices, PPE). Quantitative exposure monitoring required for validation of actual exposure. | | | Quantitative Assessment not conducted | | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status. | |
| L.C-12 | ANILINE | 62-53-3 | VaporGas | Solution Preparation Area | Solution Preparation Open the bottle. Transfer a small quantity into a beaker. Pipette from the beaker the necessary amount of solvent for solution preparation. Introduce the prepared quantity into a volumetric flask and dilute. Transfer into a labeled brown bottle. | 15 | <1Month | 15Min ex x2 Hourly | < 10 g or < 50 ml | Non volatile liquid | Open bench, general exhaust ventilation | Unlikely | Very High | Unacceptable Exposure | Specific skills and hand-on training | Full Face Respirator; Safety glasses | Unacceptable Exposure Continue to maintain the existing control measures. Additional control measures need to be adopted to reduce the Exposure potential (examples based on priority - engineering controls, work practices, PPE). Quantitative exposure monitoring required for validation of actual exposure. | | | Quantitative Assessment not conducted | | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status. | |
| L.C-13 | ANILINE | 62-53-3 | VaporGas | Waste Collection Station | Collection of HPLC waste | 15 | <1Month | < 15 Min x 1 Hourly | < 10 g or < 50 ml | Non volatile liquid | Open bench, general exhaust ventilation | Unlikely | Very High | Unacceptable Exposure | Specific skills and hand-on training | Full Face Respirator | Unacceptable Exposure Continue to maintain the existing control measures. Additional control measures need to be adopted to reduce the Exposure potential (examples based on priority - engineering controls, work practices, PPE). Quantitative exposure monitoring required for validation of actual exposure. | | | Quantitative Assessment not conducted | | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status. | |
| L.C-14 | ANILINE | 62-53-3 | VaporGas | General Laboratory Waste Collection Area | collection of bench waste | 15 | <1Month | < 15 Min x 1 Hourly | < 10 g or < 50 ml | Non volatile liquid | Open bench, general exhaust ventilation | Unlikely | Very High | Unacceptable Exposure | Specific skills and hand-on training | Full Face Respirator | Unacceptable Exposure Continue to maintain the existing control measures. Additional control measures need to be adopted to reduce the Exposure potential (examples based on priority - engineering controls, work practices, PPE). Quantitative exposure monitoring required for validation of actual exposure. | | | Quantitative Assessment not conducted | | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status. | |
| L.C-15 | Sulfadiazole | 108-17-1 | Powder | Solution Preparation Area | Manual solution preparation | 15 | <1Month | 15Min ex x2 Hourly | > 100 g or > 1 l | Very dusty solid | Ventilated weight station with HEPA recirculated or fume hood | Possible | High | Unacceptable Exposure | Specific skills and hand-on training, Specific skills and hand-on training, Specific medical surveillance | | Unacceptable Exposure Continue to maintain the existing control measures. Additional control measures need to be adopted to reduce the Exposure potential (examples based on priority - engineering controls, work practices, PPE). Quantitative exposure monitoring required for validation of actual exposure. | | | Quantitative Assessment not conducted | | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status. | |
| L.C-16 | Sulfadiazole | 108-17-1 | Powder | Waste Collection Station | Collection of bench or HPLC waste | 15 | <1Month | 15Min ex x2 Hourly | > 100 g or > 1 l | Very dusty solid | Open bench, general exhaust ventilation | Probable | High | Unacceptable Exposure | Specific skills and hand-on training, Specific skills and hand-on training, Specific medical surveillance | Safety glasses, Full Face Respirator | Unacceptable Exposure Continue to maintain the existing control measures. Additional control measures need to be adopted to reduce the Exposure potential (examples based on priority - engineering controls, work practices, PPE). Quantitative exposure monitoring required for validation of actual exposure. | | | Quantitative Assessment not conducted | | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status. | |



LABORATORY - NON APIs QUALITATIVE RISK ASSESSMENT

LABORATORY - NON APIs QUALITATIVE RISK ASSESSMENT

| LC-50 | Mercuric iodide | 7774-290 | Powder | Weighing room | Weighing of Reactants and SCR | 15 | <1Month | < 15 Min@3h | < 10 gr + 50 ml | Very dusty solid | Ventilated weight station with HEPA recirculated or fume hood | Unlikely | Very High | Sustained Exposure | Specific skills and hand-on training | | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health); Controls need to be implemented and quantitative sampling is required to verify risk status | |
|-------|-----------------------|-----------|-----------|--|--|----|----------------|---------------------|-------------------------------|---------------------|---|----------|-----------|-----------------------|--------------------------------------|-------------------------------------|--|--|---------------------------------------|--|--|
| LC-60 | Mercuric iodide | 7774-290 | Powder | Solution Preparation Area | solution preparation | 15 | <1Month | 15 Min ex 2 Hour@3h | < 10 gr + 50 ml | Very dusty solid | Ventilated weight station with HEPA recirculated or fume hood | Unlikely | Very High | Sustained Exposure | Specific skills and hand-on training | | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health); Controls need to be implemented and quantitative sampling is required to verify risk status | |
| LC-61 | Mercuric iodide | 7774-290 | Powder | General Laboratory Waste Collection Area | collection of bench waste | 15 | <1Month | 15 Min ex 2 Hour@3h | 10 X 100 gr or 50 ml ex < 1 l | Very dusty solid | Open bench, general exhaust ventilation | Probable | Very High | Unacceptable Exposure | Specific skills and hand-on training | | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health); Controls need to be implemented and quantitative sampling is required to verify risk status | |
| LC-62 | Mercury nitrate | 10045-940 | Powder | Weighing room | Weighing of Reactants and SCR | 15 | <1Month | < 15 Min@3h | < 10 gr + 50 ml | Very dusty solid | Ventilated weight station with HEPA recirculated or fume hood | Unlikely | Very High | Sustained Exposure | Specific skills and hand-on training | | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health); Controls need to be implemented and quantitative sampling is required to verify risk status | |
| LC-63 | Mercury nitrate | 10045-940 | Powder | Solution Preparation Area | solution preparation | 15 | <1Month | 15 Min ex 2 Hour@3h | < 10 gr + 50 ml | Very dusty solid | Open bench, general exhaust ventilation | Possible | Very High | Unacceptable Exposure | Specific skills and hand-on training | Safetyglasses, Full Face Respirator | | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health); Controls need to be implemented and quantitative sampling is required to verify risk status |
| LC-64 | Mercury nitrate | 10045-940 | Powder | General Laboratory Waste Collection Area | collection of bench waste | 15 | <1Month | 15 Min ex 2 Hour@3h | 10 X 100 gr or 50 ml ex < 1 l | Very dusty solid | Open bench, general exhaust ventilation | Probable | Very High | Unacceptable Exposure | Specific skills and hand-on training | Safetyglasses, Full Face Respirator | | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health); Controls need to be implemented and quantitative sampling is required to verify risk status |
| LC-65 | Mercuric(II) chloride | 7487-847 | Powder | Weighing room | Weighing of Reactants and SCR | 15 | <1Month | < 15 Min@3h | < 10 gr + 50 ml | Very dusty solid | Ventilated weight station with HEPA recirculated or fume hood | Unlikely | Very High | Sustained Exposure | Specific skills and hand-on training | | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health); Controls need to be implemented and quantitative sampling is required to verify risk status | |
| LC-66 | Mercuric(II) chloride | 7487-847 | Powder | Solution Preparation Area | Solution Preparation | 15 | <1Month | 15 Min ex 2 Hour@3h | < 10 gr + 50 ml | Very dusty solid | Ventilated weight station with HEPA recirculated or fume hood | Unlikely | Very High | Sustained Exposure | Specific skills and hand-on training | Safetyglasses, Full Face Respirator | | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health); Controls need to be implemented and quantitative sampling is required to verify risk status |
| LC-67 | Mercuric(II) chloride | 7487-847 | Powder | General Laboratory Waste Collection Area | collection of bench waste | 15 | <1Month | 15 Min ex 2 Hour@3h | 10 X 100 gr or 50 ml ex < 1 l | Very dusty solid | Open bench, general exhaust ventilation | Probable | Very High | Unacceptable Exposure | Specific skills and hand-on training | Safetyglasses, Full Face Respirator | | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health); Controls need to be implemented and quantitative sampling is required to verify risk status |
| LC-68 | N-HEXANE | 110-543 | VapourGas | Solution Preparation Area | Manual solution preparation involves: -Opening the bottle. -Transferring a small quantity into a beaker. -Placing the necessary amount of liquid from the beaker for solution preparation. -Introducing the pipetted quantity into a volumetric flask and diluting. -Transferring the solution into a labeled brown bottle. | 15 | <1Month | 15 Min ex 2 Hour@3h | 10 X 100 gr or 50 ml ex < 1 l | Visible liquid | Fume hood performance not documented, cluttered | Unlikely | Moderate | Acceptable Exposure | Specific skills and hand-on training | | | | | Quantitative Assessment not conducted | Acceptable (Low risk to health) |
| LC-69 | N-HEXANE | 110-543 | VapourGas | General Laboratory Waste Collection Area | collection of bench waste | 15 | <1Month | 15 Min ex 2 Hour@3h | 10 X 100 gr or 50 ml ex < 1 l | Visible liquid | Open bench, general exhaust ventilation | Possible | Moderate | Sustained Exposure | Specific skills and hand-on training | Full Face Respirator | | | | Quantitative Assessment not conducted | Acceptable (Low risk to health) |
| LC-70 | Social sulfate | 7786-814 | Powder | Weighing room | Weighing of Reactants and SCR | 15 | <1Month | < 15 Min@3h | < 10 gr + 50 ml | Very dusty solid | Ventilated weight station with HEPA recirculated or fume hood | Unlikely | Very High | Sustained Exposure | Specific skills and hand-on training | | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health); Controls need to be implemented and quantitative sampling is required to verify risk status | |
| LC-71 | Social sulfate | 7786-814 | Powder | Solution Preparation Area | solution preparation | 15 | <1Month | 15 Min ex 2 Hour@3h | < 10 gr + 50 ml | Very dusty solid | Ventilated weight station with HEPA recirculated or fume hood | Unlikely | Very High | Sustained Exposure | Specific skills and hand-on training | | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health); Controls need to be implemented and quantitative sampling is required to verify risk status | |
| LC-72 | Social sulfate | 7786-814 | Powder | General Laboratory Waste Collection Area | collection of bench waste | 15 | <1Month | < 15 Min@3h | < 10 gr + 50 ml | Very dusty solid | Open bench, general exhaust ventilation | Possible | Very High | Unacceptable Exposure | Specific skills and hand-on training | Full Face Respirator | | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health); Controls need to be implemented and quantitative sampling is required to verify risk status |
| LC-73 | Silicic Acid | 7697-372 | VapourGas | Titration area | Manual Titration | 15 | 1 month - 1day | 15 Min ex 2 Hour@3h | 10 X 100 gr or 50 ml ex < 1 l | Non volatile liquid | Fume hood performance not documented, cluttered | Unlikely | Very High | Sustained Exposure | Specific skills and hand-on training | | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health); Controls need to be implemented and quantitative sampling is required to verify risk status | |
| LC-74 | N-NDIMETHYLFORMAMIDE | 68-122 | VapourGas | Reagent Preparation Area | manual preparation of a reagent involves: -Opening the reagent bottle. -Transferring a pipetted quantity into a graduated cylinder. -Placing the measured reagent into a labeled brown bottle. | 15 | <1Month | < 15 Min@3h | < 10 gr + 50 ml | Non volatile liquid | Fume hood performance not documented, cluttered | Unlikely | High | Sustained Exposure | Specific skills and hand-on training | | | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health); Controls need to be implemented and quantitative sampling is required to verify risk status |
| LC-75 | N-NDIMETHYLFORMAMIDE | 68-122 | VapourGas | Solution Preparation Area | Manual solution preparation involves: -Opening the bottle. -Transferring a small quantity into a beaker. -Placing the necessary amount of liquid from the beaker for solution preparation. -Introducing the pipetted quantity into a volumetric flask and diluting. -Transferring the solution into a labeled brown bottle. | 15 | <1Month | 15 Min ex 2 Hour@3h | < 10 gr + 50 ml | Non volatile liquid | Fume hood performance not documented, cluttered | Unlikely | High | Sustained Exposure | Specific skills and hand-on training | Full Face Respirator | | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health); Controls need to be implemented and quantitative sampling is required to verify risk status |
| LC-76 | N-NDIMETHYLFORMAMIDE | 68-122 | VapourGas | General Laboratory Waste Collection Area | Collecting of bench waste | 15 | <1Month | 15 Min ex 2 Hour@3h | 10 X 100 gr or 50 ml ex < 1 l | Non volatile liquid | Open bench, general exhaust ventilation | Possible | High | Sustained Exposure | Specific skills and hand-on training | Full Face Respirator | | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health); Controls need to be implemented and quantitative sampling is required to verify risk status |
| LC-77 | Picric acid 70% | 7601-903 | VapourGas | Titration area | Manual Titration | 15 | 1 month - 1day | 15 Min ex 2 Hour@3h | 10 X 100 gr or 50 ml ex < 1 l | Non volatile liquid | Open bench, general exhaust ventilation | Possible | Very High | Unacceptable Exposure | Specific skills and hand-on training | Safetyglasses, Full Face Respirator | | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health); Controls need to be implemented and quantitative sampling is required to verify risk status |



LABORATORY - NON APIs QUALITATIVE RISK ASSESSMENT

LABORATORY - NON APIs QUALITATIVE RISK ASSESSMENT

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|--------|------------------------|------------|-----------|--|---|----|---------------|-----------------------|------------------------------------|---------------------|---|----------|-----------|-----------------------|--------------------------------------|--------------------------------------|--|--|--|---------------------------------------|--|
| LC-100 | Potassium Permanganate | 7222-647 | Powder | General Laboratory Waste Collection Area | collection of bench waste | 15 | 1Month - 1day | < 15 Min x 1h | < 10 g or < 50 ml | Very dusty solid | Open bench, general exhaust ventilation | Possible | Very High | Unacceptable Exposure | Specific skills and hand-on training | Full Face Respirator | Unacceptable Exposure Continue to maintain the existing control measures Additional control measures need to be adopted to reduce the Exposure potential (examples based on priority - engineering controls, work practices, PPE) Quantitative exposure monitoring required for validation of actual exposure | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status |
| LC-101 | Sodium Nitrite | 7632-00-0 | Powder | Weighing room | Weighing of Reagents and SCR | 15 | <1Month | < 15 Min x 1h | < 10 g or < 50 ml | Very dusty solid | Ventilated weight station with HEPA recirculated or fume hood | Unlikely | Moderate | Acceptable Exposure | Specific skills and hand-on training | | Acceptable Exposure Due to low Exposure potential and low hazard chemical | | | Quantitative Assessment not conducted | Acceptable (Low risk to health) |
| LC-102 | Sodium Nitrite | 7632-00-0 | Powder | Solution Preparation Area | solution preparation | 15 | <1Month | 15 Min x 2 Hour shift | < 10 g or < 50 ml | Very dusty solid | Open bench, general exhaust ventilation | Possible | Moderate | Unacceptable Exposure | Specific skills and hand-on training | Full Face Respirator | Acceptable Exposure Due to low Exposure potential and low hazard chemical | | | Quantitative Assessment not conducted | Acceptable (Low risk to health) |
| LC-103 | Sodium Nitrite | 7632-00-0 | Powder | General Laboratory Waste Collection Area | collection of bench waste | 15 | <1Month | 15 Min x 2 Hour shift | 10 x X x 100 g or 50 ml x x x 1.0l | Very dusty solid | Open bench, general exhaust ventilation | Probable | Moderate | Unacceptable Exposure | Specific skills and hand-on training | Full Face Respirator | Acceptable Exposure Due to low Exposure potential and low hazard chemical | | | Quantitative Assessment not conducted | Acceptable (Low risk to health) |
| LC-104 | Sodium nitroprusside | 13755-38-9 | Powder | Weighing room | Weighing of Reagents and SCR | 15 | <1Month | < 15 Min x 1h | < 10 g or < 50 ml | Very dusty solid | Ventilated weight station with HEPA recirculated or fume hood | Unlikely | Moderate | Acceptable Exposure | Specific skills and hand-on training | | Acceptable Exposure Due to low Exposure potential and low hazard chemical | | | Quantitative Assessment not conducted | Acceptable (Low risk to health) |
| LC-105 | Sodium nitroprusside | 13755-38-9 | Powder | Solution Preparation Area | solution preparation | 15 | <1Month | 15 Min x 2 Hour shift | < 10 g or < 50 ml | Very dusty solid | Ventilated weight station with HEPA recirculated or fume hood | Unlikely | Moderate | Acceptable Exposure | Specific skills and hand-on training | | Acceptable Exposure Due to low Exposure potential and low hazard chemical | | | Quantitative Assessment not conducted | Acceptable (Low risk to health) |
| LC-106 | Sodium nitroprusside | 13755-38-9 | Powder | General Laboratory Waste Collection Area | collection of bench waste | 15 | <1Month | 15 Min x 2 Hour shift | 10 x X x 100 g or 50 ml x x x 1.0l | Very dusty solid | Open bench, general exhaust ventilation | Probable | Moderate | Unacceptable Exposure | Specific skills and hand-on training | Safety glasses, Full Face Respirator | Acceptable Exposure Due to low Exposure potential and low hazard chemical | | | Quantitative Assessment not conducted | Acceptable (Low risk to health) |
| LC-107 | Sulfuric Acid | 7664-93-9 | Vapor/Gas | Titration area | Manual Titration | 15 | 1Month - 1day | 15 Min x 2 Hour shift | 10 x X x 100 g or 50 ml x x x 1.0l | Non volatile liquid | Open bench, general exhaust ventilation | Possible | Very High | Unacceptable Exposure | Specific skills and hand-on training | Safety glasses, Full Face Respirator | Unacceptable Exposure Continue to maintain the existing control measures Additional control measures need to be adopted to reduce the Exposure potential (examples based on priority - engineering controls, work practices, PPE) Quantitative exposure monitoring required for validation of actual exposure | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status |
| LC-108 | Tetrahydrofuran | 100-99-0 | Vapor/Gas | Reagent preparation area | manual preparation of a reagent involves: -Opening the reagent bottle. -Transferring a specified quantity into a graduated cylinder. -Pouring the measured reagent into a labeled brown bottle. | 15 | 1Month - 1day | 15 Min x 2 Hour shift | 10 x X x 100 g or 50 ml x x x 1.0l | Volatle liquid | Fume hood performance not documented, enclosed | Unlikely | Very High | Unacceptable Exposure | Specific skills and hand-on training | | Unacceptable Exposure Continue to maintain the existing control measures Additional control measures need to be adopted to reduce the Exposure potential (examples based on priority - engineering controls, work practices, PPE) Quantitative exposure monitoring required for validation of actual exposure | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status |
| LC-109 | Tetrahydrofuran | 100-99-0 | Vapor/Gas | Solution Preparation Area | Manual solution preparation involves: -Opening the bottle. -Transferring a small quantity into a beaker. -Pouring the necessary amount of solvent from the beaker for solution preparation. -Introducing the pipetted quantity into a volumetric flask and diluting. -Transferring the solution into a labeled brown bottle. | 15 | 1Month - 1day | 15 Min x 2 Hour shift | < 10 g or < 50 ml | Volatle liquid | Open bench, general exhaust ventilation | Possible | Very High | Unacceptable Exposure | Specific skills and hand-on training | Safety glasses, Full Face Respirator | Unacceptable Exposure Continue to maintain the existing control measures Additional control measures need to be adopted to reduce the Exposure potential (examples based on priority - engineering controls, work practices, PPE) Quantitative exposure monitoring required for validation of actual exposure | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status |
| LC-110 | Tetrahydrofuran | 100-99-0 | Vapor/Gas | General Laboratory Waste Collection Area | collection of bench waste | 15 | 1Month - 1day | 15 Min x 2 Hour shift | 10 x X x 100 g or 50 ml x x x 1.0l | Volatle liquid | Open bench, general exhaust ventilation | Probable | Very High | Unacceptable Exposure | Specific skills and hand-on training | Full Face Respirator | Unacceptable Exposure Continue to maintain the existing control measures Additional control measures need to be adopted to reduce the Exposure potential (examples based on priority - engineering controls, work practices, PPE) Quantitative exposure monitoring required for validation of actual exposure | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status |
| LC-111 | Thioacetamide | 62-55-5 | Powder | Weighing room | Weighing of Reagents and SCR | 15 | <1Month | < 15 Min x 1h | < 10 g or < 50 ml | Dusty solid | Ventilated weight station with HEPA recirculated or fume hood | Unlikely | Very High | Unacceptable Exposure | | | Unacceptable Exposure Continue to maintain the existing control measures Additional control measures need to be adopted to reduce the Exposure potential (examples based on priority - engineering controls, work practices, PPE) Quantitative exposure monitoring required for validation of actual exposure | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status |
| LC-112 | Thioacetamide | 62-55-5 | Powder | Solution Preparation Area | solution preparation | 15 | <1Month | 15 Min x 2 Hour shift | < 10 g or < 50 ml | Dusty solid | Ventilated weight station with HEPA recirculated or fume hood | Unlikely | Very High | Unacceptable Exposure | Specific skills and hand-on training | | Unacceptable Exposure Continue to maintain the existing control measures Additional control measures need to be adopted to reduce the Exposure potential (examples based on priority - engineering controls, work practices, PPE) Quantitative exposure monitoring required for validation of actual exposure | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status |
| LC-113 | Thioacetamide | 62-55-5 | Powder | Waste Collection Station | Collection of HPLC waste | 15 | <1Month | < 15 Min x 1h | < 10 g or < 50 ml | Dusty solid | Open bench, general exhaust ventilation | Unlikely | Very High | Unacceptable Exposure | Specific skills and hand-on training | Full Face Respirator | Unacceptable Exposure Continue to maintain the existing control measures Additional control measures need to be adopted to reduce the Exposure potential (examples based on priority - engineering controls, work practices, PPE) Quantitative exposure monitoring required for validation of actual exposure | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status |
| LC-114 | Thioacetamide | 62-55-5 | Powder | General Laboratory Waste Collection Area | collection of bench waste | 15 | <1Month | < 15 Min x 1h | < 10 g or < 50 ml | Dusty solid | Open bench, general exhaust ventilation | Unlikely | Very High | Unacceptable Exposure | Specific skills and hand-on training | Full Face Respirator | Unacceptable Exposure Continue to maintain the existing control measures Additional control measures need to be adopted to reduce the Exposure potential (examples based on priority - engineering controls, work practices, PPE) Quantitative exposure monitoring required for validation of actual exposure | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status |
| LC-115 | Vinyl-pyrrolidone | 88-12-0 | Powder | Reagent preparation area | manual preparation of a reagent involves: -Opening the reagent bottle. -Transferring a specified quantity into a graduated cylinder. -Pouring the measured reagent into a labeled brown bottle. | 15 | <1Month | 15 Min x 2 Hour shift | 10 x X x 100 g or 50 ml x x x 1.0l | Very dusty solid | Ventilated weight station with HEPA recirculated or fume hood | Possible | Very High | Unacceptable Exposure | Specific skills and hand-on training | | Unacceptable Exposure The proposed action to control the exposure the existing engineering controls, work practices and other control and respiratory protection equipment Required to conduct quantitative exposure assessment | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status |
| LC-116 | Vinyl-pyrrolidone | 88-12-0 | Powder | Reagent preparation area | manual preparation of a reagent involves: -Opening the reagent bottle. -Transferring a specified quantity into a graduated cylinder. -Pouring the measured reagent into a labeled brown bottle. | 15 | <1Month | 15 Min x 2 Hour shift | < 10 g or < 50 ml | Very dusty solid | Open bench, general exhaust ventilation | Possible | Very High | Unacceptable Exposure | Specific skills and hand-on training | Safety glasses, Full Face Respirator | Unacceptable Exposure Continue to maintain the existing control measures Additional control measures need to be adopted to reduce the Exposure potential (examples based on priority - engineering controls, work practices, PPE) Quantitative exposure monitoring required for validation of actual exposure | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status |
| LC-117 | Vinyl-pyrrolidone | 88-12-0 | Powder | General Laboratory Waste Collection Area | collection of bench waste | 15 | <1Month | 15 Min x 2 Hour shift | 10 x X x 100 g or 50 ml x x x 1.0l | Very dusty solid | Open bench, general exhaust ventilation | Probable | Very High | Unacceptable Exposure | Specific skills and hand-on training | Full Face Respirator | Unacceptable Exposure Continue to maintain the existing control measures Additional control measures need to be adopted to reduce the Exposure potential (examples based on priority - engineering controls, work practices, PPE) Quantitative exposure monitoring required for validation of actual exposure | | | Quantitative Assessment not conducted | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status |

Appendix **F**

Laboratory API Qualitative Risk Assessment

Table with 17 columns: Step 1 (Step 1), Step 2 (Step 2), Step 3 (Step 3), Step 4 (Step 4), Step 5 (Step 5), Step 6 (Step 6), Step 7 (Step 7), Step 8 (Step 8), Step 9 (Step 9), Step 10 (Step 10), Step 11 (Step 11), Step 12 (Step 12), Step 13 (Step 13). Rows include activities like 'Weighing of Reagents and SCR', 'Manual solution preparation involves', and 'Collection of batch or HPLC waste' for various APIs such as AMISULPRIDE, CARBODIC TEINE, FEDEFENSIN HCI, and GIMEPIDOL.

| LABORATORY - APIs QUALITATIVE RISK ASSESSMENT | | | | | | | | | | | LABORATORY - APIs QUALITATIVE RISK ASSESSMENT | | | | | | | |
|---|------------------|------------|--------|--|--|----|-------------|-----------|----------------|------|---|-------------------------|--|----------------------|--|---|---------------------------------------|---|
| LA-57 | Ramipril | 87333-19-S | Powder | Raw Material Sampling Area | Introduction of the raw material to be sampled opening bag Take a defined quantity of the product and place in a labeled bag/bottle Close it at the bag | 3 | Short (min) | Small (g) | Key every year | EP-2 | Very High | Lab_Containment_Level_3 | Powder Weighing hood with HEPA Filter - Reducized | YES | Low risk to health (Meets all requirements of the containment strategy level) | Quantitative Assessment not conducted | Acceptable (Low risk to health) | |
| LA-58 | SODIUM VALPROATE | 1089-66-S | Powder | Weighing room | Weighing of Resublets and SCR | 15 | Short (min) | Small (g) | Key every year | EP-2 | Very High | Lab_Containment_Level_3 | Powder Weighing hood with HEPA Filter - Reducized | YES | Low risk to health (Meets all requirements of the containment strategy level) | Quantitative Assessment not conducted | Acceptable (Low risk to health) | |
| LA-59 | SODIUM VALPROATE | 1089-66-S | Powder | Solution Preparation Area | Manual solid preparation involves -Opening the bottle -Transferring a exact quantity into a beaker -Dispensing the necessary amount of solvent from the beaker for solution preparation -Combining the prepared quantity into a volumetric flask and diluting -Transferring the solution into a labeled brown bottle. | 15 | Short (min) | Small (g) | Key every year | EP-2 | Very High | Lab_Containment_Level_3 | Powder Weighing hood with HEPA Filter - Reducized | Half Face Respirator | YES | Low risk to health (Meets all requirements of the containment strategy level) | Quantitative Assessment not conducted | Acceptable (Low risk to health) |
| LA-60 | SODIUM VALPROATE | 1089-66-S | Powder | Spectroscopy Room | Handling Infrared Spectrophotometer | 15 | Short (min) | Small (g) | Key every year | EP-2 | Very High | Lab_Containment_Level_3 | Open bench or bench top barrier or shield (in LEV) (Transfer of open solids only for solvent without generating activities) | Half Face Respirator | NO | Not a low risk to health Need to implement additional control measures: - Focus on hierarchy of controls, don't rely on PPEs - Qualitative Exposure monitoring is required - Containment equipment performance validation is required | Quantitative Assessment not conducted | Not acceptable Not low risk to health: Controls need to be implemented and quantitative sampling is required to verify risk status |
| LA-61 | SODIUM VALPROATE | 1089-66-S | Powder | Waste Collection Station | Collection of bench or HPLC waste | 15 | Short (min) | Small (g) | Key every year | EP-2 | Very High | Lab_Containment_Level_3 | Open bench or bench top barrier or shield (in LEV) (Transfer of open solids only for solvent without generating activities) | Half Face Respirator | NO | Not a low risk to health Need to implement additional control measures: - Focus on hierarchy of controls, don't rely on PPEs - Qualitative Exposure monitoring is required - Containment equipment performance validation is required | Quantitative Assessment not conducted | Not acceptable Not low risk to health: Controls need to be implemented and quantitative sampling is required to verify risk status |
| LA-62 | SODIUM VALPROATE | 1089-66-S | Powder | General Laboratory Waste Collection Area | collection of bench waste | 15 | Short (min) | Small (g) | Key every year | EP-2 | Very High | Lab_Containment_Level_3 | Open bench or bench top barrier or shield (in LEV) (Transfer of open solids only for solvent without generating activities) | Half Face Respirator | NO | Not a low risk to health Need to implement additional control measures: - Focus on hierarchy of controls, don't rely on PPEs - Qualitative Exposure monitoring is required - Containment equipment performance validation is required | Quantitative Assessment not conducted | Not acceptable Not low risk to health: Controls need to be implemented and quantitative sampling is required to verify risk status |
| LA-63 | SODIUM VALPROATE | 1089-66-S | Powder | Sample Return Waste Collection Area | Collection of solid waste (sample return) | 15 | Short (min) | Small (g) | Key every year | EP-2 | Very High | Lab_Containment_Level_3 | Open bench or bench top barrier or shield (in LEV) (Transfer of open solids only for solvent without generating activities) | Half Face Respirator | NO | Not a low risk to health Need to implement additional control measures: - Focus on hierarchy of controls, don't rely on PPEs - Qualitative Exposure monitoring is required - Containment equipment performance validation is required | Quantitative Assessment not conducted | Not acceptable Not low risk to health: Controls need to be implemented and quantitative sampling is required to verify risk status |
| LA-64 | SODIUM VALPROATE | 1089-66-S | Powder | Raw Material Sampling Area | Introduction of the raw material to be sampled opening bag Take a defined quantity of the product and place in a labeled bag/bottle Close it at the bag | 3 | Short (min) | Small (g) | Key every year | EP-2 | Very High | Lab_Containment_Level_3 | Powder Weighing hood with HEPA Filter - Reducized | YES | Low risk to health (Meets all requirements of the containment strategy level) | Quantitative Assessment not conducted | Acceptable (Low risk to health) | |

Appendix **G**

Manufacturing API Qualitative Risk Assessment

| sanofi | | MANUFACTURING SCALE - APIs QUALITATIVE RISK ASSESSMENT | | | | | | | | | | MANUFACTURING SCALE - APIs QUALITATIVE RISK ASSESSMENT | | | | | | | | | |
|--------|------------------|--|--------|------------------------|--|----|-------------|------------|------------------|------|-----------|--|---|--|-----|--|--|---------------------------------------|--|---|--|
| PA-35 | OXYMERAZINE | 3889-50-7 | Powder | Weighting ROOM | bring the raw materials into the weighting room Open the raw material bags Divide the material to be weighed into the double polyethylene bag Seal the original bag, and seal the weighed bag Return the raw material's MANUAL | 23 | Short (min) | High (Ton) | Very dusty solid | EP-3 | High | Prod_Containment_Level_3 | Open bench (no LEV) | | NO | <ul style="list-style-type: none"> Not a low risk to health Need to implement additional control measures. Focus on hierarchy of controls, don't rely on PPEs Quantitative Exposure monitoring is required Containment equipment performance validation is required | | Quantitative Assessment not conducted | | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status | |
| PA-36 | OXYMERAZINE | 3889-50-7 | Powder | Material Handling Room | granulation and mixing the materials manual | 23 | Short (min) | High (Ton) | Very dusty solid | EP-3 | High | Prod_Containment_Level_3 | Open bench (no LEV) | | NO | <ul style="list-style-type: none"> Not a low risk to health Need to implement additional control measures. Focus on hierarchy of controls, don't rely on PPEs Quantitative Exposure monitoring is required Containment equipment performance validation is required | | Quantitative Assessment not conducted | | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status | |
| PA-37 | OXYMERAZINE | 3889-50-7 | Powder | cleaning | cleaning the material manual | 23 | Short (min) | Small (g) | Very dusty solid | EP-2 | High | Prod_Containment_Level_3 | Open bench (no LEV) | | NO | <ul style="list-style-type: none"> Not a low risk to health Need to implement additional control measures. Focus on hierarchy of controls, don't rely on PPEs Quantitative Exposure monitoring is required Containment equipment performance validation is required | | Quantitative Assessment not conducted | | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status | |
| PA-38 | Paracetamol | 103-90-2 | Powder | Weighting ROOM | bring the raw materials into the weighting room Open the raw material bags Divide the material to be weighed into the double polyethylene bag Seal the original bag, and seal the weighed bag Return the raw material's MANUAL | 23 | Short (min) | High (Ton) | Very dusty solid | EP-3 | Moderate | Prod_Containment_Level_3 | Open bench (no LEV) | | NO | <ul style="list-style-type: none"> Not a low risk to health Need to implement additional control measures. Focus on hierarchy of controls, don't rely on PPEs Quantitative Exposure monitoring is required Containment equipment performance validation is required | | Quantitative Assessment not conducted | | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status | |
| PA-39 | Paracetamol | 103-90-2 | Powder | Material Handling Room | granulation and mixing the materials manual | 23 | Short (min) | High (Ton) | Very dusty solid | EP-3 | Moderate | Prod_Containment_Level_3 | Open bench (no LEV) | | NO | <ul style="list-style-type: none"> Not a low risk to health Need to implement additional control measures. Focus on hierarchy of controls, don't rely on PPEs Quantitative Exposure monitoring is required Containment equipment performance validation is required | | Quantitative Assessment not conducted | | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status | |
| PA-40 | Paracetamol | 103-90-2 | Powder | tableting room | tableting material manual | 23 | Long (hour) | High (Ton) | Very dusty solid | EP-4 | Moderate | Prod_Containment_Level_3 | Open bench (no LEV) | | NO | <ul style="list-style-type: none"> Not a low risk to health Need to implement additional control measures. Focus on hierarchy of controls, don't rely on PPEs Quantitative Exposure monitoring is required Containment equipment performance validation is required | | Quantitative Assessment not conducted | | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status | |
| PA-41 | Paracetamol | 103-90-2 | Powder | cleaning | cleaning the material manual | 23 | Long (hour) | Small (g) | Very dusty solid | EP-3 | Moderate | Prod_Containment_Level_3 | Open bench (no LEV) | | NO | <ul style="list-style-type: none"> Not a low risk to health Need to implement additional control measures. Focus on hierarchy of controls, don't rely on PPEs Quantitative Exposure monitoring is required Containment equipment performance validation is required | | Quantitative Assessment not conducted | | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status | |
| PA-42 | ranipril | 87333-19-5 | Powder | Weighting ROOM | bring the raw materials into the weighting room Open the raw material bags Divide the material to be weighed into the double polyethylene bag Seal the original bag, and seal the weighed bag Return the raw material's MANUAL | 23 | Short (min) | Small (g) | Very dusty solid | EP-2 | Very high | Prod_Containment_Level_3 | Powder Weighing Hood with HEPA Filter (Re-circulated) | | YES | <ul style="list-style-type: none"> Low risk to health Review all requirements of this containment strategy. (link) | | Quantitative Assessment not conducted | | Acceptable (Low risk to health) | |
| PA-43 | ranipril | 87333-19-5 | Powder | Material Handling Room | granulation and mixing the materials manual | 23 | Short (min) | Small (g) | Very dusty solid | EP-2 | Very high | Prod_Containment_Level_3 | Open bench (no LEV) | | NO | <ul style="list-style-type: none"> Not a low risk to health Need to implement additional control measures. Focus on hierarchy of controls, don't rely on PPEs Quantitative Exposure monitoring is required Containment equipment performance validation is required | | Quantitative Assessment not conducted | | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status | |
| PA-44 | ranipril | 87333-19-5 | Powder | tableting room | tableting material manual | 23 | Long (hour) | Small (g) | Very dusty solid | EP-3 | Very high | Prod_Containment_Level_4 | Open bench (no LEV) | | NO | <ul style="list-style-type: none"> Not a low risk to health Need to implement additional control measures. Focus on hierarchy of controls, don't rely on PPEs Quantitative Exposure monitoring is required Containment equipment performance validation is required | | Quantitative Assessment not conducted | | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status | |
| PA-45 | ranipril | 87333-19-5 | Powder | packaging room | packaging 1 material manual | 29 | Long (hour) | Small (g) | Very dusty solid | EP-3 | Very high | Prod_Containment_Level_4 | Open bench (no LEV) | | NO | <ul style="list-style-type: none"> Not a low risk to health Need to implement additional control measures. Focus on hierarchy of controls, don't rely on PPEs | | Quantitative Assessment not conducted | | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status | |
| PA-46 | ranipril | 87333-19-5 | Powder | cleaning | cleaning the material manual | 23 | Short (min) | Small (g) | Very dusty solid | EP-2 | Very high | Prod_Containment_Level_3 | Open bench (no LEV) | | NO | <ul style="list-style-type: none"> Not a low risk to health Need to implement additional control measures. Focus on hierarchy of controls, don't rely on PPEs Quantitative Exposure monitoring is required Containment equipment performance validation is required | | Quantitative Assessment not conducted | | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status | |
| PA-47 | SODIUM VALPROATE | 1069-68-6 | Powder | Weighting ROOM | bring the raw materials into the weighting room Open the raw material bags Divide the material to be weighed into the double polyethylene bag Seal the original bag, and seal the weighed bag Return the raw material's MANUAL | 23 | Long (hour) | High (Ton) | Very dusty solid | EP-4 | Very high | Prod_Containment_Level_4 | Powder Weighing Hood with HEPA Filter (Re-circulated) | | NO | <ul style="list-style-type: none"> Not a low risk to health Need to implement additional control measures. Focus on hierarchy of controls, don't rely on PPEs Quantitative Exposure monitoring is required Containment equipment performance validation is required | | Quantitative Assessment not conducted | | Unacceptable (Not low risk to health). Controls need to be implemented and quantitative sampling is required to verify risk status | |

Appendix H

Dermal hazard Qualitative Risk Assessment

| Step 1 | | Step 2 | | Step 3 | Step 4 | Step 5 | | | Step 6 | | Step 7 | | |
|--------|---------------------------------------|-------------|----------|--|---|-----------------------------------|--|-------------------------|--------------------|---------------------|---|---------------------------------------|---------|
| S. No | Chemical name | CAS number | State | Write the area of chemical handled (Lab name/location) | Description of the activity (similar activities can be grouped) | HEG (Number of employees exposed) | Dermal exposure risk | Skin exposure potential | Skin Hazard rating | Dermal risk ranking | Conclusion | Personal protective controls in place | Remarks |
| 1 | Chloroform | 67-66-3 | VaporGas | | Preparation of Reagents: Open the bottle Transfer a quantity into a test tube Transfer into a labeled brown bottle | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |
| 2 | 1,4-Dioxane | 123-91-1 | VaporGas | | Preparation of Reagents: Open the bottle Transfer a quantity into a test tube Transfer into a labeled brown bottle | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 3 | 4-Aminophenol | 123-30-8 | Powder | | Weighing of reagents and standard reference materials | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 4 | 4-Nitrophenol | 100-02-7 | Powder | | Weighing of reagents and standard reference materials | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 5 | Acetaldehyde | 75-07-0 | VaporGas | | Preparation of Reagents: Open the bottle Transfer a quantity into a test tube Transfer into a labeled brown bottle | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 6 | ACETONITRILE | 75-05-8 | VaporGas | | Collection of HPLC waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 7 | ALPHA AMYLASE | 9000-90-2 | Powder | | Weighing of reagents and standard reference materials | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 8 | AMISULPRIDE | 71675-85-9 | Powder | | Weighing of reagents and standard reference materials | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 9 | ANILINE | 62-53-3 | VaporGas | | Preparation of Reagents: Open the bottle Transfer a quantity into a test tube Transfer into a labeled brown bottle | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |
| 10 | Cesium chloride | 7647-17-8 | Powder | | Weighing of reagents and standard reference materials | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |
| 11 | CLOPIDOGREL HYDROGENSULFATE (form II) | 120202-66-6 | Powder | | Weighing of reagents and standard reference materials | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 3 | High | Take immediate action to control skin exposure. Conduct quantitative exposure assessment. | | |
| 12 | Formaldehyde | 50-00-0 | VaporGas | | Preparation of Reagents: Open the bottle Transfer a quantity into a test tube Transfer into a labeled brown bottle | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 3 | High | Take immediate action to control skin exposure. Conduct quantitative exposure assessment. | | |

| | | | | | | | | | | | | | |
|----|-------------------------------|-----------|----------|--|---|----|---|---|---|--------|---|--|--|
| 13 | FORMAMIDE | 75-12-7 | VaporGas | | Preparation of Reagents: Open the bottle Transfer a quantity into a test tube Transfer into a labeled brown bottle | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 14 | HYDROCHLOROTHIAZIDE | 58-93-5 | Powder | | Weighing of reagents and standard reference materials | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 15 | Mercuric iodide | 7774-29-0 | Powder | | Weighing of reagents and standard reference materials | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 16 | METHANOL | 67-56-1 | VaporGas | | Collection of HPLC waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |
| 17 | N-NDIMETHYLFORMAMIDE | 68-12-2 | VaporGas | | Preparation of Reagents: Open the bottle Transfer a quantity into a test tube Transfer into a labeled brown bottle | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 18 | N-HEXANE | 110-54-3 | VaporGas | | Preparation of solutions: Open the bottle Transfer a small quantity into a beaker Pipette from the beaker the necessary amount of solvent for the solution preparation Transfer this pipetted quantity into a volumetric flask and dilute Transfer into a labeled brown bottle | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |
| 19 | OXOMEMAZINE | 3689-50-7 | Powder | | Preparation of solutions: Open the bottle Transfer a small quantity into a beaker Pipette from the beaker the necessary amount of solvent for the solution preparation Transfer this pipetted quantity into a volumetric flask and dilute Transfer into a labeled brown bottle | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 20 | Phenol | 108-95-2 | Powder | | Weighing of reagents and standard reference materials | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 3 | High | Take immediate action to control skin exposure. Conduct quantitative exposure assessment. | | |
| 21 | Phenylhydrazine Hydrochloride | 59-88-1 | Powder | | Weighing of reagents and standard reference materials | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |
| 22 | Sodium Hydroxide | 1310-73-2 | VaporGas | | Manual titration | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 3 | High | Take immediate action to control skin exposure. Conduct quantitative exposure assessment. | | |
| 23 | SODIUM VALPROATE | 1069-66-5 | Powder | | Bring the Raw Materials into the weighing workshop Open the bags of Raw Materials Transfer the material to be weighed into the double polyethylene bag Seal the original bag and seal the weighed bag Return the Raw Materials | 23 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |
| 24 | Sulfuric Acid | 7664-93-9 | VaporGas | | Manual titration | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 3 | High | Take immediate action to control skin exposure. Conduct quantitative exposure assessment. | | |
| 25 | Thioacetamide | 62-55-5 | Powder | | Weighing of reagents and standard reference materials | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |
| 26 | TRIETHANOLAMINE | 102-71-6 | VaporGas | | Preparation of solutions: Open the bottle Transfer a small quantity into a beaker Pipette from the beaker the necessary amount of solvent for the solution preparation Transfer this pipetted quantity into a volumetric flask and dilute Transfer into a labeled brown bottle | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |
| 27 | TRIETHANOLAMINE | 102-71-6 | VaporGas | | Collection of HPLC waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |

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|----|---------------|-----------|----------|--|---|----|---|---|---|--------|---|--|--|
| 28 | 1,4-Dioxane | 123-91-1 | VaporGas | | Collection of bench waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 29 | 4-Aminophenol | 123-30-8 | Powder | | Preparation of solutions: Open the bottle Transfer a small quantity into a beaker Pipette from the beaker the necessary amount of solvent for the solution preparation Transfer this pipetted quantity into a volumetric flask and dilute Transfer into a labeled brown bottle | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 30 | 4-Aminophenol | 123-30-8 | Powder | | Collection of HPLC waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 31 | 4-Aminophenol | 123-30-8 | Powder | | Collection of bench waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 32 | Chloroform | 67-66-3 | VaporGas | | Preparation of Solutions: Open the bottle Transfer a small amount into a beaker Pipette the necessary amount of solvent from the beaker for the preparation of the solution Introduce this pipetted amount into a volumetric flask and dilute Transfer into a labeled brown bottle | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |
| 33 | Chloroform | 67-66-3 | VaporGas | | collection of bench waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |
| 34 | 4-Nitrophenol | 100-02-7 | Powder | | solution preparation | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 35 | 4-Nitrophenol | 100-02-7 | Powder | | Collection of HPLC waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 36 | Acetaldehyde | 75-07-0 | VaporGas | | Preparation of Solutions: Open the bottle Transfer a small amount into a beaker Pipette the necessary amount of solvent from the beaker for the preparation of the solution Introduce this pipetted amount into a volumetric flask and dilute Transfer into a labeled brown bottle | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 37 | Acetaldehyde | 75-07-0 | VaporGas | | Potentiometer manipulation | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 38 | Acetaldehyde | 75-07-0 | VaporGas | | collection of bench waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 39 | ALPHA AMYLASE | 9000-90-2 | Powder | | Solution Preparation: Open the bottle Transfer a small quantity into a beaker Pipette from the beaker the necessary amount of solvent for solution preparation Introduce this pipetted quantity into a volumetric flask and dilute Transfer into a labeled brown bottle | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 40 | ALPHA AMYLASE | 9000-90-2 | Powder | | Collection of HPLC waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 41 | ALPHA AMYLASE | 9000-90-2 | Powder | | collection of bench waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 42 | ALPHA AMYLASE | 9000-90-2 | Powder | | Solid Waste Collection (return of samples) | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |

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|----|--|-------------|----------|--|----|---|---|---|--------|---|--|--|
| 43 | ALPHA AMYLASE | 9000-90-2 | Powder | Introduction of the Material to be Sampled Open the bag Take a defined quantity of the product and place it into a labeled bag/flask Close/seal the bag | 3 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 44 | AMISULPRIDE | 71675-85-9 | Powder | Solution Preparation: Open the bottle Transfer a small quantity into a beaker Pipette from the beaker the necessary amount of solvent for solution preparation Introduce this pipetted quantity into a volumetric flask and dilute Transfer into a labeled brown bottle | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 45 | AMISULPRIDE | 71675-85-9 | Powder | Collection of HPLC waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 46 | AMISULPRIDE | 71675-85-9 | Powder | collection of bench waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 47 | AMISULPRIDE | 71675-85-9 | Powder | Collection of Solid Waste (return of samples) | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 48 | AMISULPRIDE | 71675-85-9 | Powder | Introduction of the Raw Material to be Sampled Open the bag Take a defined quantity of the product and place it into a labeled bag/flask Close/seal the bag | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 49 | ANILINE | 62-53-3 | VaporGas | Solution Preparation: Open the bottle Transfer a small quantity into a beaker Pipette from the beaker the necessary amount of solvent for solution preparation Introduce this pipetted quantity into a volumetric flask and dilute Transfer into a labeled brown bottle | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |
| 50 | ANILINE | 62-53-3 | VaporGas | Collection of HPLC waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |
| 51 | ANILINE | 62-53-3 | VaporGas | collection of bench waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |
| 52 | Cesium chloride | 7647-17-8 | Powder | soution preparation | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |
| 53 | Cesium chloride | 7647-17-8 | Powder | collection of bench waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |
| 54 | CLOPIDOGREL HYDROGENSULFAT E (form II) | 120202-66-6 | Powder | Preparation of Solutions: Open the bottle Transfer a small quantity into a beaker Pipette from the beaker the necessary amount of solvent for the solution preparation Introduce this pipetted quantity into a volumetric flask and dilute Transfer into a labeled brown bottle | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 3 | High | Take immediate action to control skin exposure. Conduct quantitative exposure assessment. | | |
| 55 | CLOPIDOGREL HYDROGENSULFAT E (form II) | 120202-66-6 | Powder | Collection of HPLC waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 3 | High | Take immediate action to control skin exposure. Conduct quantitative exposure assessment. | | |
| 56 | CLOPIDOGREL HYDROGENSULFAT E (form II) | 120202-66-6 | Powder | collection of bench waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 3 | High | Take immediate action to control skin exposure. Conduct quantitative exposure assessment. | | |
| 57 | CLOPIDOGREL HYDROGENSULFAT E (form II) | 120202-66-6 | Powder | Collection of Solid Waste (return samples) | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 3 | High | Take immediate action to control skin exposure. Conduct quantitative exposure assessment. | | |

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|----|--|-----------------|----------|--|----|---|---|---|------|---|--|--|
| 58 | CLOPIDOGREL HYDROGENSULFAT E (form II) | 120202-66- 6 | Powder | Introduction of the Raw Material to be Sampled Open the bag Take a defined quantity of the product and place it into a labeled bag/flask Close/seal the bag | 3 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 3 | High | Take immediate action to control skin exposure. Conduct quantitative exposure assessment. | | |
| 59 | Formaldehyde | 50-00-0 | VaporGas | Preparation of Solutions: Open the bottle Transfer a small quantity into a beaker Pipette from the beaker the necessary amount of solvent for the solution preparation Introduce this pipetted quantity into a volumetric flask and dilute Transfer into a labeled brown bottle | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 3 | High | Take immediate action to control skin exposure. Conduct quantitative exposure assessment. | | |
| 60 | Formaldehyde | 50-00-0 | VaporGas | Potentiometer Handling | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 3 | High | Take immediate action to control skin exposure. Conduct quantitative exposure assessment. | | |
| 61 | Formaldehyde | 50-00-0 | VaporGas | collection of bench waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 3 | High | Take immediate action to control skin exposure. Conduct quantitative exposure assessment. | | |
| 62 | FORMAMIDE | 75-12-7 | VaporGas | Preparation of Solutions: Open the bottle Transfer a small quantity into a beaker Pipette from the beaker the necessary amount of solvent for solution preparation Introduce this pipetted quantity into a volumetric flask and dilute Transfer into a labeled brown bottle | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 63 | FORMAMIDE | 75-12-7 | VaporGas | Potentiometer Handling | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 64 | FORMAMIDE | 75-12-7 | VaporGas | collection of bench waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 65 | HYDROCHLOROTHI AZIDE | 58-93-5 | Powder | Preparation of Solutions: Open the bottle Transfer a small quantity into a beaker Pipette from the beaker the necessary amount of solvent for solution preparation Introduce this pipetted quantity into a volumetric flask and dilute Transfer into a labeled brown bottle | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 66 | HYDROCHLOROTHI AZIDE | 58-93-5 | Powder | Infra-Red Strephtophotometer Handling | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 67 | HYDROCHLOROTHI AZIDE | 58-93-5 | Powder | Collection of HPLC waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 68 | HYDROCHLOROTHI AZIDE | 58-93-5 | Powder | collection of bench waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 69 | HYDROCHLOROTHI AZIDE | 58-93-5 | Powder | Solid Waste Collection (Return of Samples) | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 70 | HYDROCHLOROTHI AZIDE | 58-93-5 | Powder | Introduction of the Material to be Sampled Open the drum Take a defined quantity of the product and place it into a labeled bag/flask Close/seal the bag | 3 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 71 | Mercuric iodide | 7774-29-0 | Powder | solution preparation | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 72 | Mercuric iodide | 7774-29-0 | Powder | collection of bench waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |

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|----|-------------------------------|-----------|----------|--|--|----|---|---|---|--------|---|--|--|
| 73 | N-NDIMETHYLFORMAMIDE | 68-12-2 | VaporGas | | Preparation of Solutions: Open the bottle Transfer a small quantity into a beaker Pipette from the beaker the necessary amount of solvent for solution preparation Introduce this pipetted quantity into a volumetric flask and dilute Transfer into a labeled brown bottle | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 74 | N-NDIMETHYLFORMAMIDE | 68-12-2 | VaporGas | | collection of bench waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 75 | N-HEXANE | 110-54-3 | VaporGas | | collection of bench waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |
| 76 | OXOMEMAZINE | 3689-50-7 | Powder | | Collection of HPLC waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 77 | OXOMEMAZINE | 3689-50-7 | Powder | | collection of bench waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 78 | OXOMEMAZINE | 3689-50-7 | Powder | | Collection of solid waste (sample return) | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 79 | OXOMEMAZINE | 3689-50-7 | Powder | | Weighing of Reagents and Standard Reference Materials | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 80 | OXOMEMAZINE | 3689-50-7 | Powder | | Introduction of the Material to be Sampled Open the bag Take a defined quantity of the product and place it into a labeled bag/flask Close/seal the bag | 3 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 1 | Low | Consider further control action. Review risk assessment periodically or in event of change. | | |
| 81 | Phenol | 108-95-2 | Powder | | Preparation of Solutions: Open the bottle Transfer a small quantity into a beaker Pipette from the beaker the necessary amount of solvent for solution preparation Introduce this pipetted quantity into a volumetric flask and dilute Transfer into a labeled brown bottle | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 3 | High | Take immediate action to control skin exposure. Conduct quantitative exposure assessment. | | |
| 82 | Phenol | 108-95-2 | Powder | | collection of bench waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 3 | High | Take immediate action to control skin exposure. Conduct quantitative exposure assessment. | | |
| 83 | Phenylhydrazine Hydrochloride | 59-88-1 | Powder | | Preparation of Reagents: Open the bottle Transfer a quantity into a test tube Transfer into a labeled brown bottle | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |
| 84 | Phenylhydrazine Hydrochloride | 59-88-1 | Powder | | Preparation of Solutions: Open the bottle Transfer a small quantity into a beaker Pipette from the beaker the necessary amount of solvent for solution preparation Introduce this pipetted quantity into a volumetric flask and dilute Transfer into a labeled brown bottle | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |
| 85 | Phenylhydrazine Hydrochloride | 59-88-1 | Powder | | collection of bench waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |
| 86 | SODIUM VALPROATE | 1069-66-5 | Powder | | Open the bags of Raw Materials and vacuum the powder using a flexible hose | 23 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |
| 87 | SODIUM VALPROATE | 1069-66-5 | Powder | | Initial Packaging | 20 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |
| 88 | SODIUM VALPROATE | 1069-66-5 | Powder | | Cleaning | 20 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |

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|----|-----------------|----------|----------|--|--|----|---|---|---|--------|---|--|--|
| 89 | Thioacetamide | 62-55-5 | Powder | | Preparation of Solutions: Open the bottle Transfer a small quantity into a beaker Pipette from the beaker the necessary amount of solvent for solution preparation Introduce this pipetted quantity into a volumetric flask and dilute Transfer into a labeled brown bottle | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |
| 90 | Thioacetamide | 62-55-5 | Powder | | Collection of HPLC waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |
| 91 | Thioacetamide | 62-55-5 | Powder | | collection of bench waste | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |
| 92 | TRIETHANOLAMINE | 102-71-6 | VaporGas | | Preparation of Solutions: Open the bottle Transfer a small quantity into a beaker Pipette from the beaker the necessary amount of solvent for solution preparation Introduce this pipetted quantity into a volumetric flask and dilute Transfer into a labeled brown bottle | 15 | Significant risk of indirect contact (e.g. workers handle tools which are in direct contact. Minor risk of direct contact. Surface contamination in work area is possible) | 2 | 2 | Medium | Apply best practice control measures. Consider quantitative exposure assessment. | | |

Appendix I

Containment Strategy

| Containment Strategy Matrix | | | | |
|---|---|---|--|---|
| Containment Level | 1 | 2 | 3 | 4 |
| EXAMPLES OF CONTAINMENT OPTIONS • In all cases, the selected ventilation/containment option must meet the exposure control objective specified in the risk assessment and/or OH Sampling Plan; • If a recommendation described in this matrix is not feasible, review applicability and demonstrate that alternatives achieve effective exposure control | | | | |
| Laboratory (Drug Discovery/Research), Small Scale Formulations and Scale-Up Operations | Typical Unit Operations: Drying Activities Filtration Activities Lab Analysis Liquid Dispensing & Handling Milling and Sizing | | | |
| Open Bench or Benchtop Barrier or Shield (no LEV) | <ul style="list-style-type: none"> Solids: transfer of gram quantities | No, except for <10 grams API in aqueous solutions | No, except for < 10 grams API in aqueous solutions | No, except for <10 grams API in aqueous solutions |
| Laminar Flow Hood (Clean Bench) | <ul style="list-style-type: none"> Liquids: Yes, but no solvent aerosol generating activities | <ul style="list-style-type: none"> Solids: transfer of gram quantities Liquids: Yes, but no solvent aerosol generating activities | No | No |
| Powder Weighing Hood with HEPA Filter (recirculated) | Yes | Yes | Yes | Yes, if OH monitoring demonstrates containment |
| Powder Weighing Hood with HEPA Filter and Exhausted to the Outdoors | Yes | Yes | Yes | Yes, if OH monitoring demonstrates containment |
| Laboratory Hood Exhausted to the Outdoors | Yes | Yes | Yes | Yes, if OH monitoring demonstrates containment |
| Class II Type A1/A2/B1/B2 Biosafety Cabinet recirculated or when connected to building exhaust system | Yes | Yes, if in solution /suspension. Not for powder handling unless OH monitoring demonstrates containment | | |
| Glovebox or Isolator with HEPA Filter and Exhausted to the Outdoors | Yes | Yes | Yes | Yes |

Figure I.1: laboratory containment strategy matrix

| Containment Strategy Matrix | | | | |
|---|--|---|--|---|
| Containment Level | 1 | 2 | 3 | 4 |
| Pilot Plant & Manufacturing Operations | Typical Unit Operations: Bagging & Bulk Transfers, Blending Capsule Filling Compounding Compression & Filling | Drying Activities Filtration Activities Finish Product Manufacturing Formulation Activities Granulating Lab Analysis | Liquid Dispensing, Handling, & Transfers Milling & Sizing Powder Weighing & Dispensing Sampling Sieving/Sifting Solids Charging & Transfers | |
| Open Bench (no LEV) | Yes | <ul style="list-style-type: none"> • Solids: No for kg quantities • Wet cake: Yes • Liquids: Yes, but no open solvent aerosol generating activities Other - Contact Site HSE | No | No |
| Laboratory Fume Hood Exhausted to the Outdoors | Yes | <ul style="list-style-type: none"> • Wet cake • Must be in solution with no powder aerosol generating activities | | Contact Site HSE or OH expert |
| Powder Weighing Hood with HEPA Filter (recirculated) | Yes | | Yes | No |
| Powder Weighing Hood with HEPA Filter/ Exhausted to the Outdoors | Yes | Yes | Yes | No |
| LEV at Equipment or Bag Opening | Evaluate on a case-by-case basis | | | |
| Class II Type A1, A2, B1, B2 Biosafety Cabinet | Evaluate on a case-by-case basis for powder handling | | | |
| Glovebox or Isolator with HEPA Filter/ Exhausted to the Outdoors | Yes | Yes | Yes, if has airlock | Yes, if has airlock and Rapid transfer port(s) |
| Downflow Booth Note: additional controls may include speciality valves, continuous liners, vacuum conveyors; bulk bags | Yes | <ul style="list-style-type: none"> • Requires closed/dust-tight transfer with LEV and work practice controls • Contact Site HSE or OH expert for review and approval | | <ul style="list-style-type: none"> • Booth with glove bag shield or bag • Spilt butterfly valve with extraction or liquid rinse |
| LEV - Slot Exhaust (e.g., barrel slot exhaust, Keissler ring) | Yes | <ul style="list-style-type: none"> • Wet cake – review toxicity, frequency, and type of tasks • Dry solid – review bulk density of solid | Evaluate on a case-by-case basis | |
| Vacuum Conveyor (closed) | Yes | Yes | Yes | Yes |

Figure I.2: Manufacturing containment strategy matrix

Appendix J

Permit to work SOP

PROCEDURE PERMIS DE TRAVAIL

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1. OBJECTIF

Cette procédure vise à expliquer les différentes autorisations de travail requises lors d'une opération comportant des risques spécifiques ou impliquant une entreprise extérieure au site distribution de Sanofi Algérie « Sidi Abdellah DC ».

Elle inclut également les lois locales applicables pour assurer un environnement de travail sûr et conforme à la réglementation.

2. DOMAINE D'APPLICATION

Cette procédure s'applique à l'ensemble de la main-d'œuvre supervisée, y compris les employés de Sanofi et des entreprises extérieures engagées par Sanofi pour travailler sur le site distribution de Sanofi Algérie « Sidi Abdellah DC ».

3. RESPONSABILITÉS

| Rôle | Description |
|--|---|
| Le Responsable de site | <ul style="list-style-type: none">- Garantit la mise en œuvre et le respect de la procédure d'autorisation de travail sur le site. |
| Le Responsable d'exploitation | <ul style="list-style-type: none">- Supervise le processus d'autorisation de travail pour ses équipes respectives.- S'assure que tous les employés sous sa responsabilité ont les permis de travail appropriés avant de commencer à travailler.- Collabore avec le Responsable HSE pour identifier les besoins en matière d'autorisation de travail et mettre en œuvre les solutions adéquates.- Communique les exigences en matière d'autorisation de travail aux employés et aux superviseurs. |
| Le Chef de chantier | <ul style="list-style-type: none">- Identifie les besoins en matière d'autorisation de travail pour les activités sur son chantier.- S'assure que tous les travailleurs sur son chantier ont les permis de travail appropriés avant de commencer à travailler.- Veille au respect des conditions de sécurité définies dans l'autorisation de travail. |
| Le Responsable de la zone | <ul style="list-style-type: none">- Assure la conformité des conditions de travail avant de donner l'autorisation. |
| Donneur d'ordre | <ul style="list-style-type: none">- S'assure que le périmètre, la planification du travail, ainsi que la mise en place du travail sont conformes aux conditions définies avant d'autoriser le travail.- Signe et approuve le permis de travail. |
| Le Responsable HSE et maintenance | <ul style="list-style-type: none">- Valide les demandes d'autorisation de travail et communique les autorisations aux parties prenantes.- Mène des audits réguliers pour s'assurer du respect de la procédure et de la conformité aux réglementations locales.- Intègre les exigences en matière de sécurité et de santé dans le processus d'autorisation de travail. |
| Exécutant | <ul style="list-style-type: none">- Signe et approuve le permis de travail |

4. DOCUMENTS RÉFÉRENCES ET / OU DOCUMENTS LIÉS

- Standard STD-000416 Exigences HSE dans le processus d'autorisation de travail
- Standard STD-000308 Gestion des travaux par points chauds

5. DÉFINITIONS / ABRÉVIATIONS

| | |
|-------------------------------------|--|
| | |
| Permis de travail spécifique | Une autorisation écrite établis avec des mesures de sécurité et des contrôles renforcés, des rôles supplémentaires bien définis et des signatures obligatoires pour maîtriser les dangers et les risques associés aux travaux dangereux. |
| Travaux à chaud | Travaux impliquant l'utilisation de flammes nues, d'outils produisant de la chaleur ou d'autres sources d'inflammation. |
| Travail en hauteur | Travail effectué à une hauteur égale ou supérieure à 1,8 mètre du sol ou de la plateforme de travail. |

6. HISTORIQUE

| N° de version | Date | Description de la modification |
|---------------|------|--------------------------------|
| | | La création de la procédure |

7. ANNEXES

ANNEXE 01 : Processus d'autorisation de travail

ANNEXE 02 : Permis de travail simple

ANNEXE 03 : Liste des travaux dangereux

8. CONTENUE DE LA PROCEDURE

8.1 STANDARISATION DU FORMAT DE PERMIS DE TRAVAIL

Dans une zone reconnue, un seul modèle de permis de travail est valide, sous la responsabilité opérationnelle du responsable de la zone.

8.2 LES TYPES DE PERMIT DE TRAVAIL

Il y a 2 types :

- **Permis de travail simple** : pour les travaux standards.
- **Permis de travail spécifique** : pour les travaux dangereux, y compris :
 - **Un Permis de travail par points chauds** : pour effectuer des travaux dans des zones présentant un danger particulier. (Découpage, perçage, soudage ...)
 - **Un permis de travail en hauteur** : Pour les tâches effectuées à une hauteur de 1m80 ou plus, du sol jusqu'aux pieds de l'opérateur. (Travaux sur les toits et activités sur des surfaces fragiles, utilisation d'échelles ...).
 - **Un permis opérations sur des équipements** (consignation électrique, consignation mécanique, hydraulique)

8.3 AUTORISATION DE TRAVAIL

Le processus d'autorisation de travail, géré de manière efficace par un système informatique spécialisé (QualiPSO). Lors de la délivrance d'un permis de travail, le demandeur peut fournir des consignes de sécurité spécifiques, assurant ainsi une préparation adéquate pour les travailleurs.

L'autorisation de travail est formellement accordée dès que le permis de travail est signé conjointement par le donneur d'ordre et le responsable de la zone d'intervention. Tous deux se sont assurés des conditions de sécurité (coactivité, environnement de la zone de travail) de l'intervention.

En cas d'intervention en dépannage sans la présence physique du donneur d'ordre, le responsable de la zone d'intervention signe un formulaire d'autorisation de travail, assurant ainsi la continuité du processus d'autorisation dans des circonstances exceptionnelles.

8.4 CHANGEMENTS DANS LES CONDITIONS

En cas de modifications dans les conditions de travail susceptibles de mettre les travailleurs en danger, le responsable de la zone doit prendre des mesures immédiates. Il évalue les changements, décide de suspendre ou d'annuler les travaux si nécessaire, informe les travailleurs et rectifie les conditions dangereuses avant de reprendre le travail. Enfin, il documente les changements et les actions prises pour assurer la sécurité des travailleurs.

8.5 FORMULAIRE DE PERMIS DE TRAVAIL

-Il doit définir les mesures, les moyens, et les supervisions requis.

-Il doit comprendre au minimum les exigences suivantes :

- Numéro de référence du permis de travail
- Informations d'urgence / numéros de contact ou dispositions spécifiques de communication
- Donneur d'ordre
- Description / Emplacement / ID de l'équipement
- Durée de validité du permis
- Dangers/risques réels et potentiels des tâches du travail
- Dangers/risques réels et potentiels de la zone/équipement
- Permis de travail spécifique demandé (y compris numéro)

- Moyen de mise à disposition de l'équipement/machine sur lequel sera réalisé le travail ou moyen de mise à disposition de la zone
- Nécessité de consignation et référence de la consignation
- Mesures de contrôle requises et mises en place
- Contrôles requis et effectués
- Coordination requise et mise en place
- Autorisation(s) - Nom/signature
- Clôture(s) - Nom/signature

8.6 Préparation et Délivrance du Permis de Travail

- Le formulaire de permis doit offrir la possibilité de détailler et de formaliser toutes les mesures, moyens et supervisions nécessaires. Il doit également permettre de documenter la mise en œuvre effective de ces mesures, moyens et supervisions. De plus, il doit être conçu de manière à garantir que toutes les conditions requises soient remplies avant d'autoriser les travaux.
- Avant d'autoriser le travail, il est impératif que tous les exécutants soient informés des dangers et des risques associés à leur tâche, ainsi que des conditions environnementales dans lesquelles ils évolueront, ainsi que des mesures et moyens de contrôle nécessaires.
- Un permis de travail ne peut être délivré que pour une seule entité ou pour un groupe d'entités supervisées par un seul superviseur. Par exemple, le superviseur de l'entité A peut superviser l'entité B sous-traitée par l'entité A.
- Seules les personnes autorisées sont habilitées à remplir un permis de travail ou à délivrer une autorisation de travail. Il est strictement interdit de s'auto-délivrer un permis de travail. Ainsi, le demandeur ne doit en aucun cas travailler sous un permis qu'il aurait lui-même délivré.

8.7 GESTION DE PERMIS DE TRAVAIL

8.7.1 Durée de validité

Le permis de travail est valable pour la période et la durée spécifiées sur le document, avec une limite maximale de 5 jours ouvrables.

8.7.2 Transfert d'équipe

Lorsqu'un permis de travail est délivré pour une période dépassant le temps d'une équipe de travail, les transferts de responsabilité lors du changement d'équipe doivent être consignés dans le permis de travail.

8.7.3 Clôture en pause

En cas de suspension des travaux laissés sans surveillance, y compris pendant les pauses normales de travail (par exemple, la pause de nuit) pendant la validité du permis, celui-ci doit être clôturé conformément aux procédures établies. Un transfert ordonné de retour à l'état sûr de la zone ou de l'équipement doit être mis en place avant la fermeture du permis, et une inspection doit être effectuée à la reprise du travail pour vérifier la validité des conditions du permis.

8.7.4 Gestion des dépassements

En cas de dépassement des conditions du permis de travail, celui-ci doit être suspendu jusqu'à ce que le donneur d'ordre détermine s'il convient d'apporter des modifications au permis existant ou s'il est nécessaire d'annuler le permis et d'en délivrer un nouveau.

8.7.5 Continuité de communication

Pour assurer la continuité de la communication pendant l'exécution des travaux, au moins une personne de contact, parmi le donneur d'ordre ou le responsable de la zone, doit être disponible sur site. Les transferts de responsabilité doivent être enregistrés dans le permis de travail.

8.7.6 Enregistrement des actions

Le formulaire de permis de travail doit permettre d'enregistrer toutes les situations de gestion du permis rencontrées sur le site, y compris les rôles, noms, dates et signatures associés.

8.7.7 Gestion des documents

Pendant l'exécution du travail, l'exécutant ou le superviseur de l'équipe doit avoir à portée de main une copie de tous les formulaires de permis de travail en cours d'exécution pour assurer la conformité et la sécurité des opérations.

8.7.8 Retour à un état sûr

Une fois les travaux terminés, il est important d'organiser un retour ordonné à l'état sécurisé de la zone ou de l'équipement au responsable de la zone. Cela permet de s'assurer que la zone et l'équipement utilisés durant les travaux sont sûrs et prêts à reprendre les opérations normales.

8.7.9 Clôture du permis de travail

À la clôture des travaux, le permis doit être signé par au moins les personnes qui ont effectué les travaux et le responsable de la zone. En apposant leur signature (avec leur nom, la date et l'heure).

8.7.10 Un travail non sûr

Le personnel du site doit être informé qu'il a le pouvoir et la responsabilité d'arrêter toute tâche qu'il juge dangereuse.

8.8 PERMIS SPECIFIQUE

8.8.1 PERMIS DE TRAVAIL PAR POINTS CHAUDS

8.8.1.1 CONTENUE D'UN PERMIS DE TRAVAIL PAR POINTS CHAUDS

Le permis à chaud comporte les parties suivantes à compléter :

- Entreprise Utilisatrice (Sanofi)
- Intervenants
- Organisation des Travaux (durée, lieu)
- Nature de l'Intervention (type de travail par point chaud, organes/équipements utilisés)
- Risques Identifiés
- Mesures de Prévention (avant, pendant et après les travaux)
- Moyens d'Alerte et d'Intervention (téléphone le plus proche, extincteur...)
- Signature (donneur d'ordre, agent de surveillance, intervenant, représentant du service HSE)

8.8.1.2 RÉALISATION D'UN PERMIS DE TRAVAIL PAR POINTS CHAUDS

Le permis à chaud est réalisé sur le lieu de l'intervention conjointement entre le donneur d'ordre, le responsable de l'entreprise (et/ou les intervenants), le responsable de zone et un représentant du service HSE

Il est établi pour une durée maximale de 5 jours et doit être validé et signé tous les jours par le donneur d'ordre, l'intervenant et le responsable de zone pour s'assurer que les risques n'ont pas évolué.

8.8.2 Le permis de travail en hauteur

Les travaux en hauteur sont une source d'accidents graves ou mortels. Ils nécessitent une préparation pour déterminer les moyens d'intervention adaptés et sécurisés. Le permis de travail en hauteur est un outil crucial pour sélectionner le moyen d'intervention et contrôler les éléments nécessaires à l'utilisation de l'équipement.

8.8.2.1. Contenu du permis de travail en hauteur

Le permis de travail en hauteur inclut les parties suivantes à remplir :

- Les différents acteurs impliqués (internes et externes)
- La nature de l'intervention (date, lieu, type)
- L'évaluation du moyen d'intervention
- Les mesures de prévention associées aux différents équipements
- Les mesures de prévention liées aux travaux en hauteur
- Les signatures (donneur d'ordre, intervenants, service HSE, responsable de zone)

8.8.2.2 Réalisation du permis de travail en hauteur

Un permis de travail en hauteur doit être établi sur le lieu de l'intervention, en collaboration avec les intervenants, le responsable de chantier et le service HSE, pour toute intervention en hauteur utilisant un équipement dont le plancher de travail est à plus de 1.80m du sol.

Ce permis doit être affiché sur la zone et transmis au service HSE dès la fin de l'intervention.

Le permis de travail en hauteur est valide pour une durée maximale de 5 jours et doit être validé et signé.

FORMATION

Tous les personnels impliqués dans la procédure de permis de travail doivent suivre une formation adéquate. Cette formation doit couvrir les éléments suivants :

- Les objectifs de la procédure de permis de travail
- Les types de permis de travail et leur utilisation
- Les dangers et les risques associés aux travaux dans la zone
- Les mesures de sécurité à mettre en place
- Les rôles et responsabilités des différents intervenants
-

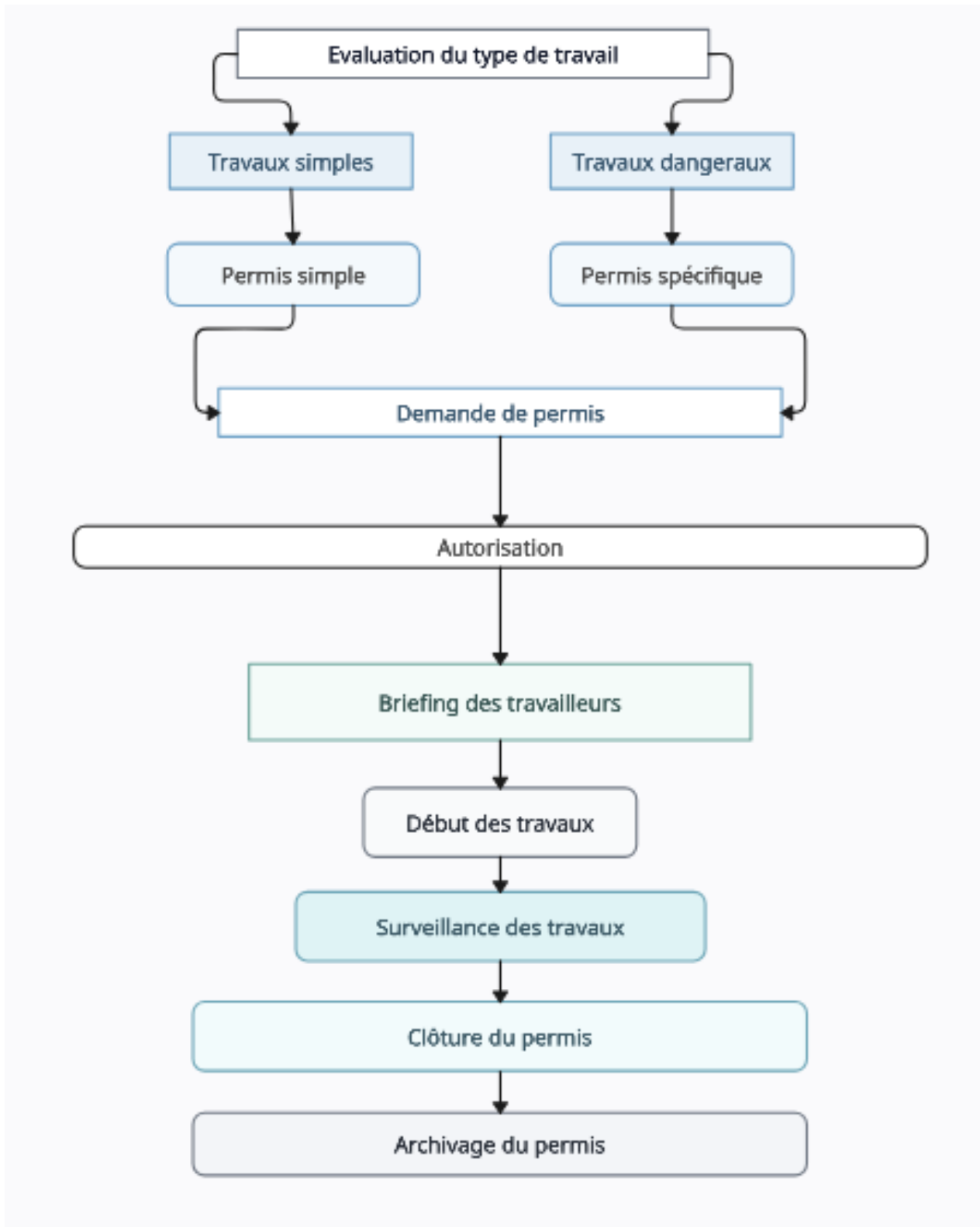
AUDIT

Le processus d'autorisation de travail doit faire l'objet d'un audit périodique pour s'assurer que le processus et les procédures d'autorisation de travail sont exécutés correctement conformément à la procédure du site.

ARCHIVAGE

Après leur utilisation, les permis de travail doivent être archivés pendant un an.

ANNEXE01 : PROCESSUS D'AUTORISATION DE TRAVAIL



Appendix K

the new permit to work

1- PREPARATION DE L'INTERVENTION (avant de commencer les travaux) / *Champs réservé uniquement au rédacteur du permis*

A/ Lieux travaux: **Bâtiment :** **Plan de prévention Requis Réf:**..... **Induction EHS EE réalisée** Oui Non NA

B/ Descriptif des travaux :.....

| C/ Etapes de travail | | | D/ Equipements Utilisés | | |
|----------------------|--------------|---------------------|-------------------------|---------|-------------|
| Etape | Risques liés | Moyen de prévention | Outils | Accepté | Non accepté |
| | | | | | |
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E/ LOTO 'Consignation' (Cocher les sources d'énergies à isoler et isolées par l'Engineering) Type : Simple Complexe NA

Electrique Hydraulique Pneumatique Mécanique Chimique Thermique Autre

Attestation LOTO 1 N Energie isolé Dispo de verrouillage Mise en place : .. / .. /H Nom VISA

Attestation LOTO 2 N Energie isolé Dispo de verrouillage Mise en place : .. / .. /H Nom VISA

Attestation LOTO 3 N Energie isolé Dispo de verrouillage Mise en place : .. / .. /H Nom VISA

F/ Permis spéciaux requis : Permis de Feu Réf :..... Permis d'entrée Espace Confiné Réf :..... Permis travail en Hauteur Réf :.....

permis d'Excavation Réf :..... Permis de Travail isolé Réf :..... Permis manipulation Amiante Réf :..... HT/MT Réf :.....

G/ Mesures de prévention EPI/EPC (Assistance EHS requise): Balisage de la Zone Signalisation (Affichages pictogrammes) Fermeture des accès

Casque de sécurité Lunettes de protection Protection panoramique Stop-Bruit Gants de Manutention Gants de

Filtre resp particules Filtre resp Gaz Combinaison étanche produits chimiques Combinaison étanche particules Chaussures de sécurité

Harnais Antichute Trépied Masque à souder Combinaison Ignifuge Autres :.....

H / Supervision : Supervision chaque :H..... à partir du : .. / .. / .. à .. H Par : Visa :

I/ Signatures, PREPARATION DE L'INTERVENTION (Champs réservé uniquement au Délivreur) Préparation de l'intervention établie le .. / .. / .. à .. H

Délivreur VISA Nom Récepteur VISA Responsable de la zone : VISA

Intervenant 1 Nom VISA Intervenat2Nom VISA Intervenant 3 Nom VISA Intervenant 4 Nom VISA

Intervenant 5 Nom VISA Intervenant6 Nom VISA Intervenant 7 Nom VISA Intervenant 8 Nom VISA

Intervenant 9 Nom VISA Intervenant10Nom VISA Intervenant11 Nom VISA Intervenant12 Nom VISA

2- DEMARRAGE DES TRAVAUX

A/ Signatures, Autorisation de DEMARRAGE DES TRAVAUX AUTORISATION. Par ma signature, j'atteste avoir compris mes responsabilités, avoir complété LA PREPARATION DES TRAVAUX et je m'engage à respecter et à faire respecter scrupuleusement les instructions figurant sur ce permis. J'atteste aussi que les conditions de sécurité sont toutes complètes, que les mesures de prévention et de protection sont en place et autorise par conséquent le commencement des travaux :

Démarrage prévu le .. / .. / .. à .. H Fin des travaux prévue le .. / .. / .. à .. H

B/ Extensions (5 Extensions permis chacune de 24h, si les conditions de travail change ou si des étapes de travail changent refaire un nouveau permis :

Extension 1 du .. / .. / .. au .. / .. / .. Délivreur VISA / Récepteur VISA

Extension 1 du .. / .. / .. au .. / .. / .. Délivreur VISA / Récepteur VISA

Extension 1 du .. / .. / .. au .. / .. / .. Délivreur VISA / Récepteur VISA

Extension 1 du .. / .. / .. au .. / .. / .. Délivreur VISA / Récepteur VISA

Extension 1 du .. / .. / .. au .. / .. / .. Délivreur VISA / Récepteur VISA


3- CLOTURE DU PERMIS Les activités normales dans la zone ne doivent pas reprendre si des cases 'Non' sont sélectionnées / Champs réservé au Délivreur et Récepteur

Travaux Terminée ? Oui Non Si 'Oui' terminés le .. / .. / .. à .. H Lieux évacués et nettoyés ? Oui Non LOTO Déconsignés ? Oui Non NA

Permis spéciaux clôturés ? Oui Non NA Lieux sécurisés ? Oui Non NA Reprise des activités autorisée ? Oui Non Visa du responsable de la zone :

Par ma signature, j'atteste les travaux sont terminés, que les lieux sont propres et évacués, que les LOTO sont enlevés, que les permis spéciaux sont tous clôturés et par conséquent les lieux sont sûrs et les activités normales peuvent reprendre :

Intervention déclarée terminée le : .. / .. / .. à .. H Par Délivreur : VISA : et Récepteur : VISA :

| | |
|---|--|
|  | Respecter les consignes de sécurité ! En cas d'incident appelez les Numéros d'urgence / Poste de garde au N° 7777 |
| | Contacts Téléphoniques : Responsable HSE : Récepteur : Animatrice HSE : |

Important ! : Ce permis a une durée de validité de 24h, seulement 5 extensions de 24h sont permises dans les même conditions de travail, si les conditions de travail ou les étapes de travail changent un nouveau permis est exigé

Appendix L

LOTO SOP

Procédure Consignation et Déconsignation :

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1. OBJET

Cette procédure décrit le processus Consignation/Déconsignation à mettre en place pour prévenir les accidents sur le personnel et l'environnement liés aux énergies ou aux substances dangereuses lors d'activités d'entretien, de maintenance ou opérationnelles avec des machines ou des équipements.

La procédure ne prétend pas détailler toutes les solutions techniques pouvant être mises en œuvre pour une consignation. Elle fournit simplement une démarche à appliquer par les responsables, chargés des travaux et de consignation, ainsi que les techniciens intervenants pour l'application d'un système de consignation et de déconsignation correct quel que soit le type de risque.

2. DOMAINE D'APPLICATION

Cette procédure s'applique au site de distribution de Sanofi Algérie « Sidi Abdellah DC ».

Cette procédure s'adresse à toutes les activités impliquant des machines et des équipements, telles que l'entretien, la maintenance et les opérations, où une remise en énergie, un redémarrage, une remise en produit ou une libération d'énergie/produit accumulé pourrait entraîner des conséquences néfastes sur la santé des individus et sur l'environnement.

Elle traite du contrôle des énergies/substances dangereuses lorsque le personnel, de toutes catégories, est impliqué dans des activités d'entretien, de maintenance ou opérationnelles et peut être exposé à ces dangers. Cette procédure établit des exigences minimales de performance pour ce contrôle.

Si la réglementation locale impose des exigences plus strictes que cette procédure le site doit se conformer à ces exigences supplémentaires.

Dès que cette Procédure est applicable, l'équipement doit être arrêté, isolé de toutes les sources d'énergie/substances, et les dispositifs d'isolement doivent être verrouillés et étiquetés. De plus, les responsables de la consignation doivent effectuer les vérifications nécessaires pour s'assurer de l'absence d'énergie/substance et de l'isolement efficace de toutes les sources d'énergie.

Le processus de Consignation/Déconsignation s'applique systématiquement Aux travaux et interventions sur installations et équipements qui mettent en jeu des sources d'énergie/fluides de type :

- Electrique : force motrice, éclairage, rayonnements, chauffage...
- Mécanique : ressorts sous tension, effet de la gravité, ventilateurs en rotation...

Le risque électrique : Cette procédure est applicable Pour intervenir sur ou travailler à proximité de conducteurs nus sous tension, si et seulement si la tension est supérieure ou égale à 50 Volt, où la priorité est d'arrêter l'installation électrique et de la consigner

Dans des situations particulières telles que la recherche de panne, le diagnostic ou la nécessité de maintenir le service, des compétences et des exigences spécifiques, y compris un permis de travail spécial, seront nécessaires pour intervenir sur ou à proximité de composants électriques nus sous tension.

Activités opérationnelles (ou de production/ manufacturing) : les activités opérationnelles sur des équipements énergisés pendant la production ne sont pas concernées par ce standard si et seulement si :

- Une évaluation du risque au poste de travail a été effectuée.
- La tâche doit être exécutée par un personnel bien formé.

3. RESPONSABILITÉS

| Rôle | Description |
|--|--|
| Responsable de la distribution | <ul style="list-style-type: none"> - Garantir l'élaboration et la mise en place d'un système de consignation et déconsignation. |
| Responsable HSE | <ul style="list-style-type: none"> - Développer un système de consignation et de déconsignation et de garantir son application efficace en : <ul style="list-style-type: none"> o Organiser des audits internes. o Analyser les écarts et s'assurer que des mesures correctives ont été prises. |
| Charge de consignation/ technicien de maintenance | <ul style="list-style-type: none"> - Identifier les sources d'énergie dangereuses. - Élaborer un protocole et des méthodes d'isolement des sources d'énergie. - Mettre en place et retirer les dispositifs de verrouillage et d'étiquetage. - Effectuer des tests d'isolement et vérifier l'absence d'énergie. - Appliquer la procédure de maîtrise des énergies. |
| Responsable de consignation | <ul style="list-style-type: none"> - Coordonner toutes les tâches associées à la consignation/déconsignation afin d'assurer une protection effective des entités à protéger par la consignation/déconsignation. - Exécuter toutes les notifications au personnel à protéger et à l'autorité de délivrance. - Assurer l'enregistrement précis des informations dans la procédure de maîtrise des énergies et les registres appropriés. |

4. DOCUMENTS RÉFÉRENCES ET / OU DOCUMENTS LIÉS

- Standard « Lock-Out Tag-Out process GHSE-QU-STD-0000197 »

5. DÉFINITIONS / ABRÉVIATIONS

| | |
|------------------------------------|---|
| Consignation | C'est l'ensemble des dispositions permettant de mettre et de maintenir en sécurité (si possible par un moyen physique) une machine, un appareil ou une installation de façon qu'aucun changement d'état (remise en état de marche d'une machine, fermeture d'un circuit électrique, ouverture d'une vanne sur un circuit de fluide) ne soit possible sans l'action volontaire de tous les intervenants. |
| Déconsignation | C'est l'ensemble des dispositions permettant de remettre en état de fonctionnement une machine, un appareil ou une installation préalablement consignée, en assurant la sécurité des intervenants et des exploitants. |
| Chargé de consignation | Une personne qui évalue les risques liés aux énergies dangereuses, définit les points d'isolement et les moyens d'isolement, définit comment tester les isolements et l'absence d'énergie, teste l'isolement et l'absence d'énergie, utilise la procédure de maîtrise des énergies, verrouille et étiquette les organes d'isolement de la machine ou équipement afin de réaliser l'entretien ou la maintenance de la machine/équipement. |
| Responsable de consignation | Un responsable de consignation qui est assigné de la responsabilité de coordination de toutes les tâches liées au processus consignation/déconsignation afin d'assurer une continuité de protection des « Personnes à protéger ». Il est également responsable des enregistrements et de l'usage de la procédure de maîtrise des énergies et de tout autre registre approprié. Toute consignation/déconsignation appliquée sur une machine (Ou équipement) est sous la responsabilité d'un responsable de consignation. |
| EPI | Équipement de protection individuel. |
| LOTO | Consignation/déconsignation |

6. HISTORIQUE

| DATE | INDICE DE RÉVISION | MOTIF |
|------------|--------------------|--|
| 10/08/2017 | a | Création de la procédure |
| 10/10/2021 | b | Intégrer le processus Consignation/Déconsignation et la procédure de maîtrise des énergies (PME) |
| 28/08/2023 | V1.0 | Chargement de la version scannée sur QualiPSO |
| 17/01/2023 | V2.0 | Chargement de la version Word sur QualiPSO Changement des anciens codes par les nouveaux Mise à jour des annexes Mise à jour des documents liés |
| | | |

7. ANNEXES

Annexe 01 : Etapes de la consignation/déconsignation

Annexe 02 : Attestation de consignation

Annexe 03 : Points d'isolation des énergies

Annexe 04 : Kit de consignation

8. CONTENU DE LA PROCÉDURE

8.1 PROGRAMME CONSIGNATION/ DECONSIGNATION

Chaque site doit avoir un programme consignation/déconsignation établissant une Politique et des procédures d'exécution de la consignation/déconsignation et de maîtrise des énergies dangereuses. Des organes et dispositifs spécifiques doivent être mis en place ainsi que des Procédures de Maîtrise des Énergies. La bonne pratique est de construire préalablement les PME mais peuvent être établis à la demande. Tous les PME doivent être capitalisés en intégrant le retour d'expérience des interventions précédentes. La procédure Consignation/déconsignation doit préciser le champ, l'objectif, les autorisations, les règles et les moyens techniques que le personnel utilisera pour maîtriser les sources d'énergies dangereuses mais également les mesures de contrôles mises en place pour assurer le respect des règles. Cette procédure doit préciser au personnel les informations minimales suivantes :

- Une explication sur l'usage de cette procédure
- Les étapes spécifiques d'arrêt, d'isolement, de verrouillage et d'étiquetage des machines ou équipement
- Les étapes spécifiques de placement des dispositifs de verrouillage et d'étiquetage, leur retrait (déconsignation), leur transfert ainsi que les responsabilités du processus consignation/déconsignation
- Les étapes de déconsignation et de déconsignation temporaire
- Les exigences spécifiques de sélection des organes d'isolement, de test des isollements, de test de l'absence d'énergie des machines et des équipements et de toute autre mesure de maîtrise des énergies dangereuses.

8.2 ETAPES PRINCIPALES

Avant de débiter une activité sur une machine/équipement ayant été énergisée (énergie ou substance dangereuse), les étapes suivantes doivent être exécutées selon cet ordre :

1. Préparation de l'arrêt de la machine et de sa consignation ;
2. Arrêt de la machine et isolement de la machine des sources d'énergie ;
3. Placement des dispositifs de verrouillage et d'étiquetage sur les organes d'isolement ;
4. Attente du Niveau d'Energie le Plus Bas (NEPB) ;
5. Vérification par test de l'isolement et de l'absence d'énergie ;
6. Notification aux personnels à protéger et à l'entité de délivrance ;
7. Déconsignation

Voir le schéma en annexe 1.

8.2.1 PRÉPARATION DE L'ARRÊT DE LA MACHINE ET DE SA CONSIGNATION

La procédure de Maitrise des Energies doit être :

- Elaborée sous la coordination d'un chargé de consignation,
- Validée par un autre chargé de consignation
- Utilisée pour l'enregistrement d'exécution des étapes 2, 3, 4, 5, 6 et pour la déconsignation (Y sera également enregistrée toute déconsignation partielle) avec les informations suivantes :
 - Etat de l'équipement
 - Arrêt de l'équipement,
 - Isolement des sources d'énergies (consigné ou déconsigné),
 - Test des isollements,
 - Atteinte du niveau d'Energie le Plus Bas,
 - Test de l'absence d'énergie.
 - Identité du chargé de consignation qui fixe le dispositif de verrouillage et l'étiquetage à l'organe d'isolement ainsi que la date de consignation
 - Identité du chargé de consignation qui retire le dispositif de verrouillage et l'étiquetage à l'organe d'isolement ainsi que la date de déconsignation
- Disponible à tous les chargés de consignation engagés dans la consignation/déconsignation ainsi que toutes les personnes à protéger.

L'enregistrement des informations dans la procédure de maîtrise de énergies est sous la responsabilité du responsable de consignation.

8.2.2 ARRÊT ET ISOLEMENT DES SOURCES D'ÉNERGIES

Le(s) chargé(s) de consignation doit(vent) réaliser, dans cette séquence, les étapes suivantes :

- Identifier toutes les sources d'énergies qui exposent le personnel, pendant l'entretien (ou maintenance ou activités opérationnelles) à une blessure si la machine (ou équipement) est accidentellement remise en énergie, démarrée ou si de l'énergie accumulée est libérée
- Identifier un point d'isolement pour chacune de ces sources d'énergie
- Vérifier que la machine (ou équipement) a été arrêté de toutes ses sources d'énergie
- Isoler tous les points d'isolement identifiés.

8.2.3 VERROUILLAGE/ÉTIQUETAGE

8.2.3.1 Verrouillage

Tous les organes d'isolement verrouillable doivent être verrouillés. Le verrouillage utilisera des dispositifs permettant de bloquer et verrouiller l'organe d'isolement dans sa position de sécurité ou d'arrêt afin de prévenir toute remise en énergie ou démarrage de la machine (ou équipement).

Le cadenas de verrouillage doit posséder qu'une seule clé unique ne pouvant ouvrir ou fermer qu'un cadenas (Cadenas individuel).

Organe d'isolement non verrouillable

Dans le cas d'un organe d'isolement non verrouillable par un dispositif dédié à la consignation/déconsignation alors :

- Rechercher la possibilité d'un autre point d'isolement ('en amont) avec un organe pouvant être verrouillé.
Si cela n'est pas possible ou génère des risques supplémentaires (par exemple, situation en hauteur), alors l'organe d'isolement sera étiqueté :
- Dans ce cas, l'étiquetage sera fixé le plus près possible de l'organe d'isolement et devra être en évidence à toute personne qui serait tentée de manipuler (ou manœuvrer) l'organe d'isolement. L'étiquetage alertera le personnel du danger lié à une remise en énergie et avertira le personnel de l'interdiction de manipuler (ou manœuvrer) l'organe de séparation tant que l'étiquetage reste en place selon la procédure.
- Des mesures de sécurité compensatoires doivent être mises en place afin d'atteindre un niveau de protection du personnel à protéger équivalent à celui qui serait atteint avec verrouillage de l'organe d'isolement (ex. : retrait d'un fusible d'un disjoncteur, blocage d'un sectionneur, retrait d'un volant de vanne, démontage d'une conduite).

Lorsqu'un organe d'isolement n'est pas verrouillable, le site doit planifier pour modification ou remplacement de l'organe d'isolement afin de le rendre verrouillable. Dans le cadre de remise à niveau, rénovation, modification d'une machine (ou équipement) ou installation d'une nouvelle machine (ou équipement), le site doit s'assurer que les organes d'isolement sont tous verrouillables.

8.2.3.2 Étiquetage

L'étiquette doit :

- Être solidement attachée et aussi près que possible à chaque organe d'isolement et devra être en évidence à toute personne qui serait tentée de manipuler (ou manœuvrer) l'organe d'isolement des énergies.
- Comporter un label permettant d'identification de l'organe d'isolement, la date et l'identité de chargé de consignation qui a exécuté le verrouillage et l'étiquetage.

8.2.4 ATTEINTE DU NIVEAU D'ÉNERGIE LE PLUS BAS (NEPB)

Après placement des dispositifs de verrouillage et d'étiquetage aux organes d'isolement, toutes les énergies accumulées ou résiduelles et potentiellement dangereuses doivent être libérées, déconnectées et maîtrisées pour atteindre le niveau d'énergie le plus bas possible.

Si, pendant la durée des activités d'entretien (maintenance ou activité opérationnelle), un risque de re-accumulation d'énergie existe alors un suivi du niveau d'énergie sera régulièrement effectué afin de le maintenir à un niveau non potentiellement dangereux.

Si le risque de re-accumulation d'énergie peut potentiellement atteindre un niveau dangereux pour les personnes à protéger alors une vérification régulière de l'état des isollements (étanchéité...) sera effectué.

Ces suivis seront mentionnés et enregistrés dans la procédure de maîtrise des énergies (PME).

8.2.5 VÉRIFICATION PAR TEST DE L'ISOLEMENT ET DE L'ABSENCE D'ÉNERGIE

Avant de débiter une activité sur une machine (ou équipement) qui a été consignée, le chargé de consignation doit :

- Vérifier que les isolements de la machine (ou équipement) ont été réalisés
- Tester l'absence d'énergie ou de substance (résiduelle et accumulée) : Absence de tension, absence de pression, absence de produits...

Si l'énergie éventuelle accumulée ne peut être identifiée de manière sûre ou des doutes subsistent, des actions complémentaires sont à mettre en place et seront définies par une analyse de risque.

- Tester les organes d'isolement et les machines/équipements pour s'assurer qu'ils soient effectivement rendus inopérants :
 - Tout système mu par de l'énergie (organe d'isolement, machine/équipement) ne doit pas pouvoir être démarré, être changé de position ou être remis en énergie lors du test,
 - Toute source de substances dangereuses ne doit pas pouvoir être démarrée ou émettre de substance et exposer les personnes à protéger.

8.2.6 NOTIFICATION AUX PERSONNELS À PROTÉGER ET À L'ENTITÉ DE DÉLIVRANCE

Le personnel à protéger (ou le responsable de l'entité à protéger) qui exécute une activité protégée par consignation et l'autorité de délivrance doivent être informés par le responsable de consignation de ces 2 étapes critiques :

- La machine (ou équipement) protégée par consignation est sûre pour toutes interventions dessus.
- Lorsqu'il existe une possibilité de re-accumulation d'énergie/substance ou d'énergie/substance résiduelle.

8.2.7 DÉCONSIGNATION

Avant de débiter tout retrait d'un dispositif de verrouillage et d'étiquetage (déconsignation), le responsable de consignation doit réaliser, dans cette séquence, les étapes suivantes :

- Avoir informé le personnel à protéger (ou le responsable de l'entité à protéger) qui a exécuté des activités sur l'équipement (ou machine) du besoin de déconsignation;
- Avoir vérifié sur la zone de travaux que toutes les activités sur la machine (ou équipement) sont effectivement arrêtées et que toutes les personnes sont positionnées dans un endroit pour être en sécurité;
- Avoir inspecté que la machine (ou équipement) a été remise dans son état de marche normale afin d'être sûre;

Avant de débiter le retrait de l'isolement (remise des organes d'isolement en position de marche) de la machine (ou équipement), le responsable de consignation doit s'assurer que le personnel à protéger (celui qui va utiliser/manipuler ou travailler avec la machine (ou l'équipement) et celui qui a exécuté des activités sur), a été informé de la fin de déconsignation et que par conséquent la machine (ou équipement) peut redémarrer, être remis en énergie ou en substance.

8.2.7.1 Déconsignation temporaire

Besoin de tester ou positionner

La procédure autorise la déconsignation temporaire et la remise en énergie de la machine (ou équipement) seulement si pour des situations réduites à des activités des tests, ou de positionnement exigeant la remise en marche et pour une durée limitée.

Une protection efficace du personnel contre les risques liés à ces activités particulières doit être mise en place.

Les mêmes étapes que celles de la déconsignation doivent être exécutées avant la mise en énergie nécessaire au test ou au positionnement.

Lorsque les activités de test ou de positionnement sont terminées et que la machine (ou équipement) nécessite la poursuite des activités (entretien, maintenance), alors les étapes 2, 3, 4, 5 et 6 du processus LOTO doivent être strictement et intégralement réappliquées sur les points d'isolement ayant fait l'objet de la déconsignation temporaire.

Parce qu'une déconsignation temporaire introduit des risques significatifs d'erreur sur l'état de la machine (ou équipement), le site doit développer la Procédure de Maitrise des Énergies (PME) en y intégrant le suivi des étapes de la déconsignation et de la (re)consignation (étapes 2, 3, 4, 5 et 6 du processus LOTO).

Notification aux personnels à protéger

Le responsable de consignation doit informer le personnel à protéger (ou le responsable de l'entité à protéger) du besoin de déconsignation temporaire.

8.3 CAS DE MULTIPLES ENTITES A PROTEGER

Si un point d'isolement protège plus d'une entité à protéger (équipe, entreprise extérieure ou permit/autorisation de travail), le processus de Consignation/Déconsignation doit maintenir le même niveau de protection à toutes les entités. Le système par cadenas de verrouillage sera alors renforcé avec un des 2 systèmes proposés de Consignation de Groupe.

8.3.1 CONSIGNATION DE GROUPE

Si utilisée, elle doit être en accord avec la procédure Consignation/Déconsignation avec les exigences spécifiques suivantes :

- Pour chacune des entités à protéger, un chargé de consignation appartenant à cette entité sera investi responsable du personnel de cette entité protégée par une consignation de groupe.
- Il est de la responsabilité de chaque chargé de consignation investi de s'assurer de l'application stricte de la procédure consignation/déconsignation du site et d'informer tous les membres de son équipe lorsque la machine (ou équipement) est sûre et disponible pour débiter les activités d'entretien (ou maintenance).

a. Condamneuse multiple

Le chargé de consignation bloque et verrouille l'organe d'isolement dont il a la charge à l'aide d'un condamneuse multiple et d'un cadenas. Ensuite chaque chargé de consignation investi apposera un cadenas de verrouillage au condamneuse multiple après y avoir été autorisé par le responsable de consignation et devra le retirer lorsque les travaux de son entité sont terminés sur la machine (ou équipement).

b. Boite de Consignation de Groupe

Les clés des cadenas fixés aux dispositifs de verrouillage par les chargés de consignation sont déposées dans la boîte. Ensuite, les chargés de consignation investis pour chacune des entités à protéger fixent leur cadenas pour verrouiller et fermer la boîte.

8.3.2 COORDINATION PROCÉDURALE PAR UN RESPONSABLE DE CONSIGNATION

Si utilisée, elle doit être en accord avec la procédure Consignation/Déconsignation avec les exigences spécifiques suivantes :

- Les cadenas et les étiquettes sont fixées aux dispositifs de verrouillage des points d'isolement par le(s) chargé(s) de consignation,
- Les clés des cadenas sont collectées par le responsable de consignation,
- La procédure de Maitrise des Energies doit collecter les informations supplémentaires suivantes :

Pour toutes les entités protégées par la consignation/déconsignation :

- Identifiant du permis de travail ou de l'autorisation de travail
- Nom de la personne responsable de l'entité protégée

8.4 CONTINUITÉ DE PROTECTION DE LA CONSIGNATION/DECONSIGNATION

Chaque dispositif de verrouillage et d'étiquetage devrait être retiré par le chargé de consignation qui l'a fixé. Mais, pour des raisons opérationnelles, ce n'est pas toujours possible. Dans ce cas, différentes situations spécifiques sont décrites ci-après :

8.4.1 CHANGEMENT DE PERSONNES OU D'ÉQUIPES (À PROTÉGER)

Lorsqu'une consignation/déconsignation se poursuit sur un changement de poste, la protection des personnes à protéger doit être maintenue. Le transfert de la consignation/déconsignation de poste en poste doit permettre une continuité dans la protection. Des procédures et processus spécifiques doivent être établies et utilisées pour rendre sur tout transfert de consignation/déconsignation :

a) Transfert direct sur le lieu des travaux

Transfert ordonné du cadenassage et de l'étiquetage entre les chargés de consignation partant et entrant.

Le chargé de consignation entrant fixe un cadenas avant le retrait du cadenas fixé par le chargé de consignation sortant.

La date et l'identité des chargés de consignation entrant sont mises à jour sur le dispositif d'étiquetage.

b) Transfert par le responsable de consignation sur le lieu des travaux

Le responsable de consignation entrant coordonne le transfert en fixant les cadenas sur tous organes de verrouillage avant le retrait des cadenas par le responsable de consignation sortant.

La date et l'identité du responsable de consignation entrant sont mises à jour sur le dispositif d'étiquetage.

c) Transfert procédural par le responsable de consignation avec la Procédure de Maitrise des Energies

Cette méthode permet aux chargés de consignation de partir sans avoir à retirer les cadenas fixés par eux-mêmes

Le transfert de la consignation/déconsignation s'effectue entre les responsables de consignation entrant et sortant.

Les clés des cadenas fixés par les chargés de consignation sont collectées par le responsable de consignation. Les clés collectées sont rassemblées avec la Procédure de Maitrise des Energies.

La procédure de Maitrise des Energies doit collecter les enregistrements supplémentaires (date et identité) concernant le transfert de la consignation/déconsignation entre les responsables de consignation entrant et sortant.

Pour les dispositifs de consignation de Groupe :

- Transfert direct entre les chargés de consignation investis (pour chacune des entités à protéger) entrant et sortant,

Où

- Transfert de la consignation/déconsignation entre les responsables de consignation entrant et sortant.

8.4.2 DISCONTINUITÉ DE CHARGÉS DE CONSIGNATION

En absence de relève de chargé de consignation (les chargés de consignation partant ne sont pas relevés par un chargé de consignation entrant), les chargés de consignation partant laisseront les cadenassages et étiquetages fixés par eux-mêmes sur l'équipement.

Une procédure de Maitrise des Énergies est requise lorsque cette situation se présente.

- Le transfert de la consignation/Déconsignation s'effectue entre les responsables de consignation entrant et sortant.
- Les clés des cadenas fixés par les chargés de consignation sont collectées par le responsable de consignation. Les clés collectées sont rassemblées avec la Procédure de Maitrise des Énergies.
- La Procédure de Maitrise des Énergies doit collecter les enregistrements supplémentaires (date et identité) concernant le transfert de la consignation/déconsignation.
- Avant la reprise des travaux, les étapes 4, 5 et 6 du processus LOTO doivent être strictement et intégralement réappliquées par les chargés de consignation entrant.

8.5 CAS EXCEPTIONNEL DE DESTRUCTION DE CADENAS POUR DECONSIGNATION

Lors de la phase de déconsignation, la clé d'un cadenas fixé par un chargé de consignation (présumé en dehors du site) peut ne pas être disponible (perdue, manquante). Pour terminer la déconsignation, ce cadenas doit être retiré.

Pour terminer la déconsignation, le responsable de consignation ou le responsable chargé de consignation (présumé en dehors du site), doivent suivre ces trois étapes dans l'ordre :

- Vérifier que le chargé de consignation n'est plus sur le site.
- Déployer tous les efforts raisonnables pour contacter le chargé de consignation.
- Confirmer et informer le chargé de consignation à son retour que le cadenas a été retiré.

Ce processus exceptionnel de déconsignation doit être formalisé et enregistré.

8.6 CONSIGNATION/DECONSIGNATION ET ENTREPRISES EXTERIEURES

Le site doit informer les entreprises extérieures du processus consignation/déconsignation et de sa procédure.

L'entreprise extérieure doit appliquer le processus consignation/déconsignation et de la procédure consignation/déconsignation du site.

Le site doit veiller à ce que la compréhension et le respect du processus consignation/déconsignation par le personnel de l'entreprise extérieure permettent une protection effective du personnel engagé dans les activités concernées.

Si une entreprise extérieure dispose de sa propre procédure de consignation/déconsignation, le site et l'entreprise extérieur doivent s'informer mutuellement de leurs procédures respectives. Si les exigences de la procédure de consignation/déconsignation d'une entreprise extérieure sont plus strictes, le site peut accepter d'appliquer ces exigences. Le site et l'entreprise doivent informer l'ensemble des personnels Sanofi et entreprises extérieures impliqués dans le processus LOTO de ces exigences spécifiques.

Le site ne devra jamais accepter d'appliquer une procédure de verrouillage/étiquetage d'une entreprise extérieure qui est moins stricte que cette procédure.

8.7 AUDITS PERIODIQUES DU PROCESSUS CONSIGNATION/DECONSIGNATION

Des audits périodiques doivent être réalisés par le site sur le processus de consignation/déconsignation. Au moins 1 audit annuel doit être réalisé pour s'assurer que les exigences de la procédure de consignation/déconsignation du site est effectivement suivie et appliquées sur le terrain.

L'audit périodique est effectué par au moins un chargé de consignation et une personne de l'HSE. Le chargé de consignation qui réalise l'audit ne doit pas être impliqué dans la consignation qui est auditée.

Les écarts ou faiblesses identifiés doivent être signalés au superviseur et l'HSE. Les écarts doivent être corrigés.

8.8 FORMATION

Le site doit former spécifiquement les chargés de consignations et les personnes à protéger.

La formation doit s'assurer que les personnes possèdent un niveau de compréhension suffisant sur le champ d'application, les fonctions/responsabilités et les règles, interdictions de la procédure consignation/déconsignation du site ainsi que du processus consignation/déconsignation du site.

Le site doit certifier que la formation a été dispensée à tous les chargés de consignations et les personnes à protéger. La certification doit contenir le nom et les dates de formation de chaque personne.

8.8.1 CHARGÉ DE CONSIGNATION

Il a besoin de connaissances et des compétences spécifiques pour :

- L'identification des sources d'énergie dangereuses et,
- Les méthodes et les moyens d'isolement pour maîtriser les sources d'énergie et,
- L'utilisation et le retrait des organes d'isolement des sources d'énergie et,
- L'élaboration et l'utilisation de la Procédure de Maîtrise des énergies et,
- L'utilisation et la mise à jour des registres appropriés et,
- Le processus et la procédure de consignation/déconsignation.

8.8.2 PERSONNE À PROTÉGER

En exécutant une activité sur une machine/équipement qui est sous consignation/déconsignation, les personnes à protéger doivent recevoir une formation concernant l'objectif et les restrictions du processus consignation/déconsignation. Ils doivent également être en mesure de :

- Reconnaître lorsque le processus de consignation/déconsignation est appliqué,
- Comprendre l'importance de ne jamais retirer un dispositif de verrouillage et d'étiquetage.

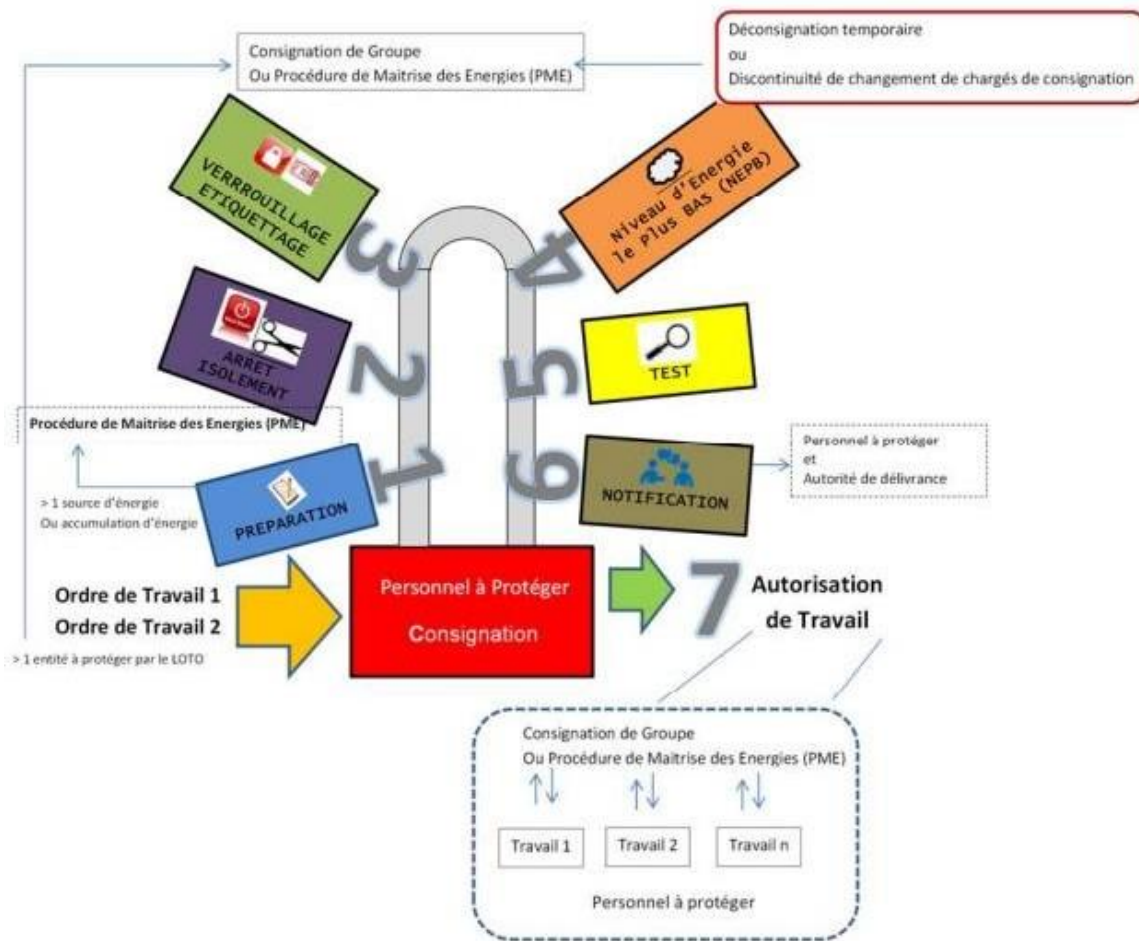
Toutes les autres personnes dont les tâches sont ou peuvent être dans une zone où la consignation/déconsignation est appliquée doivent recevoir des instructions concernant la procédure de consignation/déconsignation et l'interdiction de retirer un dispositif de verrouillage ou d'étiquetage.

8.8.3 RECYCLAGE

Le site doit recycler tous les chargés de consignation et toutes les personnes à protéger à chaque changement dans la procédure de consignation/déconsignation.

Le recyclage est également nécessaire chaque fois qu'un audit révèle des lacunes significatives, ou des événements survenus sur site relèvent de lacunes dans la connaissance ou l'utilisation de la procédure consignation/déconsignation.





Annexe 01 : Etapes de la consignation / déconsignation







ANNEXE 02 : Attestation de consignation

| ATTESTATION DE CONSIGNATION | | sanofi |
|---|---|---|
| PREPARATION ET INFORMATION DE LA CONSIGNATION | | |
| N° DE L'ATTESTATION DE CONSIGNATION <i>La consignation et la déconsignation (simple ou complexe) peut concerner un appareil, une machine, un équipement ou une installation</i> | DOCUMENTS ASSOCIES <input type="checkbox"/> Plan de prévention <input type="checkbox"/> Autorisation de travail N° du documents : | |
| NATURE DES TRAVAUX / ZONES / EQUIPEMENTS <i>Descriptif des travaux des lieux et sources de consignations</i> | | |
| DATES DES TRAVAUX Heure de début de consignation : Heure de fin de déconsignation : | LISTE DES INTERVENANTS : Nom et prénom et visa / EE : 1. Visa 2. Visa 3. Visa 4. Visa | |
| ETAPES DE CONSIGNATION | | |
| Avant le démarrage veuillez indiquer la nature ou la complexité de la consignation . Consignation simple <input type="checkbox"/> Consignation complexe <input type="checkbox"/> La consignation doit passer par les cinq phases indissociables décrites ci-dessous : | | |
| 1)- Préparation « Identification et information » | | |
| Electrique <input type="checkbox"/> | | Mécanique <input type="checkbox"/> |
| Permis général rédigé et les différentes sources d'énergies sont identifiées, le personnel concernés (opérateurs, machiniste...) des équipements/Installation sont informés | | |
| 2)- Arrêt et isolement | | |
| Electrique <input type="checkbox"/> | | Mécanique <input type="checkbox"/> |
| Séparation des sources d'énergie qui alimentent l'installation, Certains équipements sont alimentés par plusieurs énergies. | | |
| Disjoncteur sur armoire(source)/TGBT <input type="checkbox"/> | sectionneur <input type="checkbox"/> | Vanne <input type="checkbox"/> |
| Prise électrique <input type="checkbox"/> | Dispositif mécanique <input type="checkbox"/> | |
| 3)-Verrouillage / Etiquetage | | |
| Verrouillage par un dispositif personnalisé et difficilement naturalisable | | |
| Electrique <input type="checkbox"/> | | Mécanique <input type="checkbox"/> |
| Sélecteur/Disjoncteur cadenassé et identifié <input type="checkbox"/> | Condamner les éléments de transmission : | |
| Clé retiré <input type="checkbox"/> | Dispositif de consignation adapté installé, cadenassé et identifié <input type="checkbox"/> | |
| NB : Les circuits hydrauliques doivent être mis au repos avant condamnation. | | |
| La signalisation permet une information claire et permanente de la réalisation de la condamnation, la signalisation se fait par : Un panneau <input type="checkbox"/> Une bande zébrée <input type="checkbox"/> identification de consignation comporte nom, prénom et date <input type="checkbox"/> | | |
| 4)-Dissipation (NEPB) | | |
| Electrique <input type="checkbox"/> | | Mécanique <input type="checkbox"/> |
| Mise à la terre et en court-circuit des conducteurs <input type="checkbox"/> | Mise au niveau d'énergie le plus bas par : | |
| Décharge des condensateurs <input type="checkbox"/> | Arrêt des mécanismes <input type="checkbox"/> | |
| Mise à la pression atmosphérique <input type="checkbox"/> | | |
| 5)-Vérification | | |
| Electrique <input type="checkbox"/> | | Mécanique <input type="checkbox"/> |
| Absence de tension entre : Tension au niveau des conducteurs <input type="checkbox"/> Conducteurs neutres <input type="checkbox"/> Conducteurs et la terre <input type="checkbox"/> | | Absence d'énergie : Pression <input type="checkbox"/> Mouvement <input type="checkbox"/> Rotation <input type="checkbox"/> |
| Le chargé de la consignation Je certifie avoir participé à l'évaluation des risques liés à ces travaux et avoir pris connaissance des mesures de sécurité à mettre en place pour assurer la sécurité des biens et des personnes. Nom et Visa | Responsable HSE & Maintenance Par ma signature de certifie que toutes les étapes nécessaires a l'évaluation des risques ont été suivies et appliqué afin de protéger l'intervenant Nom et Visa | |
| 6)-Fin des travaux et déconsignation | | |
| S'assurer qu'aucune activité ne se fait au même temps <input type="checkbox"/> | Responsable HSE & Maintenance | |
| Retirer le dispositif de consignation <input type="checkbox"/> | Par ma signature de certifie que la consignation est finalisée, l'intervenant peut déconsigner et la reprise de l'activité est autorisée | |
| Le chargé de consignation Nom et Visa | Nom et Visa | |
| IMPORTANT / NUMEROS D'URGENCE Personnes à contacter en cas d'accident ou d'incident : M. BELKESSA responsable HSE, N° de téléphone : 0770 11 30 17 //// Poste de garde, N° de téléphone : 0770 91 52 29 | | |

Annexe 03 : Points d'isolation des énergies

| Type de source | Point de consignation |
|--|--|
| <p>Electrique sur équipement 380V et prise électrique</p> |  |
| <p>Hydraulique sur Vanne à bille et Vanne manuelle</p> |  |
| <p>Electrique sur disjoncteur et commutateur</p> |  |
| <p>Cable de consignation, pour les équipements ou la consignation est complexe</p> |  |

Annexe 04 : Kit de consignation

| Nom de l'outil | Exemple |
|---|--|
| <p>Cadenas de consignation ;</p> <p>Nb : le code couleur des est utilisé pour des faits différente mais a objectif commun</p> |  |
| <p>Affiche de consignation</p> <p>L'affiche est taguée par le nom et prénom du technicien ou chargé de consignation et dans certains cas l'affiche est personnalisée avec photo individuel.</p> |  |
| <p>L'outil d'isolation de l'Energie</p> |  |
| <p>Dispositif de consignation multiple</p> |  |

Appendix M

Use Of Extinguisher SOP

Procédure D'utilisation d'un Extincteur



Direction Santé Sécurité Environnement

AVRIL 2024

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1. OBJET

Cette procédure décrit les types d'extincteurs présents sur site ainsi que leurs méthodologies d'utilisation. Elle fournit une démarche claire et concise de leurs utilisations.

L'objectif est de garantir que le personnel est équipé des connaissances et des compétences nécessaires pour répondre rapidement et correctement aux situations d'urgence incendie, réduisant ainsi les risques pour la vie humaine et les dommages matériels.

2. DOMAINE D'APPLICATION

Cette procédure s'applique au site distribution de Sanofi Algérie « Sidi Abdellah DC ».

Elle concerne toutes les activités impliquant l'utilisation des extincteurs. Elle vise à garantir la sécurité incendie en fournissant des directives claires et précises sur l'identification, l'emplacement et l'utilisation des extincteurs disponibles sur le site.

Tout le personnel, quel que soit son niveau, pourrait être confronté à une situation d'incendie qui devrait être capable d'utiliser efficacement les extincteurs pour contenir ou éteindre un feu.

3. RESPONSABILITE

| Role | Description |
|--|--|
| Le Responsable HSE et maintenance | <ul style="list-style-type: none">- Mettre en œuvre de la procédure- Répartir les extincteurs sur site selon l'évaluation des risques.- Former le personnel- Assurer le suivi et le rappel des prestataires responsables de la maintenance des extincteurs |
| Le Responsable de zone | <ul style="list-style-type: none">- Vérifier régulièrement l'emplacement de chaque extincteur correspond à son numéro de référence.- Maintenir l'accessibilité des emplacements sans obstruction.- Inspecter périodique le positionnement adéquat des extincteurs sur le site. |
| Le Personnel | <ul style="list-style-type: none">-Utiliser d'une manière appropriée les extincteurs en cas d'urgence incendie selon les procédures établies-Signaler les extincteurs endommagés ou nécessitant une recharge |
| Le Prestataire | <ul style="list-style-type: none">-Inspecter régulièrement des extincteurs conformément aux normes en vigueur-Recharger périodiquement lorsque nécessaire (tous les 6 mois). |

4. DOCUMENTS RÉFÉRENCES ET / OU DOCUMENTS LIÉS

- Rapports d'inspection des extincteurs.

5. DÉFINITIONS / ABRÉVIATIONS

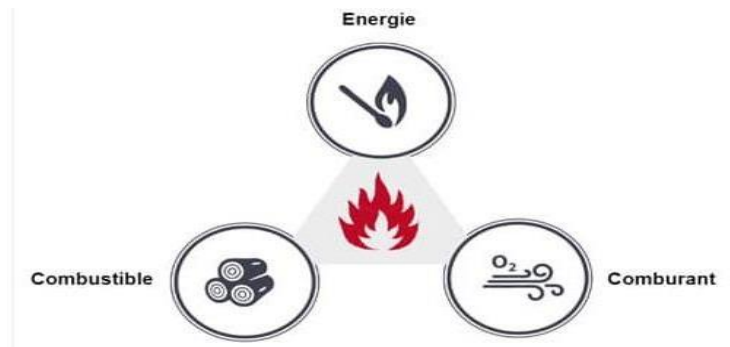
| | |
|----------------------------|---|
| Un extincteur | Est un appareil sous pression qui permet sous l'effet d'une pression interne de diriger un agent extincteur sur un foyer d'incendie. Cette pression peut être fournie, soit par une compression permanente, soit par une réaction chimique, soit la libération d'un gaz auxiliaire. |
| Agent extincteur | La substance contenue dans un extincteur qui éteint le feu. |
| Classe de feu | Les classes de feu les plus courantes sont A (combustibles ordinaires), B (liquides inflammables), C (gaz) et D (métaux combustibles). |
| Indice d'extinction | Un nombre qui indique la taille et le type de feu qu'un extincteur peut éteindre. |
| Manomètre | Un indicateur qui mesure la pression dans l'extincteur. |

6. CONTENU DE LA PROCÉDURE

6.1 Le triangle de feu

Pour qu'il y ait le feu, il faut la combinaison des 3 éléments :

- **Combustible** : bois, papier, carton, plastique...
- **Comburant** : de l'oxygène de l'air...
- **Energie d'activation** : flamme, frottement, étincelle...



Triangle de feu

6.2 Les classes de feu

Pour lutter efficacement contre un début d'incendie, il faut utiliser l'agent extincteur approprié à la nature du feu.

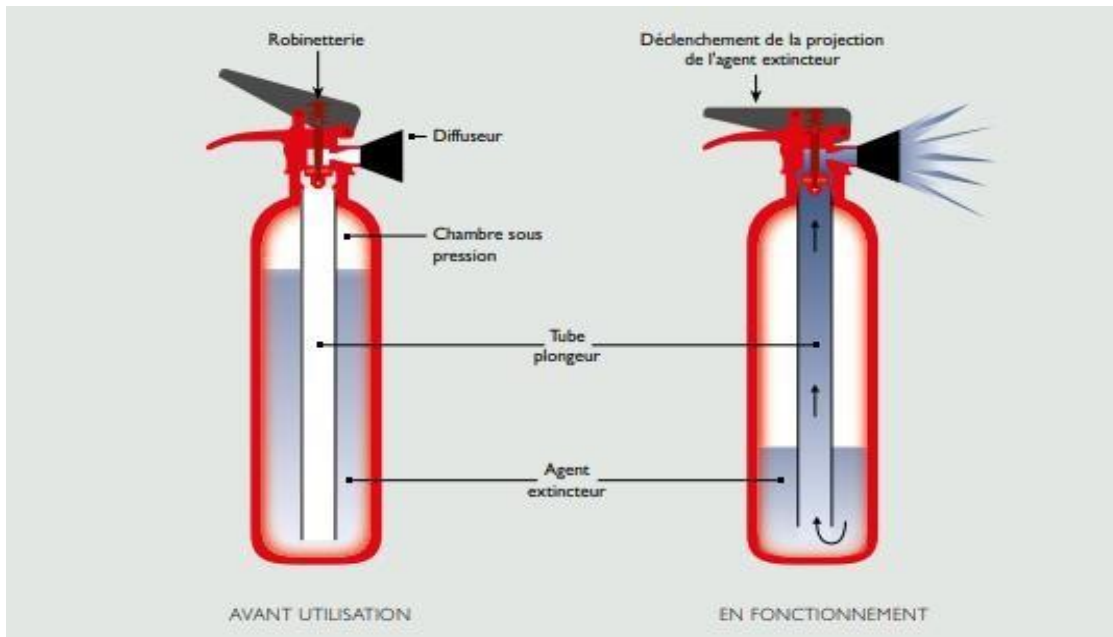
- Classe A : Feux secs (bois, papier, tissus...).
- Classe B : Feux gras (essence, Alcool, plastiques...).
- Classe C : Feux de gaz (Les feux de gaz nécessite en premier lieu l'arrêt de la source du gaz).
- Classe D : Feux de métaux (sodium, uranium, magnésium, aluminium...)
- Classe F : Feux d'huiles et auxiliaires de cuisson (ex : friteuse)

6.3 Les procédés d'extinction

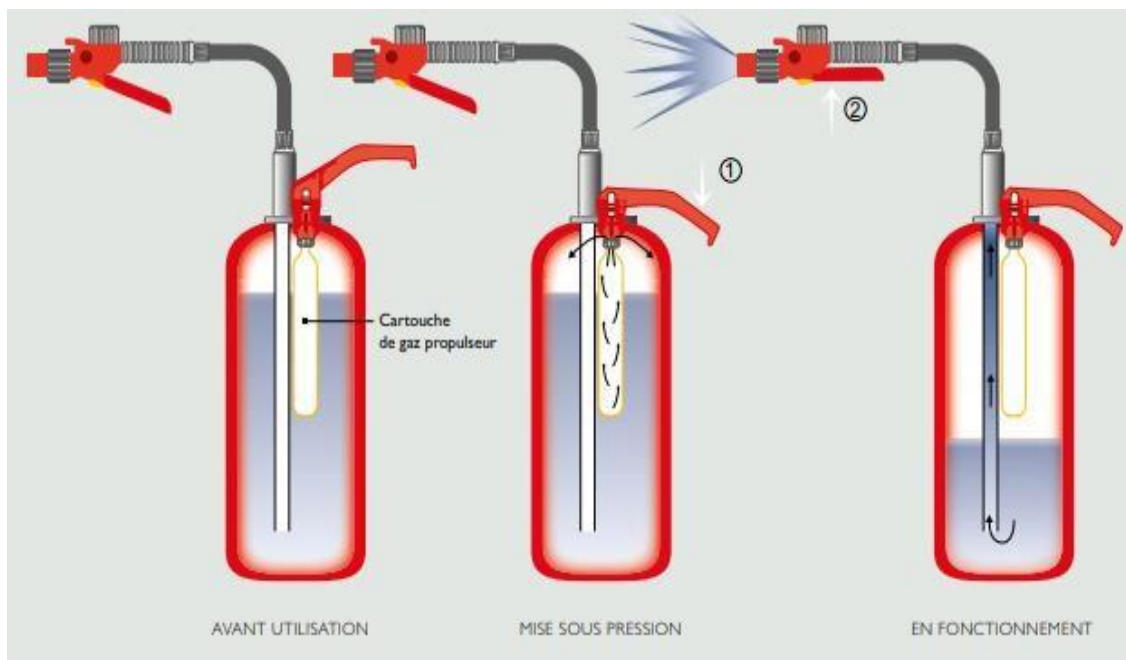
- Le refroidissement
- L'étouffement
- L'inhibition

6.4 Les types d'extincteurs

- **Extincteurs à pression permanente** : Ces extincteurs sont préchargés en usine et maintiennent une pression constante. Ils sont généralement simples à utiliser et ne nécessitent pas de rechargement périodique.



- **Extincteurs à pression auxiliaire :** Ces extincteurs ont un gaz propulseur séparé qui est utilisé pour expulser l'agent extincteur. Ils nécessitent souvent un entretien plus régulier pour s'assurer que le gaz propulseur est à la pression appropriée.



6.5 Les agents d'extinction :

- L'eau avec ou sans additif (AFFF).
- Les poudres : chaque type de poudre (A, B, C, D)
- Le CO₂

6.6 Présentation des extincteurs

Les renseignements permettant de reconnaître et d'utiliser un extincteur sont portés sur le corps de celui-ci sous forme de décalcomanie, plaque, impressions sérigraphiques ou tout autre procédé similaire. Des inscriptions diverses sont visibles parallèlement à celle-ci, elles comprennent :

- Le numéro d'homologation,
- La masse à vide,
- La nature et la quantité de l'agent extincteur,
- Les appareils en comportant, ou la pression interne à 15°C pour les extincteurs à pression permanente,
- La ou les températures de conservation et d'efficacité

6.7 L'utilisation des extincteurs

- Tirer la goupille de sécurité pour déverrouiller l'extincteur.
- Diriger le jet ou le nuage vers la base du feu en gardant une distance sécuritaire.
- Balayer de gauche à droite pour couvrir toute la zone en feu.
- Évacuer la zone immédiatement après l'extinction du feu et alerter les secours si nécessaire.

6.8 Date de Contrôle

La date de la dernière inspection est clairement affichée sur chaque extincteur pour faciliter le suivi. Tous les extincteurs contrôlés périodiquement chaque 6 mois par un prestataire de Sanofi.

6.9 Emplacement des extincteurs

Chaque emplacement désigné pour un extincteur est clairement identifié par un pictogramme et le numéro de l'extincteur.

Les numéros sont placés de manière visible à la fois sur l'extincteur lui-même et sur l'emplacement dédié à l'extincteur, tel que défini dans le plan de sécurité.

Les extincteurs sont stratégiquement placés dans tout le site selon les classes de feu et les risques identifiés.

Voir l'annexe 8.1

6.10 Mode de stockage des extincteurs

6.10.1 Stockage en intérieur :

- Les extincteurs doivent être stockés dans des endroits accessibles et clairement indiqués.
- Évitez de placer les extincteurs dans des zones exposées à des températures extrêmes, à l'humidité excessive ou à des risques de chocs mécaniques.
- Assurez-vous que les extincteurs sont fixés sur des supports appropriés pour éviter tout renversement ou dommage.

6.10.2 Stockage en extérieur :

- Si des extincteurs doivent être stockés en extérieur, ils doivent être protégés des intempéries par des abris ou des boîtiers spécifiques.
- Vérifiez régulièrement l'état des extincteurs stockés en extérieur pour vous assurer qu'ils restent en bon état de fonctionnement.

6.10.3 Enregistrement des stocks :

- Tenez un Logbook précis de tous les extincteurs en stock, y compris leur emplacement, leur type, leur capacité et leur date de dernière inspection.

6.11 Stock de réserve d'extincteurs

6.11.1 Disponibilité immédiate :

- Maintenez un stock de réserve d'extincteurs équivalent à 10% du nombre total d'extincteurs installés sur le site.
- Ce stock de réserve garantit une disponibilité immédiate d'extincteurs supplémentaires en cas d'utilisation intensive ou de remplacement nécessaire.

6.11.2 Types d'extincteurs :

- Assurez-vous que le stock de réserve comprend une variété d'extincteurs adaptés aux différents types de feux (classe A, B, C, D, feux d'origine électrique).
- La composition du stock de réserve doit refléter les risques spécifiques identifiés sur le site et les besoins en matière de sécurité incendie.

6.11.3 Contrôle et maintenance :

- Effectuez des contrôles réguliers du stock de réserve pour vérifier la pression, l'état général et la date de validité des extincteurs.
- Assurez-vous que les extincteurs du stock de réserve sont maintenus en parfait état de fonctionnement et prêts à être utilisés en cas d'urgence.

6.12 Critères de choix des extincteurs

6.12.1 Adaptation au type de feu :

Les extincteurs doivent être choisis en fonction de la nature du combustible et des risques associés. (Voir l'annexe 8.2)

6.12.2 Limitations d'emploi :

Certains environnements ou situations peuvent restreindre l'utilisation d'un type spécifique d'extincteur, comme l'interdiction d'utiliser de l'eau sur les feux de classe D ou la présence de conducteurs sous tension.

6.12.3 Contraintes de mise en œuvre :

Le poids, la configuration (comme la présence de roues) et la facilité de manipulation de l'extincteur doivent être pris en compte en fonction de l'utilisateur.

7. HISTORIQUE

| N° de version | Date | Description de la modification |
|---------------|------|--------------------------------|
| | | La création de la procédure |

8. ANNEXES

ANNEXE 01 : EMBLACEMENT DES EXTINCTEURS PRESENTS SUR LE SITE DE DISTRIBUTION DE SANOFI ALGERIE « SIDI ABDELLAH DC »

| Niveau | Le type d'extincteur | La capacité d'extincteur | N° d'extincteur |
|--------|----------------------|--------------------------|-----------------------------------|
| 0 | À eau | 50 L | 8,9,10,11,12,16,17,18,22,23,25,31 |
| | | Non mentionnée | 20,27 |
| | À CO2 | 10Kg | 1,6,7,21,29,30,48 |
| | | 6Kg | 3,36,37,46 |
| | À poudre | 50Kg | 41,45 |
| | | Non mentionnée | 38,39,40,42,43,47 |
| 1 | À eau | Moyen | 62,64,65,66,67 |
| | À CO2 | 7Kg | 61, |
| | | 10Kg | 63,65, |
| | | 2Kg | 53,54,70 |
| | À poudre | Non mentionnée | 51,57 |

ANNEXE 02 : TABLEAU POUR LE CHOIX D'EXTINCTEUR

| Classe \ type | L'eau | Les poudre | Le CO2 |
|---------------------------|-----------|------------|------------|
| Classe A | Oui | Oui \ Non | Inefficace |
| Classe B | Oui \ Non | Oui | Oui |
| Classe C | Non | Oui | Oui |
| Classe D | Non | Oui | Non |
| Feux d'origine électrique | Non | Oui | Oui |




ANNEXE 03 : AFFICHAGE EXTINCTEUR



ANNEXE 04 : CARTE DES EXTINCTEURS POUR LE NIVEAU 0

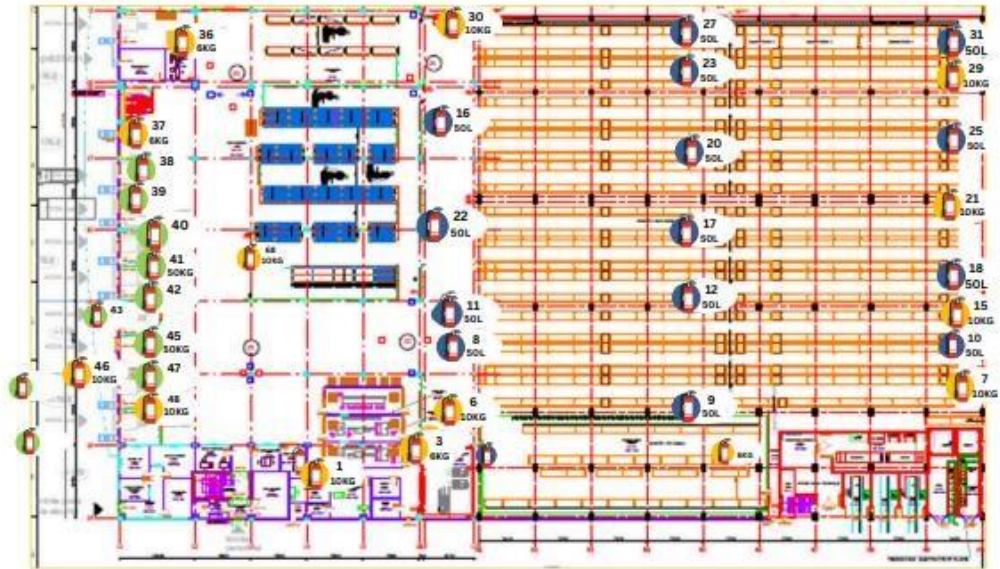
Niveau 0

Légende:

-  Extincteur à CO2
-  Extincteur à eau pulvérisée
-  Extincteur à poudre

-Numéro étiquette : N°

-Capacité: N° (KG\L)






Carte des extincteurs

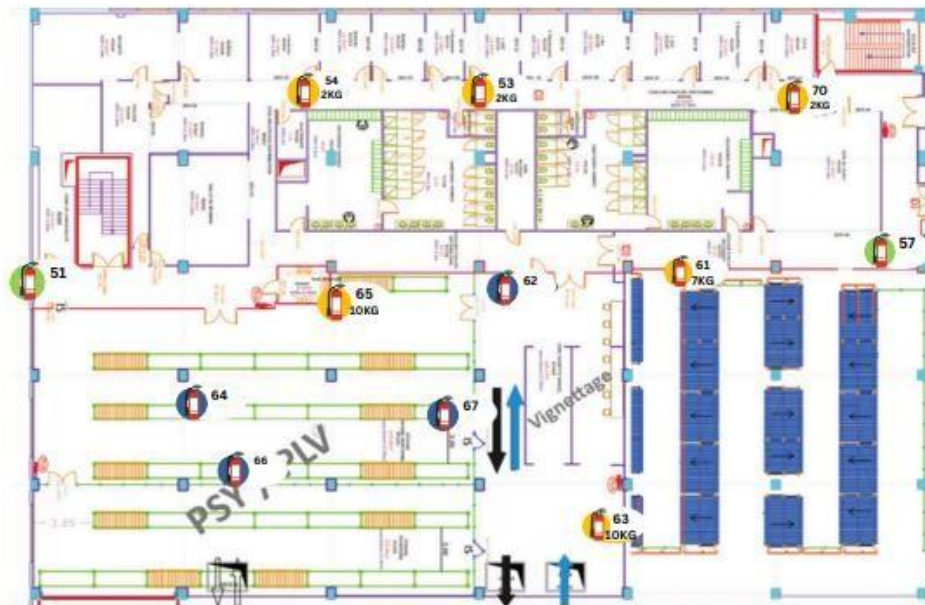
ANNEXE 05 : CARTE DES EXTINCTEURS POUR LE NIVEAU 1

Niveau 1

Légende:

-  Extincteur à CO2
-  Extincteur à eau pulvérisée
-  Extincteur à poudre

- Numéro d'étiquette : N°
- Capacité: N° (KG/L)



Carte des extincteurs

ANNEXE 06 : LE LOGBOOK

| N° Extincteur | Emplacement | Dernière vérification | Commentaire | Prochaine vérification |
|----------------------|-------------------------------|------------------------------|--------------------|-------------------------------|
| N°3 | À l'entrée de local de charge | | | |
| N°6 | À l'entrée des MGH | | | |
| N°8 | À l'entrée des MGH | | | |
| N°11 | À l'entrée des MGH | | | |
| N°22 | À l'entrée des MGH | | | |
| N°16 | À l'entrée des MGH | | | |
| N°30 | À l'entrée des MGH | | | |
| N°27 | Au milieu des MGH | | | |
| N°23 | Au milieu des MGH | | | |
| N°20 | Au milieu des MGH | | | |
| N°17 | Au milieu des MGH | | | |
| N°12 | Au milieu des MGH | | | |
| N°9 | Au milieu des MGH | | | |
| N°7 | Au fond des MGH | | | |
| N°10 | Au fond des MGH | | | |
| N°15 | Au fond des MGH | | | |
| N°18 | Au fond des MGH | | | |
| N°21 | Au fond des MGH | | | |
| N°25 | Au fond des MGH | | | |
| N°29 | Au fond des MGH | | | |
| N°31 | Au fond des MGH | | | |

| N° Extincteur | Emplacement | Dernière vérification | Commentaire | Prochaine vérification |
|----------------------|---|------------------------------|--------------------|-------------------------------|
| N°1 | À cote des box de vignettage | | | |
| N°48 | Quai n°1 | | | |
| N°47 | Quai n°2 | | | |
| N°46 | Quai n°3 | | | |
| N°45 | Quai n°3 | | | |
| N°43 | Quai n°5 | | | |
| N°42 | Quai n°5 | | | |
| N°41 | Quai n°6 | | | |
| N°40 | Quai n°6 | | | |
| N°39 | Quai n°7 | | | |
| N°38 | Quai n°8 | | | |
| N°37 | Quai n°8 | | | |
| N°36 | Quai n°9 | | | |
| N°68 | À côté de la zone 916 | | | |
| N°51 | À l'entrée du local de maintenance | | | |
| N°64 | À droite dans le local de Stockage des Materials promotionnel et HSE | | | |
| N°65 | À l'entrée dans le local de Stockage des Materials promotionnel et HSE | | | |
| N°66 | Au fond dans le local de Stockage des Materials promotionnel et HSE | | | |

| N° Extincteur | Emplacement | Dernière vérification | Commentaire | Prochaine vérification |
|----------------------|---|------------------------------|--------------------|-------------------------------|
| N°67 | À gauche dans le local de Stockage des Materials promotionnel et HSE | | | |
| N°62 | A cote des entrées des box de vignettage | | | |
| N°63 | Derrière les box de vignettage | | | |
| N°61 | Dans le couloir à cote des vestiaires hommes | | | |
| N°57 | A côté de la salle des réunions Cocolico | | | |
| N°70 | A cote de bureau de responsable qualité | | | |
| N°53 | A cote des sanitaires femmes | | | |
| N°54 | A l'entrée du local ménage | | | |

VISA HSE :

VISA PRESTATIRE :

Appendix N

SOP's update

N.1 Permit to Work (PTW)

Table N.1: Comparison of Old and New PTW Procedures

| Category | Old Procedure | New Procedure | Gap/Comment |
|------------------|---|--|--|
| Objective | Ensure safety and compliance with safety measures for external companies | Explain the different work permits required during operations involving specific risks | Both aim to ensure safety during operations involving external companies |
| Responsibilities | Responsibilities divided among the client, the HSE department, and the area manager | Includes responsibilities for the area manager, order issuer, HSE and maintenance manager, and executor | New procedure provides more detailed role definitions |
| Definitions | Provides definitions of key terms used in the procedure | Detailed definitions for specific work permits like hot work, work at height, and hazardous work | New procedure includes more detailed definitions |
| Preparation | Details the preparation for external companies before starting work | Detailed preparation steps including safety measures and necessary permits | New procedure includes more comprehensive preparation steps |
| Permit to Work | Specific work permits required for hazardous operations | Two types of work permits: simple and specific, including hot work, work at height, and equipment operations | New procedure provides more detailed and specific permits |
| Authorization | Details the authorization process involving signatures from various parties | Formal authorization through a signed permit by the order issuer and area manager | New procedure includes a formalized and detailed authorization process |
| Verification | Verification of safety measures before work begins | Detailed verification steps to ensure all safety measures are in place | More detailed in the new procedure |

APPENDIX N. SOP'S UPDATE

| Category | Old Procedure | New Procedure | Gap/Comment |
|-----------------------|--|---|---|
| Training | Includes training requirements for personnel involved | Detailed training requirements and regular audits to ensure compliance | More detailed in the new procedure |
| Audits | Periodic audits to ensure compliance | Regular audits to ensure adherence to safety and local regulations | New procedure includes more detailed audit requirements |
| Continuous Protection | Ensuring continuous safety during work involving external companies | Detailed measures for maintaining safety during personnel changes and process discontinuities | More comprehensive in the new procedure |
| Exceptional Cases | Specific instructions for exceptional cases like dealing with locks and external companies | Specific permits for exceptional cases like hot work and work at height | More detailed and specific in the new procedure |
| Annexes | Includes necessary annexes for additional details | Detailed annexes including process flowcharts and specific permit forms | New procedure includes comprehensive annexes |

N.2 Use of Extinguisher

Table N.2: New Procedure for Use of Extinguishers

| Category | New Procedure |
|------------------|--|
| Objective | This procedure describes the types of fire extinguishers present on site and their methods of use. It provides a clear and concise approach to their usage to ensure that personnel are equipped with the knowledge and skills necessary to respond quickly and correctly to fire emergencies, thus reducing the risks to human life and material damage. |
| Scope | This procedure applies to the Sanofi Algeria distribution site "Sidi Abdellah DC". It covers all activities involving the use of fire extinguishers. The aim is to ensure fire safety by providing clear and precise guidelines on the identification, location, and use of extinguishers available on site. All personnel, regardless of their level, may face a fire situation and should be able to effectively use fire extinguishers to contain or extinguish a fire. |
| Responsibilities | <p>HSE and Maintenance Manager: Implement the procedure, distribute extinguishers on-site according to risk assessment, train personnel, and monitor and remind service providers responsible for extinguisher maintenance.</p> <p>Zone Manager: Regularly verify that each extinguisher's location corresponds to its reference number, maintain unobstructed access to the extinguishers, and periodically inspect the adequate positioning of extinguishers on site.</p> <p>Personnel: Properly use extinguishers in case of fire emergency according to established procedures and report damaged or requiring recharge extinguishers.</p> <p>Service Provider: Regularly inspect extinguishers according to applicable standards and periodically recharge when necessary (every 6 months).</p> |

| Category | New Procedure |
|-------------------|--|
| Definitions | <p>Extinguisher: A pressure device that directs an extinguishing agent onto a fire. The pressure can be provided either by permanent compression, chemical reaction, or the release of auxiliary gas.</p> <p>Extinguishing Agent: The substance contained in an extinguisher that extinguishes the fire.</p> <p>Fire Classes: The most common fire classes are A (ordinary combustibles), B (flammable liquids), C (gases), and D (combustible metals).</p> <p>Extinguishing Index: A number indicating the size and type of fire an extinguisher can extinguish.</p> <p>Manometer: An indicator measuring the pressure in the extinguisher.</p> |
| Procedure Content | <p>6.1 The Fire Triangle: For a fire to occur, the combination of three elements is needed: Fuel (wood, paper, plastic...), Oxidizer (oxygen from the air...), Activation Energy (flame, friction, spark...).</p> <p>6.2 Fire Classes: Use the appropriate extinguishing agent for the type of fire.</p> <p>6.3 Extinguishing Methods: Cooling, Smothering, Inhibition.</p> <p>6.4 Types of Extinguishers: Permanent pressure and auxiliary pressure.</p> <p>6.5 Extinguishing Agents: Water with or without additives (AFFF), Powders (A, B, C, D), CO₂.</p> <p>6.6 Extinguisher Presentation: Information on the extinguisher's body.</p> <p>6.7 Extinguisher Use: Pull the safety pin, aim at the base of the fire, sweep side to side, evacuate immediately after use and alert rescue services if necessary.</p> <p>6.8 Inspection Date: Clearly displayed on each extinguisher.</p> <p>6.9 Extinguisher Location: Clearly identified and strategically placed.</p> <p>6.10 Extinguisher Storage: Guidelines for indoor and outdoor storage and stock recording.</p> <p>6.11 Reserve Stock: Immediate availability, variety, and regular checks of the reserve stock.</p> <p>6.12 Extinguisher Selection Criteria: Adaptation to fire type, usage limitations, implementation constraints.</p> |

| Category | New Procedure |
|----------|---|
| Annexes | ANNEXE 01: Extinguisher Locations ANNEXE 02: Extinguisher Selection Table ANNEXE 03: Extinguisher Display ANNEXE 04: Extinguisher Map for Level 0 ANNEXE 05: Extinguisher Map for Level 1 ANNEXE 06: Logbook |

N.3 LOG-OUT TAG-OUT

Table N.3: Comparison of Old and New LOTO Procedures

| Category | Old LOTO Procedure | New LOTO Procedure | Gap/Comment |
|------------------|--|--|--|
| Objective | Prevent accidents related to hazardous energies during maintenance | Prevent accidents during maintenance or operational activities involving dangerous energies or substances | Both have similar objectives |
| Responsibilities | Defined roles for implementing and overseeing the LOTO process | Detailed roles for distribution manager, HSE manager, maintenance technician, and person in charge of LOTO | New procedure includes more specific roles |
| Definitions | Provides definitions for key terms | Provides detailed definitions for key terms like LOG-OUT, TAG-OUT and EPI | New procedure includes more detailed explanations |
| Preparation | Emphasizes the importance of preparation | Detailed preparatory steps, including energy identification | New procedure includes more detailed preparatory steps |
| Isolation | Steps for energy isolation | Detailed steps for isolating energy sources, including handling non-lockable devices | More detailed in new procedure |

APPENDIX N. SOP'S UPDATE

| Category | Old LOTO Procedure | New LOTO Procedure | Gap/Comment |
|-----------------------|---|---|--|
| Lockout/Tagout | Procedures for lockout/tagout | Detailed locking/tagging procedures, including additional steps for achieving the lowest energy state | New procedure is more detailed |
| Verification | Verification of isolation and absence of energy | Detailed verification steps to ensure the absence of energy | More detailed in new procedure |
| Deconsignation | Steps for safe de-isolation | Detailed steps for de-isolation, including handling complex scenarios | More detailed in new procedure |
| Training | Includes training requirements | Detailed training requirements | More detailed in new procedure |
| Audits | Periodic audits | Detailed audit requirements | More detailed in new procedure |
| Continuous Protection | Mechanisms for continuous protection | Detailed measures for ensuring continuous protection during personnel changes and process discontinuities | More comprehensive in new procedure |
| Exceptional Cases | General guidelines | Specific instructions for exceptional cases like destruction of locks and dealing with external companies | More specific and detailed in new procedure |
| Annexes | Not specified | Includes annexes for additional details and specific steps | New procedure includes detailed annexes and removed unnecessary ones |

