Non-sterile preparations : How to assess occupational risk for pharmacy technicians ?

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GERPAC EUROPEAN SOCIETY OF HOSPITAL PHARMACEUTICAL TECHNOLOGIES
COM25-21395

Objective

Handling of **hazardous and carcinogenic, mutagenic, or toxic to reproduction (CMR) substances** by pharmacy technicians in the preparation of non-sterile preparations (NSPs)

⇨ Need to establish a **method for assessing chemical and CMR-related risks** in order to adapt **protective equipment (PPE) and collective protective equipment (CPE)**[1]

Methods

1) Analysis of NSPs over 5 years and identification of those presenting health risks

2) Risk score calculation : **Potential risk hierarchization** (PRH) based on the simplified chemical risk assessment methodology developed by the French National Research and Safety Institute (Institut national de recherche et de sécurité, INRS, Paris, France)[2] :

- **Quantity class** (amount of substance used compared to the most used substance)
- **Usage frequency**
- **Hazard class** (summary of product characteristics (SPC), safety data sheet, and information on the European Chemicals Agency (ECHA) website)

3) Weighting of quantity class according to the **amount handled** and the **preparation process** (bulk volatile powders, grinding operations…)

Results

32/36 NSPs included a **health hazard statement**

<u>High Priority (corrective measures required) if :</u>

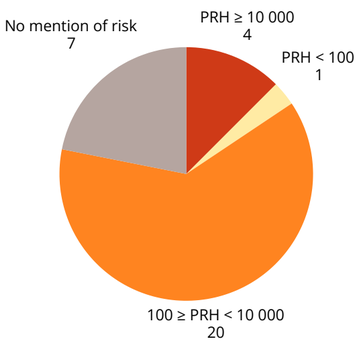
- PRH ≥ 10 000 for ocular, skin, or respiratory risks
- PRH ≥ 3 000 for CMR risk

<u>Preventive measures according to type of risk :</u>

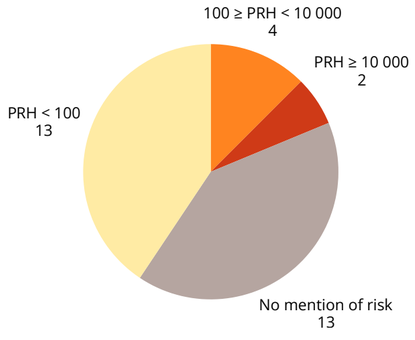
- Skin risk : wear gloves compliant with EN 374
- Ocular risk : wear safety goggles
- CMR risk : handling in cytotoxic safety cabinet
- Respiratory risk : handling in cytotoxic safety cabinet

<u>Preparations examples :</u>

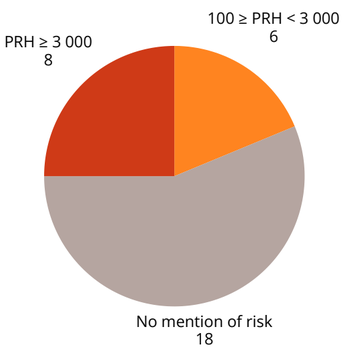
Preparation	Quantity class	Frequency class	Potential exposure class	Hazard mention and class	PRH score
Clonidine capsules	2	1	2	H330 Fatal if inhaled → Class 5	30 000
Salicylic vaseline	3	2	3	H318 Causes serious eye damage → Class 4	10 000



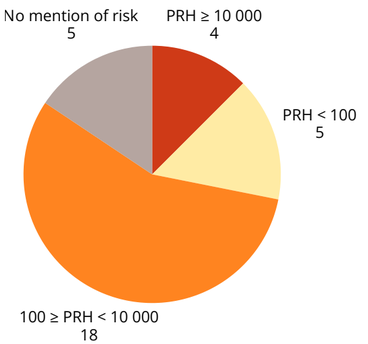
Skin risk



Ocular risk



CMR risk



Respiratory risk

Discussion/Conclusion

⇨ Identification of the highest-risk NSPs for laboratory personnel
⚠ Methodological bias regarding intrinsic toxicity : limited data in SPC, varying risk statements depending on the supplier, lack of consensus on risk classification for several substances
⇨ Development of a standardized risk analysis sheet to categorize NSPs and adapt PPE and CPE, attached to the preparation file

[1]*Bonnes pratiques de Préparation, ANSM 2023, LD2 PRÉPARATION DE MÉDICAMENTS CONTENANT DES SUBSTANCES POUVANT PRÉSENTER UN RISQUE POUR LA SANTÉ ET L'ENVIRONNEMENT*
[2]*R Vincent, Francis Bonthoux, G. Mallet, J.F. Iparraguirre, S. Rio. MÉTHODOLOGIE D'ÉVALUATION SIMPLIFIÉE DU RISQUE CHIMIQUE : un outil d'aide à la décision. Hygiène et Sécurité du Travail, 2005, HST - Cahiers de notes documentaires - 3ème trimestre 2005, ND 2233 (200), pp.39 - 62. ffhal-03752064f*