SUBSTANCE- AND PRODUCT ASSESSMENT OF THE WIDES DATABASE

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Content

INTRODUCTION

The routine use of disinfectants in hospitals and other hygienic areas at risk serves to protect against infections and thus to protect health. On the other hand, many disinfectants have properties that are harmful to the environment and health. With frequent contact, disinfectants can damage the skin and mucous membranes or cause allergies. If active substances enter the wastewater, depending on their longevity and toxicity, they damage aquatic organisms or impair the function of sewage treatment plants. Disinfectant agents burden people and the environment in different types and intensity. The information available on products – labelling, safety data sheet and product data sheet – does not constitute an instrument for making a quick and reliable selection in procurement and application. The disinfectant database of the City of Vienna (WIDES) fulfils this requirement: it brings together the available information, evaluates the hazard potentials and illustrates them by means of a colour code. The basis is a comparative substance and product assessment developed for this purpose, the WIDES assessment. Their basics and rules are presented and explained here.

For the assessment of the risks of substances and products, information is required on which dose an organism is exposed to or which concentrations enter or are expected to enter the environment. This exposure assessment, together with the characterisation of the risk potential, is part of a risk assessment, which in turn is the basis for restrictions, bans or limit values.

The assessment in WIDES does NOT provide an exposure assessment and is therefore NOT a risk assessment. The WIDES assessment cannot and does not want to make any statements about the probability of risks occurring. Instead, the WIDES assessment is based on the precautionary principle by enabling product comparisons and a substitution test in the sense of an integrated occupational and environmental protection. It is most comparable to occupational health and safety assessment models.

The aim of the assessment is to compare products with identical applications. For example, products for hand disinfection, wiping surface disinfection or manual instrument disinfection are compared with each other.

SUBSTANCE ASSESSMENT

The WIDES database currently contains 204 substance entries (December 2023). Each substance is assigned to one of the following groups. Biocidal active substance: Is included in the EU Biocidal Products Regulation (BPR) as active substance in Product type 1 and/or 2[1]. Co-formulant: Covers ingredients listed in the safety data sheet having hazardous properties. A co-formulant has neither biocidal nor pronounced surface-active properties. A list entry is used to record fragrances and dyes that are not further specified in the safety data sheet Fragrance: These are substances added to disinfectants primarily because of their odour. Surfactant: Covers ingredients which are applied primarily because of their surface-active properties. The following table shows the assignations:

Biocidal active substances in Product type 1 and/or 2	51
Co-Formulants (including 7 list entries)	86
Surfactants	56
Flagrances	11
ALL	204

HAZARD CATEGORIES

The WIDES substance assessment is the basis of the WIDES product assessment and considers health and environmental effects by means of hazard categories. These categories describe adverse properties of disinfectants for humans and the aquatic environment. 6 categories are applied both to substances and products. Hazard category "Flammability" assesses the fire hazard arising with the application of flammable, predominantly alcoholic products.

Hazard category	Type of hazard	Applied to
Acute toxicity (respiratory tract)	Health	Substances & products
Irritation and corrosivity		
Sensitisation, allergenic potential		
Mutagenic, carcinogenic, toxic for reproduction, chronically toxic		
Behaviour in surface waters - acute	Aquatic environment	
Behaviour in surface waters - chronic		
Flammability	Fire hazard	Only products (with alcohol)

[1] These product types are reserved for biocidal products which are directly applied to humans or applied to surfaces, instruments, laundry and dishes for disinfecting purposes.

ASSESSMENT NUMBERS

The extent of a hazard is described in the substance assessment by integer assessment numbers and a colour code:

1	No hazard
2	Low toxic hazard
3	Medium toxic hazard
4	High toxic hazard
5	Very high toxic hazard
6	Very very high toxic hazard
7, 8	Extremly high toxic hazard
n.b.	No assessment
?	Incomplete database

The relationship between assessment numbers (AN) and testing data respectively substance classifications will be explained in detail in the following sections. While assessment numbers 2 to 7[2] express an increasing hazard potential, assessment number 1 excludes a hazard potential on a sufficient data basis. Data gaps or data insecurities are indicated by a question mark. If a substance – and this only affects surfactants – is not assessed in a hazard category, this is indicated by “n.b.” for "not assessed". assigned

[2] Currently, assessment numbers > 7 are not needed for the WIDES assessment. In principle numbers higher than 7 may be required for H-statement H400 with an M-factor ≥ 100,000 respectively H410 with M-factor ≥ 10,000.

ASSESSMENT SCHEME (OVERVIEW)

The WIDES assessment scheme mainly relies on hazard statements. A hazard statement respectively H phrase consists of the letter H and a three-digit number. H statements are used for labelling and classification of the hazardous properties of substances and preparations. Hazard statements are used world-wide in accordance with the globally harmonised classification and labelling system, or GHS system for short. In the EU it is are implemented with the CLP Regulation. The following table shows how hazard statements in a specific hazard category are assigned to assessment numbers:

Assessment number	7	6	5	4	3	2
Acute toxicity (respiratory tract)	-	H300 H310 H330	H301+H314 H311+H314 H331+H314 EUH032	H301 H311 H331 EUH029 EUH031 EUH070 H370	H302 H312 H332 H371	H304 H336*
Irritation and corrosivity	-	-	H314 (A)	H314 (B,C) H318 H281	EUH071	H315 H319 H335 EUH066*
Sensitisation, allergenic potential	-	-	H334	H317	-	-
Mutagenic, carcinogenic, toxic to reproduction, chronically toxic	-	H340 H350 H360	H372	H341 H351 H361df H362	H373	-
Behaviour in surface waters - acute	H400 (M10000)	H400 (M1000)	H400 (M100)	H400 (M10)	H400 (M1)**	-
Behaviour in surface waters - chronic	H410 (M1000)	H410 (M100)	H410 (M10)	H410 (M1)**	H411	H412 H413

* Currently no assessment practice; ** or no value

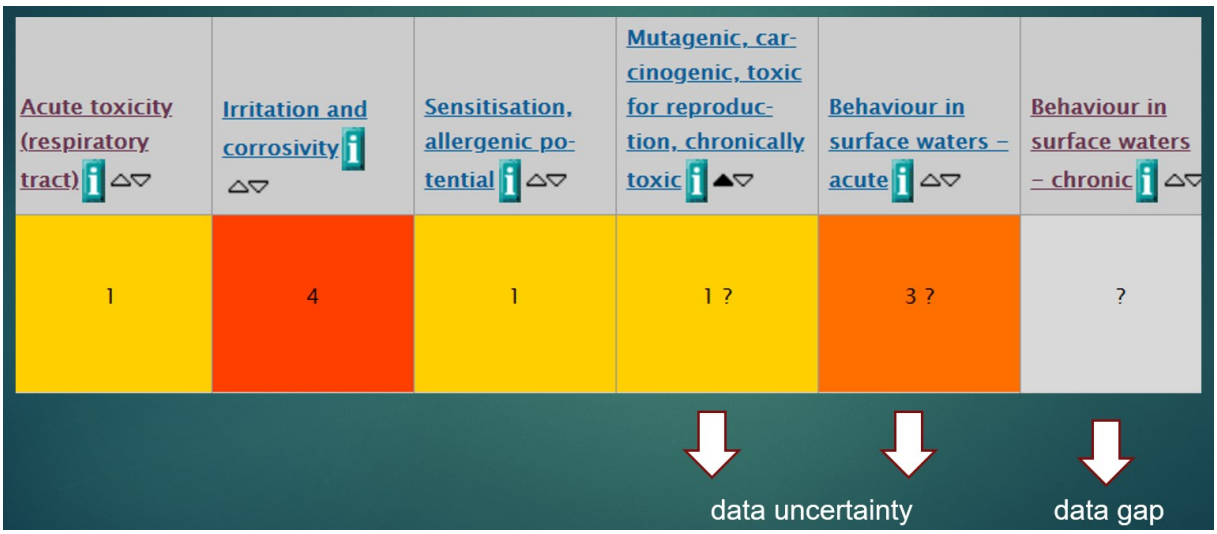
DATA BASIS

Since the hazard statements play such an important role in the assessment of substances, the origin of the H-statements is of relevance. WIDES prefers classifications drawn up or audited by an independent authority. These may include, for example, classifications drawn up under the EU Biocidal Products Regulation. Such independent sources are currently only partially available. For this reason, the WIDES mainly uses chemical classifications from the manufacturer's REACH registration dossiers. The sources of classification of WIDES substances are (April 2021):

REACH Registration Dossier	50 %
ECHA Infocard	20 %
Harmonised Classification	19 %
Risk Asssessment Report, Opinion of the Biocidals Product Committee (BPC), Opinion of the Committee for Risk Asssessment (RAC)	6 %
Material Safety Data Sheet	2 %
Without classification (because list entry)	3 %

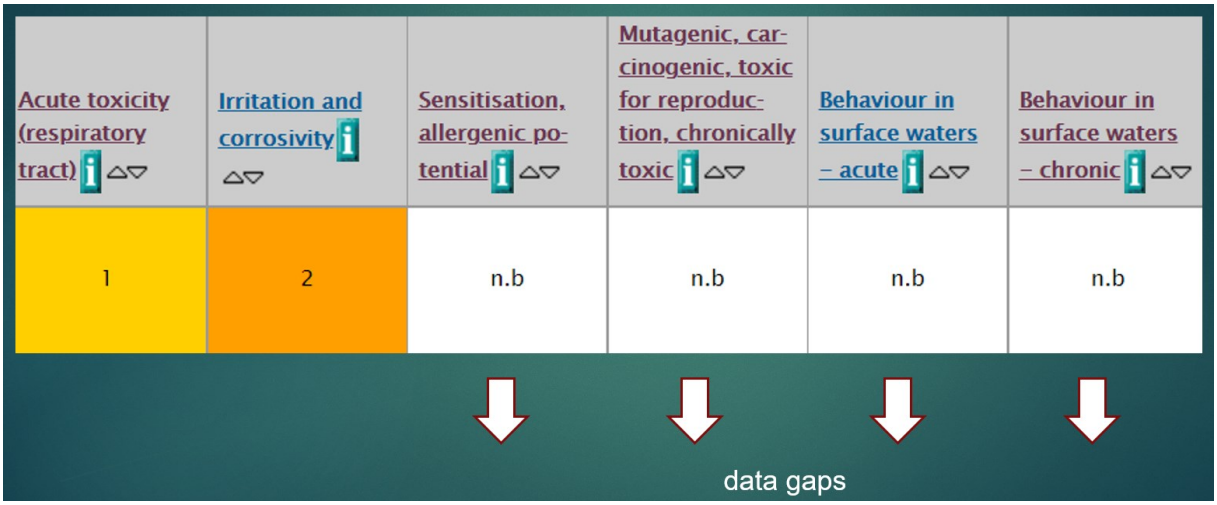
DATA GAP, DATA UNCERTAINTY

If a data gap or data uncertainty occur during the assessment of a substance, the WIDES assessment indicates this by a question mark. "Data gap" means: There are no data available to assess the substance in the hazard category. "Data uncertainty" means, that the available data are fraught with insecurity. In this case, we add a question mark to the assigned assessment number. The following screenshot shows a substance assessment in 6 hazard categories with a data gap and data insecurities in 3 hazard categories:



DATA GAP IN SURFACTANTS

The assessment of surfactants differs from that of other ingredients in the following point: data gaps in the hazard categories sensitization- allergenic potential, mutagenic, carcinogenic, toxic for reproduction, chronically toxic and behaviour in surface waters acute and chronic are not indicated with a question mark but are reported as not assessed (with n.b.). This ensures that question marks are only used as an indicator of data gaps for substance groups of high concern, especially for biocidal active substances. We further assume that surfactants are fully investigated concerning their acute toxic and irritating hazard potential. If there is no classification in the hazard categories “Acute toxicity (respiratory tract)” and “Irritation and corrosivity”, then assessment number 1 is assigned.



HAZARD CATEGORIES

The following section describes the hazard categories in detail:

ACUTE TOXICITY (RESPIRATORY TRACT)

Acute toxicity is the harmful effect that occurs when a substance is administered orally or dermally in a single dose or within 24 hours in several doses or inhaled for 4 hours. If a substance has both a toxic and a corrosive effect, then hazard statements are combined.

AN	H-statement	Wording
6	H300, H310, H330	Fatal if: swallowed, in contact with skin, inhaled
5	H301, H311, H331 + H314	Toxic if: swallowed, in contact with skin, inhaled AND causes severe skin burns and eye damage
	EUH032	Contact with acids liberates very toxic gas
4	H301, H311, H331	Toxic if: swallowed, in contact with skin, inhaled
	EUH029	Contact with water liberates toxic gas
	EUH031	Contact with acids liberates toxic gas
	EUH070	Toxic by eye contact
	H370	Causes damage to organs
3	H302, H312, H332	Harmful if: swallowed, in contact with skin, inhaled
	H371	May cause damage to organs
2	H304	May be fatal if swallowed and enters airways
	H336*	May cause drowsiness and dizziness
1	Available data exclude a hazard potential	
?	Available data do not exclude a hazard potential	

* Currently not assessed

IRRITATION AND CORROSIVITY

A substance is classified as irritating or corrosive based on results of animal experiments. Irritant effect is a reversible skin damage after exposure of up to 4 hours. A substance is considered corrosive if, after exposure of more than 4 hours in at least one tested animal, it has destroyed the skin tissue.

AN	H-statement	Wording
5	Skin Corr. 1A, H314	Causes severe skin burns and eye damage
4	Skin Corr. 1 (1B or 1C), H314	Causes severe skin burns and eye damage
	H318	Causes serious eye damage
	H281	Contains refrigerated gas; may cause cryogenic burns or injury
3	EUH071	Corrosive to the respiratory tract
2	H315	Causes skin irritation
	H319	Causes serious eye irritation
	H335	May cause respiratory irritation
	EUH066*	Repeated exposure may cause skin dryness or cracking
1	Available data exclude a hazard potential	
?	Available data do not exclude a hazard potential	

* Currently not assessed

SENSITISATION, ALLERGENIC POTENTIAL

An inhalation allergen is a substance that causes hypersensitivity of the airways when inhaled. Evidence that a substance can cause specific respiratory hypersensitivity usually results from human experience. Hypersensitivity is usually expressed as asthma, but other hypersensitivity reactions such as rhinitis/conjunctivitis and alveolitis can also occur. These are clinical appearances of an allergic reaction. A skin allergen is a substance that triggers an allergic reaction when in contact with the skin. Effects observed either in humans or in animals usually justify a classification as skin allergens.

AN	H-statement	Wording
5	Resp. Sens. 1 (1A or 1B), H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
4	Skin Sens. 1 (1A or 1B), H317	May cause an allergic skin reaction
3, 2	Evidence of sensitising potential from literature but no classification	
1	Available data exclude a hazard potential	
?	Available data do not exclude a hazard potential	
n.b.	Not assessed (provided for surfactants with no biocidal activity)	

MUTAGENIC, CARCINOGENIC, TOXIC TO REPRODUCTION, CHRONICALLY TOXIC

This hazard category consists of the four subcategories. The overall assessment is determined by the highest assessment number (worst case). If a subcategory cannot be assessed, then the highest assessment number is shown together with a "?".

CARCINOGENICITY

A substance that can cause cancer or increase the incidence of cancer is considered carcinogenic. In the case of substances which have induced benign and malignant tumors in properly conducted animal studies, it must also be assumed that a person's exposure to the substance is likely to produce cancer unless there is clear evidence that the mechanism of tumor formation in humans is not relevant. Substances known to be carcinogenic in humans are classified as Carc. 1A, while substances that are likely to be carcinogenic in humans are classified in category Carc. 1B. The classification of a substance in category Carc. 2 is based on evidence from studies carried out by humans and/or animals, but not sufficient to classify the substance in category 1A or 1B.

AN	H-statement	Wording
6	Carc. 1A or 1B, H350 H350i	May cause cancer May cause cancer by inhalation
4	Carc. 2, H351	Suspected of causing cancer
1	Available data exclude a hazard potential	
?	Available data do not exclude a hazard potential	
n.b.	Not assessed (provided for surfactants with no biocidal activity)	

GERM CELL MUTAGENICITY

This category covers substances that can trigger mutations in the germ cells of humans, which can be passed on to the offspring. Classification in the Category Muta. 1A is based on positive findings from epidemiological studies in humans, 1B on positive findings in mutagenicity tests. Substances that are of concern to humans because they may trigger hereditary mutations in human germ cells will be included in the Muta. 2 based on positive findings in tests on mammals and/or in some cases from in vitro trials.

AN	H-statement	Wording
6	Muta. 1A or 1B, H340	May cause genetic defects.
4	Muta. 2, H341	Suspected of causing genetic defects
1	Available data exclude a hazard potential	
?	Available data do not exclude a hazard potential	
n.b.	Not assessed (provided for surfactants with no biocidal activity)	

REPRODUCTIVE TOXICITY

Reproductive toxicity includes impairments of sexual function and fertility in men and women as well as developmental toxicity in offspring. For classification, the sub-category reproductive toxicity is divided into the impairment of sexual function, fertility or development and in effects on or via lactation. It is known that reproductive toxic substances are placed in the category of Repr. 1A largely based on human findings. Category Repr. 1B classified substances are likely to be toxic to reproduction, the classification is largely based on data from animal studies. Substances are considered toxic to reproduction in the category Repr. 2 if findings are available in humans or in experimental animals, but these evidences are not sufficiently valid for classification of the substance in category 1.

AN	H-statement	Wording
6	Repr.1A or 1B, H360	May damage fertility or the unborn child
	H360F	May damage fertility
	H360D	May damage the unborn child
4	Repr. 2, H361	Suspected of damaging fertility or the unborn child
	H361f	Suspected of damaging fertility
	H361d	Suspected of damaging the unborn child
	Lact., H362	May cause harm to breast-fed children
1	Available data exclude a hazard potential	
?	Available data do not exclude a hazard potential	
n.b.	Not assessed (provided for surfactants with no biocidal activity)	

CHRONIC TOXICITY

A classification based on target organ toxicity (repeated exposure) means that a substance acts on a specific target organ and can thus affect the health of exposed persons. These adverse effects on health include consistent and recognisable toxic effects in humans or, relevant to human health, toxicologically clear changes in experimental animals which impair the function or morphology of a tissue/organ or have caused serious changes in the biochemistry or hematology of the organism. Target organ toxicity of STOT RE 1 are classified substances that have a clear toxic effect in humans or which, based on findings from animal studies, can be assumed to have a clear toxic effect in humans after repeated exposure. STOT RE 2 are classified substances on observations in animal studies which have produced toxic effects with relevance to human health in moderate exposure concentrations.

AN	H-statement	Wording
5	STOT RE 1, H372	Causes damage to organs through prolonged or repeated exposure
3	STOT RE 2, H373	May cause damage to organs through prolonged or repeated exposure
1	Available data exclude a hazard potential	
?	Available data do not exclude a hazard potential	
n.b.	Not assessed (provided for surfactants with no biocidal activity)	

BEHAVIOUR IN SURFACE WATERS – ACUTE

The assessment applies the classification rules for the hazard class „acute (short-term) aquatic hazard“ of the CLP regulation. Substances with a L(E)C_{50} value ≤ 1 mg/ l are classified as aquatic acute 1, H400. Additionally, a Multiplying factor (M-factor) has to be provided:

L(E)C_{50} value	Multiplying factor (M-factor)
0,1 < L(E)C_{50} ≤ 1	1
0,01 < L(E)C_{50} ≤ 0,1	10
0,001 < L(E)C_{50} ≤ 0,01	100
0,0001 < L(E)C_{50} ≤ 0,001	1000
0,00001 < L(E)C_{50} ≤ 0,0001	10000
Continue in factor 10 intervals	

AN	Classification
8	Acute 1, H400 (M 100,000)
7	Acute 1, H400 (M 10,000)
6	Acute 1, H400 (M 1,000)
5	Acute 1, H400 (M 100)
4	Acute 1, H400 (M 10)
3	Acute 1, H400 (M 1 or not specified*)
2	-
1	Available data exclude a hazard potential
?	Available data do not exclude a hazard potential
n.b.	Not assessed (provided for surfactants with no biocidal activity)

* If for H400 no M-factor is available, then the assessment number 3 is complemented with a “?” (data uncertainty)

BEHAVIOUR IN SURFACE WATERS – CHRONIC

The assessment applies the classification rules for hazard class “Long-term aquatic hazard” of the CLP regulation. Substances are classified as Chronic 1, H410 which are

- rapidly degradable with a NOEC or EC_x ≤ 0,01 mg/ l or non-rapidly degradable with a NOEC or EC_x ≤ 0,1 mg/ l or non-rapidly degradable with a $L(E)C_{50}$ ≤ 1 mg/l and/or BCF ≥ 500 or log K_{ow} ≥ 4.

Substances are classified as Chronic 2, H411 which are

- rapidly degradable with a NOEC or EC_x > 0,01 to ≤ 0,1 mg/ l or non-rapidly degradable with a NOEC or EC_x > 0,1 to ≤ 1 mg/ l and/or non-rapidly degradable with a $L(E)C_{50}$ > 1 to ≤ 10 mg/l and/or BCF ≥ 500 or log K_{ow} ≥ 4

Substances are classified as Chronic 3, H412 which are

- rapidly degradable with a NOEC or $L(E)C_x$ > 0,1 mg/ l to ≤ 1 mg/ l or non-rapidly degradable with a LC_{50}>10 to ≤ 100 mg/l and/or BCF ≥ 500 or log K_{ow} ≥ 4.

Additionally a Multiplying Factor (M-factor) has to be provided:

NOEC – value (mg/l)	Multiplying factor (M-factor)	
	Non-rapidly degradable	Rapidly degradable
0.01 < NOEC ≤ 0.1	1	-
0.001 < NOEC ≤ 0.01	10	1
0.0001 < NOEC ≤ 0.001	100	10
0.00001 < NOEC ≤ 0.0001	1000	100
0.000001 < NOEC ≤ 0.00001	10,000	1000
Continue in factor 10 intervals		

AN	Classification
8	Chronic 1, H410 (M 10,000)
7	Chronic 1, H410 (M 1,000)
6	Chronic 1, H410 (M 100)
5	Chronic 1, H410 (M 10)
4	Chronic 1, H410 (M 1 or not specified)*
3	Chronic 2, H411
2	Chronic 3, H412
1	Available data exclude a hazard potential
?	Available data do not exclude a hazard potential
n.b.	Not assessed (provided for surfactants with no biocidal activity)

* If for H410 no M-factor is available, then the M-Factor for H400 is taken. If for H400 also no M-Factor is available, then the assessment number is complemented with a “?” (data insecurity)

ABC CATEGORIZATION

This identifies active ingredients and ingredients with a colour code, making it easier to select safe disinfectants. A distinction is made between hazards of concern and those of less concern. Based on the substance classification (H-phrases)[3] and (missing) data that exclude a hazard, a category is assigned to a substance respectively it is marked with red, yellow, or white.

CATEGORY A (RED)

Category A with colour RED stands for a very high hazard. Substances classified as mutagenic, carcinogenic, toxic to reproduction[4], chronically toxic, allergenic, or very highly toxic to water are assigned to this category. Disinfectants containing category A substances should be avoided or replaced (i.e. substituted) with less harmful ones. Category A covers substances that can cause high and/or irreversible damage even in low concentrations.

However, the following should be noted: The hazard posed by a substance always depends on the context of application. For this reason, the need for substitution must always be considered in the context of the actual exposure of humans and the environment in the application and disposal of disinfectants.

Here is a practical example: If an active ingredient with a high hazard potential for surface disinfection is used for surface disinfection in disposable wipes, the unreacted active ingredient ends up in the waste incineration plant with the used cloth. In this case, there is hardly any reason to fear a water hazard and substitution for the protection of water bodies is therefore not necessary.

Substances that are assigned to category A due to their carcinogenic, mutagenic, reprotoxic, chronically toxic or allergenic properties develop their health-endangering effect if persons are permanently exposed due to the application (e.g. surface disinfection). However, if such substances are used in closed systems (e.g. washing machines, endoscope reprocessing), this is less of a concern if exposure is largely avoided in the work process. However, for such application examples, environmental hazards are a relevant topic.

To achieve a desired antimicrobial effect (e.g. sporicidal in surface disinfection), sometimes only a very limited number of suitable active ingredients or products are available. In extreme cases, the selection may be limited to one active ingredient. When weighing up the benefit-risk ratio, there may therefore be no alternative to using a disinfectant with a category A substance.

The substance categorisation of the WIDES serves the precautionary principle. Ultimately, however, it remains the responsibility of the procurers to make the best selection in each case, considering employee protection, environmental protection and infection protection at the same time. Currently, about 40 (out of a total of about 200) substances are assigned to

[3] A hazard statement consists of the letter H and a three-digit number, are used under the Globally Harmonised System for Classification and Labelling of Chemicals (GHS) and implemented in the EU-CLP Regulation.

[4] Substances for which the hazard to damage the unborn child is only suspected also fall into this category.

category A in the WIDES, most of them due to allergenic (skin-sensitizing) properties. The substance category can be queried in the WIDES under "Show ingredient overview". If you want to know due to which properties or H-phrases category A was assigned to a certain substance, this information can be found on the respective ingredient page under "General substance information".

Category A – high concern (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
H361d	Suspected of damaging the unborn child
H362	May cause harm to breast-fed children
H340 **H350** **H360**	May cause genetic defects May cause cancer May damage fertility or the unborn child
Category A – high concern (aquatic hazard)	
H400 (M ≥ 1000)[5]	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 highe than 100

CATEGORY B (YELLOW)

Category B covers hazards with significant adverse effects on human health and the aquatic environment. These include, among other things, acute-toxic as well as suspected carcinogenic, mutagenic, and repro-toxic effects. Data gaps and data uncertainties are also assigned to category B. If a substance is assigned to category B, product alternatives should also be considered depending on the context of use.

H-phrases, which classify acute toxicity, are assigned to category B because their effect is concentration-dependent and decreases significantly with the usual dilution. Long-term exposure to a substance that is acutely toxic (H300: fatal if inhaled) and at the same time corrosive (e.g. H314: causes severe skin burns and eye damage) can generate chronic symptoms if exposed to it over a long period of time (e.g. peracetic acid).

This means that even for substances that are "only" assigned to category B (yellow) based on their acute toxic properties, substitution by alternatives should be considered in the event of a very high and permanent exposure. Here, too, substance categorisation can only support selection processes and it ultimately remains the responsibility of the procurer to select

[5] M is a multiplication factor that weights highly toxic substances accordingly. If a substance is classified as aquatic acute 1 or aquatic chronic 1, then a multiplication factor is to be assigned to the H-phrase according to the EU CLP Regulation.

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properly. If you want to know on which properties or H-phrases a certain substance is assigned to category B, this information can be found on the ingredient page under "General substance information".

Category B – considerable concern (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**	May probably cause genetic effects May probably cause cancer May likely affect fertility
H373	May cause damage to the organs through prolonged ore repeated use
EUH029 **EUH031** **EUH070**	Contact with water liberates toxic gases Contact with acid liberates toxic gases Toxic by eye contact
H370	Causes damage to the organs
Category B – considerable concern (hazard for the aquatic environment)	
H400 (M ≥ 10)[6]	Very toxic to aquatic life and M-factor equal or higher than 10
H410 (M ≥ 1)[5]	Very toxic to aquatic life with long-lasting effects and M-factor equal to or higher than 1
Category B – considerable concern (data gap, data uncertainty)	
The WIDES database indicates that there is not enough knowledge about the acute-toxic, allergenic, mutagenic, carcinogenic, reprotoxic or chronically toxic hazard.	
The WIDES database indicates that there is not enough knowledge about the acute or chronically aquatic hazard.	

[6] M is a multiplication factor that weights highly toxic substances accordingly. If a substance is classified as aquatic acute 1 or aquatic chronic 1, then a multiplication factor is to be assigned to the H-phrase according to the EU CLP Regulation.

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CATEGORY C (WHITE)

Category C, marked with the colour white, mainly covers corrosive properties expressed by the H-phrases H314 and H318. In compliance with the prescribed protective measures such as the obligation to wear gloves, safety goggles, etc., this category can be assumed to have rather limited, controllable health hazards with mostly only reversible damage. We consider that corrosive properties decrease with dilution and that most disinfectants have low concentrations of highly corrosive active ingredients. Although hazards associated with category C are not negligible, preference should be given to the use of such substances. This applies to category C biocidal active substances, such as oxygen separators or organic acids.

Category C – low concern (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
Category C – low concern (aquatic hazard)	
H400 (M < 10)[7]	Very toxic to aquatic life and M-factor lower than 10
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] M is a multiplication factor that weights highly toxic substances accordingly. If a substance is classified as aquatic acute 1 or aquatic chronic 1, then a multiplication factor is to be assigned to the H-phrase according to the EU CLP Regulation.

ASSESSMENT GLUTARALDEHYDE

The following shows the assessment of biocidal active ingredient “Glutaraldehyde” in 6 hazard categories. First of all important substance data such as substance name incl. synonyms, CAS number, substance category, substance group, classification, vapour pressure including correction factors and a reference link to substance data are displayed:

Name:	Glutaraldehyd
Synonyms:	1,5-pentanedial Glutaral
CAS number:	111-30-8
EINECS number:	203-856-5
Substance category:	Kategorie A (hohe Gefährdung) / Category A (high hazard)
Group of substances:	Biozider Wirkstoff (notifiziert in PT1 und/oder PT2) / Biocidal substance (notified in PT1 and/or PT2)

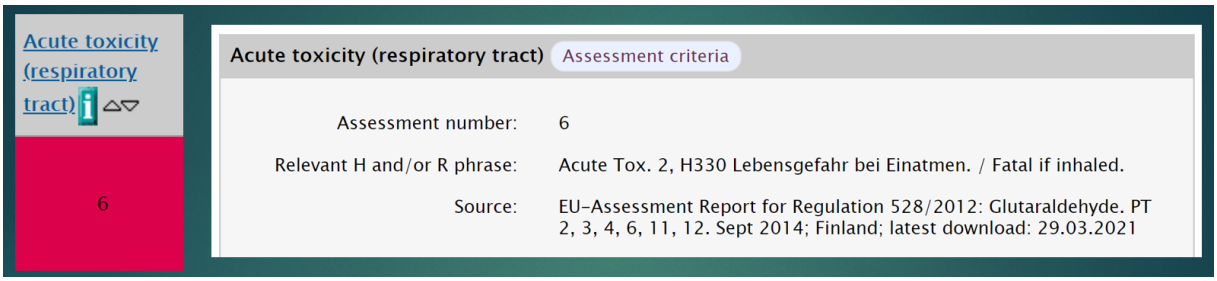
Classification as hazardous material according to WIDES:	GHS05-GHS06-GHS08-GHS09
H and/or R phrases:	H400 (M1) : Sehr giftig für Wasserorganismen mit M-Faktor 1 / very toxic to aquatic life with M-factor 1 H411 : Giftig für Wasserorganismen, mit langfristiger Wirkung. / Toxic to aquatic life with long lasting effects. EUH 071 Wirkt ätzend auf die Atemwege. / Corrosive to the respiratory tract. Acute Tox. 3, H301 Giftig bei Verschlucken / Toxic if swallowed. Skin Corr. 1B, H314 Verursacht schwere Verätzungen der Haut und schwere Augenschäden / Causes severe skin burns and eye damage Skin Sens. 1A, H317 Kann allergische Hautreaktionen verursachen / May cause an allergic skin reaction. Acute Tox. 2, H330 Lebensgefahr bei Einatmen. / Fatal if inhaled. Resp. Sens. 1, H334 Kann bei Einatmen Allergie, asthmaartige Symptome oder Atembeschwerden verursachen / May cause allergy or asthma symptoms or breathing difficulties if inhaled STOT SE 3, H335 Kann die Atemwege reizen. / May cause respiratory irritation.
Source:	EU-Assessment Report for Regulation 528/2012: Glutaraldehyde. PT 2, 3, 4, 6, 11, 12. Sept 2014; Finland; latest download: 29.03.2021

Vapour pressure:	28 hPa(25°C)
Human toxicity factor:	0.70
Eco-toxicity factor:	0.70

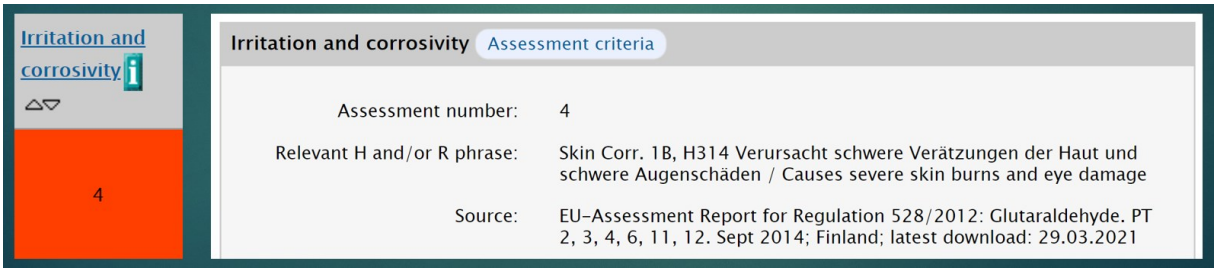
Links to substance data

https://echa.europa.eu/de/information-on-chemicals/biocidal-active-substances/-/disas/substance/100.003.506

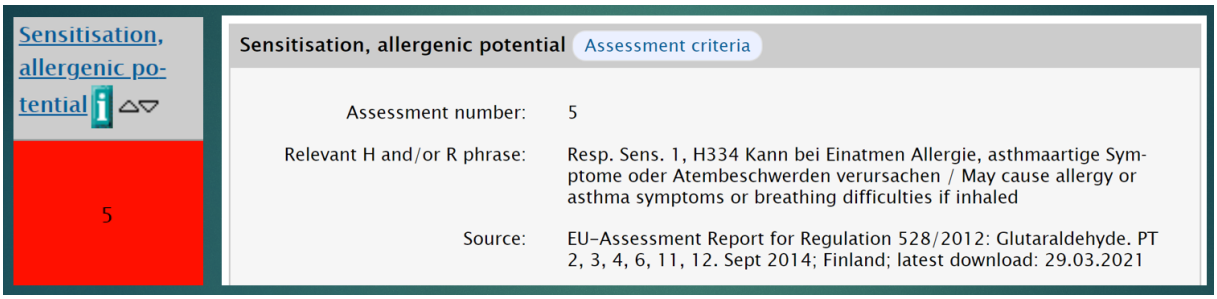
Glutaraldehyde is classified with the hazard statement H330 – fatal if inhaled – causing assessment number 6 in the hazard category Acute toxicity:



Then glutaraldehyde is classified with hazard statement 1B, H314 - causes severe burns to the skin and severe eye damage. This classification leads to assessment number 4 in the hazard category Irritation and corrosivity:



Glutaraldehyde is further classified with hazard statement 334: may cause allergy or asthma symptoms or breathing difficulties if inhaled. This leads to assessment number 5 in the hazard category Sensitisation, allergenic potential. The source of the classifications is an assessment report prepared for the EU Biocidal Products Regulation:



The assessment of Glutaraldehyde in the hazard category Mutagenic, carcinogenic, toxic for reproduction, chronically toxic is the result of 4 partial assessments. The total assessment number results from the highest partial assessment number. In the present example a hazard is excluded in all partial assessments based on the data available and thus glutaraldehyde is assessed with 1 in the overall hazard category:

mutagenic:

assessment number 1

Substance data

Substance data set	Impact type	Test method	Results	Notes
Muta 2	Mutagenität/Gentoxizität		"Classification for genotoxicity is not proposed."	
	Source: EU-Assessment Report for Regulation 528/2012: Glutaraldehyde. PT 2, 3, 4, 6, 11, 12. Sept 2014; Finland; latest download: 29.03.2021			
Muta 1	Mutagenität/Gentoxizität		"Germ cell mutagenicity conclusive but not sufficient for classification."	
	Source: REACH registration dossier - glutaraldehyde - full registration (GHS classification & labelling, latest download: 29.03.2021)			

carcinogenic:

assessment number 1

Karz 3	Kanzerogenität		"Risk Assessment Committee (RAC) did not consider the appearance of LGLL and Leydig cell tumours as being relevant to humans and classification for carcinogenicity was not proposed."	
	Source: EU-Assessment Report for Regulation 528/2012: Glutaraldehyde. PT 2, 3, 4, 6, 11, 12. Sept 2014; Finland; latest download: 29.03.2021			
Karz 1	Kanzerogenität		"Carcinogenicity conclusive but not sufficient for classification."	
	Source: REACH registration dossier - glutaraldehyde - full registration (GHS classification & labelling, latest download: 29.03.2021)			

toxic to reproduction:

assessment number 1

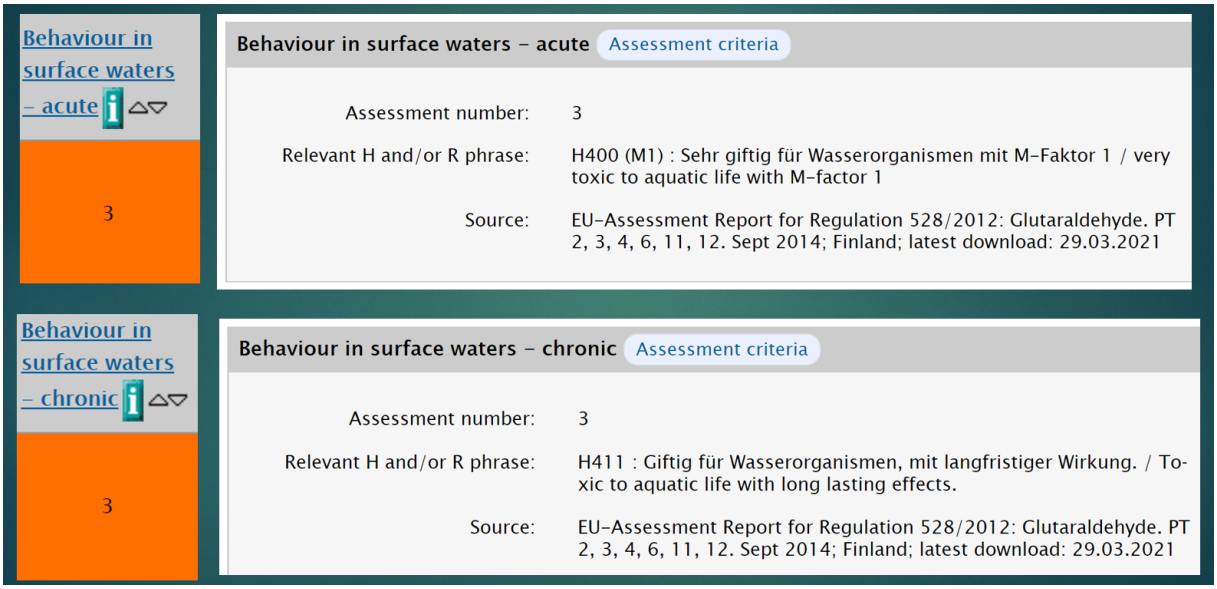
Substance data set	Impact type	Test method	Results	Notes
Repro 2	Reproduktionstoxizität		"There is no ground for classification for teratogenicity."	
	Source: EU-Assessment Report for Regulation 528/2012: Glutaraldehyde. PT 2, 3, 4, 6, 11, 12. Sept 2014; Finland; latest download: 29.03.2021			
Repro 1	Reproduktionstoxizität		"Reproductive toxicity / effects via lactation conclusive but not sufficient for classification."	
	Source: REACH registration dossier - glutaraldehyde - full registration (GHS classification & labelling, latest download: 29.03.2021)			

chronically toxic:

assessment number 1

Substance data set	Impact type	Test method	Results	Notes
STOT wdh 2	Spezifische Zielorgan-Toxizität-wiederholte Exp.		"NOAEL/LOAEL not established: skin irritation but no systemic effects."	
	Source: EU-Assessment Report for Regulation 528/2012: Glutaraldehyde. PT 2, 3, 4, 6, 11, 12. Sept 2014; Finland; latest download: 29.03.2021			
STOT wdh 1	Spezifische Zielorgan-Toxizität-wiederholte Exp.		"Specific target organ toxicity - repeated conclusive but not sufficient for classification."	
	Source: REACH registration dossier - glutaraldehyde - full registration (GHS classification & labelling, latest download: 29.03.2021)			

As far as the hazard for the aquatic environment is concerned, glutaraldehyde is classified with hazard statement H400 - very toxic to aquatic organisms - and hazard statement 411 - toxic to aquatic organisms with long-term effects. These hazard statements require the assessment number 3 - both in the hazard category - behaviour in surface waters - acute and chronic.



PRODUCT ASSESSMENT

The central element of the product assessment is a logarithmic scaling of the substance assessment number (AN) and the multiplication by the substance fraction. Logarithmic scaling means that from an assessment number according to the formula 10^{AN} a hazard factor is calculated. The aim of the product assessment is to compare hazards for types of applications.

READY TO USE PRODUCTS

Ready to use products are not diluted before use. These include skin and hand sanitizers, as well as alcoholic and aqueous products for rapid disinfection of surfaces and disinfectants for hand washing. In the example an aqueous disinfectant contains ingredient A and B. A is classified as respiratory sensitizing with hazard statement H334. For that reason, A receives assessment number 5. The logarithmic scaling with the formula 10 high assessment number leads to the hazard factor 100,000. B is not classified but indicated to be a “very weak contact allergen” in a data base for occupational health. It therefore receives assessment number 2. “Unrated substance content” means the solvent water and any other ingredient without a hazard statement and therefore not mentioned with classification in the safety data sheet. Approximately it is assumed that this product share does not cause any hazards and therefore assigns the assessment number 1 (no hazard) and the hazard factor 10.

Ingredient	Data basis for AN	AN	Hazard factor 10^{AN}
A	Resp. Sens 1, H334	5	100,000
B	„very weak contact allergen“	2	100
Unrated substance content	-	1	10

The hazard factors are multiplied by the respective substance fraction – this is the concentration divided by 100. Then all shares are summed up and the sum is delogarithmized. In this example the product assessment number of the disinfectant in the hazard category “Sensitisation, Allergenic Potential" is 2.0.

Ingredient	Conc. %	Substance fraction $\frac{Conc\ (\%)}{100}$	Hazard factor x substance fraction
A	0.08	0.0008	100,000 x 0.0008 = 80
B	10	0.1	100 x 0.1 = 10
Unrated substance content	89.92	0.8992	10 x 0.8992 = 8.992
Product assessment number			$\log_{10}$ 99 = 2.0

CONCENTRATES (WITH DILUTION)

Concentrates are products for instrument-, laundry-, dishes- and wiping surface disinfection. The calculation example shows an aqueous disinfectant with two ingredients A and B. A is classified as respiratory sensitising with hazard statement H334 and assessment number 5. 5 receives with the formula $10^{\text{Assessment Number}}$ the hazard factor 100,000. B is not classified but indicated to be a "very weak contact allergen" in a data base for occupational health. It therefore receives assessment number 2. "Unrated substance content" means the solvent water and any other ingredient without a hazard statement and therefore not mentioned in the safety data sheet. Approximately it is assumed that this product share does not cause any hazards and therefore assigns the assessment number 1 (no hazard) and the hazard factor 10.

Ingredient	Data basis for AN	AN	Hazard factor 10^{AN}
A	Resp. Sens 1, H334	5	100,000
B	„very weak contact allergen"	2	100
Unrated substance content	-	1	10

After logarithmic scaling and the multiplication with the respective substance fraction - this is the concentration divided by 100 - the results for the two ingredients as well as for the unrated substance content are summed up. The result is 10,018:

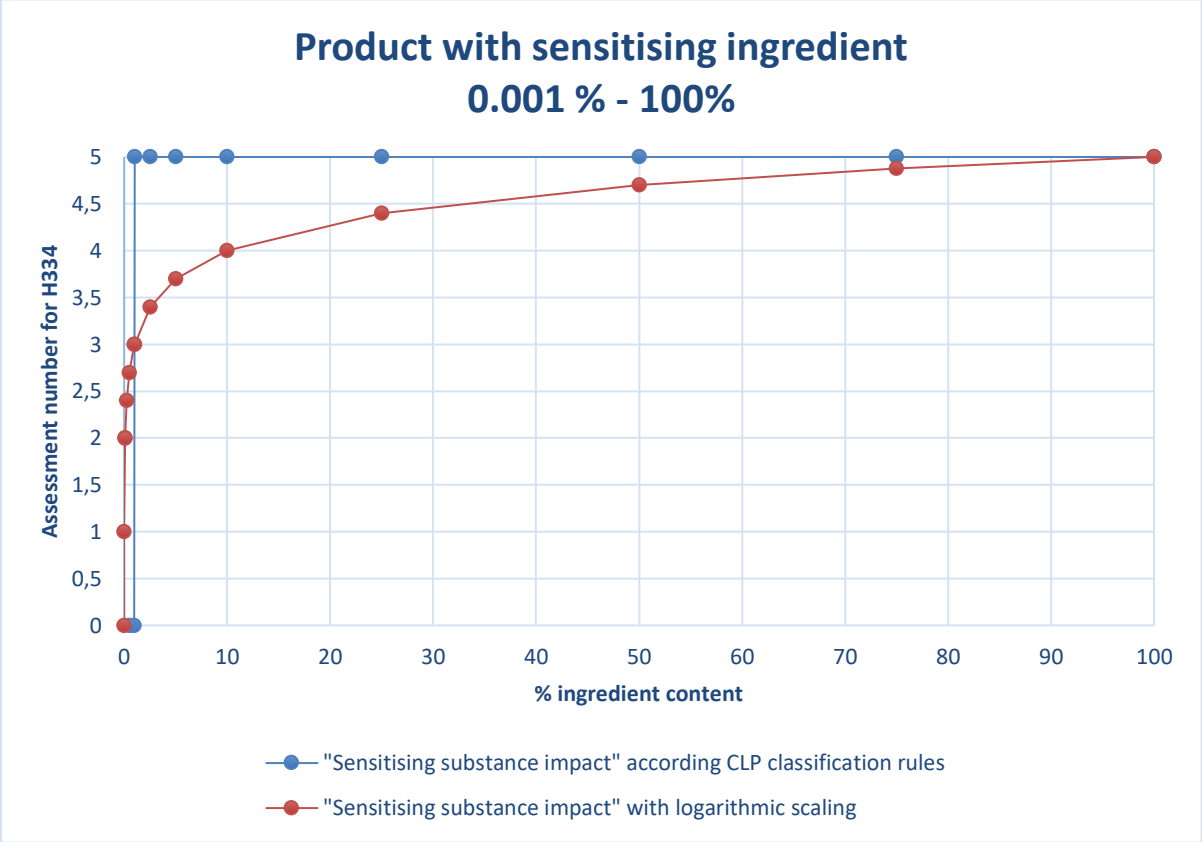
Ingredient	Conc. %	Substance fraction $\frac{Conc\ (\%)}{100}$	Hazard factor x substance fraction
A	10	0.1	100,000 x 0.1 = 10,000
B	10	0.1	100 x 0.1= 10
Unrated substance content	80	0.8	10 x 0.8 = 8

Since the concentrate must be diluted to a 0,5% solution for use, the assessment is supplemented by a dilution calculation. For that reason, the hazard factor 10,018 is multiplied by the substance fraction 0.005. In the calculation, the dilution medium water receives assessment number 0 for two reasons: Firstly, a hazard can be completely excluded with pure water and secondly, negative assessment numbers are avoided. After delogarithmization the product assessment number of application solution is 1.7:

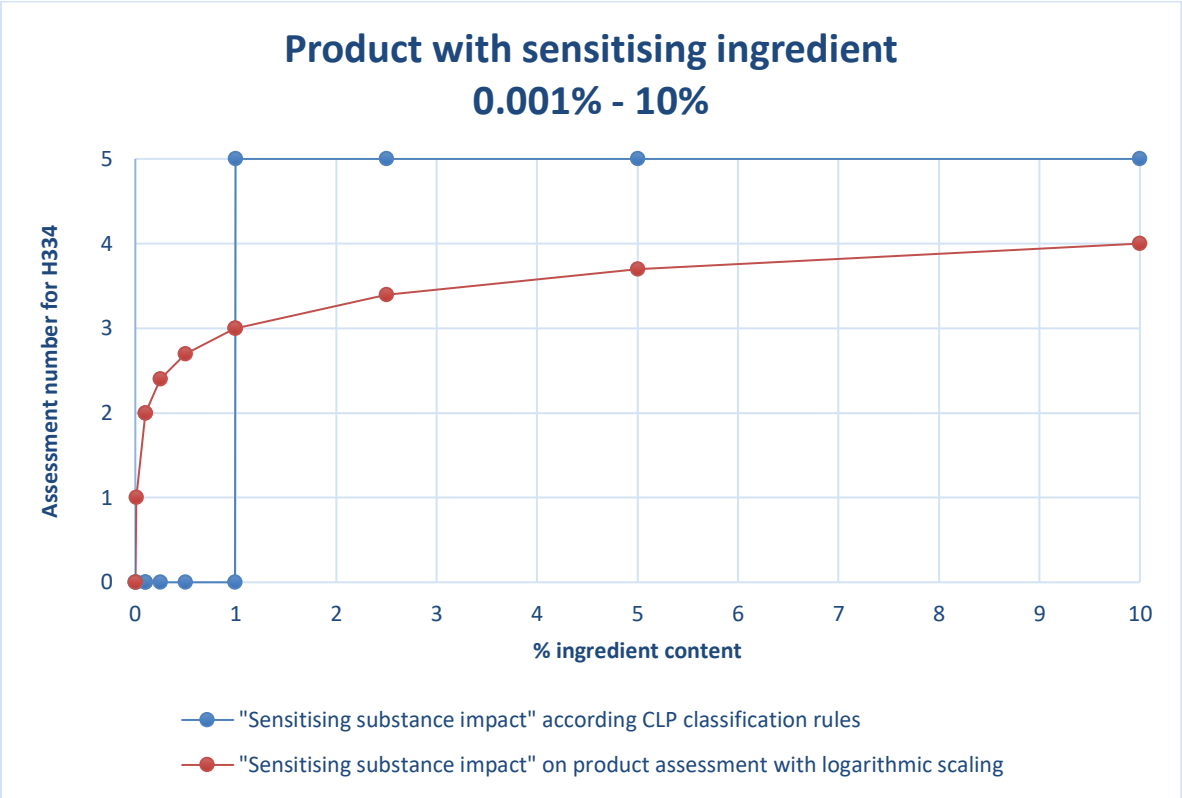
Component	AN	Conc (%)	Hazard factor (10^{AN})	Substance fraction $\frac{Conc\ (\%)}{100}$	Hazard factor x substance fraction
Concentrate		0.5	10,018	0.005	50.1
Water	0	99.5	1	0.995	1
Product assessment number of application solution					$\log_{10}$ 51.1 = 1.7

ADVANTAGES OF LOGARITHMIC SCALING

To better understand why we apply a logarithmic scaling, a comparison is made with the classification of a preparation according to the CLP Regulation containing a sensitising ingredient (classified as respiratory sensitizing H334). At a first glance it would be obvious to use classifications for product comparisons, especially as these are shown in the safety data sheet. This section therefore explains why product classifications are not useful for a comparative assessment of disinfectants as application solution. According to the CLP classification rules, a substance concentration of more than 1% requires the product to be classified as H334. If, on the other hand, the sensitizing substance is less than 1%, it is not "visible" respectively has no impact on product classification:



The effect of logarithmic scaling with low concentration (< 10 %):



Since the logarithmic scaling "smooths" the assessment over the entire concentration range and avoids jumps, product comparisons remain significant even at small concentrations and with little differences in concentration. This is particularly important when assessing substances with allergenic or CMR properties.

The following figure shows the effects of various low concentrations of the respiratory sensitising ingredient A on the product assessment number and on the corresponding colour code.

Concentrates with dilution and ready-to-use products differ in the best possible product assessment number or colour code. The reason for the difference is that in this way, in the dilution calculation of concentrates, negative assessment numbers are avoided. This difference is irrelevant since there is no possibility in the WIDES to directly compare ready-to-use products with diluted concentrates. So only products are compared which are assessed according to a completely identical calculation mode. In addition, the generally darker shade for ready to use products indicates that concentrates perform better in terms of resource consumption and transport and should be used preferentially.

EXPOSURE MODEL

The WIDES assessment considers exposure with a simple model of correction factors derived from vapour pressure. The correction factor $F\text{-}_{hum}$ considers that volatile substances can partially escape into the room air. Since they can be inhaled at the site of use, the factor weights volatile substances more strongly in the hazard category acute toxicity. Correction factor $F\text{-}_{eco}$ considers that few volatile substances can enter surface waters via the sewage treatment plant. The factor therefore weights low volatile substances more strongly in the two hazard categories behaviour in surface waters – acute and chronic.

Correction factor	Applied to	Vapour pressure (hPa/20°C)				
		≥ 1000	≥ 100 < 1000	≥ 10 < 100	≥ 1 < 10	< 1
$F\text{-}_{hum}$	Acute toxicity	1	0.8	0.7	0.5	0.3
$F\text{-}_{eco}$	Aquatic toxicity	0.3	0.5	0.7	0.8	1

The following example is intended to show how correction factor $F_{\text{-eco}}$ weights assessment in hazard category Behaviour in surface waters – chronic. For this purpose, 2 concentrates with ingredient A respectively B are compared with each other. To emphasize the effect of the exposure mode, the hazard potential, content as well as the dilution of ingredients in product 1 and 2 are identical. However, ingredient A has a low vapour pressure, ingredient B a high vapour pressure. A is therefore more likely to enter surface waters than B.

	Vapour pressure (hPa/20°C)	Data basis for AN	AN	Hazard factor (10^{AN})
PRODUCT 1				
Ingredient A	< 1	Aquat.chron.1, H410 (M10)	5	100,000
Unrated substance content	-	-	1	10
PRODUCT 2				
Ingredient B	> 1000	Aquat.chron.1, H410 (M10)	5	100,000
Unrated substance content	-	-	1	10

The integration of F_{-eco} into the product assessment gives a less favourable assessment for product 1 with the low volatile ingredient A (Assessment Number 1.9) in terms of aquatic toxicity than for product 2 with the high volatile ingredient B (Assessment Number 1.4). The difference should be perceivable in the colour code:

	Conc. %	Substance fraction $\frac{Conc.(\%)}{100}$	F_{-eco}	Hazard factor x substance fraction
PRODUCT 1 (with low volatile ingredient A)				
Ingredient A	0.06	0.0006	1	100,000 x 0.0006 x 1 = 60
Unrated substance content	99.94	0.9994	1	10 x 0.9994 x 1 = 9.994
Product Assessment Number Colour code				Log_{10} 69.994 = **1.9**
PRODUCT 2 (with high volatile ingredient B)				
Ingredient B	0.06	0.0006	0.3	100,000 x 0.0006 x 0.3 = 18
Unrated substance content	99.94	0.9994	1	10 x 0.9994 x 1 = 9.994
Product Assessment Number Colour code				Log_{10} 27.994 = **1.4**

FLAMMABILITY

The hazard category assessing the flammability is only applied to products classified as flammable. In the present case, this is caused by significant concentrations of alcohol. The overall assessment number for flammability consists of a basic assessment number derived from the product classification and supplemented by surcharges or discounts. The latter depend on the ignition temperature class, the lower explosion limit, the explosion range and/or flash point of the product.

Basic assessment number	5	4	3	2	1
Product classification	H224 Extremely flammable liquid and vapour	H225 Highly flammable liquid and vapour	H226 Flammable liquid and vapour	-	-
Surcharge & discount	-1	- 0,5	0	+ 0,5	+ 1
Ignition temperature class (°C) *	> 450 (T1)	300 - 450 (T2)	200 - 300 (T3)	135 - 200 (T4)	< 135 (T5)
Lower explosion limit** (Vol. %)	> 4	> 3-4	> 2-3	> 1-2	≤ 1
Explosion range (Vol. %)	-	-	< 50	50-70	>70
Flashpoint (°C)			>10	0-10	< 0

* if the product contains no flammable substances other than alcohols (i.e. 1-propanol, 2-propanol, ethanol), then the surcharge in the column "ignition temperature" is - 0.5.

** if the product contains no flammable substances other than ethanol, the surcharge in the column "Lower explosion limit" is - 0.5.

PRODUCT COMPARISONS

When products are compared, the following must be noted: The product assessment numbers are transformed into respectively displayed as colour codes. This is due to the following reason: The calculation is based on simplistic assumptions which can be visualized more adequately by a colour code than by an exact numerical value.

To ensure fair product comparisons, the WIDES does not allow comparisons between ready-to-use products and diluted concentrates. This is guaranteed by a query requiring information on the field of application, the exposure time and the spectrum of activity.

After the query has been carried out, WIDES does not provide a product ranking but assessed products are ranked alphabetically. But rankings can be generated within each category with a single mouse click.