WIDES ASSESSMENT 2020

Created for: Ökokauf Wien

12.10.2020

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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.

WIDES SUBSTANCE ASSESSMENT

The WIDES database contains between 220 and 230 substances. Each substance is assigned to one of the following groups. Biocidal substance: Is included in the EU Biocidal Products Regulation (BPR) as an active substance in Product type 1 and/or 2[1]. The WIDES additionally shows whether the biocidal substance is (already) approved, whether the approval is ongoing or whether no approval has been granted. Co-formulant: This group covers product ingredients listed in the safety data sheet having hazardous properties. A co-formulant has neither biocidal nor (pronounced) surface-active properties. Fragrance: These are substances used in disinfectants primarily because of their odour. Surfactant: This group covers product ingredients which are applied primarily because of their surface-active properties. While the classification as a "biocidal substance" relies on external source[2], the assignments to the other groups are made at their own discretion. The following table shows the assignations in the WIDES at December 2019:

Substances (Total)	227
Active ingredients for PT1 and/or PT2 [1]	56
Surfactants	55
Fragrances	13
Other ingredients (Co-Formulants)	103

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 aquatic organisms. While 6 categories are applied both to substances and products, flammability is solely applied to products containing alcohols.

Hazard category	Type of hazard	Applied to
Acute toxicity (respiratory tract)	Health	Substances & products
Irritation and corrosivity		
Sensitisation, allergenic potential		
Carcinogenicity, germ cell mutagenicity, reproductive toxicity, chronic toxicity		
Behaviour in surface waters - acute	Aquatic environment	
Behaviour in surface waters - chronic		
Flammability	Physical	Products (alcohol containing)

[1] These product types are reserved for disinfectants directly applied to humans or applied (in the healthcare system) to surfaces, instruments, devices.

[2] The substance entry and approval status of an active substance can be found on the ECHA website: https://echa.europa.eu/de/regulations/biocidal-products-regulation/approval-of-active-substances/list-of-approved-active-substances

Hazards are rated with assessment numbers and each number has a colour code assigned. Both number and corresponding colour express the hazard potential:

The relationship between assessment numbers (AN) and testing data respectively substance classifications will be explained in detail in the following sections. While AN 2 to 7 [3] express an increasing hazard potential AN 1 indicates that a hazard potential can be excluded confirmed by an adequate data basis. This may be a REACH dossier[4] or a Risk Assessment Report[5]. The sole absence of a classification is not sufficient to exclude a corresponding hazard potential, since classifications are not necessarily relying on a complete data set[6]. In a first step the hazard statements[7] of a substance are assigned to a hazard category respectively assessment number. The assignment was prepared in close cooperation with occupational health and safety experts, inter alia from the Austrian Workers' Compensation Board AUVA.

[3] Currently, assessment numbers > 7 are not needed for the WIDES assessment. Such may be required for H-phrases H400 with M-factor > 10000 or H410 with M-factor > 1000.

[4] https://echa.europa.eu/information-on-chemicals/registered-substances

[5] For instance created in the course of the evaluation process for active substances under the review programme of Biocidal Products Regulation.

[6] A partly deviation from this rule concerns WIDES substances designated as “surfactants” (see also chapter “assessment of surfactants”).

[7] A hazard statement describes the nature and the severity of the hazard. It consists of the letter H and a three-digit number. Hazard statements are used under the Globally Harmonised System for Classification and Labelling of Chemicals (GHS) which is implemented in the EU with the CLP Regulation.

Hazard statements, hazard categories and assessment numbers interrelates as follows:

	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	-	-
Carcinogenicity, germ cell mutagenicity, reproductive toxicity, chronic toxicity	-	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

The table shows that the substance assessment fundamentally relies on the classification of the substance. The source should stem from an independent regulatory body or should at least be checked from such a body. The classification of WIDES substances stem from (Dec. 2019):

REACH registration dossier	140	62%
ECHA Infocard[8]	38	17%
EU-Risk Assessment Report	20	9%
Material safety data sheet	11	5%
C& L Inventory[9]	8	3%
no specified data source	10	4%

[8] the ECHA Infocard aggregates all H-statements mentioned in the C&L Inventory

[9] https://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database

DATA GAPS & DATA INSECURITY

In the substance assessment a question mark "?" indicates that the available data are not sufficient neither to assign an assessment number nor to exclude a hazard potential. The question mark may indicate either a data gap or a data insecurity. Data gap: If there are no data to assess the ingredient at all in the respective category then a question mark is integrated into the hazard category and highlighted in grey. Data insecurity: If there are data to assess the ingredient but if they are inconsistent or doubted then the assessment number is followed by a question mark. The following screenshot shows a complete substance assessment in 6 hazard categories including a data gap and a data insecurity.

Acute toxicity (respiratory tract)	Irritation and corrosivity	Sensitisation, allergenic potential	Mutagenic, carcinogenic, toxic for reproduction, chronically toxic	Behaviour in surface waters – acute	Behaviour in surface waters – chronic
1	1	1	?	1	1 ?

ASSESSMENT OF SURFACTANTS

The assessment of substances designated as surfactants deviates from the rule “exclusion of a hazard potential needs an adequate data basis”. A simplified procedure ensures that the significance of question marks is not compromised. Thereby it is assumed that surfactants pose no sensitizing, carcinogenic, mutagenic, reprotoxic or chronically toxic or environmental hazard unless they are classified accordingly. This means: If a surfactant is not explicitly classified in one of these hazard categories this circumstance is indicated by a white box and "n.b." (stands for: “not assessed”). It is further assumed that surfactants are fully investigated concerning their acute toxic and irritating hazard potential. This means: If there is no classification in the hazard categories “Acute toxicity (respiratory tract)” and “Irritation and corrosivity”, then AN 1 is assigned. The following screenshot shows a surfactant with AN 2 in hazard category “Irritation and corrosivity” and AN 3 in “Behaviour in surface waters – acute”. There is no classification in hazard category “Acute toxicity”, therefore the substance receives AN 1.

Acute toxicity (respiratory tract)	Irritation and corrosivity	Sensitisation, allergenic potential	Mutagenic, carcinogenic, toxic for reproduction, chronically toxic	Behaviour in surface waters – acute	Behaviour in surface waters chronic
1	2	n.b	n.b	3	n.b

CRITERIA FOR WIDES SUBSTANCE ASSESSMENT

The following section provides a detailed description of WIDES hazard categories and the relationship between hazard statements and assessment numbers.

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 EUH032	Toxic if: swallowed, in contact with skin, inhaled AND causes severe skin burns and eye damage Contact with acids liberates very toxic gas
4	H301, H311, H331 EUH029 EUH031 EUH070 H370	Toxic if: swallowed, in contact with skin, inhaled Contact with water liberates toxic gas Contact with acids liberates toxic gas Toxic by eye contact Causes damage to organs
3	H302, H312, H332 H371	Harmful if: swallowed, in contact with skin, inhaled May cause damage to organs
2	H304 H336*	May be fatal if swallowed and enters airways May cause drowsiness and dizziness
1	Available data are sufficient to exclude a hazard potential	
?	Available data are insufficient to 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, i.e. caused a significant necrosis of the epidermis reaching into the dermis.

AN	H-statement	Wording
5	Skin Corr. 1A, H314	Causes severe skin burns and eye damage
4	Skin Corr. 1B (1C), H314 H318 H281	Causes severe skin burns and eye damage Causes serious eye damage Contains refrigerated gas; may cause cryogenic burns or injury
3	EUH071	Corrosive to the respiratory tract
2	H315 H319 H335 EUH066*	Causes skin irritation Causes serious eye irritation May cause respiratory irritation Repeated exposure may cause skin dryness or cracking
1	Available data are sufficient to exclude a hazard potential	
?	Available data are insufficient to 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	H334 (Skins Sens. 1; Skin Sens. 1A, 1B)	May cause allergy or asthma symptoms or breathing difficulties if inhaled
4	H317 (Skin Sens. 1; Skin Sens. 1A, 1B)	May cause an allergic skin reaction
3	Evidence of sensitising potential from literature but no classification	
2		
1	Available data are sufficient to exclude a hazard potential	
?	Available data are insufficient to exclude a hazard potential	

CARCINOGENICITY, GERM CELL MUTAGENICITY, REPRODUCTIVE TOXICITY & CHRONIC TOXICITY

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 evaluated, 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	H350 (Carc. 1A, 1B)	May cause cancer
4	H351 (Carc. 2)	Suspected of causing cancer
1	Available data are sufficient to exclude a hazard potential	
?	Available data are insufficient to exclude a hazard potential	

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. category. 2, based on positive findings in tests on mammals and/or in some cases from in vitro trials.

AN	H-statement	Wording
6	H340 (Muta. 1A, 1B)	May cause genetic defects.
4	H341 (Muta. 2)	Suspected of causing genetic defects
1	Available data are sufficient to exclude a hazard potential	
?	Available data are insufficient to exclude a hazard potential	

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, the classification is largely based on human findings. To the 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 (possibly supplemented by further information) 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	H360 (Repr.1A,1B) H360F H360D	May damage fertility or the unborn child May damage fertility May damage the unborn child
4	H361 (Repr. 2) H361f H361d H362 (Lact.)	Suspected of damaging fertility or the unborn child Suspected of damaging fertility Suspected of damaging the unborn child May cause harm to breast-fed children
1	Available data are sufficient to exclude a hazard potential	
?	Available data are insufficient to exclude a hazard potential	

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 toxicy (repeated exposure) of category STOT RE 1 are classified substances that have a clear toxic effect in humans or which, on the basis of findings from animal studies, can be assumed to have a clear toxic effect in humans after repeated exposure. Target organ toxic (repeated exposure) of category STOT RE 2 are classified substances on observations in appropriate animal studies which have produced clear toxic effects with relevance to human health in generally moderate exposure concentrations.

AN	H-statement	Wording
5	H372 (STOT RE 1)	Causes damage to organs through prolonged or repeated exposure
3	H373 (STOT RE 2)	May cause damage to organs through prolonged or repeated exposure
1	Available data are sufficient to exclude a hazard potential	
?	Available data are insufficient to exclude a hazard potential	

BEHAVIOUR IN SURFACE WATERS – ACUTE

The assessment is closely related to the classification rules for the hazard class „acute (short-term) aquatic hazard“ in 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 are sufficient to exclude a hazard potential
?	Available data are insufficient to exclude a hazard potential
n.b.	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 insecurity)

BEHAVIOUR IN SURFACE WATERS – CHRONIC

The assessment is closely related to the classification rules for hazard class "Long-term aquatic hazard". 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 $logK_{ow}$ ≥ 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 $logK_{ow}$ ≥ 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 $logK_{ow}$ ≥ 4.

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

NOEC – value (mg/l)	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	10000	1000
Continue in factor 10 intervals		

AN	Classification
8	Chronic 1, H410 (M 10000)
7	Chronic 1, H410 (M 1000)
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 are sufficient to exclude a hazard potential
?	Available data are insufficient to exclude a hazard potential
n.b.	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 OF INGREDIENTS

ABC categorization facilitates the selection of safe disinfectants by using a colour code to identify critical ingredients. Hazards of substances differ in duration and severity of the effect. Some are relatively harmless or reversible (e.g. skin irritation), others may be irreversible (e.g. carcinogenic or sensitizing potential). The ABC categorization distinguishes between serious and less serious hazards. Based on the classification (H-statements)[10] and/or data gaps in the WIDES, a substance is assigned to a category.

Category A

Category A covers long-lasting, difficult-to-control and/or irreversible hazards with serious adverse consequences for human health and/or the (aquatic) environment. The severity of the hazard is expressed by the colour red. For disinfectants with ingredients assigned to category A substitution should be considered.

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[11]	Suspected of damaging the unborn child
H362[11]	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)[12]	Very toxic to aquatic life and M-factor equal to or higher than 1000
H410 (M≥100)[12]	Very toxic to aquatic life with long lasting effects and M-factor equal to or higher than 100

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

[11] Reasons for the inclusion of H361d and H362 in category A: Unborn life should be given the highest level of protection, as possible damage could affect the entire life of the adolescent child and the unborn child cannot defend himself against the influence of chemicals. Therefore, the suspicion of toxicity to the offspring is sufficient for inclusion in category A.

[12] M-factor is a multiplication factor for substances with high toxicity to the aquatic environment (i.e. at least with LC_{50} or EC_x values of < 1mg/L). If a substance is classified in the category Aquatic Acute 1 or Aquatic Chronic 1, a multiplication factor is assigned to the H-set in accordance with the EU CLP Regulation. The M-factor weights highly toxic substances accordingly.

Category B

Category B covers long-lasting, difficult-to-control and/or irreversible hazards with potentially significant adverse consequences for human health and/or the (aquatic) environment. A lack of test data or uncertainty about the existence of certain hazards is also assigned to category B ("data gap"). High acute toxic hazards expressed by the H-statements H300, H310, H330, H301, H311 and H331 are assigned to category B insofar as the substance is used in a controlled working environment with the dilution provided for this purpose[13]. Assignment to category B does not create an urgent need for substitution but should be a recommendation to weigh product alternatives. The severity of the hazard is expressed by colour yellow:

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 (aquatic hazard)	
H400 (M≥10)[12]	Very toxic to aquatic life and M-factor equal or higher than 10
H410 (M≥1)[12]	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 gap (health hazard): The WIDES database 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.	

[13] In the case of an uncontrolled release of the concentrate (e.g. during transport, storage or transfer), H-phrases H300, H310, H330 has to be assigned to category A.

Category C

Category C covers limited, easily controllable and/or reversible hazards. We assign corrosive properties expressed by the H-phrases H314 and H318 to category C to the extent that the substance is used in a controlled working environment with the dilution intended for this purpose[14]. Although hazards assigned to category C are not negligible, they do not usually justify a need for substitution.

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)	
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

[14] In case of an uncontrolled release of the concentrate (e.g. during transport, storage or transfer), H-phrases H314 and H318 has to be assigned to category A.

EXAMPLE FOR A SUBSTANCE ASSESSMENT: GLUTARALDEHYDE

The following explains the WIDES assessment by means of biocidal active ingredient "Glutaraldehyde". The first screenshots show substance identity, ABC category and the classification further applied for the assessment:

Name:	Glutaraldehyd
Synonyms:	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 (Zugelassen in PT1 und/oder PT2) / Biocidal substance (approved in PT1 and/or PT2)
General substance information:	

Classification as hazardous material according to WIDES

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 evaluation of active substances in Regulation 528/2012: Glutaraldehyde; Product-type 2,3,4,6,11,12. 30.09.2014; eCA Finland; latest download: 07.04.2020

The correction factors F_{hum} and F_{eco} are given on the "ingredient assessment" page[15]:

Correction factors

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

The assessment in the hazard categories is shown on the "ingredient assessment" page[16]:

Acute toxicity (respiratory tract) Assessment criteria

Assessment number:	6
Relevant H and/or R phrase:	Acute Tox. 2, H330 Lebensgefahr bei Einatmen. / Fatal if inhaled.
Source:	EU-Assessment Report for evaluation of active substances in Regulation 528/2012: Glutaraldehyde; Product-type 2,3,4,6,11,12. 30.09.2014; eCA Finland; latest download: 07.04.2020

Irritation and corrosivity Assessment criteria

Assessment number:	4
Relevant H and/or R phrase:	Skin Corr. 1B, H314 Verursacht schwere Verätzungen der Haut und schwere Augenschäden / Causes severe skin burns and eye damage
Source:	EU-Assessment Report for evaluation of active substances in Regulation 528/2012: Glutaraldehyde; Product-type 2,3,4,6,11,12. 30.09.2014; eCA Finland; latest download: 07.04.2020

[15] Regarding the use of correction factors see chapter "exposure model with vapour pressure"

[16] The citation of datasets which are not relevant for assessment is omitted

Sensitisation, allergenic potential Assessment criteria

Assessment number:	5
Relevant H and/or R phrase:	Resp. Sens. 1, H334 Kann bei Einatmen Allergie, asthmaartige Symptome oder Atembeschwerden verursachen / May cause allergy or asthma symptoms or breathing difficulties if inhaled
Source:	EU-Assessment Report for evaluation of active substances in Regulation 528/2012: Glutaraldehyde; Product-type 2,3,4,6,11,12. 30.09.2014; eCA Finland; latest download: 07.04.2020

The assessment in hazard category “Mutagenic, carcinogenic, toxic for reproduction, chronically toxic” is the result of 4 individual assessments. The overall assessment number is the “highest” partial assessment number. For glutaraldehyde all partial assessments are “1”, so the overall assessment number is also “1”:

Mutagenic, carcinogenic, toxic for reproduction, chronically toxic Assessment criteria

Total assessment number: 1

Summary of individual assessments:

Germ cell mutagenicity (genetically harmful)

Assessment number:	1
Relevant H and/or R phrase:	
Source:	
Additional and/or substitute criteria:	Muta 1, 2

Muta 2	Mutagenität/Gentoxizität		"Classification for genotoxicity is not proposed."	
	Source: EU-Assessment Report for evaluation of active substances in Regulation 528/2012: Glutaraldehyde; Product-type 2,3,4,6,11,12. 30.09.2014; eCA Finland; latest download: 07.04.2020			
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: 26.09. 2019)			

Carcinogenicity (causing cancer)

Assessment number:	1
Relevant H and/or R phrase:	
Source:	
Additional and/or substitute criteria:	Karz 1, 3

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 evaluation of active substances in Regulation 528/2012: Glutaraldehyde; Product-type 2,3,4,6,11,12. 30.09.2014; eCA Finland; latest download: 07.04.2020			
Karz 1	Kanzerogenität		"Carcinogenicity conclusive but not sufficient for classification."	
	Source: REACH registration dossier - glutaraldehyde - full registration (GHS classification & labelling, latest download: 26.09. 2019)			

Reproductive toxicity, teratogenicity (embryotoxic)

Assessment number:	1
Relevant H and/or R phrase:	
Source:	
Additional and/or substitute criteria:	Repro 1,2

Repro 2	Reproduktionstoxizität		"There is no ground for classification for teratogenicity."	
	Source: EU-Assessment Report for evaluation of active substances in Regulation 528/2012: Glutaraldehyde; Product-type 2,3,4,6,11,12. 30.09.2014; eCA Finland; latest download: 07.04.2020			
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: 26.09. 2019)			

Target organ toxicity under repeated exposure (chronically toxic)

Assessment number:	1
Relevant H and/or R phrase:	
Source:	
Additional and/or substitute criteria:	STOT wdh 1,2

Substance data set	Impact type	Test method	Results
STOT wdh 2	Spezifische Zielorgan-Toxizität-wiederholte Exp.		"NOAEL/LOAEL not established: skin irritation but no systemic effects."
	Source: EU-Assessment Report for evaluation of active substances in Regulation 528/2012: Glutaraldehyde; Product-type 2,3,4,6,11,12. 30.09.2014; eCA Finland; latest download: 07.04.2020		
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: 26.09. 2019)		

The two hazard categories for the aquatic environment apply hazard statements H400, H410, H411 and/or H412 in combination with M-factors:

Behaviour in surface waters – acute Assessment criteria

Assessment number:	3
Relevant H and/or R phrase:	H400 (M1) : Sehr giftig für Wasserorganismen mit M-Faktor 1 / very toxic to aquatic life with M-factor 1
Source:	EU-Assessment Report for evaluation of active substances in Regulation 528/2012: Glutaraldehyde; Product-type 2,3,4,6,11,12. 30.09.2014; eCA Finland; latest download: 07.04.2020

Behaviour in surface waters – chronic Assessment criteria

Assessment number:	3
Relevant H and/or R phrase:	H411 : Giftig für Wasserorganismen, mit langfristiger Wirkung. / Toxic to aquatic life with long lasting effects.
Source:	EU-Assessment Report for evaluation of active substances in Regulation 528/2012: Glutaraldehyde; Product-type 2,3,4,6,11,12. 30.09.2014; eCA Finland; latest download: 07.04.2020
Summary of individual findings:	

The complete outcome of the substance assessment is displayed on an overview page together with the colour codes and assessment numbers in the hazard categories:

Consecutive number	Name	CAS numbers	Substance category	Acute toxicity (respiratory tract)	Irritation and corrosivity	Sensitisation, allergenic potential	Mutagenic, carcinogenic, toxic for reproduction, chronically toxic	Behaviour in surface waters – acute	Behaviour in surface waters – chronic
146	Glutaraldehyd	111-30-8	Kategorie A (hohe Gefährdung) / Category A (high hazard)	6	4	5	1	3	3

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 content. 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. A distinction is made between a direct application (ready-to-use products) and an indirect application (dilutions prepared from a concentrate).

READY TO USE PRODUCTS

Products for rapid disinfection (both alcoholic or water-based), skin and hand disinfection and disinfecting hand washing are directly used[17]. The following explains the calculation for their product assessment: A disinfectant contains component A with a high hazard potential (AN 5) in hazard category "Irritation and corrosivity". With logarithmic scaling, from AN 5 a hazard factor of 100,000 is derived. For water with no hazard (AN 1) a hazard factor 10 is determined.

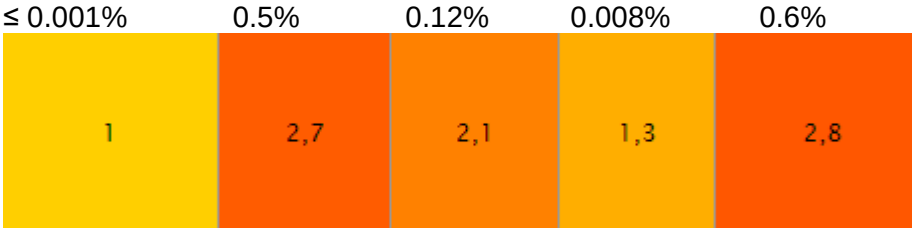
Component	Data basis for AN	AN	Hazard factor 10^{AN}
A	Skin. Corr. 1A, H314	5	100,000
Water	-	1	10

[17] concentrates are also offered to a limited extent for aqueous rapid disinfection.

In the next step a substance fraction is calculated from concentration. The hazard factor is multiplied by the substance fraction and the results are added up. The (rounded) number 510 is logarithmically rescaled (2.7) to give the product assessment number:

Component	Conc. %	Substance fraction $\frac{Conc\ (\%)}{100}$	$hazard\ factor\ x\ substance\ fraction$
A	0.5	0.005	100,000 x 0.005 = 500
Water	99.5	0.995	10 x 0.995 = 9.95 (rounded: 10)
Product assessment number			$\log_{10} 510 = 2.7$

This value can be compared with results from other ready-to-use products in the field of application. However the WIDES database in the public version doesn't foresee a comparison of the assessment number but presents them "translated" into a colour code from yellow to deep red. Reasoning is to hold the user from over-interpreting small differences in the assessment numbers since the calculation follows a simplified model of hazard determination. A finely tuned colouring enables the detection of differences in the hazard potential with a sufficient degree. Due to the logarithmic scaling, the assessment is sensitive to concentration changes in the area of high dilution: For example, for component A with highly corrosive properties, a product assessment number of 1 results only below 0.001%, with which the model shows "no hazard"[18]. The effect of low concentrations of component A on the product assessment number and associated colour code is as follows:



CONCENTRATES (WITH DILUTION)

Concentrates are applied for surface disinfection, manual instrument disinfection[19], laundry and dishware disinfection. Thereby the dilution of the concentrate before use is considered in a separate calculation step. The first part of calculation is as above:

Component	Data basis for AN	AN	Hazard factor 10^{AN}
A	Skin. Corr. 1, H314	5	100,000
B	H319	2	100
Water	-	1	10

[18] BZ 1 means "no hazard" and is the zero value for ready-to-use products

[19] For manual instrument disinfection, ready-to-use solutions are also offered

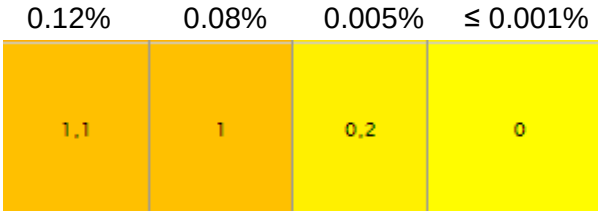
In the next step the substance fraction is calculated from concentration as above. The hazard factor is multiplied by the substance fraction and the results are added up:

Component	Conc. %	Substance fraction $\frac{Conc\ (\%)}{100}$	$hazard\ factor\ x\ substance\ fraction$
A	10	0.1	100,000 x 0.1 = 10000
B	10	0.1	100 x 0.1= 10
Water	80	0.8	10 x 0.8 = 8
Product assessment number (concentrate)			$\log_{10} 10018 = 4.0$

The concentrate receives a product assessment number of 4.0. Since the concentrate is diluted 1:20 giving a 5% application solution, the assessment is supplemented with a dilution calculation:

Component	AN Product	Conc (%)	Hazard factor (10^{AN})	$\frac{Conc\ (\%)}{100}$	$hazard\ factor\ x\ substance\ fraction$
Concentrate	4.0	5	10,018	0.05	500.9
Water	0	95	1	0.95	0.95
Product assessment number (application solution)					$\log_{10} 502 = 2.7$

The product assessment number after dilution is 502 (rounded) respectively re-scaled is 2.7. As with the ready to use products the WIDES in the public version does not foresee a comparison of the assessment number but presents them “translated” into a colour code from yellow to red. A finely tuned colouring enables the detection of differences in the hazard potential with a sufficient degree. Due to the logarithmic scaling, the assessment is sensitive to concentration changes in the area of high dilution: For example, for component A with highly corrosive properties, a product assessment number of 0 results only below 0.001%, with which the model shows "no hazard"[20]. The effect of low concentrations of component A on the product assessment number and associated colour code is as follows:



[20] AN 0 means "no hazard” and is the zero value for dilutions from concentrates

EXPOSURE MODEL WITH VAPOUR PRESSURE

The WIDES assessment considers exposure with a simple model using correction factors derived from the vapour pressure. Correction factor F_{hum} considers that volatile substances evaporate at the site of use and can be inhaled. The factor gives volatile substances a higher weight in the hazard category "Acute toxicity (respiratory tract)". Correction factor F_{eco} considers that non-volatile substances enter sewers, sewage treatment plants and finally surface waters. Therefore, F_{eco} gives non-volatile substances a higher weight in the hazard categories "Behaviour in surface waters – acute" and "Behaviour in surface waters – chronic". The factors are derived from the vapour pressure:

Vapour pressure (hPa/20°C)	≥ 1000	≥ 100 < 1000	≥ 10 < 100	≥ 1 < 10	< 1
F_{hum}	1	0.8	0.7	0.5	0.3
F_{eco}	0.3	0.5	0.7	0.8	1

In the following the integration of correction factor F_{eco} into the product assessment is illustrated. Component A has a high hazard potential and a low vapour pressure while component B has an equally high hazard potential and a high vapour pressure of 260. This means that component A has a higher probability to enter the surface waters than component B. Logarithmic scaling leads to a hazard factor of 100000 both for A and B:

Component	Vapour pressure (hPa/20°C)	Data basis for AN	AN	Hazard factor 10^{AN}
A	0.01	Aquat.chron.1, H410 (M10)	5	100000
B	260	Aquat.chron.1, H410 (M10)	5	100000
Water	-	-	1	10

Weighting with the correction factor F_{eco} causes, that the impact of component A with low vapour pressure on product assessment number is by a factor of 2 higher. Thus, the proportion of component B in the aquatic hazard is reduced. The application of the correction factor reduces the overall product assessment number from 3.0 to 2.9.

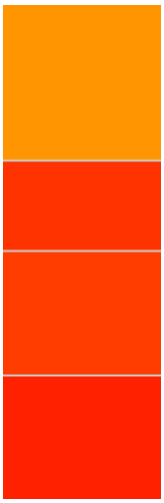
Component	Conc. %	Substance fraction $\frac{Conc\ (\%)}{100}$	F_{eco}	Weighting $hazard\ factor\ x\ substance\ fracti$
A	0.5	0.05	1	100000 x 0.05 x 1 = 500
B	0.5	0.05	0.5	100000 x 0.05 x 0.5 = 250
Water	99	0.99	1	10 x 0.99 = 9.9
Product assessment number				$\log_{10} 760 = 2.9$

When comparing or selecting products in the WIDES, the following characteristics of the product evaluation are used or should be taken into account:

- Product evaluation is only suitable for comparisons between directly usable (rtu) products on the one hand and diluted concentrates (application solutions) on the other.
- The WIDES does not offer a way to compare concentrates and ready-to-use disinfectants. This is avoided by a mandatory indication of the form of application, the application time and the spectrum of action.
- WIDES does not provide product ranking or aggregate valuation figures. The products are sorted in alphabetical order. However, this list can be revised by selecting a single hazard category. This allows a product ranking to be generated in this category.
- The product assessment numbers figures contain uncertainties due to simplified assumptions. Therefore, they only appear in a colour code and are not displayed in the public version of the database. This is to avoid justifying the product selection with numerical calculations.

Non public version:

Public version:



FLAMMABILITY

This hazard category is provided for products that are classified as flammable, mostly because of containing significant amounts of alcohols. The assessment number is the sum of a basic valuation including surcharges and discounts:

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 limit (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.