# HANDLING OF HAZARDOUS DRUGS IN HEALTHCARE SETTINGS – HAZARDOUS EVALUATION AND PROTECTIVE MEASURES RELATED TO EXPOSURE LEVELS

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## WHAT WAS DONE?

- This study aimed to evaluate drugs used in the University Hospital considered hazardous and to describe potential exposure values in connection with exposure limits. A health risk assessment was conducted regarding protective measures related to exposure levels.
- The proper handling of hazardous drugs in healthcare settings is essential to ensure occupational safety and health as the use and number of these potent drugs increase. In the last decades, protection at the workplace has become more noted, and several organizations analyze substances for this very reason.

## WHY WAS IT DONE?

- The Austrian occupational safety and health legislation claims in the act for health and safety at work (ASchG) the evaluation and assessment of potentially hazardous substances and appropriate policies to risk prevention in connection with limit values.
- Meaningful strategies, including proper graduated protective measures connected with exposure scenarios, should guarantee safety at the workplace without complicating and decelerating the workflow.

## HOW WAS IT DONE?

**Classification of potentially hazardous substances**

NIOSH identified five categories of substances with hazardous potential. According to this prioritization, substances from the corresponding ATC groups were listed line by line and assigned to categories of supposed and ascertained CMR potential based on respective H-phrases of the CLP regulation. Therefore first, H-phrases of the ECHA, EDQM, and manufacturers safety data sheets were compiled, taking into account the prevalence of notifications. The classification was interconnected with reliable data from the International Agency for Research on Cancer (IARC), NIOSH, the FDA (pregnancy categories), the German organization BGW and records of prescription information, respectively, the EPAR of medicinal products.

**Compilation of limit values**

Limit values for exposure were identified via section 8 of material safety data sheets (MSDS)and official data (“Grenzwerteverordnung”, GKV) and listed regarding the parameters MAK, TRK/KZW with optional information to duration/incidence. A conclusion by analogy is possible via the so-called (EMKG) in combination with TRGS 900.

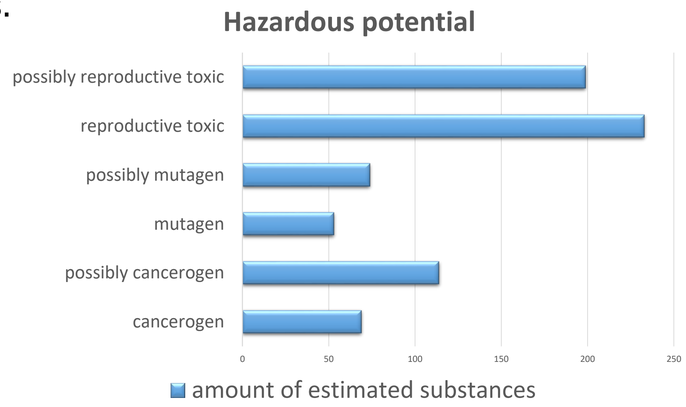
**Exposition risk relationship**

For risk assessment purposes, representative exposure scenarios of selected working processes gathered from literature research were linked to the estimated limit values. Exposure algorithm models (Stoffenmanager, EMKG, ART) were tested in order to create a quantitative assessment of exposure levels by non-technical procedures.

## WHAT WAS ACHIVED?

**Classification of potentially hazardous substances**

717 substances were analyzed, with the available information, 461 of them were categorized as potentially hazardous according to their properties.




**Compilation of limit values**

From the above mentioned 717 substances, 177 threshold values could be identified. Particularly for 124 of the estimated 461 hazardous substances, limit values could be found in MSDS and GKV. The range of the MAK value for CMR substances is located between 0,015 µg/m³ and 10 mg/m³.

| CMR | Exposure limit value (range) |
|---|---|
| cancerogen (H350) | 0,04µg/m³ – 10mg/m³ |
| possibly cancerogen (H351) | 0,02µg/m³ – 10 mg/m³ |
| Mutagen (H340) | 0,05 µg/m³ – 10mg/m³ |
| possibly mutagen (H341) | 0,02µg/m³ – 5mg/m³ |
| reproductive toxic (H360) | 0,015µg/m³ – 10mg/m³ |
| possibly reproductive toxic (H361f) | 0,08µg/m³ – 10mg/m³ |

**Exposition risk relationship**

Literature research revealed only a few environmental monitoring data (atmospheric load of dust or aerosol, concentration). The range of the data is mostly wide, results depend on individual working conditions, and sometimes details to the evaluation setting are missing. Experiments on pestling of one single tablet showed 1-4 µg/m³ atmospheric load, mixing/filling/weighing a range of 0.13-2,626 µg/m³ , opening capsules 2.1-391,7ng/m³.

## WHAT IS NEXT?

The classification of medicinal products concerning their hazardous potential and the evaluation of exposure limit values is not always possible since Material safety data sheets as an essential source are sometimes unavailable. This is especially conspicuous in the class of monoclonal antibodies. It is crucial that companies make hazardous classification and exposure limits always public.
Literature research yielded only a few public health publications referring to exposure scenarios. Moreover, measured exposure values often showed a wide range, which is not easily set in relation to the published specific exposure limit values.
In an ongoing process, every new drug will be evaluated towards the hazardous properties, respectively, associated exposure limits and communicated to the institution's health care workers.

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