Results of the SAICM project:

Hazard analysis & case studies

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Hazard Analysis of Disinfectants

supports applicators and purchasers in the selection of less hazardous products without compromising hygiene requirements.

May comprise 2 steps:

1. In a first step severe hazards arising from ingredients are indicated (Ingredient Analysis).
2. In case that a severe hazard is indicated less hazardous product alternatives may be searched and evaluated (Product Benchmarking).

1. Step Ingredient Analysis

- utilizes the Globally Harmonized System of Classification and Labelling of Substances (GHS/CLP) as the main tool to indicate hazards

- applies 3 categories to differentiate between the severity of hazards:

Category	A	B	C
Colour Code			
Presumed concern	High	Considerable	Low

Category A

hazards (hazard statements) with *proven irreversible, lasting or high impact to human health and/or on the aquatic environment already in very low concentration*

H340, H350, H360	H372	H317	H334	H400 (M≥1000), H410 (M≥100)
may cause genetic defects, may cause cancer, may damage fertility or the unborn child	causes damage to organs through prolonged or repeated exposure	may cause an allergic skin reaction	may cause allergy or asthma symptoms or breathing difficulties if inhaled	very toxic to aquatic life and M-factor equal to or higher than 1000, very toxic to aquatic life with long-lasting effects and M-factor equal to or higher than 100

Category B

hazards (hazard statements) with *suspected irreversible or high impact to human health and/or impact on the aquatic environment in low concentration.*

Additionally category B discloses data gaps as indicated by the Viennese database for disinfectants WIDES

H300, H310, H330, H301, H311, H331	H341, H351, H361, H362	H373	EUH029, EUH031, EUH070, H370	H400 (M≥100), H410 (M≥1)
fatal if swallowed, fatal in contact with skin, fatal if inhaled, toxic if swallowed, toxic in contact with skin, toxic if inhaled	suspected of causing genetic effects, suspected of causing cancer, suspected of damaging fertility or the unborn child, may cause harm to breast-fed-children	may cause damage to organs through prolonged or repeated exposure	contact with water liberates toxic gases, contact with acid liberates toxic gases, toxic by eye contact, causes damage to organs	very toxic to aquatic life and M-factor equal to or higher than 100, very toxic to aquatic life with long-lasting effects and M-factor equal to or higher than 1

Category C

comprises hazards which are either reversible, have a low impact and/or are a consequence of improper handling, accident, poor working conditions or insufficient personal protective equipment

H302, H312, H332	H314, H318	H315, H319, H335	H371, H304, EUH066, EUH071	H411, H412, H413
harmful if swallowed, harmful in contact with skin, harmful if inhaled,	causes severe skin burns and eye damage, causes serious eye damage	causes skin irritation, causes serious eye irritation, may cause respiratory irritation	may cause damage to organs, may be fatal if swallowed and enters airways, repeated exposure may cause skin dryness, corrosive to the respiratory tract	toxic to aquatic life with long-lasting effects, harmful to aquatic life with long-lasting effects, may cause long-lasting harmful effects to aquatic life

Strenght & limitation 1st step analysis

Strength

- builds on globally harmonised GHS classification
- considers all ingredients (including fragrances)
- utilises the most relevant classification (provided by WIDES)
- regards insufficient knowledge for hazard exclusion (provided by WIDES)

Limitation

If a disinfectant contains at least 1 ingredient category A, a "substitution demand" is stated. If it contains two or more ingredients category B a "limited substitution demand" is stated.

- These statements solely rely on inherent ingredient hazards independent of concentrations. They primarily display that there should be a further analysis respectively Product Benchmarking.

2.Step: Product Benchmarking

Identify alternatives for products with substitution demand as indicated.

Additionally affords:

- knowledge about ingredient concentration
- comparable product alternatives (efficacy)
- in depth exchange between evaluator and client (hospital)

A detailed description is available on: http://www.tb-klade.at/en/

Case study – hand disinfection

H16 (from South Africa) shared 9 products eligible for hazard analysis.

0 products pose a severe (category A) concern.

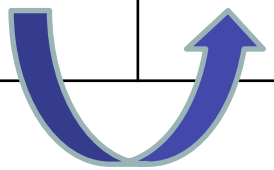
2 products used for hand hygienes contain Chlorhexidine Gluconate (CAS 18472-51-0) as biocidal ingredient Category B.

A limited recommendation for substitution is indicated by 1 step analysis.

Case study - hand disinfection

- According to both WHO recommendation and review of WIDES data base entries, alcohol hand rub is preferred for hand hygiene. So Chlorhexidine is not a necessary constituent for hand hygiene.
- As a result the hospital was encouraged to substitute the 2 products with alcohol-containing disinfectants. A list of potential alternatives was forwarded.

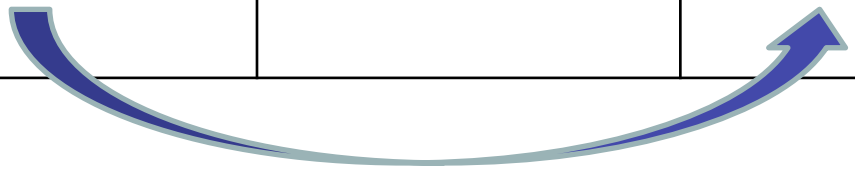
Product	A	B	C
Surgical and hygienic hand disinfection	-	Benchmarked Products	Product Alternatives



Case study – surface disinfection

H11 (Colombia) shared 7 products eligible for hazard analysis. 1 disinfectant pose a severe (category A) concern and was recommended for substitution. The product is a high-level disinfectant for surfaces of medical equipment and devices. It contains Glutaraldehyde and Formaldehyde. After extended discussion and field trial a product containing Hydrogenperoxide was chosen as alternative.

Product	A	B	C
High level disinfection of surfaces	Benchmarked Product	-	Product Alternative

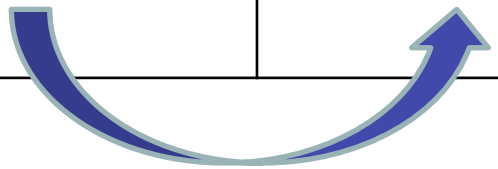


Case study – laundry disinfection

H39 (Germany) shared 21 products eligible for hazard analysis. A product for laundry disinfection contains 3 allergenic fragrances (category A) and peracetic acid (category B) as main biocidal ingredient.

A product also based on peracetic acid but without allergenic fragrances was found as an alternative.

Product	A	B	C
High level disinfection of surfaces	Benchmarked Product	Product Alternative	-



Case study – instrument disinfection

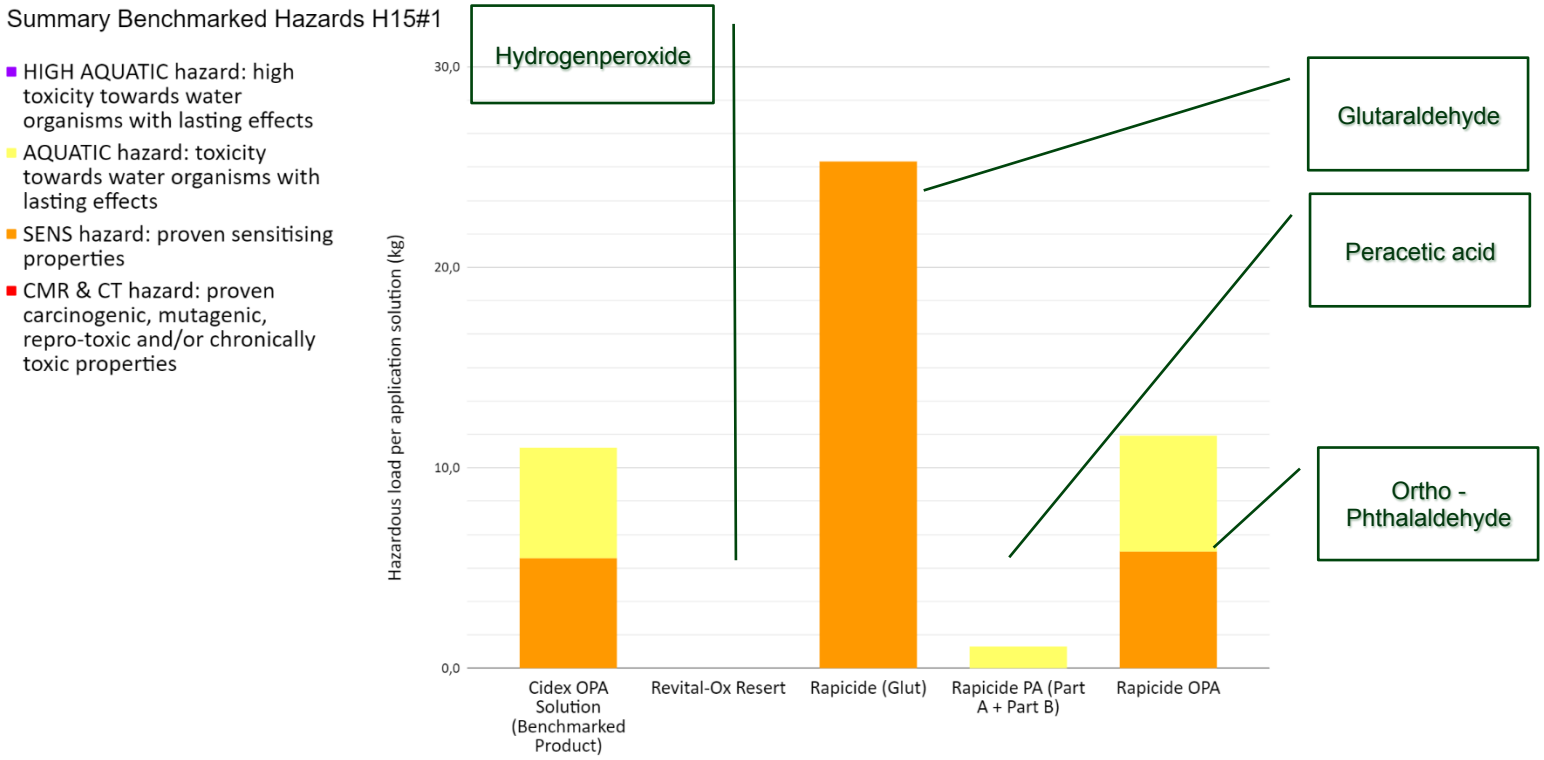
H15 (USA) shared 8 products eligible for hazard analysis. A substitution demand was constituted for 2 products for manual instrument disinfection due to main active ingredient ortho-phthaldehyde (643-79-8) which is category A due to sensitzing properties (H317).

The case study was extended to a comparison of products covering all relevant active substances applied for manual instrument disinfection:

- Hydrogen peroxide (2%)
- Peracetic acid (0.1 %)
- Glutaraldehyde (2.5%)
- Ortho-Phthaladehyde (0,5 %)

Case study – instrument disinfection

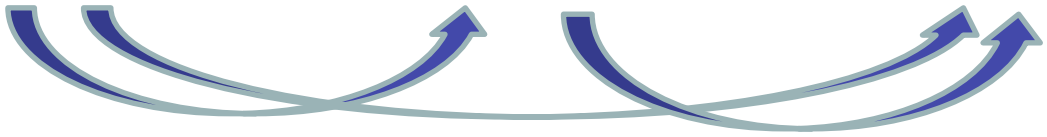
- The Benchmarking comprise 5 products with the following result



Case study – instrument disinfection

- Additionally a review of scientific literature was done to collect empirical information about risks probably not depicted by the ordinary hazard classification.
- Overall conclusion: Several options but - substitution has always go hand in hand with appropriate occupational safety measures!

Product with…	A	B	C
High level manual instrument disinfection	Benchmarked Product	Product Alternative / Benchmarked Product	Product Alternative



Thank you for your attention !

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