Hazard Analysis and Product Benchmarking of Disinfectants

The Hazard Analysis of Disinfectants compares the environmental and health related hazards of disinfectants with product alternatives. In a first step the substitution demand is estimated. A substitution demand is assumed if the disinfectant contains ingredients with a high and/or long-term adverse impact on human health or the aquatic environment. To identify such an impact a categorisation scheme is applied on the ingredient classification. Substitution demand is assumed if a product contains at least one ingredient categorised as A (high concern). In such a case the product is recommended for a Product Benchmarking[1]. The aim is to identify products which are recommendable for substitution. The analysis can be applied to hand and skin disinfectants, surface, instrument and linen disinfectants. For that information about products and their ingredients is needed. For a comprehensive analysis a list of dangerous ingredients is needed together with information about their concentration, type of application, biocidal efficacy and use amount of the products. The WIDES database supports to select the most recent ingredient classifications and enables access to potential product alternatives.

Hazard Analysis

Hazards of ingredients can be reasonably differentiated in respect to the severity and duration of the effects they induce. Some constitute rather harmless or reversible effects (e.g. skin irritation) while others are severe and/or irreversible (e.g. cancer induction, sensitisation). The core of the hazard analysis is the application of a categorisation scheme to distinct between hazards with high (category A), significant (category B) and minor (category C) concern. The categorisation scheme supports the identification of ingredients with a high hazard potential. The main tool for that is the Globally Harmonized System of Classification and Labelling of Chemicals (GHS System)[2] which provides standardized phrases - the hazard statements - to indicate hazards both for chemicals and mixtures. Each hazard statement is designated a code, starting with the letter H and followed by three digits. The assignment of category is done by means of the classification (i.e. a set of hazard statements) of the dangerous ingredient.

[1] *Benchmarking* means the comparison of single attributes of a product or product portfolio with a benchmark “. Normally the benchmark is a market leader within a product segment.

[2] GHS is an internationally standard managed by the UN. Core elements of the GHS include standardized hazard testing criteria, universal warning pictograms, and harmonized safety data sheets which provide users of dangerous goods with a host of information. The GHS System is also applied in the EU chemicals legislation (CLP-Regulation).

Category A (high concern)

Category A covers long-lasting, difficult controllable and/or irreversible hazards on human health and/or the aquatic environment. The hazards covered can damage health or kill or endanger aquatic organisms in the long-term, even in low concentrations. As far as other criteria such as spectrum of efficacy and material compatibility allow it, we recommend avoidance of products with category A ingredients. In the calculation sheets the severity of this hazards is indicated with the background colour red.

HEALTH HAZARD	
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
H340 H350 H360	May cause genetic defects May cause cancer May damage fertility or the unborn child
H361d[3]	Suspected of damaging the unborn child
H362[3]	May cause harm to breast-fed children
AQUATIC HAZARD May cause harm to breast-fed children	
H400 (M ≥ 1000)[4]	Very toxic to aquatic life and M-factor equal to or higher than 1000
H410 (M ≥ 100)[4]	Very toxic to aquatic life with long-lasting effects and M-factor equal to or higher than 100

[3] Reason for the inclusion of H361d ("Suspected of damaging the unborn child") and H362 (May cause harm to breast-fed children) in category A are: Unborn life should be given the highest level of protection, as possible injury could affect the entire life of the adolescent child and the unborn child cannot defend itself against the influence of chemicals. Therefore, in contrast to H341 (suspicion of mutagenicity) and H351 (suspicion of carcinogenicity), the suspicion of fruit-damaging effects is sufficient for inclusion in category A. This takes particular account of the precautionary principle.

[4] M-factor stands for multiplying factor for substances that are highly toxic to aquatic environment (i.e. 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. The purpose of applying M-factor is to give an increased weight to highly toxic components.

Category B (significant concern)

Category B covers hazards with still significant adverse impact on health and the aquatic environment. Category B also includes data uncertainties about the hazard potential ("data gap") in relation to certain endpoints. Acutely toxic substances are assigned to category B, provided that the substance is properly used[5]. Category B corresponds to a recommendation to examine product alternatives on a case-by-case basis. In the calculation sheets the severity of this hazards is indicated with the background colour yellow.

HEALTH HAZARD	
H300 H310 H330	Fatal if swallowed Fatal in contact with skin Fatal if inhaled
H301 H311 H331	Toxic if swallowed Toxic in contact with skin Toxic if inhaled
H341 H351 H361f	Suspected of causing genetic defects Suspected of causing cancer Suspected of damaging fertility
H373	May cause damage to organs through prolonged or repeated exposure
EUH029 EUH031 EUH070	Contact with water liberates toxic gas Contact with acid liberates toxic gas Toxic by eye contact
H370	Causes damage to organs
AQUATIC HAZARD	
H400 (M ≥ 10)[3]	Very toxic to aquatic life and M-factor equal to or higher than 10
H410 (M ≥ 1)[3]	Very toxic to aquatic life with long-lasting effects and M-factor equal to or higher than 1
DATA GAP	
WIDES data gap (health hazard): The WIDES database[6] indicates that there is not enough knowledge respectively insecurity about the acute-toxic, allergenic, mutagenic, carcinogenic, repro-toxic and/or chronically toxic hazard of the ingredient.	
WIDES data gap (aquatic hazard): The WIDES database[5] indicates that there is not enough knowledge respectively insecurity about the acute (short-term) and/or chronically (long-term) aquatic hazard of the ingredient.	

[5] Improper use or uncontrolled release of concentrates (during transport, transfer, storage or application) make H300, H310 and H330 a high hazard.

[6] The Viennese Database for Disinfectants (WIDES Database) contains information on the established effects of commercially available disinfectants and their ingredients. https://www.wien.gv.at/english/environment/protection/oekokauf/disinfectants/index.html

Category C (minor concern)

Category C covers limited, comparatively good controllable and/or reversible hazard potential to health and the aquatic environment. We assign corrosiveness, indicated by the hazard statements H314 and H318, to category C as long as a controlled use with required dilution and proper working equipment is given[7]. Although category C hazards should not be neglected, they generally do not constitute a substitution demand.

HEALTH HAZARD	
H302 H312 H332	Harmful if swallowed Harmful in contact with skin 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
AQUATIC HAZARD	
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

[7] Improper use or accident (e.g. during transport, transfilling, storage or application) make H314 and H318 a high hazard.

Example: Hazard Analysis SD5

The hazard analysis for disinfectant SD5 assigns two ingredients to category A, namely *Aminoalkylglycin* with H372 (Causes damage to the organs through prolonged and repeated exposure) and *Polyhexamethylenbiguanid* with H317 (May cause an allergic skin reaction) and H372 (Causes damage to the organs through prolonged and repeated exposure). Hazard analysis recommends substitution respectively a Benchmarking.

FIGURE 1: RESULT OF HAZARD ANALYSIS OF SD5

Ingredient			Health Hazards										Aquatic Hazards		
			Category A					Category B					Category A	Category B	
Name	CAS#	H-phrase according WIDES	H340 H350 H360	H372	H334	H317	H361d H362	H300 H310 H330 H301 H311 H331	H341 H351 H361f	H373	EUH029 EUH031 EUH070 H370	Wides data gap	H400 (M≥1000) H410 (M≥100)	H400 (M≥10) H410 (M≥1)	Wides data gap
Didecyldimethyl amonium chloride	7173-51-5	H301, H314, H400(M10), H411						x						x	
Aminoalkylglycin	139734-65-9	H302, H314, H361f, H372, H400(M10), H410(M1)		x					x					x	
Polyhexamethylen biguanid	27083-27-8	H302, H317, H318, H330, H351, H372, H400(M10), H410(M10)		x		x		x	x					x	
Propan-2-ol	67-63-0	H225, H319, H336													
"Fragrance"	-	-													
SD5				**x**		**x**		**x**	**x**					**x**	

Product Benchmarking

For the search of product alternatives additional information is required: For hazard analysis it is sufficient to know the hazardous ingredients, product benchmarking additionally requires knowledge of application concentration of each hazardous ingredient. It must be ensured that benchmarked product and possible alternative(s) are comparable in type of application and anti-microbial efficacy. Product benchmarking is designed as a standardized procedure but leaves room for specific questions. Benchmarking focus on category A ingredients, though any toxic property can be benchmarked to avoid it or keep it as low as possible.

Product Alternatives

To search product alternatives there are two basic strategies:

- The client searches for product alternatives on the market (or web). The categorisation helps to preselect: If the product contains a category A substance, it has to be discarded as a potential alternative.
- The client consults the WIDES database containing disinfectants for the hand, skin, surface, instrument and laundry disinfection together. All ingredients show category, which makes the selection even easier. However the overall product portfolio is oriented on the European market.

Hazardous load

The term “hazardous load” is synonymous with dangerous material cargo. The hazardous load is calculated on the bases of the consumption volume of the product, alternatively a default consumption value may be applied. The following information is required for calculation:

- Concentration of ingredients for benchmark product and product alternative(s): This information can be found in the safety data sheet, product information sheet and/or the WIDES database.
- Application concentration for the benchmark product and the product alternative(s): This information is required to calculate the quantity of application solution. Two types of application solution can be distinguished: One without dilution ("ready to use") or after dilution with water ("concentrate").

In product benchmarking the quantity of application solution of benchmarked product and product alternative(s) has to be equal.

Example: If the benchmarked product is a concentrate and has to be diluted to 0.5%, then 1000 litres of concentrate yield 200,000 litres of application solution. If the product alternative is applied in 1% concentration, then 2000 litres of product alternative are required to generate 200,000 litres of application solution.

The hazardous load for each ingredient i is calculated according to the following formula:

$$[\text{Hazardous load (kg)}] = Conc.i(\%) \times \frac{Cons.Vol.(l)}{100} \times Density\left(\frac{kg}{l}\right) \times \frac{Appl.\ Conc.(\%)}{100}$$

For SD5 the following information can be found in the WIDES database:

Category A or B ingredient	Classification	%
Didecyldimethylamoniumchlorid	H301, H400(M10), H411	0,53
Aminoalkylglycin	H302, H314, H361f, H372, H400(M10), H410(M1)	0,5
Polyhexamethylenbiguanid-HCL	H302, H317, H318, H330, H351, H372, H400(M10), H410(M10)	0,12

Density (kg/l)	1
Consumption volume (litres):	not known, therefore a default value of 1000
Application Concentration (%):	100 (ready for use)
Spectrum of activity:	bactericidal (not Mycobacteria) + yeasticidal, dirty conditions + mechanical acvtion
Exposure time (min):	0,5 - 15

Product alternatives can also be searched in the WIDES. In order to ensure the same range of application and a comparable spectrum of efficacy, the following search criteria should be applied in the search query:

- Surface rfu - non alcoholic
- Exposure time: 0,5 – 15 min
- Spectrum of activity: bactericidal (not Mycobacteria) + yeasticidal, dirty cond. + mechanical action.

The query result contains SD5 and 16 potential product alternatives (PA1-PA16). Of these, 4 products were selected using ingredient category (possibly category C, no category A) and product assessment (colour code):

- PA3 (Didecyldimethylammonium chloride; Benzalkonium chloride)
- PA6 (Hydrogen peroxide)
- PA12 (Didecyldimethylammonium chloride; Benzalkonium chloride; N-Alkyl-N-ethylbenzyl-N,N-dimethylammonium chloride).
- PA14 (Didecyldimethylammonium chloride)

Grouped Hazards

In Benchmarking H-phrases are grouped to sum up hazards with a comparable degree of adverse impact. One way to do this is shown in Figure 2. Thereby proven and suspected carcinogenic, mutagenic repro-toxic and chronically toxic hazards respectively their H-phrases are summed up in the grouped hazard “CMR & CT”. The precautionary principle is particularly strongly emphasised here. As an alternative only proven carcinogenic, mutagenic repro-toxic and chronically toxic hazards or their H-phrases could be grouped. Then the grouped hazard would not contain H361d, H362, H341, H351, H361f and H373.

FIGURE 2: GROUPED HAZARDS FOR SD5

		Health Hazards										Aquatic Hazards		
		Category A					Category B					Category A	Category B	
Grouped hazards	**Shortcut**	H340 H350 H360	H372	H334	H317	H361d H362	H300 H310 H330 H301 H311 H331	H341 H351 H361f	H373	EUH029 EUH031 EUH070 H370	WIDES data gap	H400 (M≥1000) H410 (M≥100)	H400 (M≥10) H410 (M≥1)	WIDES data gap
Proven and/or suspected carcinogenic, mutagenic, repro-toxic and/or chronically toxic hazard	CMR & CT	H340 H350 H360	H372			H361d H362		H341 H351 H361f	H373					
Proven sensitising hazard	SENS			H334	H317									
Hazard to the aquatic environment	AQUATIC											H400 (M≥1000) H410 (M≥100)	H400 (M≥10) H410 (M≥1)	

Adapted Hazardous Load

Per definition one ingredient can only contribute once to a grouped hazard respectively hazardous load. The hazardous load has been adapted to this specification as follows:

$$Adapted\ \text{hazardous load (kg)}] = \frac{Hazardous\ load\ (kg)}{number\ of\ H-phrases\ contributing\ to\ the\ grouped\ hazard}$$

Example (see also Figure 3): H372 and H361 of *Aminoalkylglycin* each cause 5 kg and a total of 10 kg of hazardous load. The adapted load for grouped hazard CMR & CT is 5 kg. H372 and H351 of *Polyhexamethylene biguanide* each cause 1.2 kg and a total of 2.4 kg of hazardous load. The adapted load for grouped hazard CMR & CT is 1.2 kg.

FIGURE 3: ADAPTED HAZARDOUS LOADS OF SD5

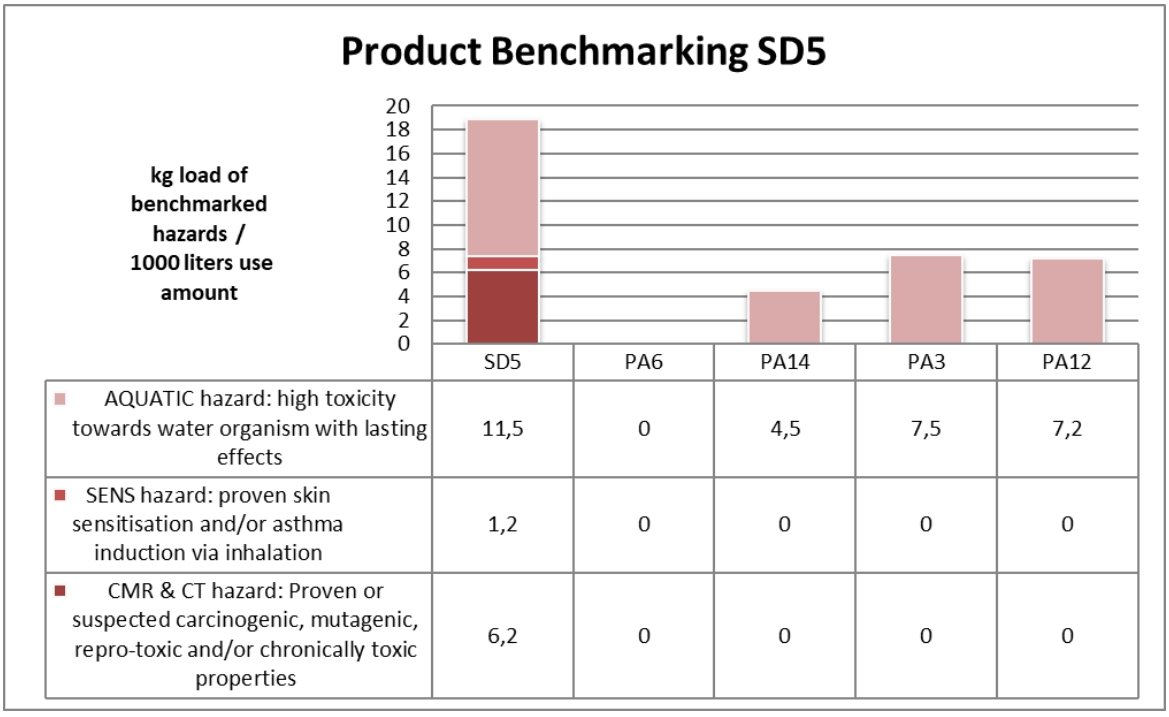
SD5			Health Hazards										Aquatic Hazards			Adapted Hazardous Load (kg)		
			Category A					Category B					Category A	Category B				
Ingredient	H-phrases	%	H340 H350 H360	H372	H334	H317	H361 d H362	H300 H310 H330 H301 H311	H341 H351 H361f	H373	EUH029 EUH031 EUH070 H370	WIDES data gap	H400 (M≥1000) H410 (M≥100)	H400 (M≥10) H410 (M≥1)	WIDES data gap	CMR & CT	SENS	AQUATIC
Didecyldimethylamoniumchlorid	H301, H314, H400(M10), H411	0,53						5,3				#		5,3				5,3
Aminoalkylglycin	H302, H314, H361f, H372, H400(M10), H410(M1)	0,5		5					5					5		5		5
Polyhexamethylenbiguanid-HCL	H302, H317, H318, H330, H351, H372, H400(M10), H410(M10)	0,12		1,2		1,2		1,2	1,2					1,2		1,2	1,2	1,2
															Overall	6,2	1,2	11,5

Benchmarking result

For SD5, the hazard analysis determines substitution requirement and a product benchmarking is carried out. The benchmarking for an (assumed) use amount of 1000 litres (concentrate) gives an overall adapted hazardous load of 18.9 kg. This load consists of 6,2 kg load with proven or suspected carcinogenic, mutagenic, repro-toxic and/or chronically toxic properties, 1,2 kg with proven sensitising properties and 11,5 kg hazardous load with a danger to the aquatic environment. The product alternatives PA3, PA6, PA12 and PA14 were selected and hazardous loads were calculated: PA3, PA6, PA12 and PA4 contain 0 kg with proven or suspected carcinogenic, mutagenic, repro-toxic and/or chronically toxic properties and 0 kg with sensitizing properties. PA6 contain 0 kg, PA14 contain 4.5 kg, PA12 contain 7.2 kg and PA3 contain 7.5 kg of hazardous load with a danger to the aquatic environment.

Therefore - with a preference for PA6 - PA6, PA14, PA12 and PA3 are all recommended product alternatives.

FIGURE 4: BENCHMARKING RESULTS FOR SD5 AND PRODUCT ALTERNATIVES



	SD5	PA6	PA14	PA3	PA12
AQUATIC hazard: high toxicity towards water organism with lasting effects	11,5	0	4,5	7,5	7,2
SENS hazard: proven skin sensitisation and/or asthma induction via inhalation	1,2	0	0	0	0
CMR & CT hazard: Proven or suspected carcinogenic, mutagenic, repro-toxic and/or chronically toxic properties	6,2	0	0	0	0