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# Hazard banding in compliance with the new Globally Harmonised System (GHS) for use in control banding tools



Regulatory Toxicology and Pharmacology

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## ABSTRACT

Many control banding tools use hazard banding in risk assessments for the occupational handling of hazardous substances. The outcome of these assessments can be combined with advice for the required risk management measures (RMMs).

The Globally Harmonised System of Classification and Labelling of Chemicals (GHS) has resulted in a change in the hazard communication elements, i.e. Hazard (H) statements instead of Risk-phrases. Hazard banding schemes that depend on the old form of safety information have to be adapted to the new rules.

The purpose of this publication is to outline the rationales for the assignment of hazard bands to H statements under the GHS. Based on this, this publication proposes a hazard banding scheme that uses the information from the safety data sheets as the basis for assignment. The assignment of hazard bands tiered according to the severity of the underlying hazards supports the important principle of substitution. Additionally, the set of assignment rules permits an exposure-route-specific assignment of hazard bands, which is necessary for the proposed route-specific RMMs.

Ideally, all control banding tools should apply the same assignment rules. This GHS-compliant hazard banding scheme can hopefully help to establish a unified hazard banding strategy in the various control banding tools.

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## 1. Introduction

According to the European Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work, employers have a general duty to ensure the safety and health of workers in every aspect related to work (EU, 1989). This includes the occupational handling of hazardous substances. To fulfil this duty, risk assessments have to be performed, enabling employers to take the measures necessary to protect the safety and health of their workers. The first step in such a risk assessment is to identify potential hazards of chemicals and assess the degree of harm due to handling-related exposure (EU-OSHA, 2008a; EU-OSHA, 2008b). In addition to physical hazards like flammability or explosiveness,

\* Corresponding author. E-mail address: mario.arnone@dguv.de (M. Arnone). hazards to human health are the main risks during the occupational handling of hazardous substances.

The health hazards are identified from the results of the available toxicological studies like in vivo tests and studies on chemicals' structure—activity relationships (QSAR studies). Besides acute health hazards such as toxicity, corrosivity or irritation, hazardous substances may also give rise to chronic health hazards such as carcinogenicity, mutagenicity, reprotoxicity (CMR) or sensitisation. Under the Dangerous Substances Directive (67/548/EEC) (DSD) (EU, 1967) it was possible to identify these hazards from the risk phrases (R-phrases) on the label and in the safety data sheet (SDS) of the chemical products.

An absolute measure of the hazard to human health from the handling of hazardous substances is impossible to define due to the differing health hazards. It is easier to categorise their severity relative to each other. This is where the concept of hazard banding comes into play. Hazard banding is the classification of hazards in hazard categories, which are also referred to as "hazard bands". The concept originated in the early 1990s, was applied to volatiles and used in the pharmaceutical industry (Zalk and Nelson, 2008). Helping firms comply with the Control of Substances Hazardous to Health (COSHH) regulations, the first widely applied risk assessment approach to make use of hazard banding was the "COSHH Essentials" (HSE, 1999; HSE, 2014). Their five hazard bands from A (low hazard) to E (high hazard) refer directly to target airborne exposure ranges (Brooke, 1998) and are assigned with the aid of the R-phrases from the DSD. Similar banding schemes are applied in control banding tools like the Stoffenmanager<sup>®</sup> (Cosanta, 2015; Marquart et al., 2008) and the GESTIS-Stoffmanager (IFA, 2015c; Koppisch and Gabriel, 2012), the easy-to-use workplace control scheme for hazardous substances (EMKG) (Kahl et al., 2012) and the International Chemical Control Toolkit of the International Labour Organisation (ILO) (ILO, 1996). The German "Column Model - An aid to substitute assessment" (Smola et al., 2014) also uses a kind of hazard banding scheme to categorize the hazards of chemicals for a substitute assessment. However the "Column Model" is not considered as control banding tool because it assumes no relation between the overall hazard of chemicals and exposure control.

A comparison of the applied hazard banding schemes reveals, however, that all these control banding tools use slightly different rules for assigning hazard bands to the R-phrases (Scheffers and Wieling, 2005). Evaluations on hazard banding schemes for control banding tools used to be performed by correlating the hazard band assigned to hazardous substances with the maximally permitted airborne concentrations for these substances, i.e. occupational exposure limit values (OELs) (Braasch and Rupprich, 2005; Brooke, 1998). For the banding scheme adopted in the COSHH Essentials, the study performed by Brooke showed that about 50% of the assessed OELs correspond with the assigned hazard band with respect to the required level of control. It also revealed that about 50% of the assessed substances would be "over-controlled" by this scheme (Brooke, 1998). In contrast, the EMKG R-phrase hazardbanding scheme shows only a poor level of protection from vapours. For 57 %-84 % (depending on the assigned hazard band) of the assessed vapours, the assigned hazard band is not as protective as the existing OEL (Braasch and Rupprich, 2005).

In 2003, the United Nations created the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) as an internationally agreed system to replace the various classification and labelling standards used in different countries (UN, 2003). It was implemented by the Classification Labelling & Packaging Regulation (EC) No 1272/2008 (CLP Regulation) (EU, 2008) throughout the European Union in January 2009. In the GHS and consequently also in the CLP regulation, the types and severities of hazard from a chemical substance are now expressed in "H(azard) statements", i.e. H315 - "Causes skin irritation". GHS and CLP have also resulted in changes to the rules for the classification of mixtures. Under this new legislation, all control banding tools that use the R-phrases from the DSD and the concentration limits from the 1999/45/EC Dangerous Preparations Directive (DPD) (EU, 1999) for the assignment of hazard bands have to be adapted to the new rules.

A first and obvious approach was to translate the R-phrases to the new H statements and use the same hazard band assignment. Since the control banding tools used to apply different rules for the assignment of hazard bands to R-phrases, this approach naturally led to different schemes for the assignment of hazard bands to the new H statements.

First evaluation studies have been performed on these 'simple translation from R-phrases to H statements' GHS hazard banding schemes of the COSHH Essentials and the EMKG (DOHSBASE, 2014; Scheffers, 2015). These studies revealed that the COSHH Essentials hazard banding scheme is much more protective than the banding

scheme applied in the EMKG. The COSHH Essentials assign the hazard bands **C** or **D** to 60% of all substances classified with health related H statements (H3xx). In contrast the EMKG bands about 70% of these substances in the lower hazard bands **A**, **B** and **C** (Scheffers, 2015). Since the tools can combine the result of the risk assessment with control strategies, the observed different assignments will lead to different control strategies. Especially in SMEs these differences can cause confusion and decreasing trust in the whole control banding concept (Scheffers, 2015).

GHS and the European CLP chemical legislation set out to unify the classification and labelling of hazardous substances. The overriding aim of the authors is to create a unified hazard banding scheme for all control banding tools that complies with this legislation. The purpose of this publication is to outline the general rationales for the assignment of hazard bands to hazards arising from the handling of hazardous substances. On the basis of these rationales, it proposes a hazard banding scheme that specifically uses the H statements and the concentration limits for mixtures from the GHS as a basis for assignment.

# 2. Rationales for the proposed assignment of hazard bands to H statements

Control banding tools assign the hazard bands to chemicals according to the properties that make these substances dangerous. For users in small and medium-sized enterprises (SMEs) particularly, the label on the product container and SDS of the products are the primary sources of information on such properties (H statements, hazard categories). On the basis of the regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH regulation) (EU, 2006), it is assumed that this information is complete and correct. The SDS provides more detailed information than the label since it differentiates all hazard categories. For fatal effects (H300/H310/H330) a distinction is made between acute toxicity category 1 (acute tox. cat. 1) and category 2 (acute tox. cat. 2), and for skin corrosion (H314) a distinction is made between H314 cat. 1A (formerly R35) and cat. 1B/1C (formerly R34). A new hazard banding scheme that complies with GHS and the CLP regulation therefore should refer to the SDS of the product concerned as the primary information source on H statements, hazard categories and the other important product properties.

Directive 98/24/EC (EU, 1998) on the protection of the health and safety of workers from the risks related to chemical agents at work states that the employer is obligated to eliminate or minimise the risk from a hazardous chemical agent to the safety and health of workers. This should be done by replacing it with a chemical agent or process which, under its conditions of use, is not hazardous or less hazardous to workers' safety and health (Stenzel, 2006). Taking into account this important principle, hazard band assignment must support the possibility of substitution. For this reason, the assignment has to be graduated according to the severity of the hazard expressed by the H statement. The possibility of substituting a proven CMR substance or a fatal acutely toxic product with a less hazardous substance should be ensured by the assignment of other hazards (suspected CMR substances, sensitisers and strong skin corrosives) to lower hazard bands.

Control banding tools are mainly used by users in SMEs when conducting risk assessments for the occupational handling of hazardous substances. In addition to risk assessment, these control banding tools can give advice on the required risk management measures (RMMs) and provide guidance on the choice of additionally appropriate RMMs. Since the selected RMMs have to be exposure-route-specific, the hazard bands also have to be assigned to H statements on the basis of the route of exposure referred to in the respective H statement. Download English Version:

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