

Hazard Analysis of Disinfectants: Intention, work steps and preliminary results

(in the course of SAICM 2.0)

Dr. Manfred Klade, Engineering Office Klade

Hazard Analysis of Disinfectants

Disinfectants are indispensable for the healthcare sector but their ingredients may pose inherent hazards. Hazards to human health are: Very high toxicity, sensitizing potential, mutagenic, repro-toxic or chronically toxic properties. Hazards to the environment are: Adverse impact to the aquatic system (water organisms) due to high aquatic toxicity and/or low biodegradability.

With no eco-labels for disinfectants it is very difficult to choose disinfectants less harmful to human health and the environment.

The Hazard Analysis of Disinfectants evaluates environmental and health related hazards of disinfectants and in a subsequent step compares them with product alternatives (Product Benchmarking).

1. Step: Ingredient Analysis

The first step of the Hazard Analysis estimates the substitution demand. Therefore hazards with very high concern are differentiated from those which are controllable or of minor concern.

3 categories (A,B,C) of hazards are designed.

The categorization criteria mainly rely on the **Hazard statements** of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). The **GHS** is an agreed-upon standard managed by the United Nations.

A few additional criteria consider EU CLP Regulation and data gaps identified in the WIDES database for disinfectants.

Criteria

Category A: Covers hazards with high concern with long-lasting and potentially irreversible impacts. Considering their severity a strong recommendation for substitution is given.

H-phrases & criteria	Category A (RED)
HUMAN HEALTH	
H300	fatal if swallowed
H310	fatal in contact with skin
H330	fatal if inhaled
H340	May cause genetic defects
H350	May cause cancer
H360	May damage fertility or the unborn child
H372	Causes damage to organs through prolonged or repeated exposure
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H317	May cause an allergic skin reaction
Allergenic fragrance	26 perfume ingredients must be labelled additionally due to their potential to cause allergies, in line with Reg. (EC) 1223/2009 on cosmetic products (Allergenic fragrances are indicated in the WIDES database)
(AQUATIC) ENVIRONMENT	
H400 (M \geq 1000)	Very toxic to aquatic life and Multiplication factor \geq 1000
H410 (M \geq 100)	Very toxic to aquatic life with long-lasting effects and Multiplication factor \geq 100

Criteria

Category B: Covers hazards which are of considerable concern but which are not thought to automatically generate a substitution demand.

Criteria	Category B (YELLOW)
HUMAN HEALTH	
H301	Toxic if swallowed
H311	Toxic in contact with skin
H331	Toxic if inhaled
H341	Suspected of causing genetic defects
H351	Suspected of causing cancer
H361	Suspected of damaging fertility or the unborn child
H362	May cause harm to breast-fed children
H373	May cause damage to organs through prolonged or repeated exposure
EUH029	Contact with water liberates toxic gas
EUH031	Contact with acids liberates toxic gas
EUH070	Toxic by eye contact
H370	Causes damage to organs
Data gap in WIDES	In one of the WIDES hazard categories a data gap is indicated („?“ in WIDES assessment):
	Acute toxicity (respiratory tract)
	Sensitisation and allergenic Potential
	Mutagenic, carcinogenic, toxic for reproduction & chronically toxic
(AQUATIC) ENVIRONMENT	
H400 (M≥10)	Very toxic to aquatic life and Multiplication factor ≥ 10
H410 (M≥1)	Very toxic to aquatic life with long-lasting effects and Multiplication factor ≥ 1
Data gap in WIDES	In the WIDES hazard category a data gap is indicated („?“ in WIDES assessment):
	Behaviour in surface waters (acute, chronically).

Criteria

Hazards assigned to category C are thought to have a controllable or rather low impact on human health and the environment. They are not further considered in the Hazard Analysis and presented for the sake of completeness.

Criteria	Category C (WHITE)
HUMAN HEALTH	
H302	Harmful if swallowed
H312	Harmful in contact with skin
H332	Harmful if inhaled
H371	May cause damage to organs
H304	May be fatal if swallowed and enters airways
H336	May cause drowsiness or dizziness
H314 (A,B,C)	Causes severe skin burns and eye damage
H318	Causes serious eye damage
EUH071	Corrosive to the respiratory tract
H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation
EUH066	May cause respiratory irritation
(AQUATIC) ENVIRONMENT	
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

Preliminary results

Within the project SAICM 2.0 the Bureau for Chemical Engineering TB-Klade is responsible for the implementation of the Hazard Analysis. Actually product related documents from 38 hospitals are processed. App. 30% of the analyses have already been finalised.

Hazard Analysis for Hospital #15 (location: USA) is taken to illustrate data processing, current problems and communication issues.

The (anonymised) results are work in progress!
(i.e.formatting is preliminary)

Data Evaluation

- For each participating hospital the received documents are „translated“ into a product list.
 - Only products with disinfecting impact are further considered.
 - Therefore the „product claim“ has to be identified. Mostly it can be derived from the Safety Data Sheet SDS).
 - Problems:
 - Not all products can be assigned free of doubt, especially cleaners have to be sorted out.
 - Description about practical application in the hospital and desired result would be helpful as additional information.
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DATA EVALUATION					
PARTICIPANT					
Applicant		XY			
Address/ Country		United States			
Code #		H15			
RECEIVED Product Information				Evaluating and complementing product information	
	Product name	Type of application	Safety data sheet (SDS)	First Step Analysis	Justification
1	Product 1	disinfection	H15-1	Yes	disinfecting impact
2	Product 2	floor cleaner	H15-2	no	no disinfecting impact
3	Product 3	restroom cleaning	H15-3	no	no disinfecting impact
4	Product 4	cleaner	H15-4	no	no disinfecting impact
5	Product 5	cleaner	H15-5	no	no disinfecting impact
6	Product 6	disinfection	H15-6	Yes	disinfecting impact
7	Product 7	disinfection	H15-7	Yes	disinfecting impact
8	Product 8	disinfection	H15-8	Yes	disinfecting impact
9	Product 9	disinfection	H15-9	Yes	disinfecting impact
10	Product 10	disinfection of endoscopes	H15-10	Yes	disinfecting impact
11	Product 11	disinfection	H15-11	Yes	disinfecting impact
12	Product 12	disinfection	H15-12	Yes	disinfecting impact
13	Product 13	cleaner	H15-13	no	no disinfecting impact

Detailed Analysis

- For each processed product the ingredients are identified by means of the CAS number.
 - Only ingredients with a named CAS number are further processed (few exceptions!).
 - To each ingredient a set of GHS based hazard phrases is assigned. The hazard phrases are provided by the WIDES database for disinfectants („WIDES classification“).
 - The hazard phrases are assigned to category A or B by „x“.
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1.STEP HAZARD ANALYSIS OF INGREDIENTS

ANALYSIS DETAILS

PARTICIPANT

Applicant Xy

Address/ Country United States

Code # H15

1	Product 1	SDS Information			Corresponding WIDES name (underlined: public accessible; not-underlined: SAICM entry /not public accessible)			H300, H310, H330	H340, H350, H360	H372	H334	H317	Allergic fragrance	H301, H311, H331	H341, H351, H361, H362	H373	EUH029, EUH031, EUH070, H370	Data gap	H400 (M≥1000) H410 (M≥100)	H400 (M≥10) H410 (M≥1)	Data gap
		Identified ingredients	CAS#	%	H-pharse according SDS	WIDES name	WIDES classification	WIDES data gap	Acute Tox. Cat.1, 2	CMR Cat. 1A, 1B	STOT RE 1	Resp. Sens.	Skin sens.		Acute Tox. Cat.3	CMR Cat. 2	STOT RE 2		health hazards	Aquatic Acute, Aquatic Chronic	Aquatic Acute, Aquatic Chronic
	ethanol	64-17-5	30	-	<u>Ethanol</u>	H226, H319	0														
	phthalaldehyde	643-79-8	10	-	Phthalaldehyde	H301, H314, H317, H318, H335, H400,	1					x		x				x		x	
	SUMMARIZED HAZARDS																				
												x		x				x		x	

7	Product 7	SDS Information			Corresponding WIDES name (underlined: public accessible; not-underlined: SAICM entry /not public accessible)			H300, H310, H330	H340, H350, H360	H372	H334	H317	Allergic fragrance	H301, H311, H331	H341, H351, H361, H362	H373	EUH029, EUH031, EUH070, H370	Data gap	H400 (M≥1000) H410 (M≥100)	H400 (M≥10) H410 (M≥1)	Data gap
		Identified ingredients	CAS#	%	H-pharse according SDS	WIDES name	WIDES classification	WIDES data gap	Acute Tox. Cat.1, 2	CMR Cat. 1A, 1B	STOT RE 1	Resp. Sens.	Skin sens.		Acute Tox. Cat.3	CMR Cat. 2	STOT RE 2		health hazards	Aquatic Acute, Aquatic Chronic	Aquatic Acute, Aquatic Chronic
	Benzyl alcohol	100-51-6	5	-	<u>Benzyl alcohol</u>	H302, H319, H332	0														
	Hydrogen peroxide	7722-84-1	1	-	<u>Hydrogen peroxide</u>	H271, H302, H314, H332, H335, H412	0														
	Potassium hydroxide	1310-58-3	1	-	<u>potassium hydroxide</u>	H290, H302, H314	0														
	Dodecylbenzene sulfonic acid	68584-22-5	1	-	Benzenesulfonic acid, C10-16-alkyl derivs.	H319	0														
	SUMMARIZED HAZARDS																				

Outcomes

- For each processed product a „Substitution Demand“ is derived from the detailed analysis of the ingredients and graduated as follows:
 - „YES“: For products with one or more ingredients categorised as „A“ a substitution by a product with lower risk is recommended.
 - „LIMITED“: Reserved for products with only „B“ categorised ingredients. Substitution is thought to be conditional.
 - „NO(LIMITED)“: For products with solely 1 „B“ categorised ingredient.
 - „NO“: Products containing only „C“ categorised“ ingredients
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1.STEP HAZARD ANALYSIS OF INGREDIENTS

OUTCOMES SUMMARY

PARTICIPANT

Applicant	
Address/ Country	United States
Code #	H15

CATEGORISATION OF HAZARDOUS INGREDIENTS

Product name	SUBSTITUTION DEMAND *	Justification
1 Product 1	Yes	1 ingredient category A
6 Product 6	Yes	1 ingredient category A
7 Product 7	No	-
8 Product 8	No(limited)	1 ingredient category B
9 Product 9	No(limited)	1 ingredient category B
10 Product 10	No(limited)	1 ingredient category B
11 Product 11	No(limited)	1 ingredient category B
12 Product 12	Limited	3 ingredients category B

Forecast 2.Step: Product Benchmarking

While the Ingredient Analysis is performed for all of the participating hospitals, Product Benchmarking is foreseen only for 4 partner hospitals.

The intention of the Product Benchmarking is to identify alternatives for products with a substitution demand.

The Product Benchmarking additionally affords knowledge about ingredient concentration as well as a set of comparable product alternatives (product data). The selection of the 4 hospitals will not only depend on the willingness to cooperate but also on the ability to provide further information.

A description of Product Benchmarking is available on:
<http://www.tb-klade.at/en/>

Please consider for further information

- A detailed description of the Hazard Analysis for Disinfectants as a whole and the Ingredient Analysis and the Product Benchmarking in particular is provided on the webpage of TB-Klade: <http://www.tb-klade.at/en/>
 - The Viennese Database for Disinfectants (WIDES Database) is publicly accessible without charge under: www.wides.at/en
 - Testing data and hazard classification of ingredients of disinfectants can be searched on the webpage of the European Chemicals Agency ECHA: <https://echa.europa.eu/en/>
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Thank you for your attention !

Dr. Manfred Klade

Bureau for chemical Engineering
Austria

office@tb-klade.at
