

## SAICM 2.0 Hazard Analysis

### Methodology and rationale

Disinfectants safety data sheets (SDS) and technical fact sheets are investigated in respect to claimed product efficacy. Only products with an explicitly named “disinfecting impact”<sup>i</sup> or with biocidal ingredients reasonably indicating a disinfecting impact and present in sufficient concentration were further considered in the analysis. Cleaning products without disinfecting impact were not further analysed.

The information extracted from products’ SDS is complemented by the corresponding WIDES name of the ingredient, the WIDES classification used for the ingredient, and an indication if WIDES data gaps exist.<sup>ii,iii</sup>

As described in the explanatory notes below, Hazard Category A (Red) indicates a high hazard potential while Hazard Category B (Yellow) still indicates a considerable hazard potential which should not be neglected. Category B may additionally indicate that the ingredient is not well investigated to exclude certain hazards; on that basis we derive a strong or limited substitution demand for the product containing one or more ingredients with a hazard categorised as A or B.

We derive no substitution demand for products containing ingredients solely with hazards categorised as C. If the product contains at least 1 ingredient classified with a Category A hazard, we strongly recommend a less hazardous alternative. The product may become a candidate for the second step of our Hazard Analysis of Disinfectants (Product Benchmarking). If the product contains  $\geq 2$  ingredients classified as a Category B hazard, we do not perceive an urgent need for substitution but recommend considering product alternatives on a case by case basis including cost-benefit considerations. If the product contains only ingredient with hazards categorised as C, we do not perceive a substitution demand.

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<sup>i</sup> e.g. “for disinfection of surfaces”

<sup>ii</sup> Based on regular data update and the extensive data background of the WIDES database provided for biocidal active ingredients and other components of disinfectants a “data gap” is a strong indication that there are not public data available for the respective ingredient to exclude certain hazards.

<sup>iii</sup> The classification of a substance or mixture reflects the type and severity of the hazards of that substance or mixture, i.e. its potential to cause harm to human beings or the environment. The Viennese Database for Disinfectants (WIDES database; see also footnote 6) applies the most relevant classifications for biocidal active ingredients and other components of disinfectants. The classifications are regularly updated and as far as possible they rely on documents of the European Chemicals Legislation such as the REACH Dossiers and Risk Assessment Reports of the Biocidal Products Regulation (BPR). These documents are generally public accessible on the webpage of the European Chemicals Agency ECHA (<https://echa.europa.eu/en/>).

## Explanatory notes:

The Hazard Analysis of Disinfectants identifies hazards of ingredients according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS System).<sup>iv</sup> Hazards of ingredients can be reasonably differentiated in respect to the severity and duration of the effects they induce; some constitute relatively harmless or reversible effects (e.g. skin irritation) while others are more severe and/or irreversible (e.g. cancer-induction, sensitisation). The GHS hazard statements provide standardised phrases to indicate such hazards both for chemicals and mixtures. Each hazard statement is designated a 3 digit code e.g. H340. For the purpose of the analysis we created three categories to distinguish between severe and less concerning hazard statements.

**Hazard Category A** covers the most severe hazards; we have additionally indicated the severity of these hazards with the colour red:

<b>Hazard Category A (health hazards)</b>	
H340	May cause genetic defects
H350	May cause cancer
H360	May damage fertility or the unborn child
H317	May cause an allergic skin reaction
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H372	Causes damage to organs through prolonged or repeated exposure
<b>Hazard Category A (aquatic hazards)</b>	
H400 (M $\geq$ 1000) <sup>v</sup>	Very toxic to aquatic life and M-factor <sup>v</sup> equal to or higher than 1000
H410 (M $\geq$ 100) <sup>3</sup>	Very toxic to aquatic life with long-lasting effects and M-factor equal to or higher than 100

<sup>iv</sup> GHS is an international standard managed by the UN; core elements include standardised hazard testing criteria, universal warning pictograms, and harmonised safety data sheets providing information to users of dangerous goods. The GHS System is also applied in the EU chemicals legislation (CLP-Regulation).

<sup>v</sup> M-factor stands for multiplying factor for substances that are highly toxic to aquatic environment (e.g. LC50 or EC50 < 1mg/L). When classifying a substance as acute aquatic toxicity category 1 or chronic aquatic toxicity category 1 under GHS, it is usually necessary to indicate an appropriate M-factor. This is mandatory under EU CLP regulation and gives an increased weight to highly toxic components.

**Hazard Category B** covers hazards of considerable concern and should not be neglected; please note that knowledge gaps or data insecurity about hazards is additionally integrated in Category B. In our analysis we additionally indicate the severity of these hazards with the colour yellow:

<b>Hazard Category B – considerable concern (health hazards)</b>	
H300	Fatal if swallowed
H310	Fatal in contact with skin
H330	Fatal if inhaled
H301	Toxic if swallowed
H311	Toxic in contact with skin
H331	Toxic if inhaled
H341	Suspected of causing genetic defects
H351	Suspected of causing cancer
H361	Suspected of damaging fertility or the unborn child
H362	May cause harm to breast-fed children
H373	May cause damage to organs through prolonged or repeated exposure
EUH029	Contact with water liberates toxic gas
EUH031	Contact with acid liberates toxic gas
EUH070	Toxic by eye contact
H370	Causes damage to organs
<b>Hazard Category B – considerable concern (aquatic hazards)</b>	
H400 (M $\geq$ 10)	Very toxic to aquatic life and M-factor equal to or higher than 10
H410 (M $\geq$ 1) <sup>4</sup>	Very toxic to aquatic life with long-lasting effects and M-factor equal to or higher than 1
<b>Hazard Category B – considerable concern (data gaps)</b>	
Data gap (health hazard): The WIDES database <sup>vi</sup> indicates that there is not enough knowledge respectively insecurity about the acute-toxic, allergenic, mutagenic, carcinogenic, repro-toxic, or chronically toxic hazard of the substance.	
Data gap (aquatic hazard): The WIDES database indicates that there is not enough knowledge respectively insecurity about the acute (short-term) or chronically (long-term) aquatic hazard of the substance.	

<sup>vi</sup> The Viennese Database for Disinfectants (WIDES) contains information on the established effects of commercially available disinfectants and their ingredients as well as the properties of these products that are of relevance for occupational safety and environmental protection.  
[www.wien.gv.at/english/environment/protection/oekokauf/disinfectants/index.html](http://www.wien.gv.at/english/environment/protection/oekokauf/disinfectants/index.html)

**Hazard Category C** covers hazards that represent a relatively small impact on human health and/or the aquatic environment. We assigned corrosive properties to Category C because we assume that this hazard is controllable by means of proper personal training, adequate clothing, and working equipment:

<b>Hazard Category C – low concern (health hazards)</b>	
H302	Harmful if swallowed
H312	Harmful in contact with skin
H332	Harmful if inhaled
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H371	Causes damage to organs
H304	May be fatal if swallowed and enters airways
EUH066	Repeated exposure may cause skin dryness or cracking
EUH071	Corrosive to the respiratory tract
<b>Hazard Category C – low concern (aquatic hazards)</b>	
H411	Toxic to aquatic life with long-lasting effects
H412	Harmful to aquatic life with long-lasting effects
H413	May cause long-lasting harmful effects to aquatic life