Promoting safer disinfectants in the healthcare sector - SAICM 2.0

INTERIM REPORT

This interim report has the objective to present the preliminary project results and recommendations. The report will remain available online for public consultation until 17 May. HCWH Europe would like to hear your views on the report and learn more about your experience with procuring disinfectants. We invite you to write your comments in this Google document (please, leave your name in the comment).

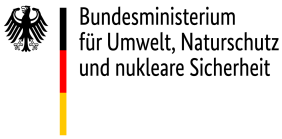
Learn more about the project here.

Your feedback and recommendations will be taken into consideration when drafting the final report.

Disclaimer:

HCWH Europe gratefully acknowledges the financial support of the European Commission (EC)'s LIFE programme, the Federal Ministry for the Environment, Nature Conservation, and Nuclear Safety (BMU) Germany, and the German Environment Agency (UBA).

HCWH Europe is solely responsible for the content of this project and related materials. The views expressed do not reflect the official views of the EC, BMU, or UBA.



Contents

Acknowledgements

[Placeholder]

List of Abbreviations

AMR	Antimicrobial resistance
AQUATIC	Indicates toxicity towards aquatic organisms with lasting effects
ATCC	American Type Culture Collection
BfArM	German Federal Institute for Medicinal Products and Medical Devices
CAS	Chemical Abstracts Service
Cat.	Category
CLP	Classification, Labelling and Packaging
CMR & CT	Indicates proven carcinogenic, mutagenic, repro-toxic and/or chronic toxicity properties
COPD	Chronic obstructive pulmonary disease
COSHH	Control of Substances Hazardous to Health (UK)
CSR	Corporate Social Responsibility
EMAS	Eco-Management and Audit Scheme
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
GPOs	Group Purchasing Organisations
H(number)	Hospital
H/H-	Hazard
HCWH	Health Care Without Harm
HIGH AQUATIC	Indicates high toxicity towards aquatic organisms with lasting effects (M≥100)
IARC	International Agency for Research on Cancer
ICAN	Infection Control Africa Network
ISO	International Organization for Standardization
MRSA	Methicillin resistant
NSG	National Substitution Group
OR	Operating room
PHMB	Polyhexamethylenebiguanide
PPE	Personal protective equipment
QAC	Quaternary Ammonium Compound
RKI	Robert Koch Institute
RTU	Ready-to-use
SAICM	Strategic Approach to International Chemicals Management
SDS	Safety Data Sheet
SENS	Indicates proven sensitizing properties
SOP	Standard Operating Procedures
SHiPP	Sustainable Health in Procurement Project
SVHC	Substance of very high concern
VAH	German Association for Applied Hygiene
WHO	World Health Organization
WIDES	Viennese Database for Disinfectants

Executive Summary

[Placeholder]

Introduction

Disinfectants are widely used in healthcare settings - they are essential to prevent cross contamination, outbreak of diseases, and hospital-acquired infections. Yet, the biocidal active substances that are so effective at disinfecting products, surfaces, and skin also pose a variety of potential hazards to human health and the environment. Health Care Without Harm (HCWH) Europe is coordinating the Strategic Approach to International Chemicals Management (SAICM) 2.0 project, which aims to raise awareness of and combat these unintended hazards by promoting safer, more environmentally friendly disinfectants without compromising on hygienic or occupational health standards (see the detailed project steps in annexes).
By expanding procurement, supply chain and health professionals' knowledge of the health and environmental impacts of disinfectants, they can better align the procurement criteria with healthcare's healing mission and reduce the risks to human and environmental health associated with disinfections. The SAICM 2.0 project, financed by the German Environmental Agency, builds upon the pioneering work of the Viennese Database for Disinfectants (WIDES) and aims to broaden its application worldwide.

Notes concerning the Covid-19 pandemic

The project SAICM 2.0 started in 2018 before the COVID19 pandemic. Although disinfectants' efficacy against certain viruses was not in the scope of the project, the report considers the need for effective disinfectants as follows:

- The chapter "Recommendations for product selection strategy – hand disinfectants" discloses a short list of products for both hygienic and surgical hand disinfection with "limited virucidal" efficacy. Such products are suitable for combating the novel coronavirus (SARS-CoV-2) since they provide efficacy against enveloped viruses.
- The WHO document "WHO-recommended Handrub Formulations" (cited in the chapter mentioned above) provides instructions for the preparation of two effective alcohol-based "handrub" formulations (i.e. hand disinfectants) for in-house/local production as alternative when suitable commercial products are either unavailable or too costly. The formulations are, according to today's knowledge, effective against Corona viruses.

Disinfectants' health and environmental hazards

Recent studies indicate that biocidal active substances pose potential occupational health hazards, environmental threats, and can even contribute to the spread of antimicrobial resistance (AMR) – a global health threat. The following session further elaborates on the identified risks.

The most reported **occupational illnesses** related to the use of disinfectants are acute illnesses, respiratory issues[1] (disinfectants can be sensitizing or irritant) and chronic obstructive pulmonary disease (COPD), skin problems, eye irritation, migraine, or other neurologic symptoms.[2] [3] Some disinfectant ingredients are also allergenic[4] and have been identified as CMR (carcinogenic, mutagenic, and repro-toxic)[5] [6] or endocrine disrupting.[7] [8]

In general, disinfectant compounds represent a major carrier for halogenated organic compounds in hospital effluents, along with solvents and drugs containing chlorine. Because of the extensiveness of their use in modern hospitals, disinfectants and the detergent surfactants with which they are paired reach the hospital wastewater network and thus treatment plants and the bodies of water that receive the effluents.[9]

---

[1] Hawley B., Casey M., Virji MA., Cummings KJ., Johnson A, Cox-Ganser J.(2018) Respiratory Symptoms in Hospital Cleaning Staff Exposed to a Product Containing Hydrogen Peroxide, Peracetic Acid, and Acetic Acid, Annals of Work Exposures and Health, Volume 62, Issue 1, Pages 28–40

[2] Dumas, Orianne, et al. "Association of Occupational Exposure to Disinfectants With Incidence of Chronic Obstructive Pulmonary Disease Among US Female Nurses." *JAMA network open* 2.10 (2019): e1913563-e1913563.

[3] Casey, M. L. et al (2017) *Health problems and disinfectant product exposure among staff at a large multispecialty hospital*. American journal of infection control, 45(10), 1133–1138. doi:10.1016/j.ajic.2017.04.003

[4] Schnuch A. & Griem P. (2018). Fragrances as allergens. Allergo Journal International, 27, 6, (173-183)

[5] Vienna City Administration (2012) The Viennese Database for Disinfectants (WIDES)

[6] International Agency for Research on Cancer

[7] European Parliament and Council (2012) Regulation EU No 528/2012

[8] Zeng F, Lerro C, Lavoué J, et al. Occupational exposure to pesticides and other biocides and risk of thyroid cancer. Occupational and Environmental Medicine 2017;74:502-510.

[9] Hawkshead, J. J. (2008). Hospital wastewater containing pharmaceutically active compounds and drug-resistant organisms: a source of environmental toxicity and increased antibiotic resistance. *J. Residuals Sci. Technol*, *5*(2), 51-60.

In terms of **environmental impact**, disinfectants may have adverse effects on the aquatic systems due to high aquatic toxicity,[10] [11] bioaccumulation and/or low biodegradability.[12] Additionally, disinfectants entering into wastewater by hospitals are supposed to disturb the wastewater treatment process and the microbial ecology in surface waters.[13]

Substituting these pollutants in the healthcare sector is therefore important to reduce the sector's environmental burden on sewage treatment plants and surface waters.

In addition, scientists have recently observed that multi-drug resistant pathogens are growing **resistance to antimicrobial disinfectants** commonly used to prevent them from spreading. [14] [15]

Reducing the negative impact of disinfectants through procurement

In light of the hazards listed above, decontamination strategies that encourage the use of non-chemical solutions (for example steam, heat or UV light[16]) and *prudent* use of biocidal substances should be the first priority, while disinfectants with an overall low hazard potential should be preferred. This is not straightforward, however, and hospitals wishing to integrate a chemical substitution programme into their procurement strategy may encounter barriers such as lack of knowledge regarding available effective alternatives or the toxicological properties of specific ingredients.[17] Furthermore, it can be difficult to easily identify and choose chemical

[10] Ton, S. S. et al (2012) Evaluation of acute toxicity and teratogenic effects of disinfectants by Daphnia magna embryo assay. *Environmental pollution*, *168*, 54-61.

[11] Emmanuel, E., Perrodin, Y., Keck, G., Blanchard, J. M., & Vermande, P. (2005). Ecotoxicological risk assessment of hospital wastewater: a proposed framework for raw effluents discharging into urban sewer network. *Journal of hazardous materials*, *117*(1), 1-11.

[12] Zhang, Chang & Cui, Fang & Zeng, Guang-Ming & Jiang, Min & Yang, Zhong-Zhu & Zhigang, Yu & Zhu, Meng-Ying & Shen, Liu-Qing. (2015). Quaternary ammonium compounds (QACs): A review on occurrence, fate and toxicity in the environment. The Science of the total environment. 518-519C. 352-362.

[13] Kümmerer, K. (2001) Drugs in the environment: emission of drugs, diagnostic aids and disinfectants into wastewater by hospitals in relation to other sources–a review. *Chemosphere*, *45*(6-7), 957-969.

[14] 'Bacteria such Enterococcus faecium, Staphylococcus aureus resisted to solutions with hydrogen peroxide at 3% and Listeria monocytogenes are becoming more tolerant to benzalkonium chloride.' Danish EPA, Biocides: Risikofaktorer og resistens, 2018. https://www2.mst.dk/Udgiv/publikationer/2018/08/978-87-93710-61-0.pdf

[15] Davin-Regli, A. and Pagès, J. M. (2012). Cross-resistance between biocides and antimicrobials: an emerging question. Rev Sci Tech. 2012 Apr; 31(1): 89–104

[16] Hospital News. *Ultraviolet and HVAC: Keys to reducing hospital acquired infections.* https://hospitalnews.com/ultraviolet-hvac-keys-reducing-hospital-acquired-infections/

[17] Bickle-Graz, M. et. al (2019) *Phthalates in the NICU: a survey.* Archives of Disease in Childhood-Fetal and Neonatal Edition fetalneonatal-2019.

disinfectants that are less harmful to human health and the environment, as biocides cannot be awarded the EU Ecolabel (Art. 6.6).[18]

Despite these challenges, substitution has been successfully demonstrated in The City of Vienna, Austria, where access to information, improved regulation, and setting sustainability criteria for public procurement has changed the market for disinfectant products. Since 1998, the city administration has been purchasing goods and services following ecological considerations, and it has implemented the *ÖkoKauf Wien* programme ("Eco Purchase") to support purchasing decisions. Among the tools provided is the **WIDES disinfectants database**, which helps procurers choose the most suitable product by comparing the hazard profiles of frequently used disinfectants available on the Austrian market for specific demands. It is mandatory for the Vienna Hospital Association, all buildings of the Vienna City Administration, kindergartens, schools, and public baths in the city to use the WIDES database when procuring disinfectant products. Using the database, hospitals in Vienna are now avoiding products classified as potential CMRs. Manufacturers have responded by changing the composition of their products to meet hospitals' demand for less harmful substances.[19]

Project status

Through the SAICM 2.0 project, HCWH Europe, together with the technical support of Manfred Klade (Chemist and Environmental Engineer at TB Klade), is currently utilising the WIDES database entries as well as promoting and disseminating the database worldwide. An advisory expert working group is also supporting the project (members of the group listed in the annexes).

The primary phase of the project was a survey about the procurement and application of disinfectants: although the initial target was to get 40 responses, over 80 healthcare facilities and/or healthcare providers completed the survey. The results are presented anonymously in this interim report. Half of the participating organisations have also shared the safety data sheets (SDSs) of the disinfectants they were using and received a hazard analysis of those products (see hazard analysis methodology and limitations in annexes). During the first hazard analysis,

[18] EU Ecolabels: "The label cannot be awarded to products containing substances classified by Regulation (EC) No 1272/2008 as toxic, hazardous to the environment, carcinogenic or mutagenic, or substances subject to the regulatory framework for the management of chemicals" (European Commission, 2017).
[19] Zainzinger, V. (2018, November 8). *Disinfectant threat*

HCWH Europe identified that some of these products may pose occupational health and environmental risks and therefore provide an opportunity for substitution with less hazardous substances.

HCWH is following up with six selected surveyed facilities that agreed to start the chemical substitution process. We are therefore supporting these facilities to find suitable alternative disinfectants and conducting a second analysis to compare hazard emissions between these alternatives and the existing disinfectants identified for substitution (see product benchmarking methodology in annexes). Although this process has not been completed by all the selected hospitals yet, the report contains these case studies highlighting their challenges and potential best practices in substituting disinfectants.

In April 2020 HCWH Europe planned to organise a workshop together with the German Environmental Agency to initiate a multi-stakeholder dialogue, receive feedback on this interim report and advance the policy and procurement harmonisation work.
*Due to health & safety concerns and travel and event restrictions surrounding the recent COVID-19 outbreak, HCWH Europe moved this event online adapting the format to a webinar with the aim to:

1. Raise awareness about the potential hazards of disinfectants in healthcare settings globally, and the need for effective chemical substitution and harmonised sustainable public procurement criteria
2. Share experience and lessons learnt in replacing disinfectants with safer, effective products

By getting in touch, HCWH Europe can identify you as key expert interested in the project and both consolidate and expand the Expert Working Group to:

- Define the group's strategic procurement priorities for 2020.
- Begin working on sustainable procurement criteria for disinfectants (following the Swedish National Chemical Substitution Group's example).

Through this work, we aim to initiate multi-stakeholder dialogue among health care facilities, procurers, policy makers, and disinfectants providers to foster the availability of safer, more sustainable-disinfectant products on the global market.

Summary and conclusions of the survey results

The survey, made available in five languages between January and April 2019, collected 87 responses from 19 countries across the globe. The detailed results can be found in the annexes.

The majority of respondents are environmental protection and/or infection and prevention control employees with more than ten years of experience from large public teaching or general hospitals.

The survey questions covered the level of awareness about disinfectants use and their potential hazards, the policies and measures adopted to minimise such hazards, and whether these are reflected in the organisations' procurement practices. The majority of participating organisations is either a member of HCWH or of one of its strategic partners, who have made a commitment to sustainability and might be more aware of environmental issues compare to their peers. In addition, the majority of participating organisations from outside Europe is also involved in the Sustainable Health in Procurement Project (SHiPP).

Although disinfectants' safety data sheets (SDSs) are considered by the respondents as the primary source of information about the product hazard properties, approximately half of the participants either struggled to obtain disinfectants' SDSs for HCWH Europe's hazard analysis or confused the SDSs with the products' technical sheet, especially the participants from Latin America and Asia. In addition, there are considerable regional differences in the level of knowledge about the Global Harmonized System of Classification and Labelling of Chemicals (GHS) that was first adopted in 2002. [20] However, not all participants live in countries where the GHS has been implemented. Out of the 87 participants, six were from countries where the GHS has not yet been implemented (Morocco and India) and 11 were from countries that are now in the process of implementing the GHS (Colombia and Chile).[21]

Overall, there is a reasonable level of awareness about the potential health and environmental hazards related to the use of disinfectants, the main causes of these risks, and ways to minimise them. Greater attention is given to patient and occupational health and safety compared to environmental protection. The majority of responding organisations have hygiene plans in place and provide training in the

[20] UNECE. About the GHS, available at http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html
[21] UNECE. GHS Implementation http://www.unece.org/trans/danger/publi/ghs/implementation_e.html [Last accessed 13/04/2020]

use and disposal of disinfectants. Two thirds of the organisations have disinfectants' disposal management protocols and provide tools and guidance to minimise threat to human health. However, given the lower rate of awareness about GHS, further research is needed on the waste management plans in place.

Half of the respondents declared to have identified areas where to safely minimise the use of disinfectants and provide tools and guidance to reduce their potential harm to the environment.

Although participants show a good level of awareness and efforts to reduce disinfectants hazards they state that a lack of product information or tools that facilitate the understanding of this information (e.g. ecolabels, list of safer alternatives, etc.) can undermine these efforts.

Data about the application of disinfectants is collected mainly at hospital level, but in the case of hand, surface and instrument disinfections, more granular data at department level are available.

Each organisation described very different procurement processes, but for half of the respondents, infection prevention and control professionals are responsible for defining the needs for disinfectant products. Half of the organisations have procurement committees or are part of group purchasing organisations (GPOs).

Although two thirds of the respondents declare that infection control, occupational health and environmental managers are involved in the procurement process, only one third of organisations have sustainable procurement policies that apply to the purchasing of disinfectants, and more than half of them do not evaluate their implementation. When setting procurement criteria, product price and efficacy, followed by occupational health, and staff's feedback prove to be decisive factors for most of the hospitals involved in the project.

In turn, sustainable procurement represents an area where improvement is needed, so that these organisations can make use of their purchasing power to demand safer and more environmentally friendly products.

Summary of the hazard analysis and case studies

This section presents the aggregated results of the hazard analysis. As illustrated in the table below, 40 organisations shared the SDS or technical information of the products used. These organisations received back a hazard analysis of their products from project technical lead TB Klade. We received information about 270 products: 167 were analysed, while the remaining 103 products were not considered for this study, as they were classified as products with no disinfecting properties (as they were mainly cleaners). Based on the responses, nine organisations were offered the opportunity to continue with the second step of the product benchmarking and received tailored support for identifying safer disinfectants.

Overview of participating organisations (highlighted in green are the participants selected for the second step):

Hospital Code	# Documents received	Identified Products	Identified as disinfectants	Not considered disinfectants (mainly cleaning products)	Second step - product benchmarking
1	9	4	4	0	
2	6	3	2	1	
3	3	1	1	0	
4	4	2	2	0	
5	5	3	3	0	
6	3	1	1	0	
7	26	18	4	14	
8	4	3	3	0	
9	7	3	3	0	
10	5	3	3	0	
11	20	7	7	0	recommended
12	6	2	2	0	
13	1	1	1	0	
14	0	0	0	0	
15	13	12	8	4	recommended
16	1 (+supplement)	32	10	22	recommended
17	12	12	11	1	recommended
18	4	4	2	2	
19	3	4	0	4	
20	13	13	13	0	recommended
21	10	10	5	5	recommended
22	4	12	3	9	
23	5	2	2	0	
24	11	11	4	7	
25	28	27	15	12	recommended
26	7	7	4	3	
27	11	11	4	7	
28	4	4	2	2	
29	4	2	2	0	
30	4	3	1	2	
31	2	2	2	0	
32	1	1	1	0	
33	1	1	1	0	
34	3	3	3	0	

35	8	8	3	5	
36	0	0	0	0	
37	0	0	0	0	
38	3	3	3	0	
39	1 (supplement)	21	18	3	recommended
40	21	20	19	1	recommended
Total	272	278	173	104	9

The hyperlinked colour-coded table summarises the results of products' hazard analysis and indicates if a product is recommended for substitution according to the methodology explained in annexes (Hazard analysis: methodology and rationale). Products are listed in alphabetical order.

Nine hospitals were selected for the second step of the hazard analysis, namely the product benchmarking. They were offered tailored support to identify less hazardous disinfectants alternatives. Selection criteria took into consideration hospitals' origin (to have a balanced geographical representation), their products' portfolio, and the presence of products that should be replaced with safer alternatives. The following table shows the geographical distribution of the selected hospitals and the number of products that were chosen for the hazard analysis.

Table: Hospitals selected for the second step of the product benchmarking

Hospital code	Country	Analysed products
11	Colombia	7
15	United States	8
16	South Africa	10
17	Canada	11
20	Iceland	13
21	India	5
25	Brazil	15
39	Germany	18
40	Sweden	19

As of March 2020, five of these hospitals have advanced in the identification of less hazardous alternatives and received the results of the product benchmarking. More information about the product benchmarking can be found here.

Based on the outcomes of this second step, this interim report contains case studies from Brazil, Colombia, Germany, Iceland, South Africa, and the United States. Each case study is summarised below, while a more detailed description is presented in annexes.

Summary Hospital 25 (H25): Brazil

The Brazilian hospital selected for the case study is a medium size general hospital, with an average of approximately 1300 inpatients per month and 450 outpatients per day. It has a large portfolio of disinfectants widely used across the country. According to the results of the first step hazard analysis, the hospital was recommended to replace two products, due to them containing ingredients with proven sensitising and chronic toxicity properties. Immediately after receiving the results, the hospital stopped using one of the two products and decided to replace the second with another one that they were already using in the facility, which did not contain category A ingredients.

By adopting this approach, there was no need to identify a suitable alternative through a market research. However, the hospital still needed to test the product on different types of surfaces, in particular more sensitive equipment like incubators, to make sure that the product would be compatible with the surface material. The product gave good results in terms of cleaning and disinfecting performance, therefore TB Klade proceeded with the second step benchmark confirming that the substitution would eliminate the CMR and sensitising emissions while also reducing the aquatic hazard. However, risks of material incompatibility remain related to the use of the products on the acrylic material of the incubators. As of March 2020, the hospital decided to test other two products for the disinfections of incubators and the preliminary results are expected in May 2020. After the testing, their standardisation committee will discuss which product will be standardised for their institution.

Summary Hospital 11 (H11): Colombia

With 17 beds, and an average of 45 inpatients and 2420 outpatients per month, the Colombian participant selected for the case study is a small health centre, part of a local hospital network. It has a moderate portfolio of disinfectants. According to the results of the first step hazard analysis, the hospital was recommended to replace one product because it contains two ingredients with proven sensitising and carcinogenic properties. The concerned product is applied for instruments and surface disinfection. After a preliminary scoping call to discuss the outcomes of the first hazard analysis, the hospital started to search for less toxic alternatives.

The identification of suitable alternatives took four months. Different steps were taken: market research to identify products containing the active substances recommended from the WIDES database, supplier survey administrated by Salud sin Daño (HCWH Latin America), and meetings with product manufacturers.

The first two proposed alternatives were analysed in terms of composition and efficacy (as disinfectant). Both products formally fulfilled the requirements of a product alternative (no identified cat. A ingredients) but with strong limitations due

to unidentifiable ingredients. Subsequently, two other alternatives were proposed by the participant, which, according to the results of the benchmarking, were considered recommendable product alternatives.

Thanks to this process, the participant is now aware of international chemical classification systems GHS and of the potential risks to human and the environment health linked to the use of substances that are extremely common in the hospital. The hospital has improved the way they select and test products, collaborating with a laboratory and group of academic experts. As of March 2020, the hospital needs to finalise the testing procedure with the aim to replace the products in three months.

Summary Hospital 16 (H16): South Africa

The participant from South Africa is a large regional hospital. Overall, none of the products listed by H16 poses particular urgency for substitution. However, two products used for routine hand disinfection contain Chlorhexidine, an active ingredient that is very toxic to aquatic life with long-lasting effects, which is considered unnecessary for this type of application and is easily substitutable with alcohol-based disinfectants. Nevertheless, the substitution requires changing the policy of the provincial government that manages the hospital's procurement contracts. To support the change in the procurement decision-making, the hospital has been provided with a list of alcohol-based disinfectants taken from the WIDES database showing the wide availability of less toxic alternatives. The second step benchmark compares these two types of hand disinfectants showing how the adoption of alcohol-based disinfectants would eliminate such hazardous emission. HCWH Europe hopes that by expanding the knowledge of procurers there will be a change in the provincial policy for future procurement of routine hand disinfectants.

Summary Hospital 20 (H20): Iceland

The hospital from Iceland is a large general hospital with 25,215 inpatients and 244,170 outpatients per year. It has a portfolio of products with high standards in terms of occupational health and environmental safety. However, the first hazard analysis suggested that six products should be considered for substitution when safer and effective alternatives are available. The hospital struggled to identify alternatives available on the local market, but was finally able to get testing samples from the manufacturer of the chosen, less hazardous, alternatives. After two months, the test of these alternatives is giving positive results. However, the test is still on-going. A second step product benchmark has been performed for four products showing the savings in hazardous loads.

Summary Hospital 39 (H39): Germany

The participant from Germany is a medium size hospital for chronic diseases in children and adolescents. It has a portfolio of products with high health and

environmental standards, but given the facility's specialisation in children's chronic diseases, they were interested in replacing some products containing allergenic fragrances and a product with a biocidal substance classified as chronic toxic. In comparison to the other hospitals involved in the project, the similarities between the Austrian and German market eased the process of identification of alternatives from the Austrian WIDES Database. Thus, multiple fragrance-free or comparable alternatives selected from the WIDES database were proposed to the hospital. However, factors like price, external cleaning services, and particular skin diseases treated in the facility posed some barriers in replacing some disinfectants. As of March 2020, the hospital took action by either phasing out or reducing the use of certain disinfectants and replacing those for which alternatives were considered adequate. The hospital is still testing the efficacy and compatibility of these alternatives, whose application is encouraged by the promising results of the product benchmarking. The hospital would welcome national guidelines for the sustainable procurement of disinfectants and chemicals used in the healthcare sector that consider both the environmental and carbon footprint of the product used.

Summary Hospital 15 (H15): United States

The participant from the United States is a hospital network that comprises almost 700 medical offices and 40 hospitals. The network has an estimated amount of 4,000 – 10,000 beds. Although this participant discontinued its participation in the project, HCWH US team was very keen in learning more about this case because many of their members use the products for which substitution was suggested and further information can help many other hospitals make procurement decisions. The US team also raised concerns about the hazards that can be caused by the mixture of different ingredients. Because this aspect is not addressed by the WIDES database, further information is provided via literature review.

After doing the first step hazard analysis, two products were recommended for substitution due to them containing a biocidal active ingredient with proven sensitising properties. In addition, this active ingredient is also toxic to aquatic life with long-lasting effects. Both products were used for reprocessing flexible endoscopes. Several substitutions were proposed for the second step product benchmarking.

On top of the information found in the SDSs and the WIDES database, a screening of scientific literature was conducted to further identify potential hazards of the ingredients found in both the products recommended for substitution and their proposed alternatives. The analysis concluded with the recommendation of two products as potential substitutes, one of which carrying no hazardous load at all and thus being preferable. The second recommended product could be used as a

valid alternative only if applied with adequate protective equipment and properly disposed of, in order to protect both staff and the environment.

Recommendations for Product Selection Strategy (Based on the WIDES Database)

Strengths and limitations of the first step hazard analysis

The recommendations in this report are based on the methodology of the hazard analysis that can be found in the annexes. However, certain strengths and limitations of the first step hazard analysis (when a potential substitution demand is determined) were identified based on the following considerations:

The analysis substantially uses the GHS Classification of ingredient hazards: The GHS Classification is a globally accepted standard for describing the nature and severity of a chemical hazard. Its application is a clear strength of the method.

The analysis categorises hazards according to a presumed "concern": To get to a ranking of hazards and finally to a recommendation, the analysis differentiates between three categories: Category A with "high concern" (red), category B with "considerable concern" (yellow) and category C with "low concern". The assignment to a category follows the following basic rule: *Hazards which are difficult to control, which have an irreversible impact, which are proven for a substance and/or which already arise in low concentration or quantity are of foremost concern*. For this report, proven sensitising and CMR properties fall into category A. On the other hand, irritating and corrosive properties are perceived as being of "low concern" (category C). The proposed categorisation of hazards may be perceived as unfair or unbalanced since skin irritation is a widespread problem when dealing with chemicals. We agree that to a certain extent the categorisation is a compromise. However, at the same time, we try not to take into consideration cases where an adverse effect is completely reversible or where it is a consequence of improper handling, accident, poor working conditions (e.g. inadequate ventilation) or insufficient personal protective equipment.

The hazard analysis states a substitution demand regardless of ingredient concentration: The result of the first step determines if a disinfectant contain(s) a category A and/or category B ingredient(s). If the disinfectant contains at least one category A ingredient, then a "substitution demand" is stated for the disinfectant. If the disinfectant contains two or more category B ingredients then a "limited substitution demand" is stated for the disinfectant. This statement considers solely the inherent hazards of ingredients independently of their concentrations. Since concentrations may vary widely, this statement should not be interpreted without further analysis (product benchmarking). During the product benchmarking, the concentrations of the (hazardous) ingredients are also considered. Additionally, findings from scientific literature may complement the overall analysis.

Manual instrument disinfectants

This chapter concerns products applied for the disinfection of medical instruments by treating them with a solution (manual instrument disinfection). Effective manual instrument disinfection requires the complete contact of all surfaces of the disinfection items. The overall procedure can be supported by cleaning steps and disinfection devices. The application covers surgical instruments, dental instruments, flexible and/or rigid endoscopes (or accessories). Endoscopes and other instruments should be pre-cleaned to remove organic matter before disinfection. For that purpose, products containing surfactants and/or enzymes are used. Such products are not investigated in this chapter.

The shortlist below is an excerpt from the WIDES database. The selected products are foreseen for manual instrument disinfection and cover typical ingredients or combination of ingredients applied for manual instrument disinfection. Applicability for flexible endoscopes is separately stated based on manufacturers' claims.

Although the products are mainly offered on the Middle European Market, they may be available worldwide. Their efficacy is certified by the German Association for Applied Hygiene (VAH) complying to EN 14561 (bactericidal) and EN 14562 (yeasticidal). Some products (indicated with*) are additionally recommended by the German Robert Koch Institute in case of disease outbreak.

The shortlist is based on a query done on 27 February 2020 using the following criteria: Manual instrument disinfection; contact time: 1h (CIDEX opa solution: 5 min); (Minimum) efficacy: bactericidal (not Mycobacteria) + yeasticidal.

In the list, biocidal active ingredients are named together with their category. Category A (red) means that this ingredient shows at least one property giving reason for high concern as there are: proven mutagenic, carcinogenic, repro-toxic, chronic toxicity, sensitising or highly environmentally toxic. Category B (yellow) still indicates a certain hazard potential for human health and/or the environment while for category C (white), an overall low hazard potential is assumed. Provided that application criteria (spectrum of activity, material compatibility) allows it, we recommend to avoid products containing category A ingredients (see also Hazard analysis Methodology Annex).

Shortlist of WIDES products for manual instrument disinfection

No	Product (Manufacturer)	Active ingredients (Category)	Application (manufacturer claim)	Flexible endoscopes	Organic load

1	Korsolex basic (Hartmann/Bode)*	Glutaraldehyde (A) Dihydroxydioxahexan (B) Formaldehyde (A)	Heat-sensitive and heat-resistant instruments	Yes	Low & high
2	Korsolex extra (Hartmann/Bode)	Dihydroxydioxahexan (B) Didecyldimethylammonium chloride (B) Benzalkonium chloride (B) Glutaraldehyde (A) Formaldehyde A)	Heat-sensitive and heat-resistant instruments	Yes	Low
3	Korsolex FF (Bode)	Didecyldimethylammonium chloride (B) Benzalkonium chloride (B) Glutaraldehyde (A)	Also for treatment of endoscopes	Yes	Low
4	Neodisher septo active (Dr.Weigert)	Peracetic acid (B)	Disinfection of thermally stable & thermally instable instruments	Yes	Low & high
5	Neodisher septo Fin (Dr.Weigert)	Glutaraldehyde (A)	Heat-sensitive and heat-resistant instruments	Yes	Low
6	Sekusept aktiv* (Ecolab)	Peracetic acid (B)	Cleaning and disinfection of heat-sensitive and heat-resistant instruments	Yes	Low & high
7	Sekusept forte* (Ecolab)	Glyoxal (A) Benzalkonium chloride (B) Glutaraldehyde (A) Formaldehyde (A)	Including heat-sensitive instruments	Yes	Low & high
8	Sekusept plus* (Ecolab)	Glucoprotamin (B)	Cleaning & disinfection of medical instruments	Yes	Low & high
9	Sekusept Pulver Classic (Ecolab)	Peracetic acid (B)	Disinfection of medical instruments	No	Low & high
10	Triacid-N (Antiseptica GmbbH)	Amines, N-C12-14-alkyltrimethylene	For medical instruments and	No	Low & high

		di- (A) 2-Propanol (C)	rigid endoscopes		
11	Descoton Forte* (Dr.Schumache)	Glutaraldehyde (A) Formaldehyde (A)	For final disinfection of medical instruments	Yes	High
12	Gigasept FF neu (Schülke+)	Reaction product of tetrahydro-2,5-dimethoxy furan, ethanol and water (B)	Disinfection of heat-sensitive and heat-resistant instruments	Yes	High
13	Korsolex med AF (Hartmann/Bode)	Amines, N-C12-14-alkyltrimethylene di- (A) N-(3-Aminopropyl)-N-dodecylpropan-1,3-diamin (B)	For medical instruments and rigid endoscopes	Yes	High
14	Korsolex plus (Hartmann/Bode)	Didecyldimethylammonium chloride (B) N-(3-Aminopropyl)-N-dodecylpropan-1,3-diamin (B)	Reprocessing of heat-sensitive and heat-resistant instruments	Yes	High
15	Cidex OPA solution**	Phthalaldehyde (CAS 643-79-8)	High level disinfectant for reprocessing heat sensitive reusable semi-critical medical devices.	Yes	High

*Recommended by German Robert Koch Institute for Instrument disinfection (RKI 2017); **Contact time according to VAH list: 5 min.

Assessment of applied active ingredients

The shortlist shows that the variety of applied biocidal active substances is rather limited. For the following ingredients at least one product with applicability for endoscopes can be found:

1. **Glutaraldehyde and/or Formaldehyde and/or QAC (1, 2, 3, 5, 7, 11):** Both aldehydes are category A (high concern). High concern of Glutaraldehyde relies on classification with H317 (may cause an allergic skin reaction) and H334 (may cause allergy or asthma symptoms or breathing difficulties if inhaled). High concern of Formaldehyde relies on its classification with H317 (may cause an allergic skin reaction) and H350 (may

cause cancer). Products only with aldehydes pose a low hazard to the aquatic environment. However, if Benzalkonium chloride is added, this changes because of its classification with H410 (very toxic to aquatic life with long lasting effects).

2. **Peracetic acid (4, 6, 9):** Peracetic acid is generated by the reaction of a peroxide with acid in aqueous solution. The most concerning human health hazard regards acute toxicity. According to WIDES it is classified with H331 (toxic if inhaled), which is category B (concern). Peracetic acid also poses a considerable hazard to the aquatic environment since it is classified with H410 (very toxic to aquatic life with long lasting effects, M-factor: 10). Sensitising and CMR properties are excluded by data.
3. **Glucoprotamin (8):** Glucoprotamin is exclusively offered by one manufacturer and data provision is limited. According to WIDES, Glucoprotamin is classified with H330 (fatal if inhaled) and H410 (very toxic to aquatic life with long lasting effects) and therefore categorised as B. Data concerning the exclusion of CMR properties are lacking.
4. **Reaction product of tetrahydro-2,5-dimethoxy furan, ethanol and water (12):** It is exclusively offered by one manufacturer and data provision is limited. According to the data in WIDES, the ingredient is category C (low concern). Data concerning the exclusion of sensitising and CMR properties are lacking.
5. **Didecyldimethylammonium chloride & N-(3-Aminopropyl)-N-dodecylpropan-1,3-diamin (14):** Didecyldimethylammonium chloride is – due to H301 - category B with no data gaps. N-(3-Aminopropyl)-N-dodecylpropan-1,3-diamin is categorised as B due to hazards H373 (may cause damage to organs through prolonged or repeated exposure) and H410 (M10) (very toxic to aquatic life with long lasting effects). Sensitising and CMR properties can be excluded.
6. **Amines,N-C12-14-alkyltrimethylenedi- and/or N-(3-Aminopropyl)-N-dodecylpropan-1,3-diamin (10, 13):** Amines, N-C12-14-alkyltrimethylenedi- (CAS 90640-43-0) is category A due to hazard H372 (causes damage to organs through prolonged or repeated exposure). N-(3-Aminopropyl)-N-dodecylpropan-1,3-diamin is category B (see also item 5)
7. **Phthalaldehyde (CAS 643-79-8):** Is category A due to hazard H317 (may cause an allergic skin reaction). CMR properties cannot be excluded. Phthalaldehyde poses a considerable hazard to the aquatic environment since it is classified with H410 (very toxic to aquatic life with long lasting effects, M-factor:unknown)

Strategy for product selection

Based on the shortlist, the following conclusions can be drawn: No products with solely low concern (category C) ingredients are available and the majority of the products rely on either Aldehydes (category A) or peracetic acid (category B). Based on these findings and on our selection rule[22], a recommendation for substitution of products containing glutaraldehyde and/or formaldehyde due to their proven sensitising respectively carcinogenic properties should be given. In contrast, the most prominent alternative, peracetic acid, is a category B, but it poses nonetheless a certain acute toxicity via inhalation and also a considerable hazard to the aquatic environment (in case of untreated release). If the application of aldehyde-containing products is accompanied by adequate containment measures (e.g. ventilation), then their human health hazards may not become relevant. As a result, the following common product selection strategy is proposed:
If during instrument treatment human exposure to formaldehyde and/or glutaraldehyde cannot be excluded or at least reduced to a minimum by means of adequate working conditions (e.g. containment, ventilation), then substitution with peracetic based products is recommended. This recommendation implies that untreated release of the used peracetic acid solution into the aquatic environment is avoided.

Additionally the following ingredients could be found in the shortlist cited above: Glucoprotamin (category B), reaction product based on tetrahydro-2,5-dimethoxyfuran (category B), Amines, N-C12-14-alkyltrimethylenedi- (category A), N-(3-Aminopropyl)-N-dodecylpropan-1,3-diamin (category B) and Phthalaldehyde (CAS 643-79-8). As long as an ingredient is category B, it can be considered equivalent to paracetic acid and serve as potential alternatives to formaldehyde and/or glutaraldehyde containing disinfectants.

There may be other non-biocidal active ingredients with category A present in the disinfectant considered as an alternative (e.g. allergenic fragrances). However, this analysis does not explore this into enough details to make a clear recommendation. A decision can be made after a detailed product benchmarking for both the product and the product alternative.

Note concerning the treatment of endoscopes

The following text is taken from *Recommendation of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI,*

[22] "avoid category A ingredients as far as application conditions allow it"

Germany) and the German Federal Institute for Medicinal Products and Medical Devices (BfArM):[23]

Concerning equivalence of manual and mechanical treatment of endoscopes:

> *In principle, an endoscope can be prepared hygienically correctly both manually and mechanically. Manual treatment poses health risks for staff (risk of infection, allergic risks) and binds human resources. Since requirements for standardisation and validity of the process are only insufficiently met during manual processing, manual procedures must always be carried out in accordance with documented standard instructions and procedures tested for effectiveness. The preparation in a closed system facilitates the reprocessing and standardizes the preparation process, therefore the machine processing is preferable [p. 1289].*

Concerning disinfection of endoscopes takes place after cleaning and rinsing:

> *Insufficient cleaning and intolerances of detergent residues and disinfectants may affect the effectiveness of disinfection. Disinfectants with proven efficacy are listed in the VAH disinfectant list for the manual disinfection of medical instruments. For machine disinfection, the effectiveness of the disinfectant must be demonstrated by expert opinions of the manufacturer. Aldehydes are regarded worldwide as reference active ingredients in the hygienic preparation of flexible endoscopes. The use of aldehydes is fraught with health risks and can lead to irritation of the mucous membranes and allergic diseases in endoscopy staff via skin and mucous membrane contact as well as via vapours. Only disinfectants with proven bactericidal, virucidal and fungicidal efficacy shall be used. The concentration and time of the disinfectant must be strictly adhered to in accordance with the manufacturer's specifications […] Since there is an increase in the load on the room air with disinfectant vapours in the treatment room, the possibility of adequate ventilation or a separate deduction of green must be given to that of occupational health and safety [p 1291].*

Concerning measures to reduce aldehyde exposure:

> *Skin contact with aldehyde-infusing drugs and inhalation of aldehyde vapours must be avoided. During cleaning and manual preparation of endoscopes, cut-tight gloves and liquid-tight protective coats must be worn. Tubs for instrument disinfection must be covered. Disinfection of flexible endoscopes and the endoscopic additional instrument should preferably be carried out in the integrated system of cleaning equipment in order to protect the personal*

[23] Published in: Bundesgesundheitsbl 2012 · 55:1244–1310 DOI 10.1007/s00103-012-1548-6 Springer-Verlag 2012

from contact with the disinfectant medium. The treatment of the endoscopes must be carried out in a separate treatment room, which must be easy to read and must not be used for other purposes (storage, dressing, social space) [p 1302]

Hand disinfectants

[Please note that all the recommendations provided below are still suitable in the context of COVID-19 as the suggested hand disinfectants are effective against the virus.[24]]

This chapter concerns products applied for the hand disinfection. The application covers hygienic hand disinfection (carried out on dry hands as a rub-in procedure without addition of water) and surgical hand disinfection (carried out before all surgical procedures and comparable invasive measures). The shortlist below is an excerpt from the WIDES database. The selected products are generally certified for both hygienic and surgical hand disinfection and cover typical ingredient or combination of ingredients applied. For some of them additionally limited virucidal activity is claimed[25]. The certification is by either VAH (for bactericidal and yeasticidal efficacy) or – in case of limited virucidal – by the manufacturer itself, by VAH or RKI. Unless otherwise stated the testing fulfil either of the following norms or is at least equal to them:

	Bactericidal	Yeasticidal	Limited virucidal
Hygienic handrub / hygienic hand disinfection	EN 13727[26]	EN 13624[27]	DVV, RKI 2015[28] EN 14476[29]

[24] WHO (2020) Water, sanitation, hygiene and waste management for COVID-19. https://www.who.int/publications-detail/water-sanitation-hygiene-and-waste-management-for-covid-19

[25] A "limited virucidal" efficacy is needed to safely combat Corona virus COVID 19

[26] EN 13727:2014-03. Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity in the medical area – Test method and requirements (phase 2, step 1).

[27] EN 13624:2013-12. Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal and yeasticidal activity in the medical area – Test method and requirements (phase 2, step 1).

[28] DVV/RKI (2015). Guideline of the German Association for the Suppression of Virus Diseases (DVV) e.V. and the Robert Koch Institute (RKI) for the testing of chemical disinfectants for efficacy against viruses in human medicine – version of 1 December 2014. Federal Health Bl 2015; 58:493–504.

[29] EN 14476/A1:2015-04. Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity in the medical area – Test method and requirements (Phase 2/Step 1).

Surgical handrub / surgical hand disinfection	EN 13727 EN 12791[30]	EN 13624	DVV, RKI 2015 EN 14476

Although the products are mainly offered on the central European market, they may be available worldwide. Their bactericidal and yeasticidal efficacy is generally certified by the VAH. For details on the product selection criteria and on the colour coding, please check the explanatory notes on ABC categorisation (Hazard analysis Methodology Annex).

Products with typical ingredient combinations for both hygienic* and surgical hand disinfection (from WIDES database):**

The following table gives a randomly selected sample of hand disinfectants with usual ingredients from the WIDES database. As additional information (claimed and/or certified), limited virucidal efficacy is indicated. A "limited virucidal" efficacy is needed to safely combat the enveloped COVID 19 virus:

	Active ingredient basis (concentration)	Product (Manufacturer)	Limited virucidal*	Limited virucidal by independent certificate**
1	Ethanol (76.7%)	ADH 2000 (Lysoform)	Yes (30 s)	Yes (30 s)
2	2-Propanol (63%)	Activin Baktokill Hände (Wero)	Yes (30 s)	-
3	1-Propanol (10%) Ethanol (55.3%)	Aseptoman viral (Dr. Schumacher)	Yes (30 s)	Yes
4	1-Propanol (10%) Ethanol (60%)	Manorapid Synergy (Antiseptica)	Yes (15 s)	Yes (30 s)
5	Ethanol (78.2%) 2-Propanol (10 %) 2-Biphenylol (0.1%)	Desderman pure gel (Schülke & Mayr)	Yes (30 s)	Yes (30 s)
6	1-Propanol (14.3%) 2-Propanol (63.14 %)	Manorapid Basic (Antiseptica)	Yes (15 s)	-
7	1-Propanol (30 %) 2-Propanol (45 %) Mecetroniumetilsulfat (0.2 %)	Sterillium classic pure (Hartmann)	Yes (30 s)	Yes (30 s)

*… according to manufacturer claim;

[30] EN 12791:2013-07. Chemical disinfectants and antiseptics — Surgical hand disinfection — Test method and requirements (phase 2, step 2).

** according to the listing of the German Robert Koch Institute (RKI) given in the Federal Health Bl 2017; 60:1274–1297.

Strategy for product selection:

The WHO document "WHO-recommended Handrub Formulations" provides instructions for the preparation of two effective alcohol-based "handrub" formulations (i.e. hand disinfectants) for in-house/local production as an alternative when suitable commercial products are either unavailable or too costly. The formulations are, according to current scientific evidence, effective against coronaviruses. The final concentrations are:[31]

1. Formulation 1: Ethanol (80%) + Hydrogen peroxide (0.125%)

Formulation 2: Isopropyl alcohol and 2-propanol (75%) + Hydrogen peroxide (0.125%)

2.

Apart from a high content of alcohol, the only additional biocidal active ingredient is 0.125 % Hydrogen peroxide (H2O2). The presence of a low concentration of H2O2 is intended to help eliminate contaminating spores in the bulk solutions and is not thought to be an active substance for hand antisepsis as such. The document concludes: *According to the available evidence on efficacy, tolerability and cost-effectiveness, WHO recommends using alcohol-based handrub for routine hand antisepsis in most clinical situations.* This leads to the following general recommendation given for product selection:

There is strong indication that in terms of efficacy, tolerability and cost-effectiveness, solely alcohol containing disinfectants are recommendable for routine hand antisepsis (hand disinfection) in most clinical situations provided that commercially available products meet accepted standards for microbial efficacy and quality standards for manufacture.

There may be other non-biocidal active ingredients with category A present in the disinfectant considered as an alternative (e.g. allergenic fragrances). In such a case, the given strategy is too broad to make a clear recommendation. A decision can be made after a detailed product benchmarking of both the product itself and the product alternative.

[31] Only concerning biocidal active ingredients

During the final discussion of the product benchmarking results (see also case study H16 in the Annex) the question arised if the addition of remanent acting antiseptic Chlorhexidine to alcohol-based hand disinfectants achieve a higher preventive effectiveness in hand disinfection. The following citation from the document *Recommendation of the Commission on Hospital Hygiene and Infection Prevention (KRINKO) to the Robert Koch-Institut (RKI)*[32] *(own translation from German)* support our assumption that this is not the case – at least not for daily routine hand disinfection:

- *The aim of the hygienic hand disinfection is the rapid sufficient reduction of the transient flora (not belonging to the single skin flora), so that the hands do not pose a risk of spreading potentially pathogenic pathogens after known or contaminated contamination. If the alcohol-based formulations do not contain a remanently effective antimicrobial additive, the effect of the alcohols is finished after their evaporation. However, there is no evidence that by addition remanent acting antiseptics (e.g. B. Chlorhexidine, octenidine) to alcohol-based hand disinfectants a higher preventive effectiveness in the hygienic hand disinfection is achieved, because only the rapid effect on the transient flora to interrupt the proliferation of superficially adhering microorganisms is decisive [….]*
- *Chlorhexidine digluconat, Octenidin hydrochloride, Polihexanide, Quaternary Ammonium compounds, Ampholyte, phenolic derivatives and triclosan added to alcoholic disinfectants do not cause a further amplification of the effect, but increase the risk of intolerances depending on the active substance or a development of resistance.*

Surface disinfectants

This chapter concerns products applied for the disinfection of surfaces. In general, the surface disinfection procedure used is wipe disinfection processes (with mechanical action). For surface disinfectants to be employed with wiping, the user has the following choices:

Type 1: Products for which application procedure is not clearly specified (e.g. use of wipe, cloth, etc.). These products are used either:

1. as dilution prepared from a concentrate
2. as a ready-to-use liquid

[32] Federal Health Bulletin - Health Protection 2016; 59: 1189-1220.

Type 2: Products that are applied as "pre-prepared disinfectant wipes". In this case the user has to pre-moisten the specific, dry wipe material supplied by the manufacturer with the product solution before use.

Type 3: Products that are supplied by the manufacturer as ready-to-use pre-saturated wipes.

The shortlist below contains excerpts from the WIDES database. The selected products cover typical ingredient or combination of ingredients applied for surface disinfection. Although the products are mainly offered on the central European Market, they may be available worldwide. Their efficacy is certified by the VAH. For details on the product selection criteria and on the colour coding, please check the explanatory notes on ABC categorisation (Hazard analysis Methodology Annex).

Typical ingredient combinations for surface disinfection (from WIDES database)

Type 1a concentrates (dirty conditions)
Spectrum of efficacy: bactericidal (not Mycobacteria), yeasticidal, dirty conditions, mechanic action; Exposure time: 1 h

#	Ingredient combination	Product (Manufacturer) (random example)
1	Didecyldimethylammonium chloride N-(3-Aminopropyl)-N-dodecylpropan-1,3-diamin	Pursept AF (Schülke)
2	Benzalkonium chloride (CAS 68424-85-1) Glutaraldehyde Didecyldimethylammonium chloride	Antiseptica Kombi Flächendesinfektion (Antiseptica)
3	Didecyldimethylammonium chloride Polyhexamethylenbiguanid-Hydrochlorid (CAS 27083-27-8 or 32289-58-0)	Neoform MED AF (Weigert)
4	Benzalkonium chloride (CAS 68424-85-1) Didecyldimethylammonium chloride	WIBU plus Flächendesinfektion (WIBU)
5	Glucoprotamin	Incidin plus (Ecolab)
7	Peracetic acid	Ultrasol active (Schumacher)
8	2-Phenoxyethanol Benzalkonium chloride (CAS 68424-85-1), N-Alkylaminopropylglycin (EG 941-419-7)	Terralin protect (Schülke)
9	Didecyldimethylammonium chloride Glutaraldehyde	Kohrsolin extra (Hartmann)

	Formaldehyde Dihydroxydioxahexan	
10	Lactic acid (CAS 79-33-4)	Apesin SDR san* (Tana Chemie)

*…only for bathroom and sanitation area

Type 1a concentrates (clean conditions)

Test conditions: Spectrum of efficacy: bactericidal (not Mycobacteria), yeasticidal, clean conditions, mechanic action; Exposure time: 1h

#	Ingredient combination	Product (Manufacturer) (random example)
1	Pentakalium-bis(peroxymonosulfat)-bis(sulfat)	Apesin AP 100 PLUS (Tana)
2	Benzalkonium chloride (CAS 68424-85-1) Glutaraldehyde Didecyldimethylammonium chloride	Antiseptica Kombi Flächendesinfektion (Antiseptica)
3	Lactic acid (CAS 79-33-4) Benzalkonium chloride (CAS 68424-85-1)	Diesin maxx (Ecolab)
4	Didecyldimethylammonium chloride N-(3-Aminopropyl)-N-dodecylpropan-1, 3-diamin	Apesin rapid (Tana)
5	Magnesiummonoperoxyphthalat Hexahydrat (CAS 84665-66-7)	Dismozon plus (Hartmann)
7	Tosylchloramid-Natrium Trihydrat	Clorina (Lysoform)
8	Benzalkonium chloride (CAS 68424-85-1) Glucoprotamin	Incidin extra N (Ecolab)
9	Didecyldimethylammonium chloride Glutaraldehyde Formaldehyde Dihydroxydioxahexan	Kohrsolin extra (Hartmann)
10	Benzalkonium chloride (CAS 68424-85-1)	Quartamon med (Schülke)

Type 1b and type 3 Ready To Use products – water based – rapid disinfection (dirty conditions)

Test conditions: Spectrum of efficacy: bactericidal (not Mycobacteria), yeasticidal, dirty conditions, mechanic action; Exposure time: 0,5-15 min

#	Ingredient combination	Product (Manufacturer) (random example)	Wipes

1	Didecyldimethylammonium chloride Benzalkonium chloride (CAS 68424-85-1)	Cleanisept wipes (Schumacher)	Yes
2	Benzalkonium chloride (CAS 68424-85-1) Didecyldimethylammonium chloride N-Alkyl-N-ethylbenzyl-N,N-dimethylammonium chloride	PuraDES DecaBAC N (Prisman)	No
3	Hydrogen peroxide	Incidin Oxy foam (Ecolab)	No
4	Hydrogen peroxide	Incidin OxyWipe (Ecolab)	Yes

Type 1b and type 3 Ready to Use products – alcohol based – rapid disinfection (dirty conditions)

Test conditions: Spectrum of efficacy: bactericidal (not Mycobacteria) + yeasticidal, dirty conditions + mechanic action; Exposure time: 0,5-15 min

#	Ingredient combination	Product (Manufacturer) (random example)	Wipes
1	1-Propanol Ethanol	Antifect N liquid (Schülke)	No
2	Ethanol	Descosept pur wipes ready-to-use (Schumacher)	Yes
3	Polyhexamethylenbiguanid-Hydrochlorid (CAS 27083-27-8 or 32289-58-0) 2-Propanol Ethanol	Biguacid liquid (Antiseptica)	No
4	2-Propanol, Glucoprotamin Benzalkoniumchlorid (CAS 68424-85-1)	Incidin foam (Ecolab)	No
5	Didecyldimethylammoniumchlorid 1-Propanol	Meliseptol rapid (Braun)	No
6	1-Propanol Ethanol	Purades decaWipes XL (Prisman)	Yes
7	1-Propanol 2-Propanol Ethanol N-Alkylaminopropylglycin (EG 941-419-7)	Bacillol 30 foam (Hartmann)	No
8	2-Propanol 1-Propanol	Incidin liquid (Ecolab)	No

Strategy for product selection

Provided that application criteria (spectrum of activity, material compatibility) allows it, we generally recommend to avoid products containing category A

ingredients. Based on the shortlist given above, the following conclusions can be drawn for products intended to be diluted:

1. Type 1a concentrates (dirty conditions): Products with only category B biocidal active ingredients are available. However, there are practically no products with only category C (the only option is solely for disinfecting for bathrooms).
2. Type 1a concentrates (clean conditions): Both products with only category B and products with only category C biocidal active ingredients are available.

The following are intended for rapid surface disinfection:

3. Type 1b and type 3 ready-to-use products – water based: Both products with only category B and products with only category C biocidal active ingredients are available.
4. Type 1b and type 3 ready-to-use products – alcohol based: Both products with only category B and products with only category C biocidal active ingredients are available.

This leads to the general conclusion that for surface disinfection (wiping) at least only Category B containing products are available. There may be other non-biocidal active ingredients with category A present in the disinfectant considered as an alternative (e.g. allergenic fragrances). In such a case the given strategy is too broad to make a clear recommendation. A decision can be made after a detailed product benchmarking for both the product itself and the product alternative. Since compatibility of surface types is not recognised by this compilation material, compatibility of a selected product alternative has to be tested separately.

Conclusions and Recommendations

The best practice from the City of Vienna presented in the introduction shows that access to information, improved regulation, and setting sustainability criteria for public procurement has changed the market for disinfectant products.

Sustainable supply chain management, innovations in green and sustainable chemistry and towards non-chemical alternatives, and adopting common best-practice approaches to biocides and disinfectants management can reduce the risks to human health and ecosystems.

The results of the SAICM 2.0 Project highlight areas of improvements and actions to be taken at both hospital, governmental and industry level.

The following recommendations aim to:

1. Address hospitals' and procurers' need to identify safer alternatives
2. Improve the current regulatory and policy framework
3. Promote sustainable procurement practices

1) How to select product alternatives by means of ABC categorisation

This section provides a strategy for the selection of product alternatives relying on the ABC categorisation of ingredients.

The ABC categorisation was developed by the operators of the WIDES database in close cooperation with experts from the Austrian Federal Agency for Environmental Protection and the Austrian Workers' Compensation Board. The categorisation aims to facilitate the selection of safer disinfectants. By means of certain criteria, one of the three substance categories (A, B or C) is assigned to each biocidal active substances or to other ingredients. It has to be noted that the assignation of a certain hazard to a category is the result of an ongoing discussion process and future changes should not be excluded. Nevertheless, the (preliminary) outcome was implemented in the WIDES database and applied in SAICM 2.0.

Although the overall hazard analysis is comprehensively outlined in the annex, the most fundamental assignments of ingredient hazards to categories are given as follows:

- Ingredients assigned to category A (red) give reason for high concern due to proven mutagenic, carcinogenic, repro-toxic, chronically toxic, sensitising or highly environmentally toxic properties. Such substances may harm humans or aquatic organisms even in low concentrations. In line with the precautionary principle and provided that other selection criteria such as the

spectrum of activity or material compatibility allow it, products containing ingredients classified as A should be avoided.
- Ingredients assigned to category B (yellow) still show a certain hazard potential for human health and the environment
- For ingredients assigned to category C (white) a manageable hazard with low concern is assumed. This is however only the case if accidents and improper treatments may be excluded. Products with category C ingredients should be preferred as far as possible.

Generally ABC categorisation provides a first orientation for the applicator and does not take into account substance concentration. It is primarily applicable to identify ingredients with high hazards to further avoid and/or substitute the corresponding disinfectant.

To support participating organisations conducting market research and identifying potential alternatives, HCWH Europe cooperates with the WIDES database in the provision of categorised ingredients of disinfectants. It is thereby rather easy to identify critical hazards of biocidal active substances and co-formulants (including fragrances and surfactants).

For such a screening the user may follow the instructions below to generate a list of all ingredients with name, CAS number, synonyms and – in the right column – the substance category. The button "I" provides basic information about the categorisation scheme. More detailed explanations regarding the ABC categorisation and the WIDES product assessment can be found in the "Introduction to the assessment framework".

The right column can be sorted by clicking on the button right to "substance category". It is generally recommended to avoid biocidal active ingredients (and co-formulants) indicated with category A (red) and preferable to use biocidal active ingredients (and co-formulants) indicated with category C (white). For the selection of product alternatives, the following publicly accessible functionalities of the WIDES are particularly helpful:

- To evaluate a single product: List of product components (recipe) indicating the category of each component by a colour field (red, yellow, white). (Image 1)
- To generate a list of comparable products: A selection function with field of application, exposure time and spectrum of activity. (Images 2-3)
- To exclude products with specified hazardous properties from a list of comparable products: A predefined or programmable filter function. (Image 4)

Image 1

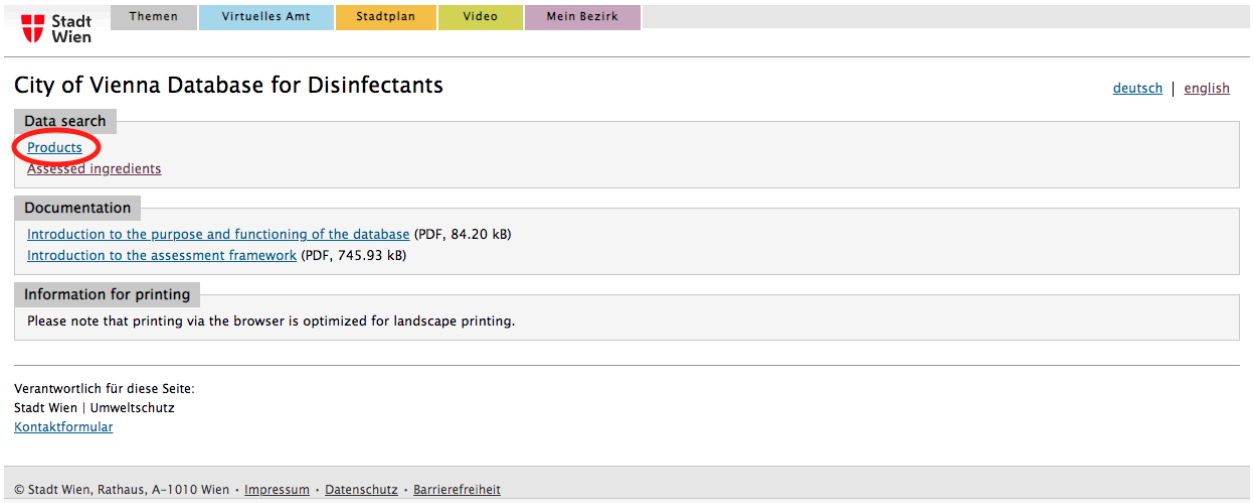


Image 2

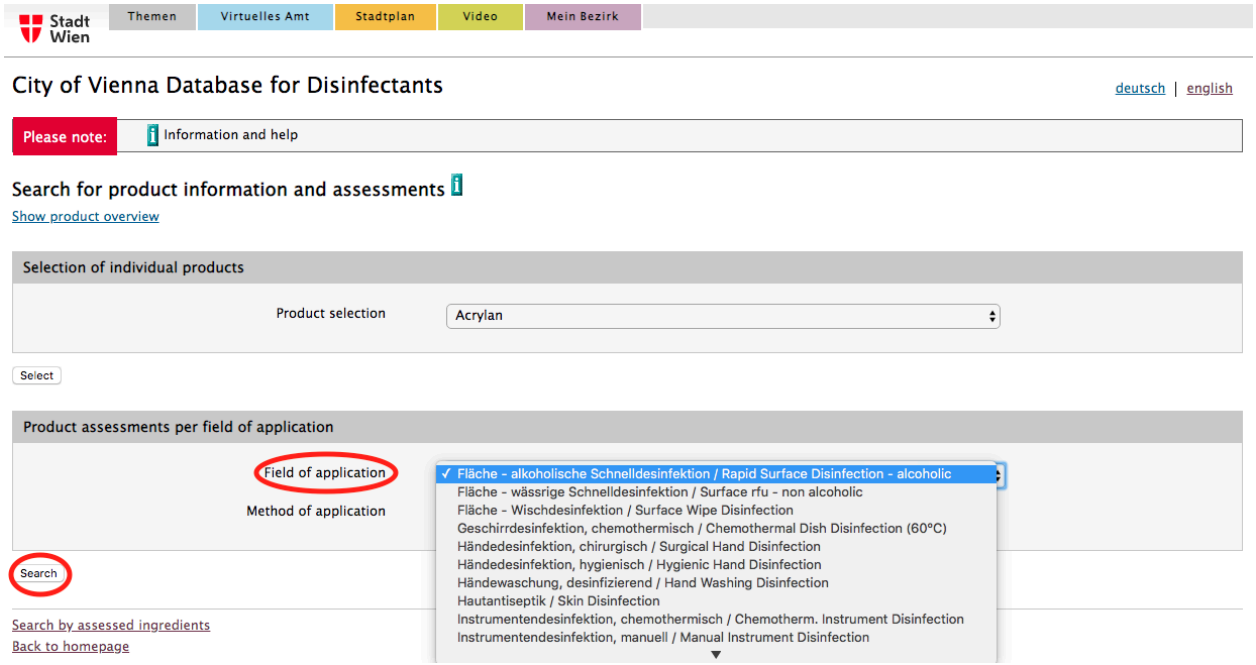


Image 3

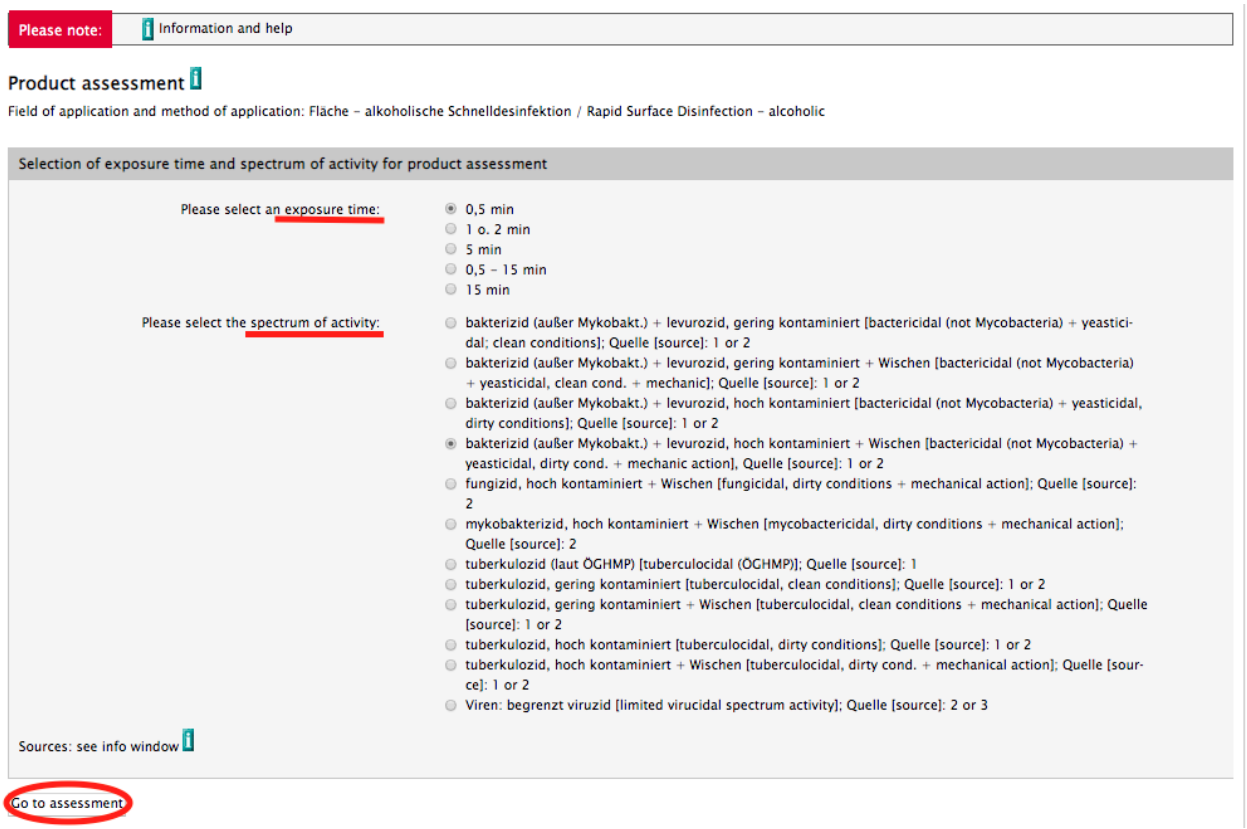
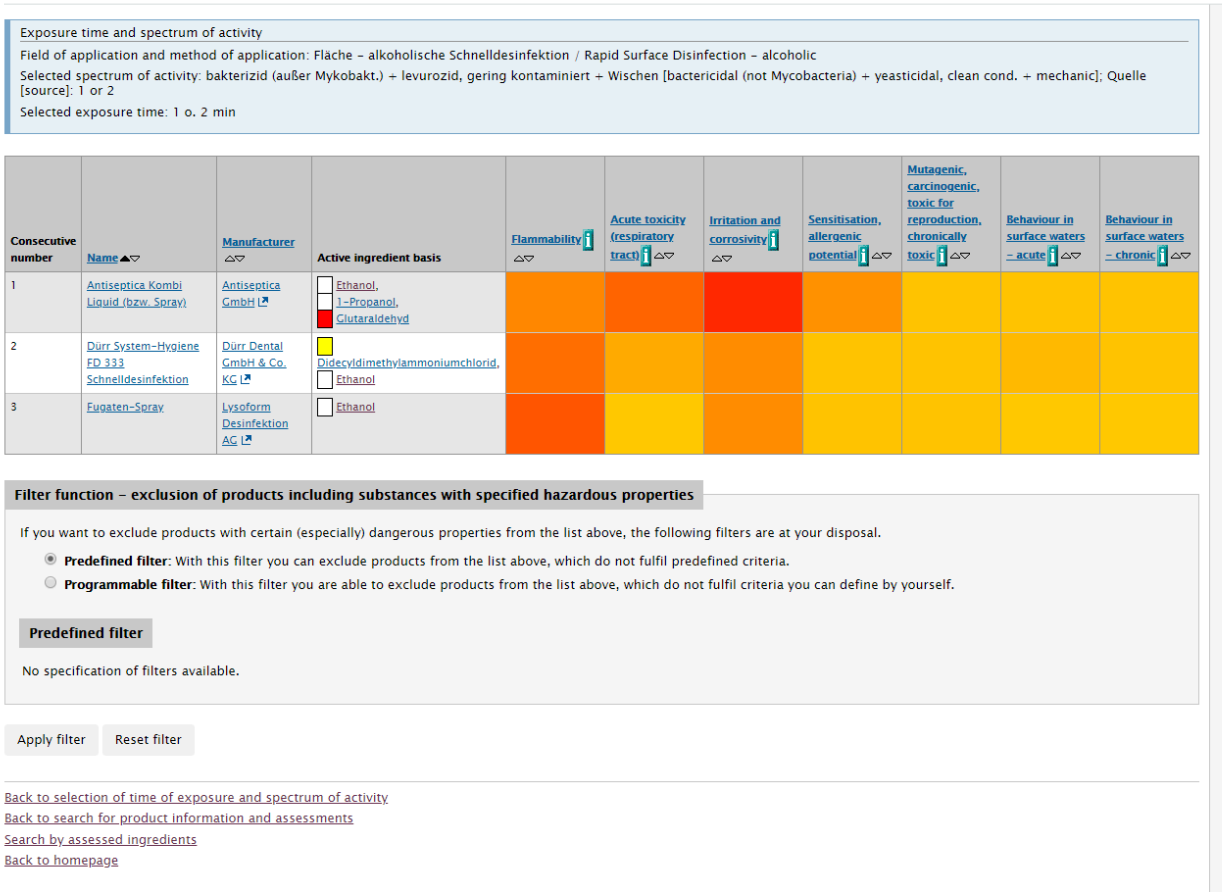

Please note:
Information and help
Product assessment
Field of application and method of application: Fläche – alkoholische Schnelldesinfektion / Rapid Surface Disinfection – alcoholic
Selection of exposure time and spectrum of activity for product assessment
Please select an exposure time:
0,5 min
1 o. 2 min
5 min
0,5 – 15 min
15 min
Please select the spectrum of activity:
bakterizid (außer Mykobakt.) + levurozid, gering kontaminiert [bactericidal (not Mycobacteria) + yeasticidal; clean conditions]; Quelle [source]: 1 or 2
bakterizid (außer Mykobakt.) + levurozid, gering kontaminiert + Wischen [bactericidal (not Mycobacteria) + yeasticidal, clean cond. + mechanic]; Quelle [source]: 1 or 2
bakterizid (außer Mykobakt.) + levurozid, hoch kontaminiert [bactericidal (not Mycobacteria) + yeasticidal, dirty conditions]; Quelle [source]: 1 or 2
bakterizid (außer Mykobakt.) + levurozid, hoch kontaminiert + Wischen [bactericidal (not Mycobacteria) + yeasticidal, dirty cond. + mechanic action], Quelle [source]: 1 or 2
fungizid, hoch kontaminiert + Wischen [fungicidal, dirty conditions + mechanical action]; Quelle [source]: 2
mykobakterizid, hoch kontaminiert + Wischen [mycobactericidal, dirty conditions + mechanical action]; Quelle [source]: 2
tuberkulozid (laut ÖGHMP) [tuberculocidal (ÖGHMP)]; Quelle [source]: 1
tuberkulozid, gering kontaminiert [tuberculocidal, clean conditions]; Quelle [source]: 1 or 2
tuberkulozid, gering kontaminiert + Wischen [tuberculocidal, clean conditions + mechanical action]; Quelle [source]: 1 or 2
tuberkulozid, hoch kontaminiert [tuberculocidal, dirty conditions]; Quelle [source]: 1 or 2
tuberkulozid, hoch kontaminiert + Wischen [tuberculocidal, dirty cond. + mechanical action]; Quelle [source]: 1 or 2
Viren: begrenzt viruzid [limited virucidal spectrum activity]; Quelle [source]: 2 or 3
Sources: see info window
Go to assessment

Image 4



Exposure time and spectrum of activity

Field of application and method of application: Fläche – alkoholische Schnelldesinfektion / Rapid Surface Disinfection – alcoholic

Selected spectrum of activity: bakterizid (außer Mykobakt.) + levurozid, gering kontaminiert + Wischen [bactericidal (not Mycobacteria) + yeasticidal, clean cond. + mechanic]; Quelle [source]: 1 or 2

Selected exposure time: 1 o. 2 min

Consecutive number	Name	Manufacturer	Active ingredient basis	Flammability	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	Antiseptica Kombi Liquid (bzw. Spray)	Antiseptica GmbH	Ethanol, 1-Propanol, Glutaraldehyd							
2	Dürr System-Hygiene FD 333 Schnelldesinfektion	Dürr Dental GmbH & Co. KG	Didecyldimethylammoniumchlorid, Ethanol							
3	Fugaten-Spray	Lysoform Desinfektion AG	Ethanol							

Filter function – exclusion of products including substances with specified hazardous properties

If you want to exclude products with certain (especially) dangerous properties from the list above, the following filters are at your disposal.

Predefined filter: With this filter you can exclude products from the list above, which do not fulfil predefined criteria.

Programmable filter: With this filter you are able to exclude products from the list above, which do not fulfil criteria you can define by yourself.

Predefined filter

No specification of filters available.

Apply filter Reset filter

Back to selection of time of exposure and spectrum of activity
Back to search for product information and assessments
Search by assessed ingredients
Back to homepage

With the support of this, hospitals can assess the hazards of their products or gauge the feasibility of substitution by following these steps (Images 5-7):

1. Use the chosen disinfectant product's SDS and/or Technical Fact Sheet (preferable the SDS) to find all the ingredients' names and CAS numbers.[33]
2. Find each product ingredient in the WIDES Database (*Assessed ingredients>Overview of ingredients table)* by cross checking the unique CAS numbers (third column in the Overview of ingredients *table)*.
3. Identify the corresponding category for each product ingredient (right-hand column in the *Overview of ingredients table*)
    - If *any* ingredient is listed under category A then alternatives will not be suitable
    - If the disinfectant product *only contains* category B or C ingredients then substitution may be possible.

Image 5

[33] A unique identifier regardless of differing regional product names

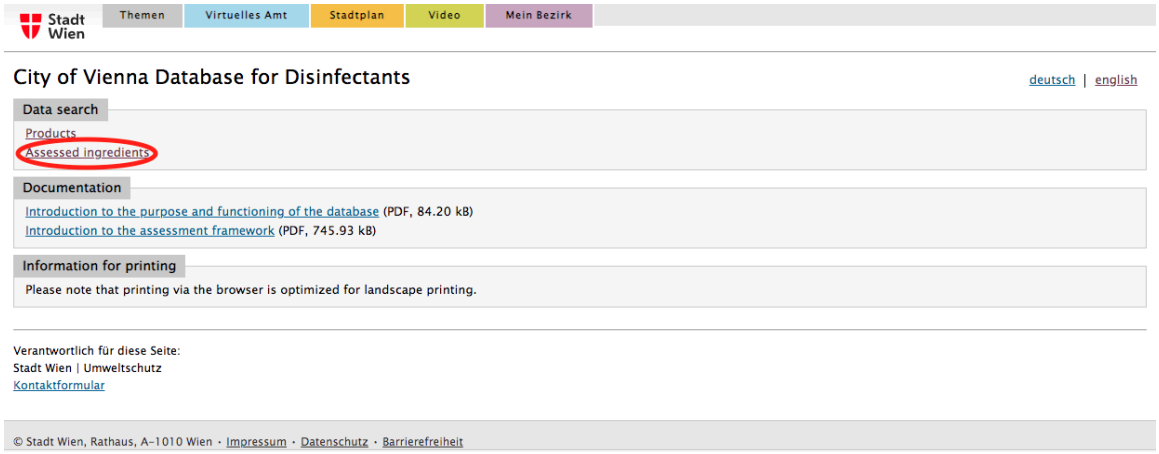


Image 6

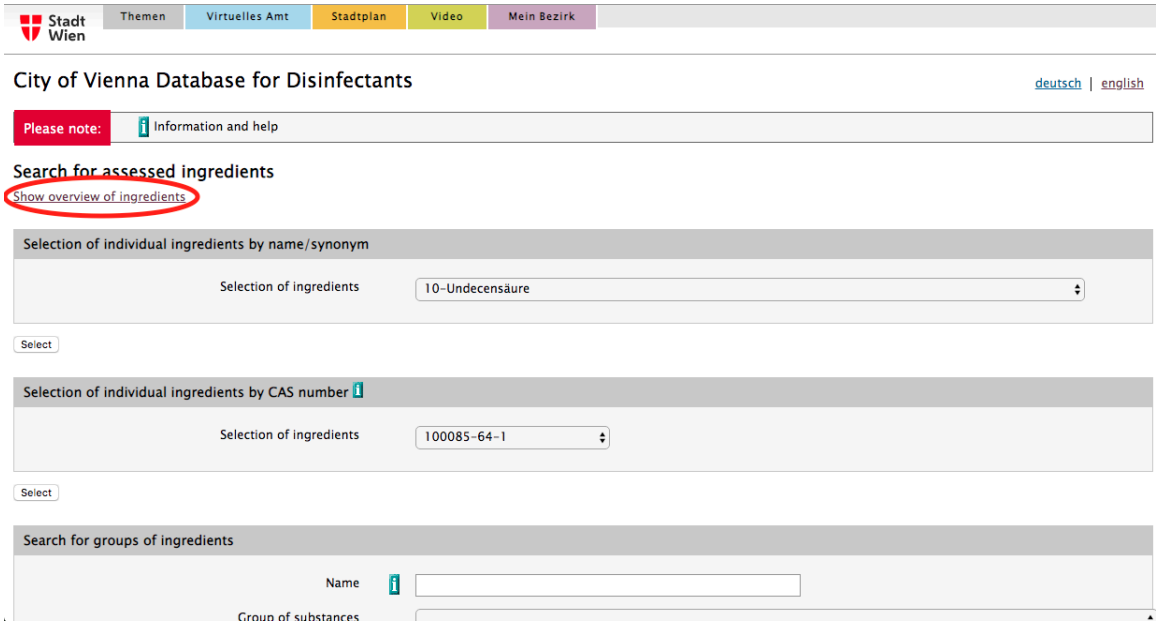
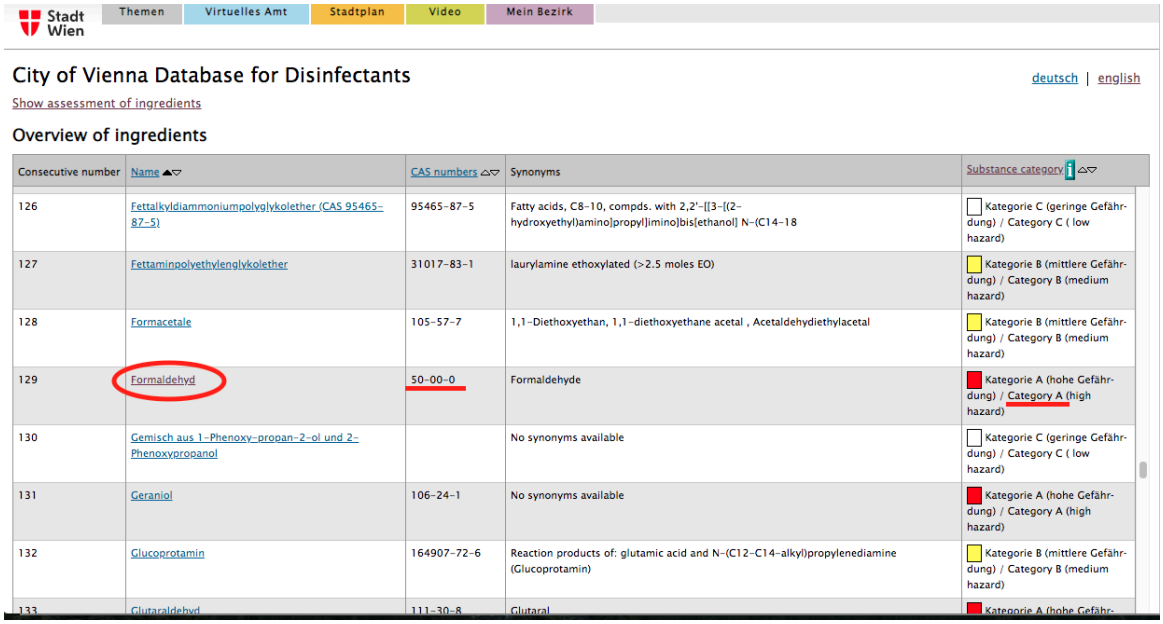


Image 7



Stadt Wien | Themen | Virtuelles Amt | Stadtplan | Video | Mein Bezirk

City of Vienna Database for Disinfectants

deutsch | english

Show assessment of ingredients

Overview of ingredients

Consecutive number	Name	CAS numbers	Synonyms	Substance category
126	Fettalkyldiammoniumpolyglykolether (CAS 95465-87-5)	95465-87-5	Fatty acids, C8-10, compds. with 2,2'-[[3-[(2-hydroxyethyl)amino]propyl]imino]bis[ethanol] N-(C14-18	Kategorie C (geringe Gefährdung) / Category C (low hazard)
127	Fettaminpolyethylenglykolether	31017-83-1	laurylamine ethoxylated (>2.5 moles EO)	Kategorie B (mittlere Gefährdung) / Category B (medium hazard)
128	Formacetale	105-57-7	1,1-Diethoxyethan, 1,1-diethoxyethane acetal , Acetaldehydiethylacetal	Kategorie B (mittlere Gefährdung) / Category B (medium hazard)
129	Formaldehyd	50-00-0	Formaldehyde	Kategorie A (hohe Gefährdung) / Category A (high hazard)
130	Gemisch aus 1-Phenoxy-propan-2-ol und 2-Phenoxypropanol		No synonyms available	Kategorie C (geringe Gefährdung) / Category C (low hazard)
131	Geraniol	106-24-1	No synonyms available	Kategorie A (hohe Gefährdung) / Category A (high hazard)
132	Glucoprotamin	164907-72-6	Reaction products of: glutamic acid and N-(C12-C14-alkyl)propylenediamine (Glucoprotamin)	Kategorie B (mittlere Gefährdung) / Category B (medium hazard)
133	Glutaraldehyd	111-30-8	Glutaral	Kategorie A (hohe Gefähr-

2) Policy recommendations

- Hazard communication

Different hazard disclosure practices observed among countries emphasise the need for harmonised regulations to guarantee better access to information and therefore safeguarding patients' and employees' health as well as reducing hospitals environmental pollution.

1. Implementation of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and the strengthening of basic chemicals and waste management systems should become a priority for governments of all countries where such system is still lacking. As of 2018, more than 120 countries had not implemented the GHS.[34] The GHS ensures that information on physical hazards and toxicity from chemicals is available and communicated, including labels and safety data sheets.

- Testing and information disclosure

Globally, there are still biocides and disinfectants on the market that have not yet been sufficiently investigated (what is referred in this report to "data gaps" and "data insecurity"). Missing knowledge regarding both human safety and environmental hazards troubles making an informed choice towards truly safer alternatives. Only in regions where specific regulation on disinfectants is in place,

34 https://www.unenvironment.org/explore-topics/chemicals-waste/what-we-do/policy-and-governance/global-chemicals-outlook

data on risks and efficacy of disinfectants is available (e.g. the European Biocidal Products Regulation 528/2012). Comparable legislation to assess and authorise disinfectants should be established globally.

It should also be noted that besides the hazards classified under GHS and described in this report, in the European Union (under the Biocidal Products Regulation 528/2012), all active substances have to additionally be assessed for their endocrine-disrupting (ED) properties - the conclusions as to whether the ED criteria are met need to be drawn separately with respect to humans and non-target organisms.[35] Active substances, which are considered as having ED properties will not be approved unless the risk from exposure to the active substance is shown to be negligible or unless there is evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment.
The European regulators are also currently discussing the possible inclusion of endocrine disrupting chemicals in the EU's Regulation on classification, labelling and packaging (CLP).

In general, global knowledge gaps regarding human safety and environmental hazards posed by disinfectants can be filled for example, by harmonising research protocols, prioritising consideration on health or environmental impact and harm caused, and strengthening the science-policy interface.[26]

-Sustainable use

Sustainable use can be defined for biocidal products as the objective of reducing the risks and impacts of the use of biocidal products on human health, animal health and the environment and of promoting the use of integrated pest management and of alternative approaches or techniques such as non-chemical alternatives to biocidal products while still protecting health and materials. With regard to the means and targeted actions, the correct, safe and sustainable use of biocidal products requires the availability and effective dissemination of appropriate guidance or information, whether that use be in a professional context or not.

Unfortunately, a data gap on the volumes of production, sale or use of biocidal products is often used as an argument against taking action for a sustainable use of biocides.[36] We agree with the German Environmental Agency, that even though a lot

[35] Commission Delegated Regulation (EU) No 2017/2100 and Commission Regulation (EU) No 2018/605
[36] UBA (2014). Biocides Proposal for a concerted European approach towards a sustainable use https://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/biocides_0.pdf

of information on the use of biocides is still missing, this is not an argument that there is no need for action.[28]

Authorities and healthcare managers should ensure better reporting and monitoring on the application of disinfectants in order to increase the evidence base and amount of data relating to occupational health and environmental protection.

Regulatory actions should ensure mandatory best practice (reducing the use of biocidal products to a minimum and use of alternatives, also non-chemical ones), including mandatory training and further education and equipment for the application of biocides.
Utmost important is adherence to best practices in the use of biocides of less concern. For example, the EU Biocidal Products Regulation 528/2012 provides mechanisms to phase out the use of substances of high and very high concern. In addition, this creates incentives to develop better alternatives. These mechanisms have not yet reached their full potential, as many active substances are still under evaluation and many biocidal products are still to be authorised. But they are expected to make a significant contribution to the sustainable use of biocides.

Training and information should also address how to avoid unnecessary applications and use possible non-chemical alternatives. In that respect, authorities and healthcare managers should make efforts to communicate the principles on the sustainable use of biocidal products to the general public and healthcare staff, respectively. For instance, some hospitals that participated in this project run evaluation tests to assess the knowledge of new hires and their employees to adapt the need of training accordingly.

The development of standards, combined with a certification process, can also be used to ensure proper and sustainable use of biocidal products, via e.g. demonstration that the healthcare institution has the necessary competence and know-how to deliver efficient disinfection, while minimising risks for staff and patients, as well as the risk of potential negative impacts on the environment.

Lastly, it should be noted that many biocidal products are still applied without equipment or the equipment used mainly concerns items like gloves and other personnel protective equipment. The use of appropriate dosing equipment designed to fit for purpose and to minimise exposure and avoid overdosing (e.g. calibrated sprayers) should be considered and promoted whenever possible.

3) Sustainable procurement

As explained above, the adequate regulatory framework is certainly crucial to support procurers leveraging their purchasing power to demand safer and environmentally friendly products.
However, the hospitals involved in the project, and procuring authorities in general, should have their organisational sustainable procurement policy and a strategy to implement it.
Given the wide use of disinfectants in healthcare facilities, hospitals' sustainable procurement strategy should include this product category among their priorities to reduce risks for workers, patients and the environment.

As mentioned by some of the survey respondents, hospitals should also build a multidisciplinary team of experts (comprising, for example, chemists, dermatologists, and physicians) to identify and set criteria to lower the potential hazard of chemicals used in the sector.
The tools provided through this project can help procurers identify preferable alternatives with equivalent efficacy and therefore advance their chemical substitution strategy.

In addition, organisations lacking the internal expertise can join group purchasing organisations, health and environmental networks, and expert groups. For instance, in Sweden, procuring authorities from the smaller regions do not have the capacity and resources to build multidisciplinary teams. However, they can use a baseline tool provided by the National Agency for Public Procurement to have a basic list of sustainable procurement criteria.[37] They can also participate in the National Substitution Group (NSG) to interact with other experts across the country to make the requirement and criteria more ambitious and harmonised.
The purpose of this group is to share best practices on the technical aspects of chemical procurement criteria and help members with contract evaluation and contract implementation. The NSG maintains a publicly available substitution list for hazardous chemicals online, where experts or members of the group can suggest substitution for specific products or compounds.[38]
Lastly, the case study from Colombia shows that maintaining dialogue with suppliers and manufactures is equally important to spark innovation of more environmentally friendly and efficient products. Despite the challenge of identifying suitable alternatives, thanks to this project, a local disinfectants manufacturer showed interest in developing and testing a product that can meet the hospital's sustainability criteria and potentially increase the offer of these type of products on the local market.

4) Suppliers' sustainability practices

[37] https://www.upphandlingsmyndigheten.se/en
[38] Region Västra Götaland. Nationella Substitutionsgruppen [SE] www.vgregion.se/nsg

It is important to emphasise that, in some regions, even basic information about disinfectants was either hard to find or inaccurate.
As illustrated by the hazard analysis, the SDSs provided by the supplier of the chemical often underestimate the hazards of the ingredients. In addition, product information lacks a full list of ingredients, misrepresenting the potential hazards caused by the mixture of different ingredients. More transparency in terms of hazards and better disclosure of ingredients is key to minimize the hazardous nature of their products.

This project shows that there is a market for safer and more environmental friendly disinfectants, but better alternatives are hard to find or not available on the local market. Suppliers should engage with their customers to discuss the changes needed to mitigate negative impacts and drive innovations in sustainable design and production of disinfectants.

The WIDES database does not include non-chemical alternatives, however there is growing evidence that several non-chemical technologies are an effective approach to disinfection.[39] Ultraviolet (UV) germicidal irradiation, for example, uses short-wavelength UV light to kill or inactivate microorganisms by destroying nucleic acids and disrupting their DNA. Experts agree that UV devices are excellent resources for healthcare facilities;[40] the use of UV light systems is becoming more widely used in healthcare facilities for disinfecting patient and operating rooms.[41] Currently, no-touch disinfection technologies cannot however entirely replace manual cleaning and disinfection processes - by utilising UV disinfection, healthcare settings can benefit from the additional assurance of protecting patients and facilities from healthcare-acquired infections, especially during outbreaks.[42]

Other methods rely on high heat and pressure, such as the conditions obtainable in an autoclave. Autoclaves are enclosed chambers that operate under increased pressure, allowing water to remain liquid at temperatures well above its normal boiling point. This can provide a very effective sterilisation environment. However, autoclaving is not an option for heat sensitive equipment. Physical methods for

[39] Zainzinger, V. (2017) *Finding safer disinfectants.* https://chemicalwatch.com/58801/finding-safer-disinfectants
[40] Nagaraja, A., Visintainer, P., Haas, J. P., Menz, J., Wormser, G. P., & Montecalvo, M. A. (2015). Clostridium difficile infections before and during use of ultraviolet disinfection. *American journal of infection control*, *43*(9), 940-945.
[41] Hospital News. *Ultraviolet and HVAC: Keys to reducing hospital acquired infections.* https://hospitalnews.com/ultraviolet-hvac-keys-reducing-hospital-acquired-infections/
[42] The Source (2017) *The Pros and Cons of Ultraviolet Light Disinfection.* https://healthtrustpg.com/thesource/technology-innovation/precise-prevention/

high-level disinfection include also hot-water disinfection (pasteurization) or steam (e.g. autoclaving at lower temperature).[43]

[43] WHO (2014) *Infection prevention and control of epidemic- and pandemic-prone acute respiratory infections in health care.*
https://www.ncbi.nlm.nih.gov/books/NBK214359/pdf/Bookshelf_NBK214359.pdf

ANNEXES

SAICM 2.0 Project

Goals of the project

This two-year project intends to promote the use of safer and more environmentally friendly disinfectants without compromising hygienic and occupational health standards.

The aim of the project is to reduce the emission of hazardous substances in the environment and thereby contribute to the implementation of the WHO Chemicals Roadmap and the UN SAICM process. These objectives can be achieved by: the adjustment of purchasing criteria for disinfectants in the healthcare sector, expanding the knowledge of purchasers about the environmental burden of disinfectants, and a more sustainable use of disinfectants within the healthcare institutions.

Over the longer term, the project will encourage transparent reporting about the application of disinfectants and increase the amount of data relating to occupational health and environmental protection. This, in turn, will ensure that hospitals and the manufacturers of disinfectants will receive feedback about the products they use and produce.

The project aims to address the environmental and health problems related to disinfectants used in healthcare at local, regional, and national levels and is doing so by engaging a broad range of stakeholders in hospitals and nursing homes.

Project steps

Expert Working Group: A group of experts in the field of occupational health and environmental management are supporting throughout the implementation of the project as an advisory body.

Survey & hazard analysis: The first step consisted in surveying healthcare facilities (target: 40) to identify obstacles to using safer and more environmentally friendly disinfectants. The survey results are integrated in a first product benchmark. In addition to this, the participating facilities willing to share

information about the disinfectant products they were using received a tailored hazard analysis and recommendations for product substitution, when applicable.

Interviews and case studies: To identify best practices examples and case studies, some of the surveyed facilities have been interviewed for a more in-depth analysis. During the interviews, healthcare facilities received support to identify suitable disinfectant alternatives. Afterwards, participants tested the alternatives (e.g. efficacy, material compatibility, practicality, odour, etc.). The product alternative was then benchmarked against the product to be replaced and savings in hazard emissions were estimated (more detailed information about benchmarking can be found here).

Interim Report: first recommendation report drafted based on the results of the surveys and interviews.

Workshop: Survey participants and other procurers are invited to take part in a capacity-building workshop where HCWH Europe will present the first draft of the recommendations and participants will have the opportunity to provide their feedback on the report and provide further input for improvement.

Publication: The outcomes and input received in the workshop will be integrated in a final project report published by HCWH Europe.

Dissemination: The outcomes of the project and the publications will be presented in several high-level international events e.g. SAICM 2020, CleanMed conferences, as well as webinars.

The Expert Working Group

The current participants of the expert working group are:

- Anders Bolmstedt, Chemist, Occupational Health Service, Region Västra Götaland, Sweden
- Antonella Risso, Environmental Manager, Project Coordinator, HCWH Latin America
- Dr. Megha Rathi, Environmental Consultant, WHO and HCWH US
- Peter Orris, Professor and Chief of Service, Occupational and Environmental Medicine, University of Illinois Hospital and Health Sciences System *and* Senior Adviser to HCWH
- Tracey Easthope, Environmental Health Director, Chemicals Program, HCWH US
- Susan Wilburn, International Sustainability Director, HCWH Global

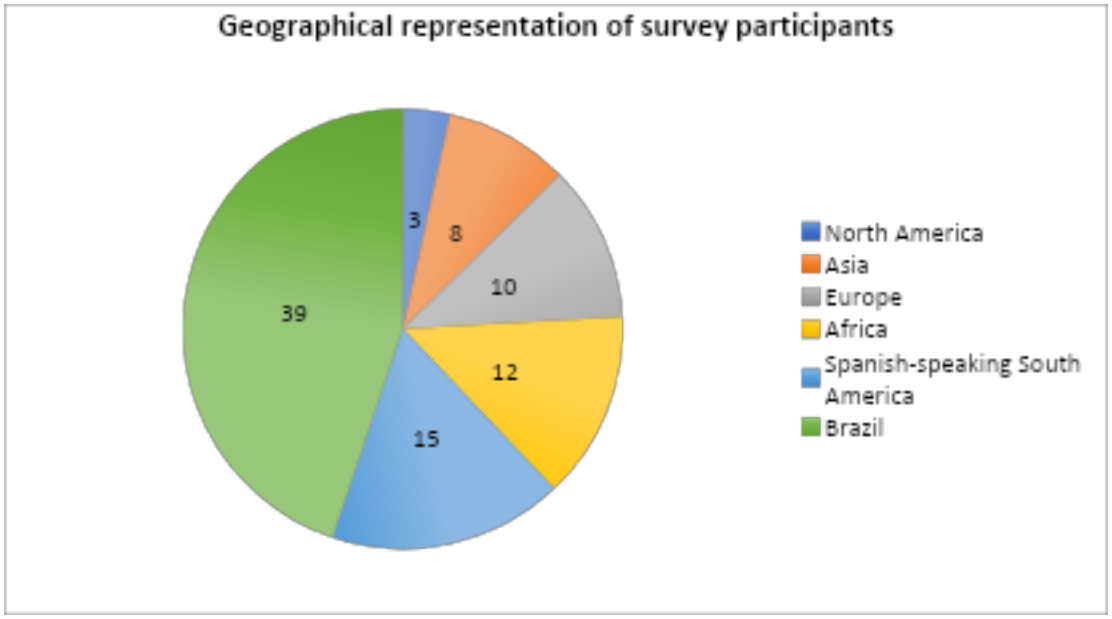
Survey results

HCWH Europe launched a survey aimed at gathering information about the practices of procurement and application of disinfectants within healthcare organisations. The survey, conducted between 6 January 2019 and 30 April 2019, was available in five languages (English, German, Mandarin, Portuguese and Spanish) and was targeted at employees of hospitals and health organisations who have a detailed insight into the procurement and application of disinfectants.

Participants and respondents' profile

A total of 87 organisations completed the survey. They were distributed as following:

- 10 in Europe (1 Austria, 1 France, 2 Germany, 1 Iceland, 2 Spain, 1 Sweden, 1 UK, 1 anonymous)
- 12 in Africa (1 Morocco, 11 South Africa)
- 3 in North America (1 Canada, 2 US)
- 8 in Asia (2 China, 1 Philippines, 5 India)
- 15 in Spanish-speaking South America (9 Colombia, 3 Argentina, 2 Chile, 1 Costa Rica).
- 39 in Brazil



Among these organisations, the majority (61%) are public hospitals with the highest percentage in Europe and Africa. Among the other respondents, 4 are not for profit organisations and 34 are private institutions. Among the private

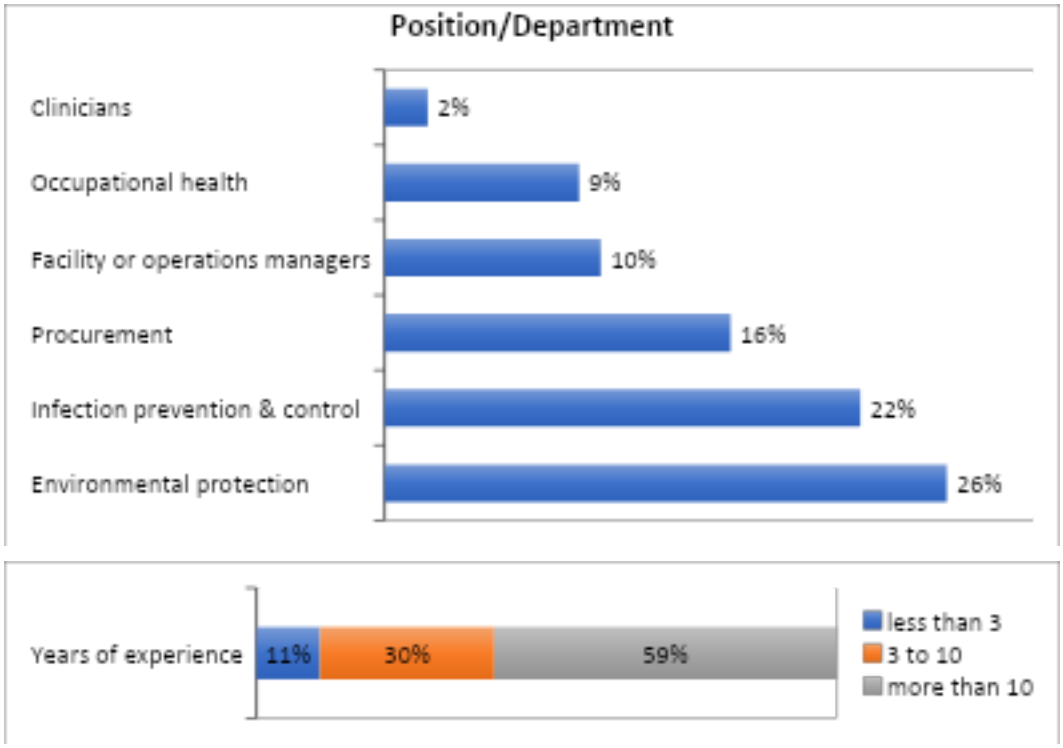
institutions, there are hospitals, but also a few companies that run hospital cleaning services and were asked to answer the survey on behalf of the hospital that they serve.

Participating hospitals represent different types of healthcare practice: the biggest groups are specialist or teaching hospitals (36%) and general hospitals (36%), while almost a fifth belong to a hospital network (18%). Only a small part of participants represents primary care centres or health clinics (5%).

Regarding the size[44] of the institutions, most of the respondents are large hospitals (42%) with more than 500 beds, with an exception for Brazilian participants, where 62% of participating hospitals are of medium size (between 101 and 499 beds).

Within their organisations, survey respondents mainly have roles related to environmental protection (26%), infection prevention and control (22%) and procurement (16%). A smaller proportion of respondents are facility or operations managers (10%), responsible for occupational health (9%), or clinicians (2%). Often, respondents have more than one of these responsibilities within their institution. For instance, they might be in charge of both environmental and occupational health. Among the other mentioned functions, some of the respondents are contract managers or work in Corporate Social Responsibility (CSR) and strategic planning. It is worth noting that almost two thirds of the respondents (59%) have more than 10 years of experience in their role, while 30% have between three and nine years and only a minority (11%) have less than three years of experience.

[44] Small hospitals: Fewer than 100 beds; Medium hospitals: 100 to 499 beds; Large hospitals: 500 or more beds. Retrieved from: https://www.gallaghermalpractice.com/blog/post/what-are-the-different-types-of-hospitals

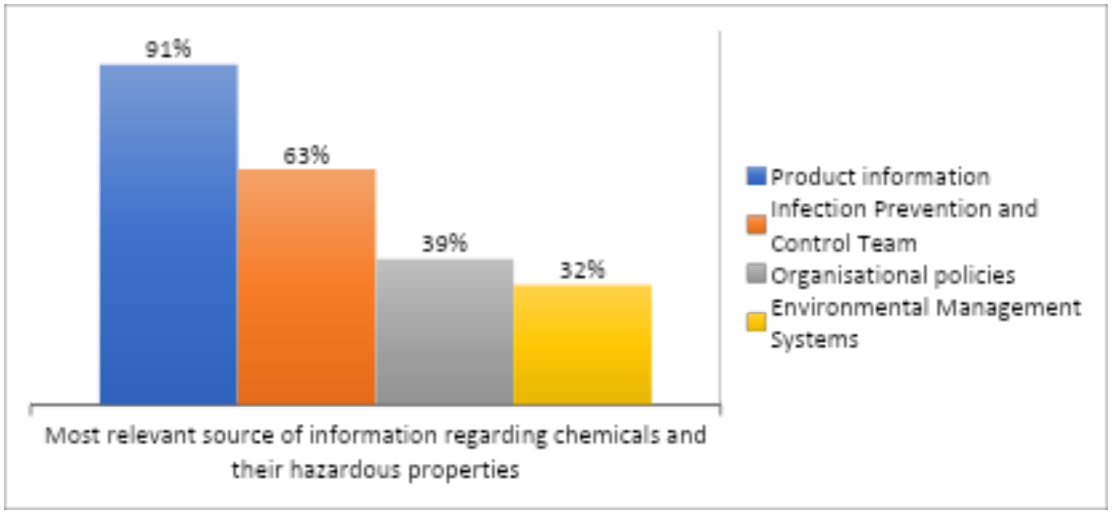


Awareness about disinfectant use and potential adverse effects

Sources of information

The survey assessed participants' knowledge of the issues related to the application of disinfectants and asked their most relevant source of information regarding chemicals and their hazardous properties. Product information (e.g. COSHH SDS) is considered one of the main sources of information by 91% of the respondents. The Infection Prevention and Control Team is also considered a prominent source of information, by 63% of respondents. Still relevant are organisational policies (39%) and Environmental Management Systems (e.g. ISO 14001, EMAS) (32%), while other sources like employers, colleagues or professional associations and networks, as well as education and scientific papers were selected by less than a quarter of the participants.

There are, however, some regional differences: for instance, among Spanish speaking Latin American countries, the local network of HCWH and organisational policies are listed among the most important sources of information (by 60% and 53% of the respondents respectively).

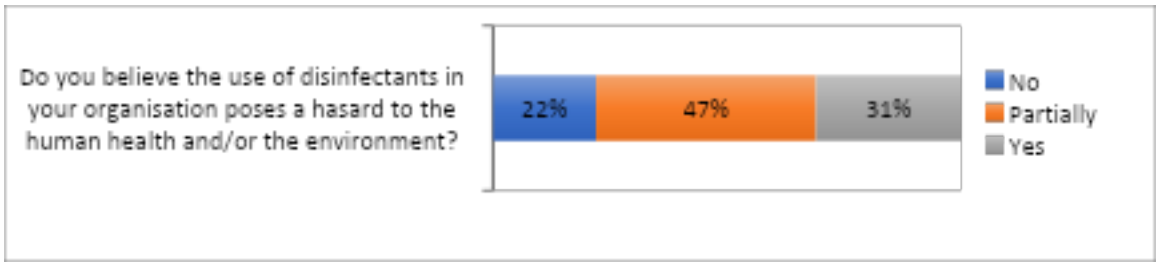


Disinfectant Safety Data Sheets (SDS)

The large majority of respondents (93%) declare to consult the disinfectant SDS either always (73%) or at least occasionally (20%). Only one respondent does not consult it, while five respondents do not consider it applicable for their roles. However, this trend was not reflected in reality when the HCWH team collected the disinfectants' SDSs from participating hospitals: at least half of them did not have the products' SDSs, especially in Latin American and Asia. Although the majority of hospitals were able to get the information from their suppliers, this process lasted several months and some of the participants were not able to provide any supporting documentation for the product benchmark analysis.

Hazard posed to human health and/or the environment

The majority of respondents believe that the use of disinfectants in their organisation poses a hazard to human health and/or the environment at least to a certain extent (almost half replied 'partially' and almost a third replied 'yes'). There is however a different degree of awareness about the types of hazards posed by these products.



Respondents stress the value of disinfectants in healthcare settings, and the need to carry out cost benefit analyses of the use of these essential products because of the harm that they can cause to people and the environment. Some respondents further explain the type of risk posed by the active ingredients of these products stating that "surface and high-level disinfectants cause or exacerbate respiratory illnesses, including asthma and chronic bronchitis; they may also be highly toxic to aquatic life and/or persistent in the environment".[45]

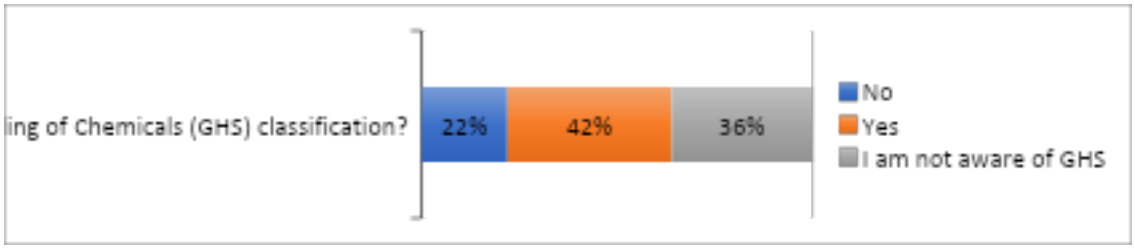
The most frequently mentioned causes of risk are: mishandling and incorrect disposal of disinfectants, lack of adequate safety information provided by the product manufacturer, lack of adequate personnel training and personal protective equipment (PPE), and the presence of active ingredients that are carcinogenic and corrosive.
Some of the respondents shared their challenges in finding products that do not pose difficulties while breathing and do not have negative effects on the skin of their employees and patients exposed to disinfectants. They emphasise their willingness to purchase safer products but point out to a lack of (wide) availability of such products for the healthcare market.

Adoption of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Part of the challenges related to the lack of information could be overcome with the implementation of an adequate regulatory framework. For example, the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) defines and classifies the hazards of chemical products, and communicates health and safety information on labels and SDSs. Nevertheless, the GHS is not widely known among respondents: on average, only 42% of respondents declare to use this system, while more than a third (36%) are not aware of its existence. It is important to mention that, depending on the region, there are great differences among these answers. For instance, in Brazil, almost half of the respondents are not aware of the GHS (42%). Meanwhile, among the Spanish speaking Latin American respondents, two thirds of them (67%) recognise the GHS. Similarly, in European and North American countries, the understanding of GHS is above average in comparison to other regions. In the EU countries, the Classification, Labelling and Packaging (CLP) Regulation ((EC) No 1272/2008), based on the UN GHS, is legally binding across the Member States and directly applicable to all industrial sectors. It requires

[45] Definition:*high-level disinfectants inactivate all micro-organisms (vegetative bacteria, mycobacteria, fungi, enveloped and non-enveloped viruses) except large numbers of bacterial spores. High-level disinfectants can inactivate spores when applied with prolonged exposure times and are called chemical sterilants.*
*(*https://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_021.pdf p.19)

manufacturers, importers or downstream users of substances or mixtures to classify, label and package their hazardous chemicals appropriately before placing them on the market.

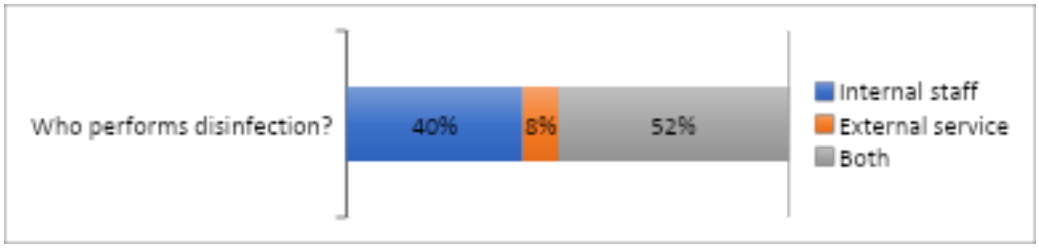


Disinfectants application and disposal

Application

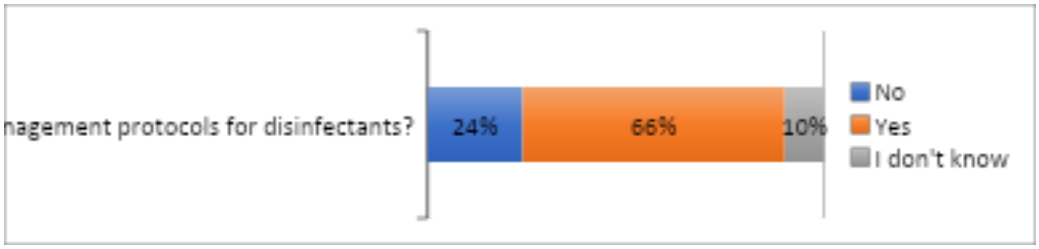
All the organisations but one declare to have hygiene plans and disinfection protocols. In addition, half of them (51.2%) have already identified areas where the use of disinfectants can be safely minimised or eliminated, like non-critical and non-clinical common areas, especially where patients do not normally have access (administration offices, corridors, some kitchens, pharmacy, laboratories and warehouses). Few respondents declare to have reduced the use of disinfectants for clinical procedures like endoscopy. Amongst the other examples, one institution replaces disinfectants with heat whenever possible and it implements a multi-level decontamination strategy to minimise the use of high-level disinfectants and to apply them only when truly needed (e.g. outbreaks). A second institution replaced chlorhexidine in the neonatal intensive care unit. In addition, another hospital is carrying out tests to replace enzymatic soaps since studies show that their use is not necessary.

In 52% of the organisations, disinfection is performed by a combination of internal staff and external service. In 40% of the organisations, only the internal staff is responsible for disinfection, while a smaller group of hospitals (8%) rely on external service only. The use of external staff and cleaning companies may have implications on the choice of purchased products (has explained in the case study from Germany).



Disposal

On average, two thirds of the organisations (66%) have disposal/waste management protocols for disinfectants. Around a quarter of the respondents (24%) do not have such protocols, while 10% do not know whether they have them or not. However, given the lower rate of awareness about GHS, further research is needed on the waste management plans in place.



Training provision

The majority of participating health organisations (77%) provide training in the use and disposal of disinfectants. The frequency of these trainings varies across organisations and it is often based on the level of experience of the employees (e.g. new hires receive it more often) and the needs of the departments (e.g. adoption of a new product, or when any deviations are observed).

The preferred training format is in-house meetings with presentations and practical demonstration from experts like hygienists, facility managers and infection control managers. Around 10% of the organisations also invite suppliers and service providers to deliver the training. Few organisations opt for online training or induction and orientation on the job.

Sixty-one organisations provided further details about the frequency of this training. Almost a third of them (19) organise trainings at least twice a year; eight organisations have quarterly training, two bimonthly, and eleven of them hold monthly trainings. Ten hospitals prefer annual training, but they also explain that frequency may increase depending on needs. A small number of hospitals run

evaluation tests to assess the knowledge of new hires and of their employees and adapt the need of training accordingly.

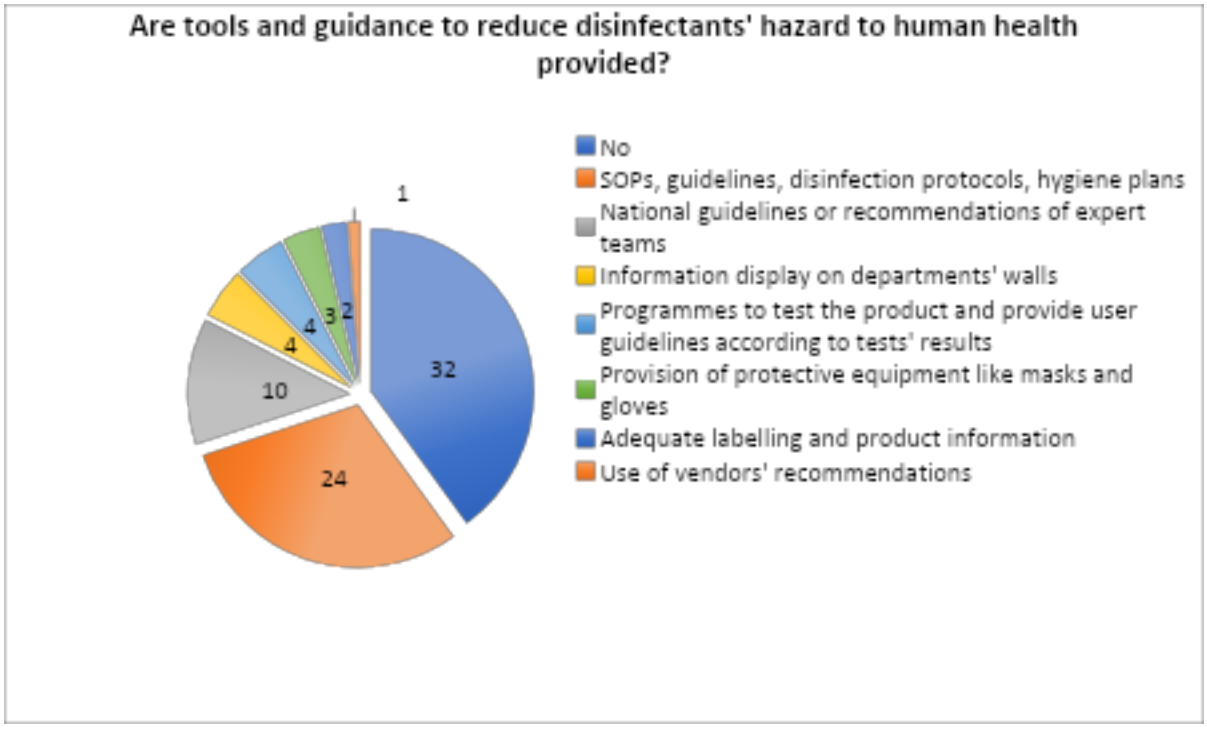
Data collection and monitoring

The majority of participating organisations (60%) state that they collect data on the quantities of disinfectants used. They were asked at what level they collect such data and were given the following options: department, clinic, hospital, hospital group, 'data are not collected', and 'I do not know'. According to the respondents, data collection mainly happens at both hospital and department levels for surface, instruments and hand disinfectants, while data about textile and dishes disinfection happens only at hospital level. Nevertheless, almost 13% of respondents were not fully aware of the data collection trends.

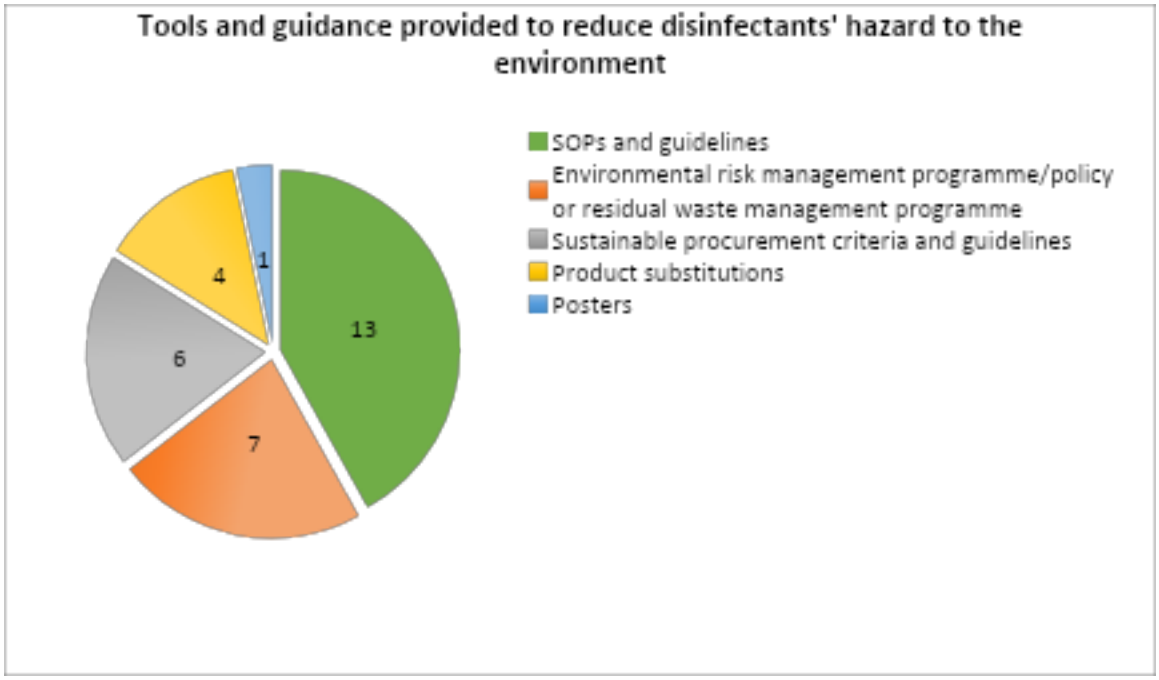
Occupational health and safety, and environmental protection

The large majority of respondents (95%) declare that their organisation has personnel dedicated to occupational health and safety. However, this percentage slightly decreases when participants are asked about the presence of staff dedicated to environmental protection (84%). The majority of respondents (75%) also state that their organisation reports on accidents related to the handling of disinfectants.

Almost two thirds of the organisations (61%) provide employees with tools, rules and guidance to minimise or avoid disinfectants/substances that pose a **threat to human health.** Among them, the majority of respondents (24) list the following measures: the adoption of Standard Operating Procedures (SOPs), provision of guidelines and implementation of disinfection protocols as well as hygiene plans. Responsible purchasing according to national guidelines or according to the recommendations of expert teams has been indicated by 10 organisations as a means to minimise or avoid harmful disinfectants/substances. Other tools adopted by the responding organisations are the display of information on departments' walls to ensure that guidelines are constantly visible to employees (4), programmes to test the product and the provision of user guidelines accordingly (4), provision of personal protective equipment like masks and gloves (3), adequate labelling and product information (2) and the use of vendors' recommendations (1).



Similarly, more than half of the respondents (55%) declare to provide tools, rules and recommendations to reduce or avoid the application of disinfectants that pose a **threat to the environment**. Apart from trainings, these tools mainly consist of SOPs and guidelines (e.g. Global Green Healthy Hospitals' Guidelines - mentioned by 13 respondents), environmental risk management programme/policy or residual waste management programme (7) or sustainable procurement criteria and guidelines (6). A smaller number of hospitals (4) explain how they substituted certain products especially for the disinfection of toilets and laundry cleaning to avoid the most hazardous substances entering the sewer systems. Other hospitals use posters and treat empty disinfectants' containers as hazardous waste.

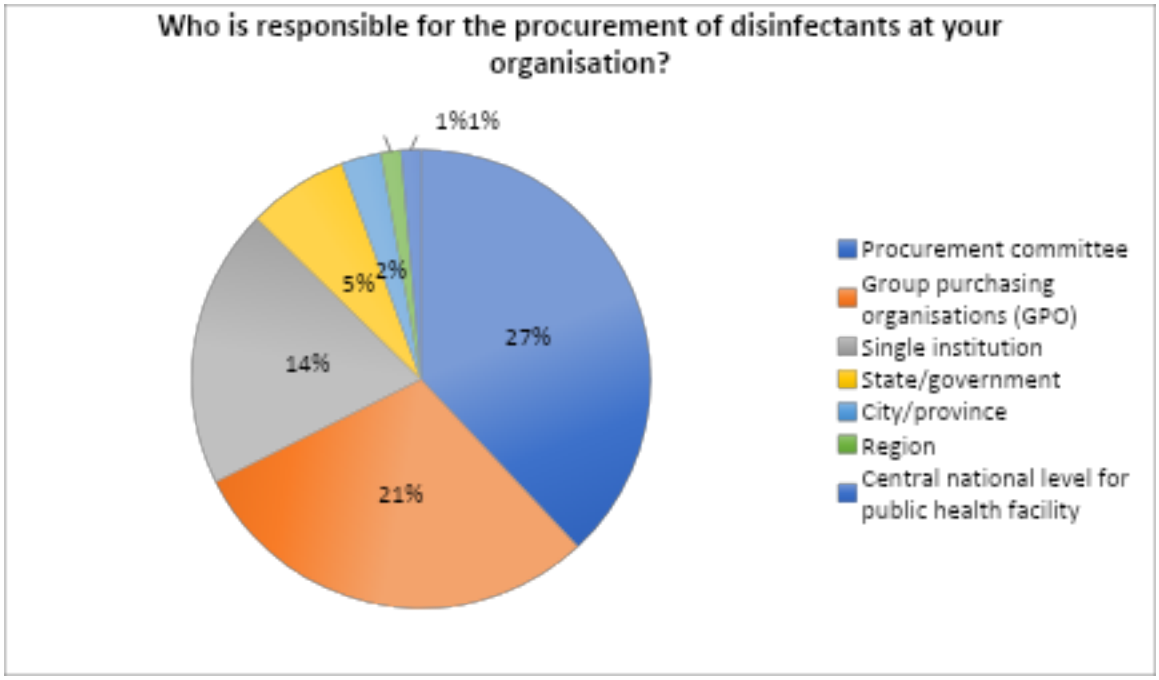


Procurement and tendering processes

The function responsible for procuring disinfectants

Participants could select multiple options to describe who is responsible for the procurement of disinfectants in their organisations. Among the listed, the most selected options are the 'procurement committee' (27%), 'group purchasing organisations' (GPOs) (21%) and the 'single institution' itself (14%). None of the other available options, namely 'state/government', 'central national level for public health facility', 'region' and 'city/province' scored higher than 5%.

In addition to this, 14 hospitals (16%) further explain that their procurement committee/team(s) collaborate with GPOs or with other departments (e.g. Infection Control, Facility Management, Medical Device Reprocessing Department, and warehouse); in some cases, this internal collaboration takes the form of an 'Expert Interdisciplinary Committee'. Thirteen hospitals (8 in Brazil) outsource the procurement of disinfectants to cleaning companies or third parties. In one hospital, the departments and/or end users that need disinfectants are directly responsible for purchasing it. In Brazil, one hospital has a Commission for Standardization of Medical-Hospital Materials in charge of procuring disinfectants.



The initiators

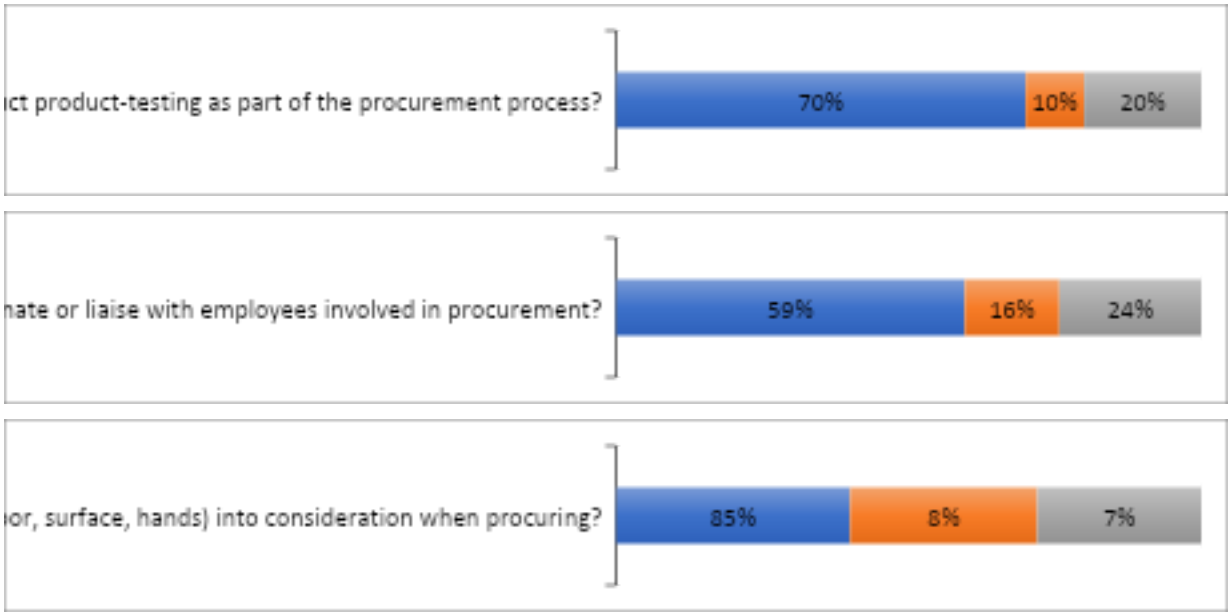
Seventy-three hospitals provided more information about who highlights the need for disinfectants (initiators). In half of the hospitals (51%), the main initiator is the Infection Prevention and Control Department, and in almost half of these cases, the department assesses the need for the product in cooperation with other units and colleagues. The units and roles mentioned vary across hospitals: pharmacy, cleaning/hygiene, environmental and waste units, sterilization units, nurses, laundry, facility managers and the warehouse.
In other hospitals, the initiator is either the facility manager who takes care of logistics and warehouse (12%), the clinical staff (12%) or the head of each department (8%). The rest of the respondents gave different answers like 'interdisciplinary commission' or 'external providers'. In addition, in one hospital, any worker can highlight the need for disinfectants.

Sustainable procurement

For almost half of the respondents (47%), procurement principles also apply to the tendering of disinfectants, but fewer organisations (35%) include sustainable procurement criteria in the overall procurement process. In addition to this, more than half of the organisations (52%) do not conduct evaluation reports on the implementation of their sustainable procurement policy.

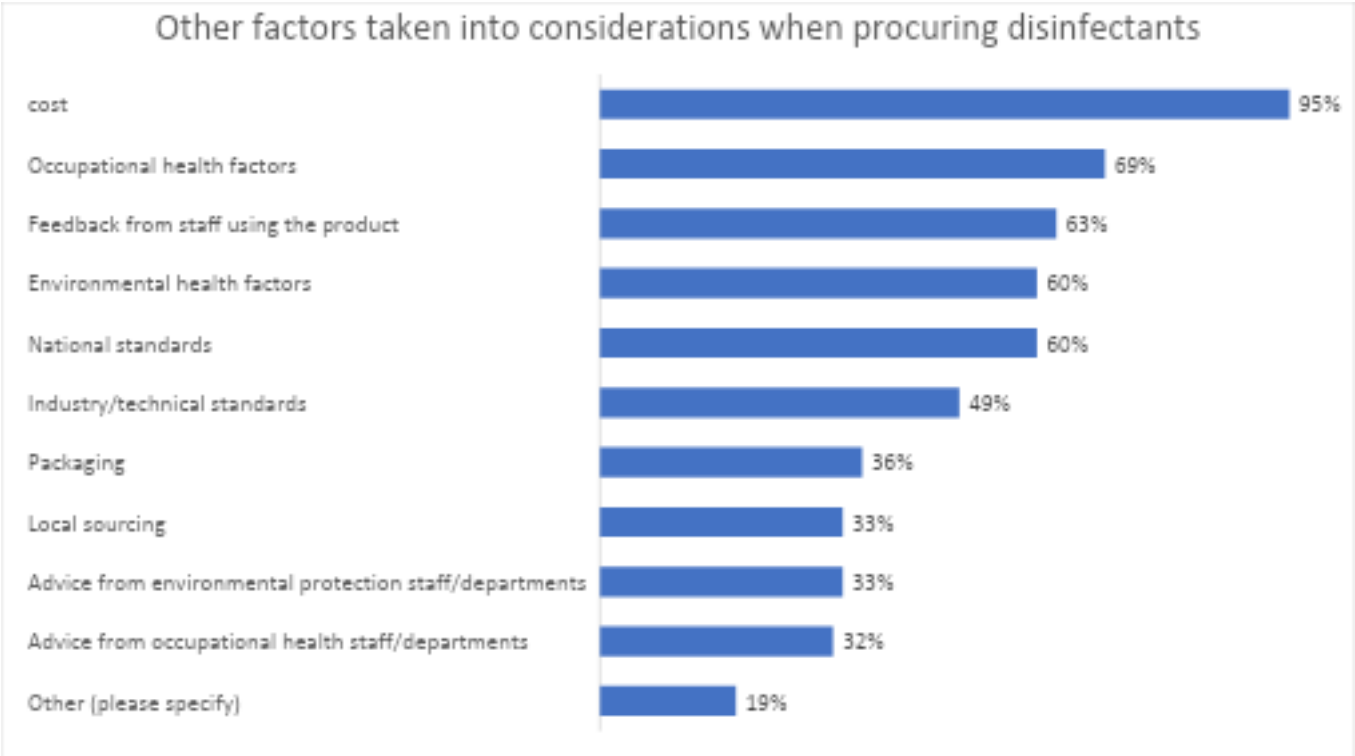
A majority of organisations (69%) document the procurement of disinfectants and conduct product testing as part of the procurement process. However, participants did not shared more information about the type of testing. Two thirds of the respondents (66%) conduct market research or contact potential providers prior to the tendering of disinfectants.

In more than half of the hospitals (59%) the employees responsible for occupational health and safety/environmental protection coordinate or liaise with the employees involved in procurement. The majority of organisations (85%) take the final use of the disinfectant (e.g. floor, surface, hands) into consideration when procuring.

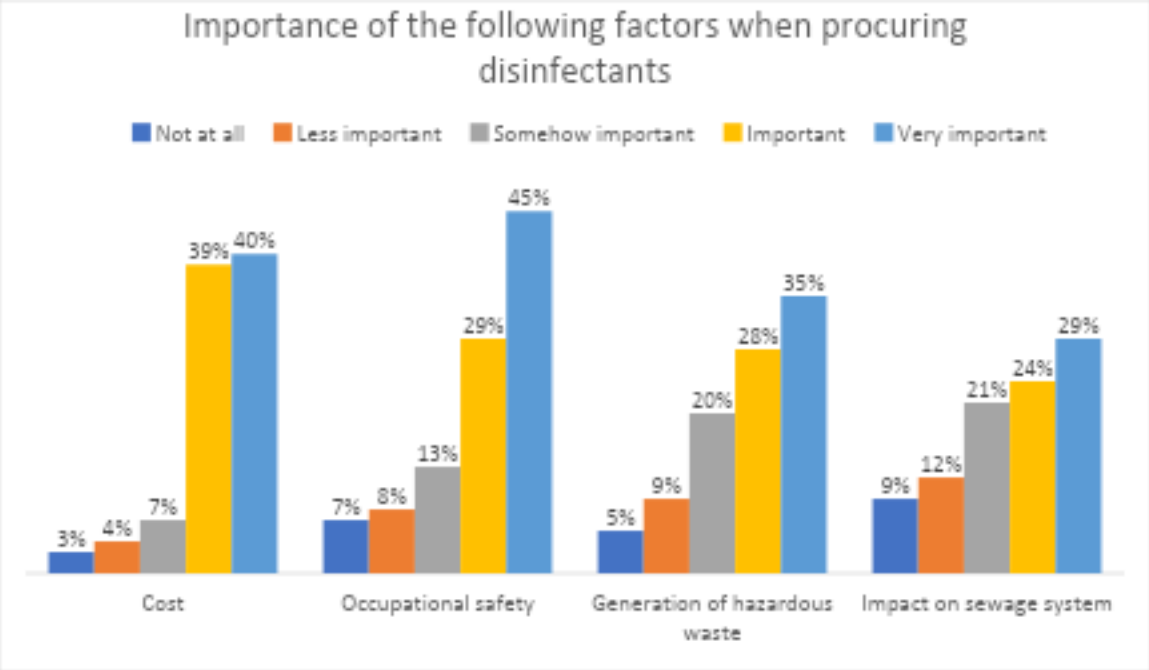


Other factors considered when procuring disinfectants

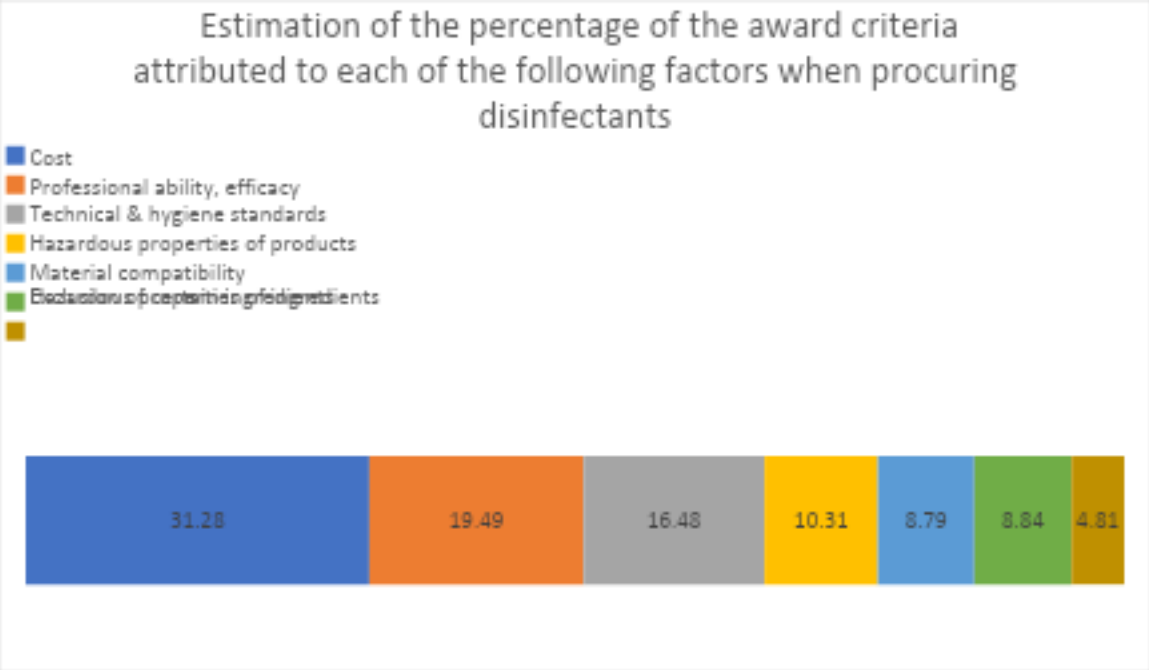
Seventy-five respondents provided more information about the other factors considered when procuring disinfectants. Almost all respondents (95%) consider the price of the product. The large majority states to take into consideration also occupational health factors (69%) and the feedback from employees using the disinfectant products (63%). While national standards and environmental factors seemed to be equally considered (60%), only a third of respondents state to consider the advice from occupational health (33%) and environmental departments (33%)



Participants were asked to rate the importance of factors like cost, occupational safety, generation of hazardous waste, and the impact on the sewage system when procuring disinfectants. Seventy-five participants replied to this question. Occupational health is very important for almost half of the respondents (45%) and important for almost a third of them (29%). Similarly, the price of the product is considered very important by 40% of respondents and important by 39% of respondents. In comparison, factors like the generation of hazardous waste or the impact on the sewage system are considered either very important or important by fewer participants.



Participants were asked to give an estimation of the percentage of the award criteria attributed to different factors in their organisation's procurement of disinfectants (the total some of award criteria should equal 100%). Sixty-seven participants replied to this question. On average, the price of the product is the criteria that weighs the most (31 points) followed by efficacy (19 points), and technical and hygiene standards (16 points).



Hazard analysis: Methodology

The hazard analysis for each hospital was done as follows:

1. Data evaluation

In a first step SDSs and technical fact sheets submitted by the participant were investigated in respect to claimed product efficacy. Only products with an explicitly named "disinfecting impact" or with biocidal ingredients reasonably indicating a disinfecting impact and present in sufficient concentration were further considered for the analysis. Products without disinfecting impact were not further considered (mainly cleaners). The participants received a summary of the data evaluation as follows:

Anonymised document of data evaluation submitted to the participant:

Product name	Type of application	SDS	Emission date	Manufacturer	First step analysis	Justification
A	Disinfection	#1	10.07.2014	Company X	Yes	Disinfecting impact
B	Hand disinfection	#2	15.12.2015	Company Y	Yes	Disinfecting impact
C	Disinfection	#3	14.07.2016	Company Z	Yes	Disinfecting impact
D	Surface disinfection	#4	06.09.2017	Company Z	Yes	Disinfecting impact

2. Detailed analysis

For detailed analysis information of each component (CAS number, product concentration, H-phrasing) given in chapter 3 of the products' SDS were extracted and transferred into an excel sheet. This information is complemented with the corresponding name and classification given in the WIDES database (right-hand columns)[46]. For the analysis, it is the WIDES classification and not the classification given by the SDS that is applied. This is because the WIDES classification considers the most relevant and recent classification given in the documentation of the European Chemicals Agency concerning REACH and Biocidal Products Regulation. In column "WIDES data gap" overall knowledge about potential hazards of the ingredient is rated as follows:

- 0 ("there is no data gap") means that – apart from the identified and classified hazards – hazards to health and the aquatic environment can reasonably be excluded due to available test data and/or expert judgment.
- 1 ("there is a data gap") means that - apart from the identified and classified hazards – a hazard to human health **or** the aquatic environment cannot be excluded.
- 2 ("there is a data gap") means that - apart from the identified and classified hazards – a hazard to human health **and** the aquatic environment cannot be excluded.

Designation of a data gap is based on ingredient assessment in the WIDES database (indicated there by an "?").

Identified ingredients	CAS#	%	H-phrase according SDS	WIDES name	WIDES classification	WIDES data gap
Benzalkonium chloride	68424-85-1	0.45	H302, H312, H314, H400	Alkyl (C12-16) dimethylbenzyl ammonium chloride (ADBAC/BKC (C12-16)	H302, H311, H314, H400(M10), H410(M1)	0
Didecyl dimethyl ammonium chloride	7173-51-5	0.4	H302, H314	Didecyldimethylammonium chloride	H301, H314, H400(M10), H411	0
Polyhexamethylenebiguanide (PHMB)	27083-27-8	0.1	H302, H315, H317, H318, H400, H410	Polyhexamethylene biguanide hydrochloride (PHMB)	H302, H317, H318, H330, H351, H372, H400(M10), H410(M10)	0

[46] In the case in which the WIDES does not already include the product component, an anonymous entry for this component is created - provided with classification and assessment data. In such a case, the WIDES name is not underlined.

In a next step, each hazard phrase of each component is assigned to a category - A, B or C. This assignment called "ABC categorisation" forms the basis of the hazard analysis and differentiates between hazards with high (category A), significant (category B) and minor (category C) concern (see also: explanatory notes to ABC categorisation). The figure below provides the analysis for a product with 3 components. H-phrases categorised as A (high concern) are coloured red and those categorised with B (significant concern) are coloured yellow. H-phrase categorised as C (minor concern) are not further indicated.

Corresponding WIDES name (underlined: public accessible; not-underlined: SAICM entry /not public accessible)			H340, H350, H360	H372	H334	H317	H300, H301, H310, H311, H330, 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
WIDES name	WIDES classification	WIDES data gap	CMR Cat. 1A, 1B	STOT RE 1	Resp. Sens.	Skin sens.	Acute Tox. Cat.1, 2, 3	CMR Cat. 2	STOT RE 2		health hazards	Aquatic Acute, Aquatic Chronic	Aquatic Acute, Aquatic Chronic	Behaviour in surface water
Alkyl (C12-16) dimethylbenzyl ammonium chloride (ADBAC/BKC (C12-16))	H302, H311, H314, H400(M10), H410(M1)	0					x						x	
Didecyldimethylammonium chloride	H301, H314, H400(M10), H411	0												
polyhexamethylene biguanide hydrochloride (PHMB)	H302, H317, H318, H330, H351, H372, H400(M10), H410(M10)	0		x		x	x	x					x	
				x		x	x	x			x		x	

Explanatory notes to ABC categorisation:

Hazards of ingredients can be reasonably differentiated in respect to the severity and duration of the effects they induce. Some constitute rather harmless or reversible effects (e.g. skin irritation) while others are severe and/or irreversible (e.g. cancer-induction, sensitisation). The core of the hazard analysis is the application of a categorisation scheme to distinguish between hazards with high (category A), significant (category B) and minor (category C) concern. The categorisation scheme supports the identification of ingredients with a high hazard potential. The main tool for that is the Globally Harmonized System of Classification and Labelling of Chemicals (GHS System), which provides standardized phrases - the hazard statements - to indicate hazards both for chemicals and mixtures. Each hazard statement is designated a code, starting with the letter H and followed by three digits. The assignment of category is done by means of the classification (i.e. a set of hazard statements) of the dangerous ingredient.[47]

[47] This approach as the following limitations:
The scheme categorises hazards according to a presumed "concern"; as mentioned, the scheme distinguishes between three categories: Category A with "high concern" (red), category B with "considerable concern" and category C with "low concern". The assignment to a category follows the basic rule: Hazards which are difficult to control, which have an irreversible impact, which are proven for a substance and/or which already arise in low concentration or quantity are of foremost concern. For the developer of the scheme proven sensitising and CMR properties fall into category A. On the other side we perceive irritating and corrosive properties to be of "low concern" (category C). The proposed categorisation of hazards may be perceived as unfair or unbalanced since skin irritation is a widespread problem when dealing with chemicals. We agree that to a certain extent the categorisation is a compromise. But, on the other side, we try to "hide" all cases where an adverse effect is

Category A (high concern): Covers long-lasting, difficult to control and/or irreversible hazards on human health and/or the aquatic environment. The hazards covered can damage health, kill or endanger aquatic organisms in the long-term, even in low concentrations. As far as other criteria such as spectrum of efficacy and material compatibility allow it, we recommend ceasing the use of products with category A ingredients. In the calculation sheets the severity of these hazards is indicated with the colour red.

Hazard Category A (health hazards)	
H340 H350 H360	May cause genetic defects May cause cancer May damage fertility or the unborn child
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
Hazard Category A (aquatic hazards)	
H400 (M≥1000)	Very toxic to aquatic life and M-factor equal to or higher than 1000
H410 (M≥100)[3]	Very toxic to aquatic life with long-lasting effects and M-factor equal to or higher than 100

Category B (significant concern): Covers hazards with still significant adverse impact on health and the aquatic environment. Category B also includes data uncertainties about the hazard potential (data gaps) in relation to certain endpoints. Category B corresponds to a recommendation to examine product alternatives on a case-by-case basis. In the calculation sheets the severity of this hazards is indicated with the colour yellow.

Hazard Category B – considerable concern (health hazards)	
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 H361	Suspected of causing genetic defects Suspected of causing cancer 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 EUH031 EUH070	Contact with water liberates toxic gas Contact with acid liberates toxic gas Toxic by eye contact
H370	Causes damage to organs
Hazard Category B – considerable concern (aquatic hazards)	

completely reversible or a consequence of improper handling, accident, poor working conditions (e.g. proper ventilation) or insufficient personal protective equipment.

H400 (M≥10)	Very toxic to aquatic life and M-factor equal to or higher than 10
H410 (M≥1)[4]	Very toxic to aquatic life with long-lasting effects and M-factor equal to or higher than 1
Hazard Category B – considerable concern (data gaps)	
Data gap (health hazard): The WIDES database indicates that there is not enough knowledge about the acute toxicity, allergenic, mutagenic, carcinogenic, repro-toxic, or chronic toxicity hazard of the substance.	
Data gap (aquatic hazard): The WIDES database indicates that there is not enough knowledge about the acute (short-term) or chronic (long-term) aquatic hazard of the substance.	

Category C (minor concern): Covers limited, comparatively controllable and/or reversible hazard potential to health and the aquatic environment. We have corrosiveness, indicated by the hazard statements H314 and H318, assigned to category C. Given a controlled use with required dilution and proper working equipment, this property poses a small hazard. Although category C hazards should not be neglected, they generally do not constitute a substitution demand.

Hazard Category C – low concern (health hazards)	
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
Hazard Category C – low concern (aquatic hazards)	
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

3. Conclusions on substitution demand

In their feedback document the participants received conclusions drawn from the detailed analysis. These conclusions constitute a strong, limited or no substitution demand for each analysed product. The criteria are as follows:

- Substitution demand "Yes": the product contains at least 1 ingredient classified with a Category A hazard. This means we strongly recommend less hazardous product alternatives. The product may be a candidate for the second step of the hazard analysis (i.e. Product Benchmarking, see below).
- Substitution demand "No/Limited" or "Limited": the product contains 1 or more ingredients classified with a Category B hazard. This means that we do

not perceive an urgent need for substitution but recommend product alternatives on a case by case basis including cost-benefit considerations.
- Substitution demand "No": The product contains only ingredients with hazards categorized as C. This means that we do not perceive a substitution demand. Instead, we recommend the application of such a product.

4. Product benchmarking

Substitution demand is assumed if a product contains at least one ingredient categorised as A (high concern). In such a case the product is recommended for a product benchmarking. The overall aim is to identify products ("product alternatives") that are recommendable for substitution. For the product benchmarking a list of dangerous ingredients is needed together with information about their concentration, type of application, biocidal efficacy and use amount both for the product and the product alternative.

To search product alternatives the following strategies may be helpful: The participant themselves searches for product alternatives (on market or web). The categorisation scheme for ingredients may be helpful for preselection: If the product contains a category A substance, it cannot be an alternative. Additionally, the participant or evaluator may consult the WIDES database containing disinfectants for the hand, skin, surface, instrument and laundry disinfection. Further support for selection of product alternatives is provided in the section "Recommendations and advice".

The potential product alternative needs to have a comparable antimicrobial efficacy as the replaced product. Lacking material comparability or system compatibility may also be a reason to reject the alternative. After a product alternative is selected, the product benchmarking may start. It affords several calculation steps that are not explained here for clarity reasons[48]. Instead the following basic elements and principles are mentioned:

Hazardous load (kg): The term "hazardous load" is synonymous with dangerous material cargo. The hazardous load is calculated on the bases of the consumption volume of the product. Alternatively, a default consumption value may be applied. For the calculation, concentration of ingredients for both the benchmarked product and the product alternative(s) is needed. This information can be found in the SDS, product information sheet and/or the WIDES database.

The quantity of application solution of the benchmarked product and the product alternative(s) has to be equal. Two types of application solutions are distinguished: One without dilution ("ready-to-use") and one used after dilution with water ("concentrate").

[48] The calculation is illustrated in the document "Hazard Analysis of Disinfectants" downloadable on the webpage of the Bureau For Chemical Engineering TB-Klade (http://www.tb-klade.at/en/).

Grouping of hazards: H-phrases are grouped to sum up hazards with a comparable degree of adverse impact. For instance, in the product benchmarking, the hand proven carcinogenic, mutagenic repro-toxic and chronic toxicity hazards respectively their H-phrases are summed up and grouped to hazard "CMR & CT hazard". Per definition one ingredient can contribute only once to a grouped hazard respectively hazardous load. The hazardous load has therefore to be adapted.

Benchmarking result: The benchmarking compares hazardous loads (in kg per application solution) of grouped hazards both in numbers and as a coloured chart. In the project the hazardous loads are grouped as follows:

- HIGH AQUATIC hazard (violet): Indicates high toxicity towards aquatic organisms with lasting effects. Applies if an ingredient is classified with one of the following hazard phrases:
    - H400 (M≥1000): Very toxic to aquatic life and M-factor equal or higher than 1000
    - H410 (M≥100): Very toxic to aquatic life with long-lasting effects and M-factor equal to or higher than 100
- AQUATIC hazard (yellow): Indicates toxicity towards aquatic organisms with lasting effects. Applies if an ingredient is classified with one of the following hazard phrases:
    - H400 (M≥10): Very toxic to aquatic life and M-factor equal or higher than 10
    - H410 (M≥1): Very toxic to aquatic life with long-lasting effects and M-factor equal to or higher than 1

a) CMR & CT hazard (red): Indicates proven carcinogenic, mutagenic, repro-toxic and/or chronic toxicity properties. Applies if an ingredient is classified with one of the following hazard phrases:
    - H340: May cause genetic effects
    - H350: May cause cancer
    - H360: May damage fertility or the unborn child
    - H372: Causes damage to organs through prolonged or repeated exposure
- SENS hazard (orange): Indicates proven sensitising properties. Applies if an ingredient is classified with one of the following hazard phrases:
    - H317: May cause an allergic skin reaction
    - H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled

Detailed case studies

Based on the outcomes of this second step, this interim report contains case studies from Brazil, Colombia, Germany, Iceland, and South Africa. Each case study is presented as follows:

1) Conclusions on the outcomes of the first hazard analysis

2) Products recommended for substitution (ingredients causing substitution demand, application, efficacy, potential barriers to replacement, etc.)
3) Identification and assessment of potential alternatives
4) Second step product benchmarking
5) Learning outcomes and next steps

Hospital 25 (H25): Brazil[49]

1. Conclusions on the outcomes of the first step hazard analysis

This Brazilian hospital has submitted a portfolio of 28 products, of which 15 have been selected for the first step of the hazard analysis because they were identified as products with disinfecting impact. Two products have been recommended for substitution: Surfic and Divosan S1. This recommendation is because both products have CMR and sensitising properties, as well as because they have long-lasting hazardous effects on water organisms.

Product name	**Substitution demand***	**Justification**
Surfic	Yes	1 ingredient category A
Anioxyde 1000	No	-
Divosan S1	Yes	2 ingredients category A, 3 ingredients category B
Drastic	Limited	2 ingredients category B
Hipoclor	No/Limited	1 ingredient category B
Oxivir Five 16 Concentrate	Limited	3 ingredients category B
Virex Detergente	No/Limited	1 ingredient category B
Master Bac Peroxyde	No	-
Cloro Link 1,0%	No/Limited	1 ingredient category B
Mikro CHLOR	No/Limited	1 ingredient category B
Virex Plus FLV	No/Limited	1 ingredient category B
Peroxide P20	No/Limited	1 ingredient category B
Peroxide P35	No/Limited	1 ingredient category B
Puristéril 340	No/Limited	1 ingredient category B
Quallix DTHS	No/Limited	1 ingredient category B

2. *Products recommended for substitution*

Divosan S1 includes the ingredients 4-tert-butylcyclohexyl acetate (CAS 32210-23-4) and citronellol (CAS 106-22-9), which are classified with H317 May cause an allergic skin reaction (cat. A). For Divosan S1, no further product

[49] Medium size general hospital (approximately 300 beds, average of 1317 inpatients per month and 443 outpatients per day)

benchmarking was considered because the product has been rarely used and the hospital stopped from using it immediately after receiving the results of the hazard analysis

Surfic	
Used for the cleaning and disinfection of floors, walls, equipment and fixed surfaces.	
Active ingredient	**Hazard**
Polyhexamethylene biguanide hydrochloride (PHMB) (CAS 27083-27-8). (Note: the received SDS cites a wrong CAS number for PHMB (112-34-5))	H317 May cause an allergic skin reaction (Cat. A)
	H330 Fatal if inhaled (Cat. B)
	H351 Suspected of causing cancer (Cat. B)
	H372 Causes damage to organs through prolonged or repeated exposure (Cat. A)
Alkyl (C12-16) dimethylbenzylammonium chloride (CAS 68424-85-1)	H311 Toxic in contact with skin (Cat. B)
	H400(M10) Very toxic to aquatic life and M-factor equal to or higher than 1000 (Cat. A)
	H410(M10) Very toxic to aquatic life with long-lasting effects and M-factor equal to or higher than 100 (Cat. A)

Conditions (received from the participant) that an alternative has to fulfill (in terms of effectiveness, material compatibility, price):

- Better efficacy
- Compatibility for use on floors, walls and more sensitive equipment
- Not requiring the use of two products (one for floors and one for more sensitive equipment)
- Better cost/benefit
- Availability of the product in the region

3. Identification and assessment of potential alternatives

Together with the results of the first step hazard analysis, the hospital was provided with a hazard categorisation list containing more than 100 active substances (this list is now integrated in the WIDES database) that they could easily use as a reference when searching for potential alternatives.

The use of Surfic was discontinued from 28 October 2019 and the product was replaced by Oxivir Five 16 Concentrate; the latter is already part of the hospital's products list and does not contain active substances categorised as A. The second step analysis is therefore a benchmarking between Surfic and Oxivir Five 16 Concentrate as alternative.

In addition, the hospital expressed the intention to test and add to their portfolio the following two products:

- Surfa'Safe, whose main active ingredient is Didecildimethylammonium chloride (CAS N ° 7173-51-5: 3 mg/g). This foam disinfectant detergent for surfaces and hospital products would be tested for more sensitive equipment such as incubators and monitors;
- Surfanios Premium NPC, with the active ingredients Didecildimethylammonium chloride (CAS N ° 7173-51-5: 25 mg/g) and N-aminopropyl dodecylpropane Dilamina (CAS N ° 2372-82-9: 51 mg/g). This is a concentrated disinfectant detergent for cleaning and disinfection of hospital surfaces, floor, walls, equipment and non-critical medical utensils.

None of the products contains active substances with category A hazard properties and therefore their use was not discouraged.

4. *Second step product benchmarking*

The product benchmarking was done between Surfic and Oxivir Five 16 Concentrate as potential alternative. In January 2020 the participant delivered data concerning use amount and dilution:

UTILIZAÇÃO DE OXIVIR FIVE 16/SURFIC							
Periodo	**Produto**	**Apresentação**	**Quantidade de total usada no periodo**	**Media consumo mês**	**Diluição usada**	**Rendimento total do produto diluido no mês**	**Rendimento total do produto diluido no ano**
01/01/18 a 31/10/19	Surfic (Quartenario de Amonia + Biguanida)	Frasco de 1L	846L	39L	1/200	7,800L/mês	93,600L/ano
01/11/19 a 17/01/20	Oxivir Five 16(Peroxido de Hidrogênio)	Frasco de 1,5L	216x 1,5 = 324L	(324/78 dias)x30 = 125L	1/64	8,000L/mês	96,600L/ano

Amount of Surfic (Concentrate) used: Between 1 January 2018 and 31 October 2019, the amount of 846L concentrate was used, resulting in an annual used amount of 468L of Surfic. Surfic is applied as a 1:200 dilution (0,5% concentrate), resulting in an annual application solution of 93,600L.

Corresponding amount of Oxivir Five 16 (Concentrate) used: Between 1 November 2019 to 17 January 2019, a monthly amount of 125L concentrate was

used by the participant, for which an annual amount of 1,500L is extrapolated. Oxivir Five 16 Concentrate is applied as a 1:64 dilution (1,56%). If Oxivir Five 16 Concentrate substitutes Surfic, then 93,600L of application solution are needed, resulting in 1,462.5L concentrate. The latter figure is used for the benchmarking calculation, since precise conformity of the quantity of application solution is a requirement. Ingredient concentrations and classified hazards are gathered from the safety data sheets and the WIDES database. Density of application solutions is assumed to be approximately 1. Claims for antimicrobial efficacy and material compatibility were gathered:

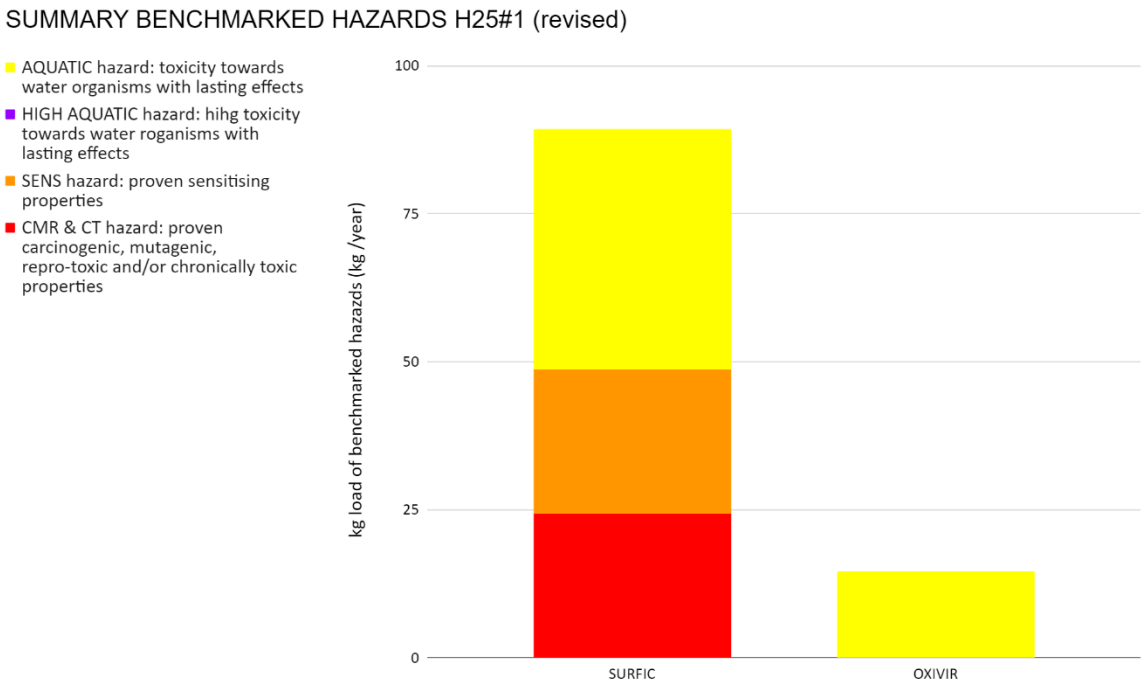
Antimicrobial efficacy & material compatibility

Claims on	Surfic	Oxivir Five 16 Concentrate (product data sheet*)
Antimicrobial efficacy	No information received or made available.	*…effective against a wide variety of pathogenic microorganisms including viruses, bacteria, antibiotic-resistant bacteria, fungi, mould and mildew…*
Material compatibility	No information received or made available	*…suitable for use on most washable non porous materials commonly encountered in environmental cleaning…not recommended for use on brass, copper or marble.*

*gathered by own data research

Calculation of hazardous loads (annual amount used: 93,600L):

Hazardous load	**CMR & CT**	**SENS**	**AQUATIC**	**HIGH AQUATIC**
	kg/application solution			
Surfic	24	24	41	0
Oxivir Five 16 Concentrate	0	0	15	0



Conclusion on substitution: Oxivir Five 16 Concentrate is a recommendable product alternative to Surfic.

Conclusion on comparability in antimicrobial efficacy: The information gathered about the product and its alternative is cited above. A sufficient comparability in bactericidal, yeasticidal and fungicidal efficacy is assumed but cannot be confirmed in detail. It is up to the hospital to review available data and decide if their requirements are met.

Conclusion on comparability in material compatibility: The information gathered about the product and its alternative is cited above. Since it does not allow a final conclusion, it is recommended to test compatibility with concerned materials.

5. Learning outcomes and next steps

Oxivir gave good cleaning and disinfection results, but some employees complained about the strong odour. Initially, the hospital also tested the product on turned-off incubators for a couple of months and obtained positive results. However, as of March 2020, the hospital decide to not test the products with the incubators on, as there is a risk of opacifying the acrylic material of the incubator and therefore damaging it., In turn, H25 is planning to further test, together with the supplier, the

products Surfanios Premium NPC and Surfa'Safe. After the testing, their standardisation committee will discuss which product will be standardised for their institution (Oxivir Five 16 Concentrate or Surfanios/Surfa'Safe).

Hospital 11 (H11): Colombia[50]

1. *Conclusion on the outcomes of first step hazard analysis*

It can be stated that the overall product portfolio of the participant presents a considerable satisfying standard in terms of occupational and environmental safety. The products applied for surface disinfection, hand and skin disinfection do not contain biocidal active substances with proven carcinogenic, mutagenic, reprotoxic, sensitising or highly persistent properties. However, one product for instrument disinfection has been recommended for substitution, namely Quiruger Plus, due to the presence of biocidal active substances Glutaraldehyde and Formaldehyde.

Product name	**Substitution demand****	**Justification**
QuineutriM	No/Limited	1 ingredient category B
Quiruger Plus	Yes	2 ingredients category A
Quigrass	Limited	2 ingredients category B
Dermocidal Sachet	No/Limited	1 ingredient category B
Quirucidal Jabon	Limited	2 ingredients category B
Quirucidal Solucion	Limited	2 ingredients category B
Supragel	No	-

2. *Products recommended for substitution*

Quiruger Plus	
Applied to disinfect instruments in the area of emergency care, hospitalization and dentistry.	
Active ingredient	**Hazard**
Glutaraldehyde	H317 May cause an allergic skin reaction (Cat. A)
	H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled (Cat. A)
Formaldehyde	H317 May cause an allergic skin reaction (Cat. A)
	H350 May cause cancer (Cat. A)
We categorised all of these hazard statements with A, meaning that they are of high concern. It was therefore recommended to replace Quiruger Plus with a product containing other biocidal active substances.	

[50] Small health centre, part of a hospital network (17 beds, average of 45 inpatients and 2420 outpatients per month)

Participant's reasons to use the product

- It is a well-known brand among the hospitals in the region
- It is a high-level microbial disinfectant with bactericidal, mycobactericidal, virucidal, fungicidal, sporicidal and sterilizing activity
- It is a cost-effective product

Conditions (received from the participant) that an alternative has to fulfil (in terms of efficacy, material compatibility, price):

- Is friendly to the environment: Does not have components such as Nonil Phenol that represent a risk H400 and H410, which are very toxic to aquatic life with lasting effects on it
- Does not cause damage to workers, contractors or to external customers: It should not have risk category A compounds (Glutaraldehyde and Formaldehyde)
- Has high efficacy in cleaning and disinfection of hospital microbial activity: Bactericidal, mycobactericidal, virucidal, fungicidal, sporicidal and sterilizing
- Easy to use

Use indication

Quiruger Plus is a high-level disinfectant for instruments and surfaces of medical equipment and devices. Before applying, the Activating Solution must be added to Quiruger Plus and the whole composition must be shaken. The activation date and the maximum date of use (30 days later) should be recorded. The product should be applied as needed: Immersion, application with cloth or spray.

According to the technical information sheet, which can be found online, the product may be applied as an immersion, with a tissue or as a spray (own translation from Spanish into English). Another form of application further considered is disinfection (bactericidal, mycobactericidal, fungicidal and sporicidal activity) of medical devices (including endoscopes) at room temperature as an immersion.

Antimicrobial Activity

By immersion		
Activity	**Duration**	**Strains of microorganisms used in standard testing**
Bactericide	5 minutes	Pseudomonas aeruginosa ATCC 15442; Staphylococcus aureus ATCC 6538; Enterococcus hirae ATCC 10541
Mycobactericide	15 minutes	Mycobacterium avium ATCC 15769; Mycobacterium terrae ATCC 15755

Virucidal	5 minutes	Adenovirus type 5; Poliovirus type one
Fungicide	5 minutes	Candida albicans ATCC 10231; Aspergillus niger ATCC 16404
Sporicide	20 minutes	Bacillus cereus CIP 7 803; Bacillus subtilis var. niger ATCC 9372; Clostridium sporogens ATCC 10541
Sterilizer	30 minutes	Clostridium sporogens ATCC 3584; Bacillus subtilis var. Niger ATCC 9372) according to the technique required by 510K (FDA)

By cloth or napkin application		
Activity	**Duration**	**Strains of microorganisms used in standard testing**
Bactericide	5 minutes	Pseudomonas aeruginosa ATCC 15442; Staphylococcus aureus ATCC 6538; Enterococcus hirae ATCC 10541
Bactericidal against multiresistant microorganisms of clinical origin	15 minutes	Pseudomonas aeruginosa 34740; Pseudomonas aeruginosa 34739; Klebsiella pneumoniae ATCC 1705; Klebsiella ATCC 2146 pneumoniae; Klebsiella pneumoniae ATCC 10353; Klebsiella pneumoniae ATCC 103239; Klebsiella oxytoca INAS1; Enterococcus faecium 34742
Fungicide	5 minutes	Candida albicans ATCC 10231; Aspergillus brasiliensis ATCC 16404; Candida auris 29927 multiresistant of clinical origin
Sporicide	15-30 minutes	Bacillus cereus CIP 7 803; Bacillus subtilis var. niger ATCC 9372; Clostridium sporogenes ATCC 10541

By spray application		
Activity	**Duration**	**Strains of microorganisms used in standard testing**
Bactericide	20 minutes	Pseudomonas aeruginosa ATCC 15442; Staphylococcus aureus ATCC 6538; Enterococcus hirae ATCC 10541
Mycobactericide	20 minutes	Mycobacterium avium ATCC 15769; Mycobacterium terrae ATCC 15755
Fungicide	20 minutes	Candida albicans ATCC 10231; Aspergillus brasiliensis ATCC 16404
Sporicide	20 minutes	

3. *Identification and assessment of potential alternatives*

The identification of suitable alternatives took four months. The main challenge was posed by the fact that the hospital could not find on the local market any products containing the active substances recommended by the consultant. These substances were indicated based on the information available on the WIDES database. The main limitation of the proposal was that it focuses mainly on the European market. Salud sin Daño (HCWH Latin America) also supported the market research by administering a supplier survey to their members to identify a company that would be able to provide suitable alternatives.

The hospital proposed to replace Quiruger Plus with two products, one for surface disinfection (Madacide-1) and another one for instrument disinfection (Alkazyme). Their adoption was discouraged due to the presence of (allergenic) fragrances in Madacide-1 and enzymes in Alkazyme. The hospital contacted the manufacturers of Madacide-1 to have more information about the fragrance used and asked about the possibility to have the product fragrance-free, but this was not possible. The same process was undertaken to ask if Alkazyme could be produced enzyme-free given the concerns posed by the presence of proteolytic enzymes. The hospital was then contacted by a US manufacturer that suggested the two alternatives Oxivir Five 16 Concentrate and Taski Virex II 256. A pre-screening of these products showed that they could be potential alternatives, so a product benchmarking was performed.

Pre-screening of proposed alternatives Madacide-1 and Alkazyme

Madacide-1		
The product is meant to disinfect hard, non-porous, inanimate, environmental surfaces, equipment and non-critical instruments. It seems to be aimed at disinfection of surfaces and not for (surgical) instruments or medical devices (including endoscopes).		
Ingredient	**Percentage**	**Comments**
Cloruro de n-Alquil (60%C14, 30%C16, 5%C12, 5%C18) dimetil bencil amonio	0.105%	Quaternary Ammonium Compound (QAC). **Hazard category B** according to WIDES
Cloruro de n-Alquil (68%C12, 32%C14) dimetil etilbencil amonio	0.105%	Quaternary Ammonium Compound (QAC). **Hazard category B** according to WIDES
Ingredientes Inertes	99.790%	
EDTA	4.210%	Identical with *Tetrasodium ethylenediaminetetraacetate (CAS 64-02-8)* and **hazard category B** according to WIDES
Neutronyx 656	0.526%	Can be identified as surfactant *Nonylphenol, 4-, Branched, ethoxylated* (127087-87-0). The ECHA webpage indicates it as a "Substance of very high concern (SVHC)" due to suspected endocrine disrupting properties
Sodiometasilicato·5H2O	0.263%	Equivalent to disodium metasilicate (6834-92-0) and **hazard category C** according to WIDES

Dietilenglicolbutileter	8.000%	Identical with *2-(2-butoxyethoxy) ethanol (112-34-5)* and **hazard category C** according to WIDES
Fragancia	0.200%	Several fragrances pose skin sensitising properties (H317), which we categorise with A in WIDES.
Agua	86.591%	

Assessing this information, Madacide-1 does not seem to be comparable to Quiruger plus since the former is recommended for surface disinfection while the latter is for instruments and medical devices.

Madacide-1 would formally fulfil the requirements for a product alternative (there was no category A ingredient identified), but with strong limitations arising from data gaps about ingredient identity (Fragrancia) and ingredient properties (Neutronyx 656).

Alkazyme		
In the received product information sheet, Alkazyme is indicated to be apt for cleaning any medical devices. It is assumed that Alkazyme is at least partly comparable to Quiruger plus. Claims about bactericidal, fungicidal and virucidal activity are given in the product information sheet but a profound interpretation and comparison to Quiruger plus would need more information. Therefore the evaluation and given conclusion is limited to the ingredients indicated in the product information sheet and the SDS.		
Product information sheet		
Ingredient	**Percentage**	**Comments**
Enzimas proteoliticas	0.6%	Proteolytic enzymes.
Agentes absorbents del decalcareo	32%	Decalcifiers
Agentes tensoactivos to ionicos	8.75%	Ionic surfactants
Cloruro de didecildimetilamonio		This is the biocidal active substance. It is **hazard category B** according to WIDES
SDS		
Ingredient	**Percentage**	**Comments**
Carbonato de sodi (497-19-8)	25-50%	Sodium carbonate, which is **hazard category C** according to WIDES
Alcohol etoxilado C16-C18 (68439-49-6)	2.5-10%	Alcohol C16-18, ethoxylated (1 - 2.5 moles ethoxylated), which is **hazard category C** according to WIDES
Alcohol etoxilado C10 (26183-52-8)	2.5-10%	Decan-1-ol, ethoxylated, which is **hazard category C** according to WIDES

Cloruro de didecildimetilamonio (7173-51-5)	2.5-10%	This is the biocidal active substance. It is **hazard category B** according to WIDES
Propan-2-ol (67-63-0)	<2.5%	**Hazard category C** according to WIDES

Alkazyme would formally fulfil the requirements for a product alternative (it does not contain any hazard category A ingredient), but with strong limitations arising from data gaps about the identity and properties of *proteolytic enzymes ("Enzimas proteoliticas")*. No conclusion can be made if the product is comparable in terms of efficacy (this would afford further information).

Based on the pre-screening above it is concluded that no meaningful outcome in product benchmarking can be expected. Additionally a disinfecting impact comparable to QUIRUGER PLUS for ALKAZYME is questionable

4. Second step product benchmarking

Based on the second proposal of the participant, a product benchmarking is performed for the disinfectant Quiruger Plus. Feedback was as follows:

In 2019, 109 units of Quiruger Plus were used (1 unit = 1L). Feedback indicates that it was used as a (activated) concentrate. The participant proposed Oxivir Five 16 Concentrate and Taski Virex II 256 as potential alternatives.. The outcomes are presented below.

Product benchmarking: Oxivir Five 16 Concentrate and Quiruger Plus

The first product benchmarking was performed for Quiruger Plus with Oxivir Five 16 Concentrate as alternative. Ingredient concentrations and classified hazards were gathered from the SDS and the WIDES database. Density of application solutions is assumed to be 1. Annual application solution of Quiruger Plus was calculated based on the annual used amount of the concentrate (109L) and no dilution (only activation without assumed volume alteration). Product alternative Oxivir Five 16 Concentrate has to generate the same quantity of application solution (i.e. 109L). A standard dilution ratio of 1:16 (6.25% of concentrate) is given in the product data sheet for disinfection activity within 5 minutes. A quantity of 7L of concentrate is calculated for the corresponding annual application solution of Oxivir Five 16 Concentrate.

Antimicrobial efficacy & material compatibility

Concerning microbial efficacy and material compatibility, the following information was found in the delivered documents (own translation from Spanish):

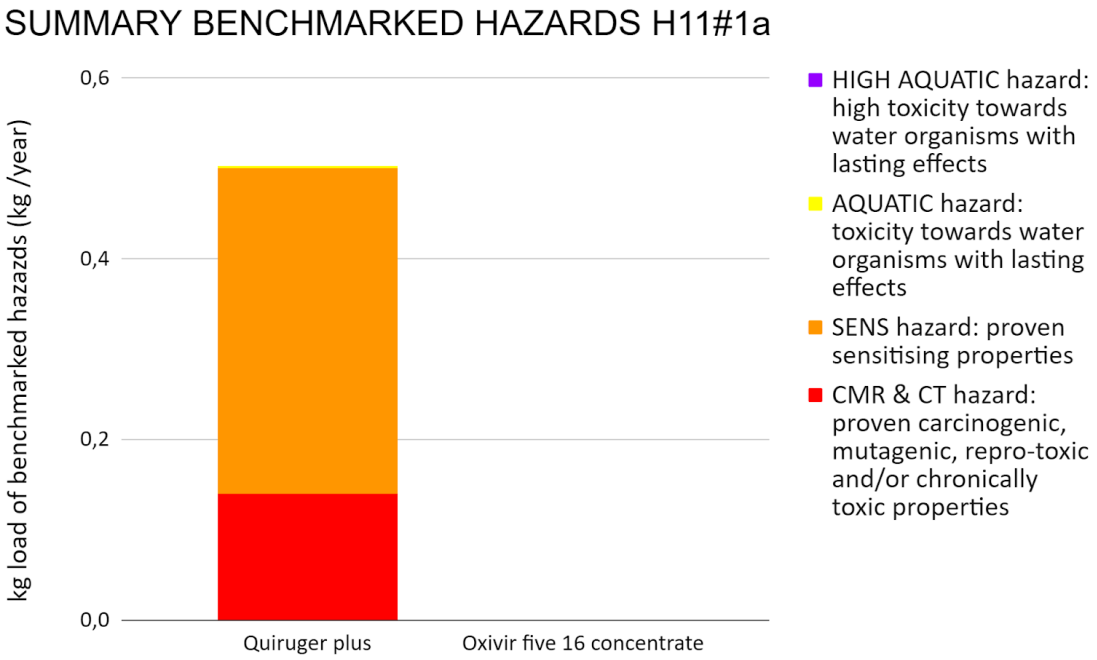
Claims on	Quiruger Plus	Oxivir Five 16 Concentrate (product data sheet)
Microbial efficacy	Disinfectant with bactericidal, mycobactericidal, virucidal, fungicidal, sporicidal and sterilizing activity *(For details see above)*	Bactericidal, fungicidal and virucidal in 5 minutes. Effective against the following microorganisms: Pseudomonas aeruginosa; Salmonella Enterica; Staphylococcus aureus; Enterococcus faecium (resistant against Vancomycin); Norovirus; VHB; VHC; VIH-1; Influenza Aviar; Parvovirus canino
Material compatibility	No information received	Compatible with the majority of hard, water resistant surfaces

The hospital (represented by research group GESPSS) in conjunction with the provider SES Diagnostics started a clinical study comparing the use of Quiruger Plus and Oxivir Five 16 Concentrate for surface disinfection and medical instruments. The study is composed of two phases: a clinical and a laboratory one.

As of March 2020, the participant has finished the clinical phase where they performed the sampling, culture, and counting of bacteria and fungi from different hospital areas and instruments that were subsequently disinfected with Quiruger, generating a new culture, and subsequently disinfecting with Oxivir, with a final culture. The laboratory phase is underway where Oxivir's ability to destroy highly pathogenic microorganisms is being measured.

Calculation of hazardous loads (annual amount used: 109L)

Hazardous loads	**CMR & CT**	**SENS**	**AQUATIC**	**HIGH AQUATIC**
	kg/annual application solution			
Quiruger plus	0.14	0.36	0.002	0
Oxivir Five 16 Concentrate	0	0	0	0



Conclusion on substitution: Oxivir Five 16 Concentrate is a recommendable product alternative to Quiruger Plus.

Conclusion on comparability in microbial efficacy: Information about microbial efficacy of both the benchmarked product and the product alternative is cited above. A sufficient comparability in bactericidal and fungicidal efficacy is assumed but cannot be finally confirmed. It is left to the hospital to review the available data and decide if their requirements are met.

Conclusion on comparability in material compatibility: The information about material compatibilities of both the benchmarked product and the product alternative does not allow for a conclusion about full comparability. It is recommended to test compatibility with the materials concerned.

Product benchmarking: Taski Virex II 256 and Quiruger Plus

The second product benchmarking was performed for Quiruger Plus with Taski Virex II 256 as alternative. Ingredient concentrations and classified hazards are gathered from the SDS and the WIDES database. Density of application solutions is assumed to be 1. Annual application solution of Quiruger Plus was calculated based on the annual use amount of concentrate (109L) and no dilution (only activation without volume alteration). Product alternative Taski Virex II 256 has to generate the same quantity of application solution (i.e. 109L). A standard dilution ratio of 1:256

(0,43% of concentrate) is given in the product data sheet for disinfection activity. A quantity of 0,4L of concentrate is calculated for the corresponding annual application solution of Taski Virex II 256.

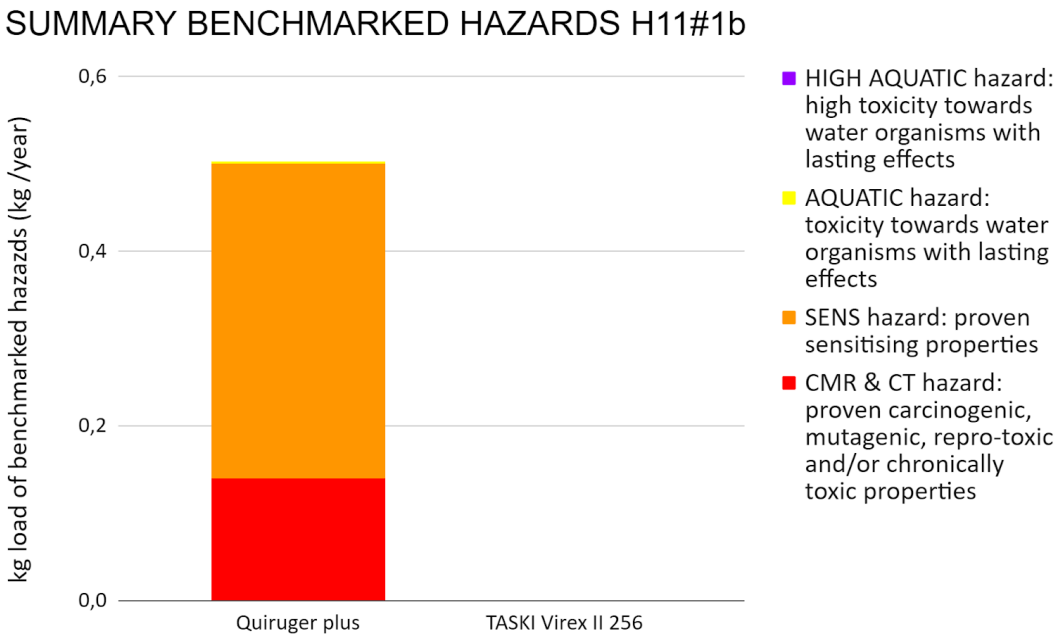
Antimicrobial efficacy & material compatibility

Concerning microbial efficacy and material compatibility, the following information was found in the delivered documents (own translation from Spanish):

Claims on	Quiruger Plus	Taski Virex II 256 (product data sheet)
Microbial efficacy	Disinfectant with bactericidal, mycobactericidal, virucidal, fungicidal, sporicidal, sterilizing activity (For details see above)	**Bactericidal in 1:256 against:** Pseudomona aeruginosa, Staphylococcus aureus, Salmonella choleraesuis, Staphylococcus aureus (methicillin resistant -MRSA), Escherichia coli, Klebsiella Pneumoniae, Listeria monocytogenes, Proteus mirabilis, Proteus vulgaris, Salmonella enteritidis, Salmonella pullorum, Salmonella typhi, Serratia marcescens, Streptococcus agalactiae, Streptococcus faecalis, Streptococcus pyogenes y Enterococcus faecalis - Resistencia Vancomycin según método AOAC. **Fungicidal in 1:256 against:** Tricophyton mentagrophytes, Candida albicans y Aspergillus niger. Virucidal in 1:256 against: HIV (AIDS virus), Influenza A2/J305, Herpes Simplex Tipo 1, Herpes Simplex Tipo 2, Adenovirus Tipo 2, Virus enfermedad New Castle, Influenza Avian y Virus Pseudorabies
Material compatibility	No information received	Compatible with surfaces

Calculation of hazardous loads (annual amount used: 109L)

Hazardous loads	**CMR & CT**	**SENS**	**AQUATIC**	**HIGH AQUATIC**
	kg/annual application solution			
Quiruger plus	0.14	0.36	0.002	0
Taski Virex II 256	0	0	0.0004	0



Conclusion on substitution: Taski Virex II 256 is a recommendable product alternative to Quiruger Plus.

Conclusion on comparability in microbial efficacy: Information about microbial efficacy of both the benchmarked product and the product alternative was cited above. No reliable statement can be made about comparability in terms of microbial efficacy. It is left to the hospital to review the available data and decide if their requirements are met.

Conclusion on comparability in material compatibility: The information about material compatibilities for both the benchmarked product and the product alternative does not allow a final conclusion about full comparability. It is recommended to test compatibility with the materials concerned.

5. Learning outcomes and next steps

The participant is now aware of international chemical classification systems and of the potential risks to human and the environment health linked to the use of substances that are extremely common in the hospital.

The hospital has improved the way they select and test products and started to collaborate with a laboratory and group of academia. They already have results for aerobic mesophylls and fungi and yeasts on surfaces and instruments. The next step is to complete the migration to the use of Oxivir and ensure that the other hospitals have all the necessary information to improve their use of disinfectants.

As of March 2020, the participant has not stopped from using Quirurger because changing provider requires an additional series of steps (e.g. calculating the volume required to meet hospital's needs) but they hope to finalise this procedure and replace products in three months.

Disinfection personnel would welcome the substitution of Quirurgel Plus with Oxivir: the latter does not require rinsing, surface dries quicker, and they can easily use smaller products amounts without having to activate the entire product as with Quirurger Plus.

In addition, the participant stated that it would be beneficial to have a 'local version' of the WIDES database to ease the categorization of the products available on the Colombian market. Disinfectants should also have effective clinical studies to facilitate their adoption. Since some hospitals might lack senior management support, the participant proposed to have an awareness and education tool created by HCWH showing the importance of switching to disinfectants with lower health and environmental risks.

Hospital 16 (H16): South Africa[51]

1. Conclusions on the outcomes of the first step hazard analysis

H16 from South Africa shared a list of 26 products, to which six other products were later added. Only ten of these products contain biocidal substances and were thus eligible for the hazard analysis.

Product name	**Substitution demand***	**Justification**
Multi Bac	No/Limited	1 ingredient category B
Bath Bac	No/Limited	1 ingredient category B
Pine Disinfectant	No/Limited	1 ingredient category B
Black Dip	Yes	1 ingredient category A, 1 ingredient category B
Household bleach	No/Limited	1 ingredient category B
Supplement received in December 2019		
Sani-Scrub	No/Limited	1 ingredient category B
GermX	No/Limited	1 ingredient category B
Saniswiss biosanitizer aHP C	No	-
Povidone Iodine Scrub	No	-
Povidone Iodine Solution	No	-

Among the first batch of analysed products, only the product Black Dip contains hazardous properties categorised as A. However, during the discussion of the results, the hospital explained that this product was not routinely used to disinfect

[51] Large regional hospital (800 beds, average of 736 inpatients and 25,000 outpatients)

in clinical practice, but rather to clean the facility drains and bins where insects may harvest (which is outside of the scope of this analysis).

In turn, the hospital supplemented the initial list with other routine disinfectants to be analysed. Although none of the new products pose a severe occupational health concern, two hand-disinfectants, namely Sani-Scrub and GermX, contain Chlorhexidine as a main active ingredient. According to both the WHO,[52] and the Infection Control Africa Network (ICAN) that collaborated on the topic with Stellenboach University in South Africa, alcohol hand rub is preferred for hand hygiene and is of equal cleansing effect to antiseptic and water hand cleaning, so chlorhexidine is not necessary, except for surgical hand scrubs.[53] As a result, the hospital was encouraged to substitute these products with alcohol-based disinfectants.

2. Products recommended for substitution

A recommendation for substitution of Sani-Scrub and Germ-X has been given due to the presence of the ingredient Chlorhexidine Gluconate (CAS 18472-51-0). Chlorhexidine gluconate poses a considerable hazard to the aquatic environment and is categorised as B in the WIDES database. Following specifications given by SANICHEM, the manufacturer of the products,[54] it is concluded that the products are generally foreseen for surgical (and hygienic) hand disinfection (own data research):

- Product description for Sani-scrub: *An antiseptic skin & pre-op surgical hand scrub. A Chlorhexidine based hand, body and pre-operative surgical disinfectant scrub (…) Chlorhexidine 4% in water, an antimicrobial preparation for pre and postoperative hand disinfection and general antisepsis*.
- Product description for Germ X: *No rinse hand sanitizer. Is an anti-septic gel for the safe disinfection of hands where soap and water are not available. Kills 99% of germs.*

To clarify if and how dispensable Chlorhexidine is as active ingredient in hand disinfectants, the evaluator TB Klade investigated scientific literature considering the following documents:

1) The book "Wallhäußer" from 2008 (available only in German) represents a standard reference for disinfection methods and ingredients in industrial and

[52] https://www.who.int/infection-prevention/tools/hand-hygiene/handrub-formulations/en/
[53] (See ICAN: Core Elements of Infection Prevention and Control): http://www.icanetwork.co.za/wp-content/uploads/2016/02/Training-Booklet-Short-Course-Revised-31Oct2017.pdf
[54] http://sanichem.co.za

medical applications. Therein the field of application of Chlorhexidingluconat (CAS 18472-51-0) is reviewed mentioning the following areas: antiseptic of mouth, vagina, skin and wounds as well as hand disinfection. The following note concerning hand disinfection is given (own translation): "Due to higher efficacy and better skin tolerability, alcohols should be favoured over detergents containing chlorhexidine. Also by adding Chlorhexidine to formulations that contain alcohol, the skin tolerability is reduced. Considering inconclusive long-term risks of Chlorhexidine and the questionable benefit of the addition of Chlorhexidine to alcoholic products in case of long-standing application, it is recommended to choose alcoholic products that do not contain Chlorhexidine. When applying Chlorhexidine containing products, the risk of an anaphylactic reaction has to be taken into account."[55]

2) The World Health Organisation (WHO) recommends Handrub Formulations. This guideline provides instructions for the preparation of two effective alcohol-based "handrub" formulations (i.e. hand disinfectants) for in-house/local production as an alternative when suitable commercial products are either unavailable or too costly. Apart from a high content of ethanol (80%) and Isopropyl alcohol (75%) the only additional biocidal active ingredient is 0,125 % Hydrogen peroxide (H_2O_2). The presence of a low concentration of H_2O_2 is intended to help eliminate contaminating spores in the bulk solutions and is NOT an active substance for hand antisepsis. The document concludes: *According to the available evidence on efficacy, tolerability and cost-effectiveness, WHO recommends using alcohol-based handrub for routine hand antisepsis in most clinical situations.*

The above-cited sources strongly support the view that hand disinfectants containing Chlorhexidine may be substituted by solely alcohol containing products without loss of efficacy.

Barrier to replace the product

Since the use of this type of products is established by provincial contracts, their replacement would require a change in the policy of the provincial government

Conditions (received from the participant) an alternative has to fulfil (in terms of efficacy, material compatibility, price)

No specifications for the performance of hand disinfectants was given by the hospital respectively considered by the evaluator.

[55] Wallhäußers Praxis der Sterilisation, Desinfektion, Antiseptik und Konservierung. Georg Thieme Verlag. 2008

3. Identification and assessment of potential alternatives

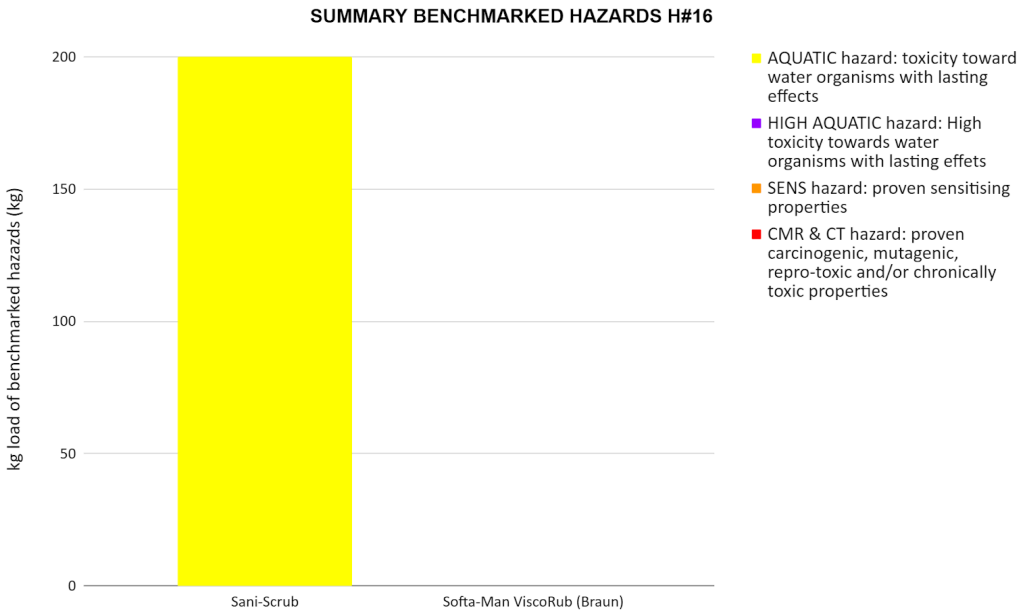
To support the change in the procurement decision-making, the hospital was provided with a list of alcohol-based disinfectants taken from the WIDES database (see also chapter "Product selection strategy for hand disinfection"). HCWH Europe encouraged the hospital to verify if any of the product listed are available on the local market. As indicated above, WHO provides a recipe for an alcohol hand rub that can be produced in the hospital pharmacy, together with recommendations on hand rub formulations.[56]

4. Second step product benchmarking

To further support the participant in his decision-making, a product benchmarking is performed for Sani-Scrub with Softa-Man ViscoRub as alternative. The alternative Softa-Man ViscoRub is a random choice of products listed in the WIDES database for disinfectants. The product alternative is marketed in Europe and there is no knowledge if it is available in South Africa. Since no annual use amount is given for Sani-Scrub, a default value of 1,000L is taken for the benchmarking calculation. The SDS shows the concentration of Chlorhexidine Gluconate with 20%, while information by the manufacturer (Sanichem) gathered online indicates an application concentration of Chlorhexidine 4% in water, which would suggest a dilution ratio 1:5, resulting in an application solution of 5,000L. Product alternative Softa-Man ViscoRub has to generate the same quantity of application solution (i.e. 5,000L). Since no dilution is foreseen this complies with 5,000L of product. The calculated emissions below are referenced to an application solution of 5,000L.

Hazardous Load	**CMR & CT**	**SENS**	**AQUATIC**	**HIGH AQUATIC**
Sani-Scrub	0	0	200	0
Softa-Man ViscoRub (Braun)	0	0	0	0

[56] https://www.who.int/infection-prevention/tools/hand-hygiene/handrub-formulations/en/



Conclusion on substitution: Softa Man Visco-Rub is a recommendable product alternative for Sani-Scrub.

Due to the lack of information from the participant, no conclusion could be made on the product's antimicrobial efficacy and material compatibility.

5. Learning outcomes and next steps

Without taking into account specific requirements of the participating hospital to the performance of their products used for hand disinfection (i.e. Sani-Scrub and Germ-X), evidence strongly indicates that Chlorhexidine Gluconate is not needed for performance of hand disinfectants and can therefore be substituted by alcoholic products. The evidence is supported by the WIDES product review (no certified hand disinfectants with Chlorhexidine but a large number of alcohol based products, see also "Product selection for hand disinfectants") and scientific reference (no benefit in efficacy and skin tolerability compared to alcohol based products). Therefore the recommendation for substituting Sani-Scrub and Germ-X is maintained. Common ingredient compositions with typical concentrations have been given to the hospital to support the selection of appropriate alternatives. Future procurement decisions should take into consideration these evidence and recommendations. It is however up to the hospital and provincial government to check efficacy of the product alternatives by interrogating the manufacturer or through microbial testing of the product, as our evaluation indicates, but cannot

fully guarantee, that mere alcohol containing products achieve the same (intended) antimicrobial of efficacy as Sani-Scrub and Germ-X.

Hospital 20 (H20): Iceland[57]

1. Conclusions on the outcomes of the first step hazard analysis

Thirteen disinfectant products have been analysed. It can be stated that the overall product portfolio of the participant presents a considerable high standard in terms of occupational and environmental safety. No biocidal active ingredients with proven carcinogenic, mutagenic, reprotoxic and highly persistent properties were found.

However, six disinfectants have been recommended for substitution because, depending on the product, they may cause allergic skin reactions or may be very toxic to aquatic life with long-lasting effects.

Product name	**Substitution demand****	**Justification**
Virkon S	Yes	2 ingredients category A
Handex 85 sotthreinsigel	No	-
Hreinsispritt	No	-
Sotthreinsispritt	No	-
Surfa'safe Premium	Yes	1 ingredient category A
Anoisurf ND premium	Yes	1 ingredient category A
Wip Anios excel	Yes	1 ingredient category A
Clinell Universal Sanitising Wipes	Yes	1 ingredient category A
Sani-Cloth70	No	-
Super Sani-Cloth Plus	Limited	2 ingredients category B
Sani-Cloth Active	No/Limited	1 ingredient category B
2% Peroxide Cleaner*	No/Limited	1 ingredient category B
Rely+On Virkon Tablets	Yes	1 ingredient category A

2. Products recommended for substitution

The following section describes the reasons for recommending the replacement of some of the products used by the hospital:

- For **Virkon S** and **Rely+On Virkon Tablets,** the substitution demand stems from the presence of Dipotassium peroxodisulphate (CAS 7727-21-1), which is classified with category A hazards H317 (may cause an allergic skin reaction) and H334 (may cause allergy or asthma symptoms or breathing difficulties if inhaled). Additionally Virkon S includes the fragrance limonene,

[57] Large general hospital (631 beds, average of 25,215 inpatients and 244,170 outpatients per year)

which is classified with category A hazard H317 (may cause an allergic skin reaction). However, the main biocidal active ingredient of both products is Pentapotassium bis (peroxymonosulfate) bis(sulphate)(CAS 70693-62-8), which is Category C and therefore recommendable for use.

- For **Surfa'Surf Premium**, **Aniosurf ND Premium** and **Wip Anios excel,** the substitution demand stems from the presence of Amines, N-C12-14-alkyltrimethylenedi- (CAS 90640-43-0), which is classified with category A hazard H372 (causes damage to organs through prolonged or repeated use) and category B hazard H410 (very toxic to aquatic life with long-lasting effects). Additionally Aniosurf ND Premium contains Chlorhexidinedigluconat (CAS 18472-51-0), which is also classified with category B hazard H410 (very toxic to aquatic life with long-lasting effects).
- For **Clinell Universal Sanitising Wipes,** the substitution demand stems from the presence of Polyhexamethylenbiguanide hydrochloride (CAS 27083-27-8), which is classified with category A hazards H317 (may cause an allergic skin reaction) and H372 (cause damage to organs through prolonged or repeated use), and category B hazard H410 (very toxic to aquatic life with long-lasting effects).

Participant's reasons to use the products

- **Rely+On Virkon Tablets** are used to clean and disinfect patient rooms, toilets and equipment, as well as operation rooms. The product is used after all contact and airborne isolations/precautions and, to ease the work of the cleaning staff, it is applied for both viruses that are easy to kill (e.g. influenza) as well as for Clostridium difficile that is hard to eliminate.
- **Surfa'safe Premium and Wip Anios excel** are used to clean and disinfect the operating rooms (OR) between operations and at the end of the day after the last operation, the anaesthesia side of the OR, as well as in the surgical side. It is used on the anaesthesia machine, the anaesthesia table, touch screens, the surgical table, IV pumps, cables, all tables in the OR room, etc. It is used mainly on all the devices that are not sterile or used on mucous membranes. This product was chosen because the hospital wanted to clean and disinfect in one-step (One-step method). They used to clean with soap and water and then disinfect with alcohol (Two-step method). The one-step method is easier and quicker and this product seems to be compatible to most of the devices and furniture used in the OR. Alcohol was a problem because it was not compatible with many of the items. In addition to this, the product is used on medical couches with Vinyl upholstery.
- **Clinell Universal Sanitizing Wipes** were initially used to clean and disinfect probes for ultrasounds (not for probes used on mucous membrane or intact skin). It is currently used all over the hospital to clean and disinfect

various types of equipment, like blood pressure cuff and machines, pulse oximeters, stainless steel tables, thermometers, cables, etc. It is preferred to alcohol wipes because it is compatible with more types of items.

Barrier to replace the product

Product	Barrier
Rely+On Virkon tablets	The hospital has been using Virkon for many years without any major problems and the cleaning staff are satisfied with the product, so it will not be easy to replace it. It was chosen instead of chlorine some years ago because people complained of headache and bad smell when using chlorine products (Chlor-clean 1000ppm).
Surfa'safe Premium and Wip Anios excel	The cleaning staff likes this product. It makes their job easier; it does not have a bad smell and does not leave any stains behind.
Aniosurf ND Premium	There are no particular barriers to replace this product. The staff do not like it because of its bad smell and the warnings written on the container. Thus, some people refuse to use it.
Clinell Universal Sanitizing Wipes	This product is widely used at the facility and the staff like to use this product.

Conditions (received from the participant) an alternative has to fulfil (in terms of efficacy, material compatibility, price)

Product	Condition
Rely+On Virkon tablets	• The product has to kill/destroy fungi, bacteria, spores and viruses like Noro. • It must have both cleaning and disinfecting effects. • It must be without strong odour. • It needs, of course, to be compatible with all kinds of materials that are used in patients' rooms and WC like plastic, wood, porcelain, steel, aluminium, vinyl, etc.
Surfa'Safe Premium and Wip Anios excel	• Has to kill/destroy most common viruses, bacteria and fungi, but does not have to kill spores. • Must have both cleaning and disinfecting effects. • Organic materials may not affect the substance/product activity. • Does not leave any residue behind that needs to be cleaned afterwards. • Must be without strong odour. • It has to be compatible with all kind of materials used in the OR but the hospital acknowledges the possibility of having to use more than one product.
Aniosurf ND Premium	• Has to kill/destroy most common viruses, bacteria and fungi, but does not have to kill spores. • Must have both cleaning and disinfecting effects.

	• Organic materials may not affect the substance/product activity. • Dries out without residue. • Must be without strong odour. • Compatible with vinyl.
Clinell Universal Sanitizing Wipes	• Has to kill/destroy most common viruses, bacteria and fungi, but does not have to kill spores. • Must have both cleaning and disinfecting effects. • Must be compatible with ultrasound probes that are not used on mucous membrane or intact skin.

3. Identification and assessment of potential alternatives

HCWH Europe and TB Klade had a call with the hospital where potential alternatives for substitution (available in the WIDES database) were discussed. More information about products' efficacy requirements, availability of alternatives and testing were exchanged via emails over four months. The following decisions have been made about the six products:

- In order to prioritise, unless the hospital wished to replace it, TB Klade did not further recommend choosing **Rely+On Virkon Tablets** (and **Virkon S**) for the second step product benchmarking. The products' main active ingredient is the biocide Pentapotassium bis (peroxymonosulfate) bis(sulphate) which is Category C and therefore does not pose severe concerns; in addition, the hospital staff is very satisfied with the product.
- The hospital decided to prioritise the replacement of **Surfa'safe Premium spray** and **Wip' Anios Exel**. The hospital chose the products Incidin Oxy Foam S and Incidin Oxy Wipes S. As they were not available on the local market, H20 got in touch with the manufacturer and managed to obtain some testing samples. As of February 2020, the hospital is still testing the new products for material compatibility and efficacy.
- As of February 2020, the hospital was not able to find a replacement for **Aniosurf ND Premium** that would meet their criteria and decided to phase out the product and clean the floors with soap and water.
- For ready-to-use disinfecting wipes like *Clinell Universal Sanitizing Wipes,* TB Klade recommended to consider product alternatives with Quaternary ammonium compounds but without the category A ingredient Polyhexamethylenbiguanid (PHMB). Thus, the product was benchmarked against the *Sani Cloth active (Ecolab*) to demonstrate attainable effects.

4. Second step product benchmarking

This second step product benchmarking focusses on the following products:

- Surfa'Safe Premium, Aniosurf ND Premium and Wip Anios Excel with product alternatives Incidin Oxy Foam S and Incidin Oxy Wipes S chosen by the hospital.
- Clinell Universal Sanitising Wipes with Sani Cloth Active proposed by the evaluator himself.
- Avoidance of hazardous loads is calculated for phasing out the product Aniosurf ND Premium.

Outcome Summary

Product	**Reason for substitution demand**	**Use amount**	**Measure**	**Avoidance hazardous load (kg)**
Surfa'safe Premium	Biocidal active ingredient with Cat. A	394.5L	Planned substitution**	19.8
Wip Anios Excel	Biocidal active ingredient with Cat. A	222.3L*	Planned substitution***	11.2
Clinell Universal Sanitising wipes	Biocidal active ingredient with Cat. A	Default value: 100L	Use reduction****	0.7*****
Aniosurf ND Premium	Biocidal active ingredient with Cat. A	40L	Phased out	6

*Estimate (1 package contains 0,45L active ingredient solution); **Planned alternative: Incidin Oxy Foam; ***Planned alternative: Incidin Oxy Wipe S; ****Product alternative to calculate avoidance: Sani Cloth Active; *****Saving based on assumed annual consumption

Benchmarking Surfa'Safe Premium and Incidin Oxy Foam S

Ingredient concentrations and classified hazards were gathered from the SDS and the WIDES database. Density of application solutions is assumed to be approximately 1. Annual application solution of Surfa'Safe Premium is calculated based on the annual use amount of the concentrate (394.5L) and no dilution (use of concentrate). Product alternative Incidin Oxy Foam S has to generate the same quantity of application solution (i.e. 394.5L).

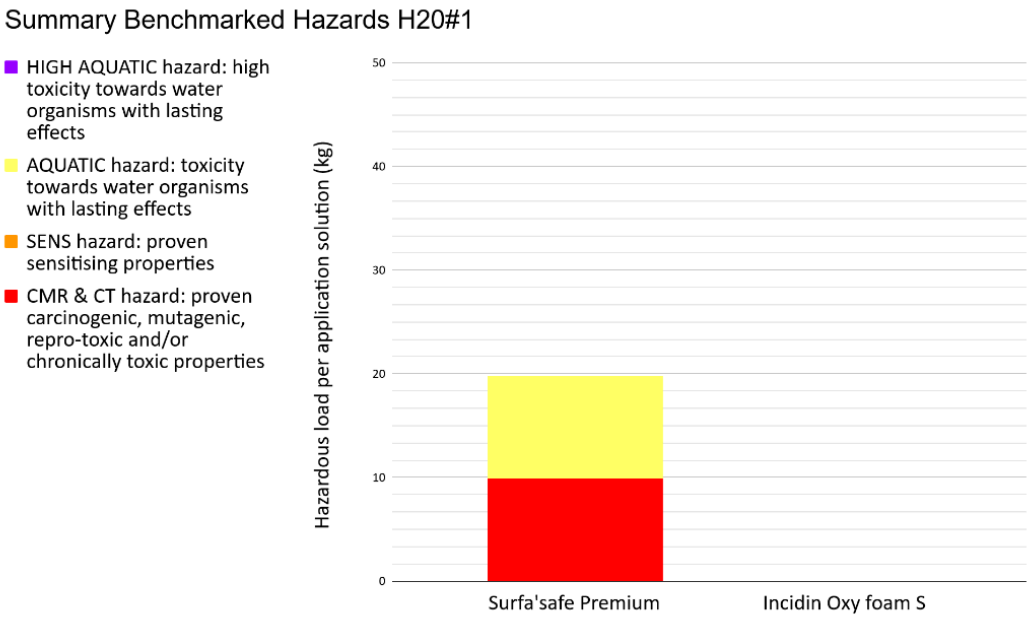
Antimicrobial efficacy & material compatibility

Claims on	Surfa'Safe Premium	Incidin Oxy Foam S (product data sheet)

Antimicrobial efficacy	Participant demands efficacy as follows: Has to kill /destroy common bacteria, viruses and fungi, but not spores. Organic materials shall not affect activity.	Bactericidal, yeasticidal & fungicidal with high organic load in 5 min.
Material compatibility	Participant demands compatibility as follows: Has to be compatible with all kind of materials used in the operation room.	Cannot be used on surfaces sensitive to oxidation (marble, copper, brass)

Calculation of hazardous loads (annual amount used: 394,5L):

Hazardous load	**CMR & CT**	**SENS**	**AQUATIC**	**HIGH AQUATIC**
	kg/application solution			
Surfa'Safe Premium	9.9	0	9.9	0
Incidin Oxy Foam S	0	0	0	0



Conclusion on substitution: Incidin Oxy Foam S is a recommendable product as an alternative to Surfa'Safe Premium.

Conclusion on comparability in antimicrobial efficacy: The requirements of the participant for antimicrobial efficacy are cited together with the basic claims for product alternative. A sufficient comparability in bactericidal, yeasticidal and fungicidal efficacy is assumed but cannot be confirmed in detail. It is left to the participant to review available data and decide if their requirements are met.

Conclusion on comparability in material compatibility: The requirements of the participant together with information about the product alternative are cited. Since it does not allow for a final conclusion, it is recommended to test compatibility with materials concerned.

Benchmarking Wip Anios Excel and Incidin Oxy Wipe S

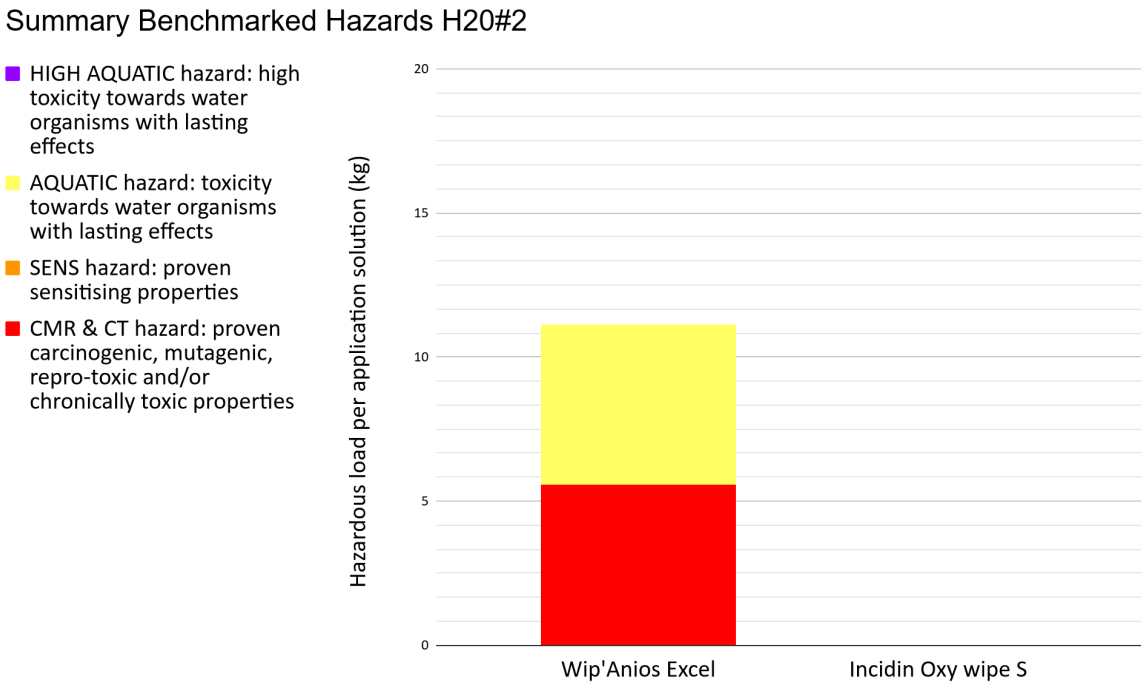
Ingredient concentrations and classified hazards were gathered from the safety data sheets and the WIDES database. Density of application solutions is assumed to be 1. Annual use amount of Wip Anios Excel was given as "494 packages". Since no specific information about the weight of one package was offered, a value of 0.5kg for package weight found online is applied. It is further assumed that 90% of the package weight consists of biocidal solution (i.e. 222.3L). This quantity is applied for both Wip Anios Excel and Incidin Oxy Wipe S.

Antimicrobial efficacy & material compatibility

Claims on	Wip Anios Excel	Incidin Oxy Wipe S (product data sheet)
Antimicrobial efficacy	Participant demands as follows: Has to kill /destroy common bacteria, viruses and fungi, but not spores. Organic materials shall not affect activity.	Bactericidal, yeasticidal & fungicidal with high organic load in 5 min.
Material compatibility	Participant demands as follows: Has to be compatible with all kind of materials used in the operation room.	Cannot be used on sensitive surfaces (marble, copper, brass).

Calculation of hazardous loads (estimate of annual amount used: 494L)

Hazardous load	**CMR & CT**	**SENS**	**AQUATIC**	**HIGH AQUATIC**
	kg/application solution			
Wip Anios Excel	5,6	0	5,6	0
Incidin Oxy Wipe S	0	0	0	0



Conclusion on substitution: Incidin Oxy Wipe S is recommendable as a product alternative to Wip Anios Excel.

Conclusion on comparability in antimicrobial efficacy: The requirements of the participant for antimicrobial efficacy are cited together with the basic claims for a product alternative. A sufficient comparability in bactericidal, yeasticidal and fungicidal efficacy is assumed but cannot be confirmed in detail. It is left to the participant to review available data and decide if their requirements are met.

Conclusion on comparability in material compatibility: The requirements of the participant together with information about product alternatives are cited. Since it does not allow for a final conclusion, it is recommended to test compatibility with the materials concerned.

Benchmarking Clinell Universal Sanitising Wipes and Sani Cloth Active

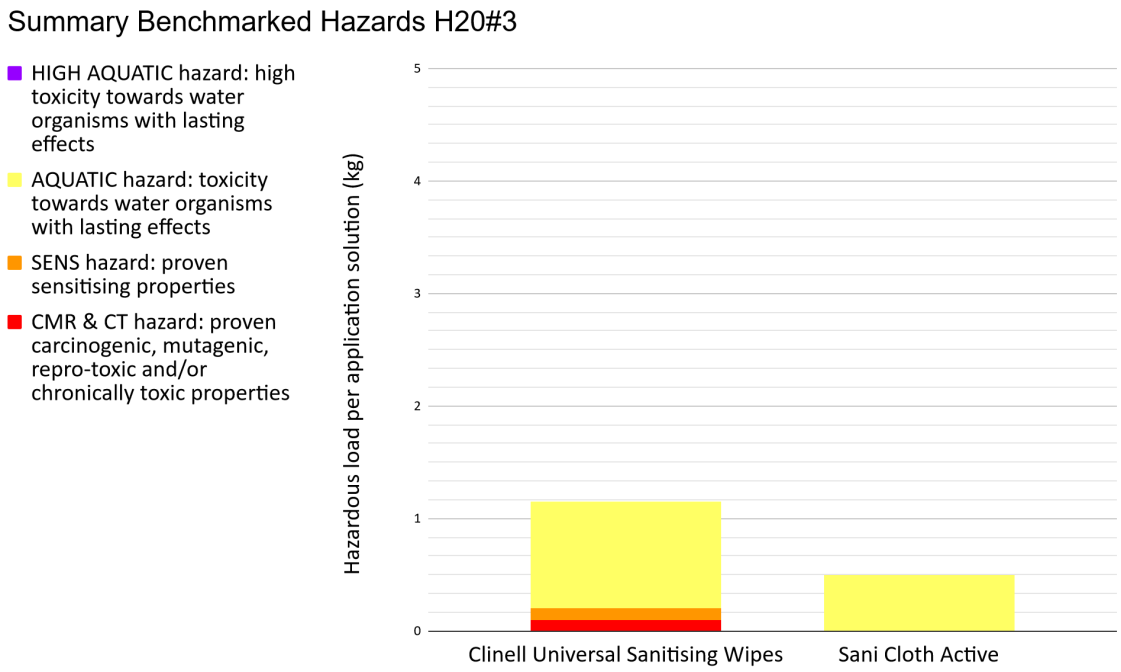
Ingredient concentrations and classified hazards were gathered from the SDS and the WIDES database. Density of application solutions is assumed to be 1. Annual use amount of Clinell Universal Sanitising Wipes is unknown, therefore a default value of 100L application solution (i.e. impregnating lotion for wet wipes) is assumed. An equal amount is therefore assumed for Sani Cloth Active.

Antimicrobial efficacy & material compatibility

Claims on	Clinell Universal Sanitising Wipes	Sani Cloth Active (product data sheet)
Antimicrobial efficacy	The participant demands as follows: Has to kill /destroy common viruses, bacteria and fungi, but does not have to kill spores.	Bactericidal, yeasticidal & fungicidal with high organic load in 5 min. A (limited) virucidal activity is claimed.
Material compatibility	The participant demands as follows: Must be compatible with ultrasound probes that are not used on mucous membrane or intact skin	Compatible to alcohol-sensitive surfaces (including ultrasound probe)

Calculation of hazardous loads (annual use amount – default value: 100L)

Hazardous load	**CMR & CT**	**SENS**	**AQUATIC**	**HIGH AQUATIC**
	kg/application solution			
Clinell Universal Sanitising Wipes	0.1	0.1	1	0
Sani Cloth Active	0	0	0.5	0



Conclusion on substitution: Sani Cloth Active is recommendable as a product alternative to Clinell Universal Sanitising Wipes.

Conclusion on comparability in antimicrobial efficacy: The requirements of the participant for antimicrobial efficacy are cited together with the basic claim for the product alternative. A sufficient comparability in bactericidal, yeasticidal and fungicidal efficacy is assumed but cannot be confirmed in detail. It is left to the participant to review available data and decide if their requirements are met.

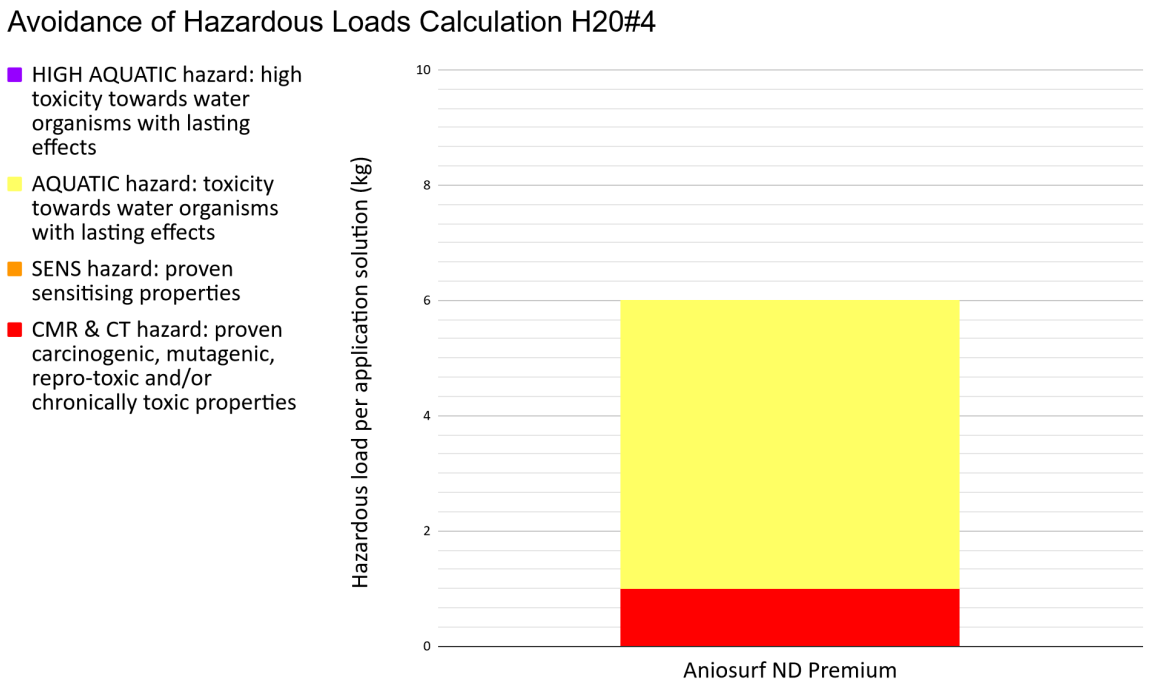
Conclusion on comparability in material compatibility: The requirements of the participant together with information about the product alternative are cited. Since it does not allow for a final conclusion it is recommended to test compatibility with the materials concerned.

Avoidance of hazardous loads calculation – Aniosurf ND Premium

Ingredient concentrations and classified hazards were gathered from the SDS. Density of application solution is assumed to be 1. Annual use amount of Aniosurf ND Premium is 40L. Since no benchmarking is performed, antimicrobial efficacy and material compatibility is not further considered.

Calculation of avoided hazardous loads (annual amount used: 40L):

Hazardous load	**CMR & CT**	**SENS**	**AQUATIC**	**HIGH AQUATIC**
	kg/application solution			
Aniosurf ND Premium	1	0	5	0



5. Learning outcomes and next steps

Although the hospital is still testing the alternatives, preliminary results seem promising. If tests continue to be positive, the next step would be to make sure that the chosen products are easily available on the Icelandic market.
The hospital also hopes to further simplify their use of disinfectants products by narrowing down the product portfolio. Based on the lessons learnt from this project, preference is given to return to the use of alcohol whenever possible, as they have been doing for many decades.

Hospital 39 (H39): Germany[58]

1. Conclusions on the outcomes of the first step hazard analysis

Twenty-one disinfectants products have been analysed. It can be stated that the overall product portfolio of the participant presents a considerable high standard in terms of occupational and environmental safety. No biocidal active substances with proven carcinogenic, mutagenic, reprotoxic, sensitising or highly persistent properties were found. However, the analysis showed that five of these disinfectants contain allergenic fragrances and one product contains the biocidal substance *N-Alkylaminopropylglycin*, which is classified as causing chronic toxicity and therefore categorised with A. The substance is also suspected to be reprotoxic.
Since this hospital focusses on treating children with chronic diseases, they decided to continue participating in the project and assess if safer alternatives could be integrated in their portfolio replacing the most problematic products.

Product name	**Substitution demand****	**Justification**
Sterilium virugard	No	-
Microbac forte	Yes	3 ingredients category A
Perform	No	-
Sterilium med	No/Limited	1 ingredient category A
Cutasept F	No/Limited	1 ingredient category B
Octenisept (farblos)	No/Limited	1 ingredient category B

[58] Medium size hospital of approximately 250 beds.Specialised in the treatment of chronic diseases in children and adolescents.

Braunol (gefärbt)	No	-
Bacillol 30 tissues	Yes	1 ingredient category A
Neodisher Z/Neodisher Mielclear	No	-
Gigasept FF	Limited	2 ingredients category B
Octenisept (see also: octenisept farblos)	No/Limited	1 ingredient category B
Apesin KDR food	No	-
Kiehl-RapiDes	No	-
Apesin SDR San	Yes	2 ingredients category A
Kiehl-AciDes	Yes	2 ingredients category A
Sensox	Limited	2 ingredients category B
Eltra (60°C)	Yes	3 ingredients category A
AciDes plus	Yes	1 ingredient category A

2. Products recommended for substitution

Six disinfectants have been recommended for substitution:

- For Microbac forte, Apesin SDR San, Kiehl-AciDes, Eltra (60°C) and Kiehl-AciDes Plus, the substitution demand stems from the presence of allergenic fragrances, not from the biocidal active substances.
- For Bacillol 30 tissues, substitution is recommended due to biocidal active substance *N-Alkylaminopropylglycin* (cat. A).

Microbac Forte	
Intended use: Surface disinfection (bactericidal and yeasticidal with mechanical action) in dilution of 0,5% (60 min). The *Desinfektionsplan* does not specify if there is a need to combat high organic load (i.e. dirty conditions).	
Ingredients	**Hazard**
Relies on 3 allergenic fragrances (R)-p-Mentha-1,8-dien, Citronellol, Hexyl Cinnamal mentioned in Safety Data Sheet (21 June 2019; Hartmann-Bode).	H317 May cause an allergic skin reaction (Cat. A)
Biocidal active substances: *Benzyl-C12-18-Alkyldimethylammoniumchlorid* &	Cat. B so does not constitute a substitution demand. It would be

N-(3-Aminopropyl)-N-dodecylpropan-1,3-di amin	sufficient to choose a product without allergenic fragrances.

Bacillol 30 Tissues	
Intended use: Surface disinfection (tissues are soaked with Bacillol 30 foam). The active ingredient solution is recommended for sensitive surfaces (displays, medical devices) with suitability for sensitive materials (Macrolon, Polysulfon, Acryl).	
Ingredients	**Hazard**
Relies on the active substance *N-Alkylaminopropylglycin*	H372 Chronic toxic (Cat. A) according to an EU-Assessment Report[59]. The substance is also suspected to be reprotoxic (H361)

Apesin SDR San	
Intended use: In the *Desinfektionsplan* Apesin SDR is indicated as "Auslaufprodukt" (i.e. phased-out) and substituted by Kiehl-AciDes. As far as a susbstitution demand results for Kiehl-AciDes alternatives will be proposed.	
Ingredients	**Hazard**
Relies on two allergenic fragrances Butylphenyl Methylpropional and Hexyl Cinnamal, as found in the SDS (13 February 2019; Werner & Mertz).	H317 May cause an allergic skin reaction (Cat. A). Butylphenyl Methylpropional is also *suspected of damaging fertility or the unborn child (H361)*
Biocidal active substances: *Lactic acid & phosphoric acid*	Cat. C

Kiehl-AciDes	
Intended use: In the *Desinfektionsplan* application is indicated as a disinfectant cleaner for bathrooms (tubs and surfaces). According to VAH, Kiehl-AciDes is applied ready-to-use (bactericidal and yeasticidal without mechanical action) and in clean conditions (low organic load).	
Ingredients	**Hazard**
Relies on 2 allergenic fragrances, namely Limonene & Benzylsalicylat, mentioned in SDS (04 May 2017; Kiehl KG).	H317 May cause an allergic skin reaction (Cat. A)
Lactic acid (active substance)	Cat. C
Didecyldimethylammonium chloride (active substance)	Cat. B so does not constitute a substitution demand. It would be sufficient to choose a product without allergenic fragrances.

Eltra (60°C)

[59] EU-Assessment Report for evaluation of active substances in Regulation 528/2012: Amines, N-C10-C16-alkyltrimethylendi-, reaction products with chloroacetic acid; Ampholyt; Product-type 2. December 2015; Ireland;

Intended use: In the *Desinfektionsplan* application is indicated for laundry. According to VAH, Eltra is applied at 60°C with bactericidal, yeasticidal, tuberculocidal, mycobactericidal and fungicidal efficacy.	
Ingredients	**Hazard**
Relies on 3 allergenic fragrances Butylphenyl Methylpropional, Hexyl Cinnamal and Limonen mentioned in SDS (18 March 2019; Ecolab).	H317 May cause an allergic skin reaction (Cat. A). Butylphenyl Methylpropional is also *suspected of damaging fertility or the unborn child (H361).*
Biocidal active substances: generates *peractetic acid*	Cat. B so does not constitute a substitution demand. It would be sufficient to choose a product without allergenic fragrances.

AciDes Plus	
Intended use: In the "Desinfektionsplan" application is indicated as a disinfectant for forefoot area in bath and sauna. According to VAH, Kiehl AciDes plus is applied (bactericidal and yeasticidal without mechanical action) ready-to-use and clean conditions (low organic load).	
Ingredients	**Hazard**
Relies on allergenic fragrance Coumarin mentioned in SDS (04.05.2017; Kiehl KG)	H317 May cause an allergic skin reaction (Cat. A). Coumarin is also toxic if inhaled (H331).
Biocidal active substances: *Didecyldimethylammonium chloride*	Cat. B so does not constitute a substitution demand. It would be sufficient to choose a product without allergenic fragrances.

Barrier to replace the products

- The hospital is subjected to public procurement rules and must therefore follow the general government indications in terms of certifications.
- Some products might be difficult to replace in the short term because the hospital uses external cleaning services and they would need to start a new procurement process.

Conditions (received from the participant) an alternative has to fulfil (in terms of efficacy, material compatibility, price)

- Some products should be legally authorized for preventing epidemic diseases and therefore be listed in Robert Koch Institute's guidelines
- Some Disinfectants must have the German VHA certification for efficiency (e.g. Eltra 60°C)
- Proposed alternative should consider the interactions between cleaning and disinfectant products
- The alternatives must be practical to use
- Price of alternatives should be comparable to that of used products

- The hospital treats patients with special skin conditions. Apesin SDR has been identified as the most effective product to clean the areas where these patients bath. The high concentration of limestone in the local water needs to be considered when cleaning toilets and common bathing areas (e.g. swimming pool, sauna, etc.), hence acid-based solution are preferred

3. Identification and assessment of potential alternatives

Compared to the other hospitals involved in the project, the identification of alternatives for H39 did not require extensive market research because most of the products listed in the Austrian WIDES database are available on the German market. Thus the database serves as a convenient source of product alternatives. It has to be mentioned that the selection of potential alternatives given below is not a comprehensive sample, which means that apart from the given manufacturer/product combinations there may be appropriate products provided by other manufacturers than those named.

Several fragrance-free options with comparable efficacy have been proposed to the hospital for the five products containing allergenic fragrances (listed below for each product). Five types of water- or alcohol-based wipes of comparable efficacy have been proposed to substitute Bacillol 30 tissues. As of February 2020, after assessing the alternatives, the hospital decided to phase out the use of Kiehl-Aci Des, prioritise the substitution of Bacillol 30 tissues and Eltra (60°C), and to partially replace Apesin SDR San whenever possible.

Microbac Forte	
According to the VAH List, Mirobac Forte can be applied to both clean and dirty conditions, so the proposal for alternatives considers these two options separately. The following is a limited selection of alternatives.	
Clean conditions	**Dirty conditions**
Dismozon plus: Granulat/active substance: Magnesiummonoperoxyphthalat Hexahydrat (CAS 84665-66-7)/VAH listed/provider: Bode	Mikro Quat Extra: Liquid – Concentrate/active substances: Benzalkoniumchlorid (CAS 68424-85-1); Didecyldimethylammoniumchlorid /VAH listed/provider: Ecolab
Apesin AP 100: Granulat/active substance: Magnesiummonoperoxyphthalat Hexahydrat (CAS 84665-66-7)/VAH listed/provider: Tana	Incidin Pro: Liquid – Concentrate/active substances: Benzalkoniumchlorid (CAS 68424-85-1); N-(3-Aminopropyl)-N-dodecylpropan-1,3-diamin/VAH listed/provider: Ecolab
Descogen F: Granulat/active substance:	Cleanisept: Liquid – Concentrate/active substances: Benzalkoniumchlorid (CAS

Pentakalium-bis(peroxymonosulfat)-bis(sulfat)/VAH listed/provider: Antiseptica	68424-85-1); Didecyldimethylammoniumchlorid/VAH listed/provider: Dr. Schuhmacher GmbH

Bacillol 30 Tissues	
According to VAH, Bacillol 30 Tissues can be applied for high organic load (dirty conditions). It is assumed that alternatives should also be tissues for high organic load (a similar material comparability cannot automatically be assumed for the proposed alternatives). The following is a limited selection of alternatives.	
Alcohol based alternatives (dirty conditions)	**Water based alternatives (dirty conditions)**
Mikrozid Universal Wipes: Tissue – rtu/active substances: ethanol; 2-propanol/VAH listed/provider: Schülke	L+R surfacedisinfect universal tissue: Tissue – rtu/active substances: Benzalkoniumchlorid, Didecyldimethylammoniumchlorid:/VAH listed/provider: Lohmann & Rauscher
PuraDES DecaWIPES XL: Tissue – rtu/active substances: ethanol; 1-propanol/VAH listed/provider: Prisman	Incidin Oxy wipe: Tissue – rtu/active substance: Hydrogen peroxide/ VAH listed/provider: Ecolab
Descosept Sensitive Wipes: Tissue – rtu/active substances: ethanol/VAH listed/provider: Dr. Schumacher	

Kiehl-AciDes	
According to VAH, Kiehl-AciDes is applied ready-to-use (bactericidal and yeasticidal without mechanical action) and in clean conditions (low organic load).	
Acid based alternatives without fragrances (clean conditions)	**Acid based alternatives with non-allergenic fragrances (clean conditions)**
No comparable acid based alternatives without fragrances could be found.	Desinfektionsreiniger AF: Concentrate/active substances: Benzalkoniumchlorid, Didecyldimethylamoniumchlorid; Citric acid/VAH listed/provider: Schülke
	Budenat azid plus D587: Concentrate/active substances: Benzalkoniumchlorid, Didecyldimethylamoniumchlorid; Lactic acid/VAH listed/provider: Buzil Werk Wagner

Eltra (60°C)
According to VAH, Eltra is applied at 60°C with bactericidal, yeasticidal, tuberculocidal, mycobactericidal and fungicidal efficacy. The following is a limited selection of alternatives.
Alternatives (60°):

Select Power und Peracid Forte: Concentrate/active substance: Peracetic acid/VAH listed/provider: Christeyns GmbH For this product, the hospital suggested another alternative: Lavo Des 60 Kompakt, VAH listed and considered as a suitable alternative also by TB Klade.

AciDes plus
According to VAH, Kiehl AciDes plus is applied (bactericidal and yeasticidal without mechanical action) ready-to-use and clean conditions (low organic load). The following is a limited selection of alternatives.
Alternative (clean conditions): Laudamonium: Concentrate/active substance: Benzalkoniumchlorid/VAH listed/provider: Ecolab

4. Second step product benchmarking

The second step benchmarking takes into consideration the following decisions made by the hospital:

- Apesin SDR San is going to be applied only in one department, especially in the areas where patients with special skin conditions wash themselves, reducing the product use by approximately 80%. The alternative selected for replacing this product in the other areas is the acid-based Budenat Azid Plus D587. Although Budenat Azid Plus D587 is perfumed, no allergenic fragrances are listed in the SDS.
- Kiehl-Aci Des has been phased out
- Eltra (60°C) is replaced with Lavo Des 60 Kompakt (identified by the hospital)
- Bacillol 30 tissues is replaced with Descosept Sensitive Wipes

As summarised in the table below, the product benchmarking shows that the replacement of Bacillol Tissues 30 with the suggested alternative results in a reduction of 6kg hazardous load with chronic toxicity properties. The product benchmarking of Eltra (60°C) shows an avoidance of hazardous load with sensitising properties. At the same time, non-quantifiable reduction of hazardous loads is achieved by reorganising product application or phasing out critical products.

Product	**Reason for substitution demand**	**Use amount**	**Measure**	**Avoidance hazardous load (kg)**
Bacillol 30 Tissues	Biocidal active substance with category A	630L*	Planned substitution**	6

Apesin SDR San	Allergenic fragrance	40L	Use reduction and (partly) substitution	Reduction of sensitising hazard load (not quantifiable)
Kiehl-Aci Des	Allergenic fragrance	-	Phased out	
Eltra (60°C)	Allergenic fragrance	130kg	Planned substitution***	0.04****

*Estimate (1 package contains 0.45L active ingredient solution); **Planned alternative: Descosept Sensitive Wipes; *** Planned alternative: Lavo Des 60 Kompakt; ****Sensitising hazard

Benchmarking: Bacillol 30 Tissues and Descosept Sensitive Wipes

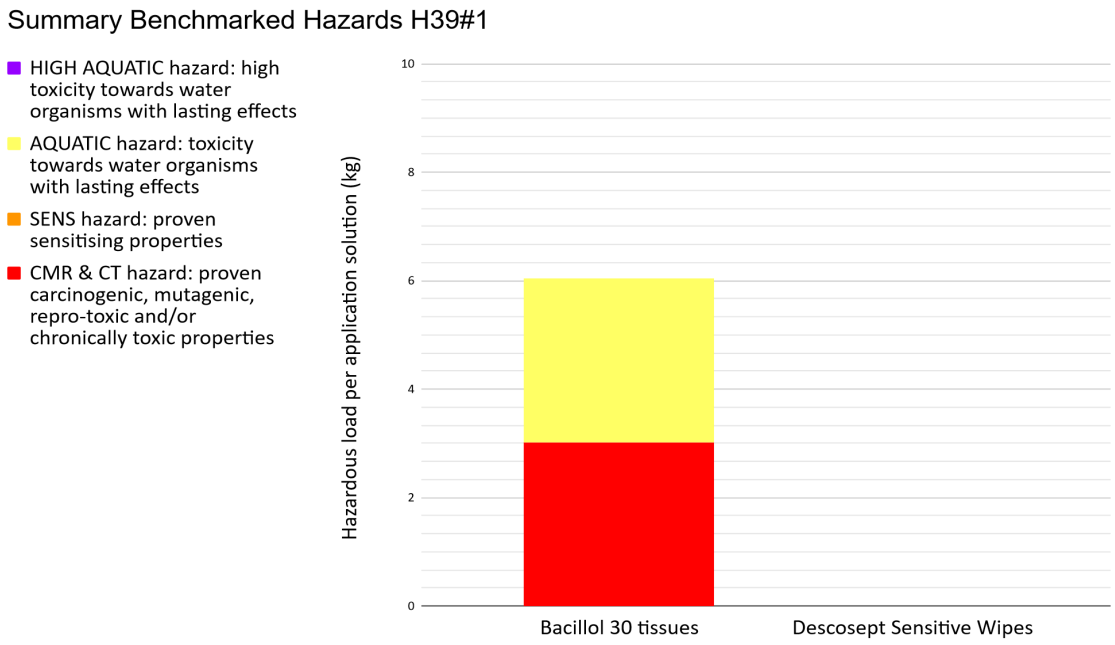
Ingredient concentrations and classified hazards were gathered from the safety data sheets, from VAH List and the WIDES database. Density of application solution is 0,96 for Bacillol 30 Tissues and 0,93 for Descosept Sensitive Wipes. Application solution is derived from the annual use amount of 1400 packages of Bacillol 30 Tissues. A search online shows that 1 package of Bacillol 30 Tissues weighs 0.5kg. It was further assumed that 90% of the package consists of biocidal solution (i.e. 0,45kg). On that basis, an application solution of 630L per year is assumed for both Bacillol 30 Tissues and Descosept Sensitive Wipes.

Antimicrobial efficacy & material compatibility

Claims on	Bacillol 30 Tissues	Descosept Sensitive Wipes
Antimicrobial efficacy	VAH listed as: bactericidal (not Mycobacteria), yeasticidal, works in dirty conditions and mechanic action in 5 minutes	VAH listed as: bactericidal (not Mycobacteria), yeasticidal, works in dirty conditions and mechanic action in 5 minutes
Material compatibility	Not applicable for acryl	Only for alcohol resistant surfaces

Calculation of hazardous loads (annual use amount: 630L):

Hazardous load	**CMR & CT**	**SENS**	**AQUATIC**	**HIGH AQUATIC**
	kg/application solution			
Bacillol 30 Tissues	3	0	3	0
Descosept Sensitive Wipes	0	0	0	0



Conclusion on substitution: Descosept Sensitive Wipes is a recommendable product alternative for Bacillol 30 Tissues.

Conclusion on comparability in antimicrobial efficacy: The requirements of the participant for antimicrobial efficacy are cited together with the basic claims for a product alternative. A sufficient comparability in bactericidal, yeasticidal and fungicidal efficacy is assumed but cannot be confirmed in detail. It is left to the participant to review available data and decide if their requirements are met.

Conclusion on comparability in material compatibility: The requirements of the participant together with information about the product alternative are cited. Since it does not allow for a final conclusion, it is recommended to test compatibility with materials concerned.

Benchmarking: Eltra (60°C) and Lavo Des 60 Kompakt

Ingredient concentrations and classified hazards were gathered from the SDS and product data sheet, while application concentration and antimicrobial efficacy were found in the RKI list.[60] Density of application solutions is assumed to be 1. Application solution is derived from the annual use amount of 130kg for Eltra (60°C), an application concentration of 7 g/L (RKI) and a liquor ratio of 1:5. Both

[60] Liste der vom Robert Koch-Institut geprüften und anerkannten Desinfektionsmittel und -verfahren. Bundesgesundheitsblatt 2017 · 60:1274-1297

Eltra (60°C) and Lavo Des 60 Kompakt are included in the RKI List for chemo-thermal laundry disinfection (*procedures with per-compounds*) with both of them having a disinfecting temperature of 60°C and a liquor ratio of 1:5. While for Eltra (60°C) the exposure time is 20 minutes, for Lavo Des 60 Kompakt it is 15 minutes.

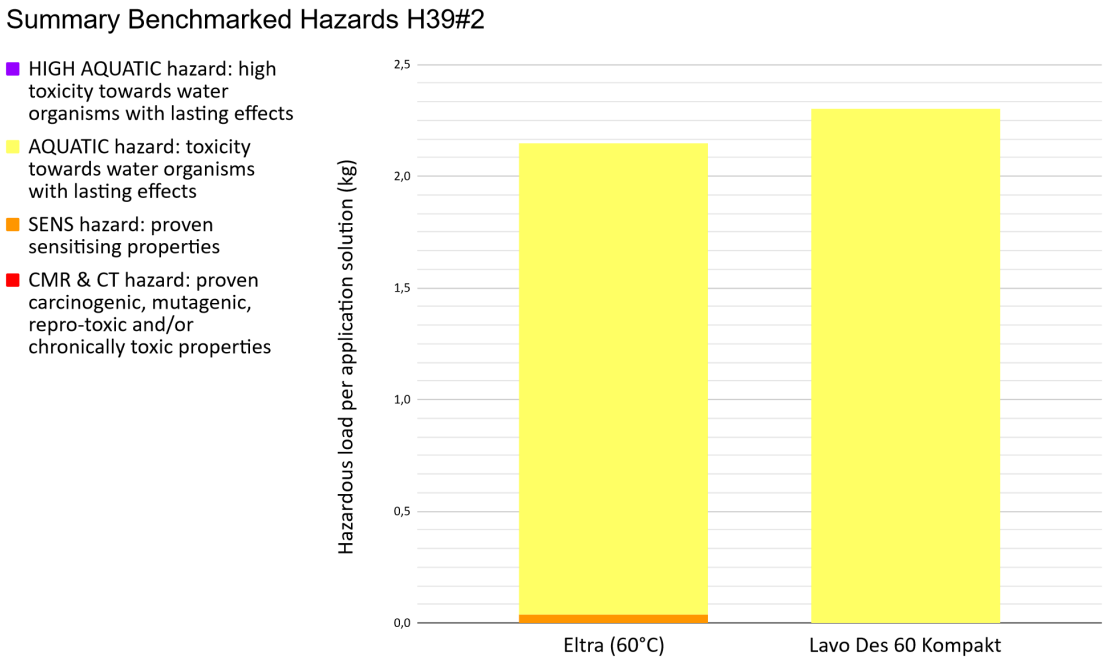
Antimicrobial efficacy & material compatibility

Claims on	Eltra (60°C)	Lavo Des 60 Kompakt
Antimicrobial efficacy	RKI list: AB*	RKI list: AB*
Material compatibility	Not indicated	Not indicated

*Bactericidal (including mycobacteria), fungicidal and virucidal

Calculation of hazardous loads (annual use amount: 92.857L)

Hazardous load	**CMR & CT**	**SENS**	**AQUATIC**	**HIGH AQUATIC**
	kg/application solution			
Eltra (60°C)	0	0.04	2.1	0
Lavo Des 60 Kompakt	0	0	2.3	0



Conclusion on substitution: Lavo Des 60 Kompakt is a recommendable product alternative for Eltra (60°C). The main reasoning for the recommendation is the absence of allergenic fragrances, thus causing no sensitising hazard. The aquatic

hazard value for Eltra (60°C) is slightly lower than the one of Lavo Des 60 Kompakt, but this difference does not outweigh the avoidance of proven sensitising loads.

Conclusion on comparability in antimicrobial efficacy: The requirements of the participant for antimicrobial efficacy are cited together with the basic claims for a product alternative. A sufficient comparability in bactericidal, yeasticidal and fungicidal efficacy is confirmed by the entry in the RKI list.

Conclusion on comparability in material compatibility: Since Lavo Des 60 Kompakt and Eltra (60°C) are nearly identical in their composition no difference in material compatibility should be expected.

5. Learning outcomes and next steps

Although the hospital is still testing the alternative products, the lessons learnt from this benchmark exercise will support their future procurement decisions. The price of products, in particular of oxygen-based alternatives, may be a barrier to substitution. Thus, there should be some incentivising mechanisms that facilitate the purchase of alternatives considered less toxic. The hospital would welcome the production of national guidelines for sustainable procurement practices in the field of disinfectants and chemicals used in the healthcare sector. These guidelines would further support the process of chemical substitution and could be used as an additional compelling argument when discussing purchasing decisions with the administrative body of the hospital. The guidelines should consider both the environmental and carbon footprint of purchased products. For instance, the hospital prefers locally produced products to reduce the costs and impact of transportation.

Hospital 15 (H15): United States[61]

1. Conclusion on the outcomes of the first step hazard analysis

This case study will have a different structure compared to the other ones because the hospitals that provided the data discontinued its participation in the project. However, HCWH US team was very keen in learning more about this case because many of their members use the products for which substitution was suggested and further information can help many other hospitals make procurement decisions. The US team also raised concerns about the hazards that can be caused by the mixture

[61] Large Hospital network (approximately 700 medical offices and 40 hospitals, estimated amount of 4,000 – 10,000 beds)

of different ingredients. Because this aspect is not addressed by the WIDES database, further information is provided via literature review.

The participant submitted a list of 13 products. However, four of them were cleaning products, and were thus out of the scope of this study. Consequently, eight disinfectants (two products counted as one because they have the same formulation) were included in the first step hazard analysis. Two disinfectants were recommended for substitution due to the presence of an ingredient of category A hazard.

Product name	**Substitution demand**	**Justification**
Cidex OPA Concentrate	Yes	1 ingredient category A
Metricide OPA Plus	Yes	1 ingredient category A
Oxivir Tb (US)	No	-
Oxycide Daily Disinfectant Cleaner	No/Limited	1 ingredient category B
Purtabs (Dilution 0.5 – 5550 ppm)	No/Limited	1 ingredient category B
Revital OX Resert	No/Limited	1 ingredient category B
Rapicide PA Part A	No/Limited	1 ingredient category B
Virex One-Step Disinfectant Cleaner and Deodorant; Quant Based Disinfectant	Limited	3 ingredients category B

2. Products recommended for substitution

Based on the hazard analysis, a substitution demand was constituted for Cidex OPA Concentrate and Metricide OPA Plus due to the presence of biocidal active ingredient *ortho-phthaladehyde (643-79-8)*, which has proven sensitizing properties (H317). Additionally, the substance is very toxic to aquatic life with long-lasting effects (H410). The products are high-level disinfectants applied for reprocessing flexible endoscopes (manual and/or automatic).

3. Identification and assessment of potential alternatives

A product benchmarking for Cidex OPA solution representing both Cidex OPA Concentrate and Metricide OPA Plus was carried out. The benchmarking comprises the potential alternatives Revital OX Resert, Rapicide (Glut), Rapicide PA and Rapicide OPA, which were proposed by our US partner organisation Practice Green

Health. Ingredient concentrations and classified hazards were gathered from the SDSs, product information available online and the WIDES database.

To ensure sufficient comparability, a data search on product claims was performed (Text taken from manufactures' website):

- Cidex OPA solution is a high level disinfectant for reprocessing heat sensitive reusable semi-critical medical devices, for which sterilization is not feasible. Cidex OPA solution is intended for use in manual (bucket and tray) systems made from polypropylene, acrylonitrile-butadiene-styrene (ABS), polyethylene, glass-filled polypropylene and/or polycarbonate plastics. Cidex OPA solution may also be used in automated endoscope reprocessors according to the manufacturer's instructions.
- Revital OX Resert HLD is an odourless, ready-to-use liquid chemical high level disinfectant formulated for the reprocessing of heat sensitive, semi-critical medical devices, such as flexible endoscopes, and their accessories. The solution can be used in manual soak applications or automated endoscope reprocessing systems designed for use with legally cleared, high level disinfectant solutions such as those containing hydrogen peroxide.
- Rapicide (Glut) is a high level disinfectant when used or reused, in a legally marketed Automated Endoscope Reprocessor.
- Rapicide PA High-Level Disinfectant is a single-use, peracetic acid-based solution (…) with proven materials compatibility. It is designed for use in the Advantage Plus Pass-Thru, Advantage Plus or DSD Edge Automated Endoscope Reprocessors.
- Rapicide OPA/28 High-Level Disinfectant is a fast-acting, long lasting, highly compatible high-level disinfectant. This reusable ortho-phthalaldehyde disinfectant is designed for use on heat-sensitive, semi-critical medical devices that are unsuitable for sterilization.

Based on these claims comparability of products is assumed to be sufficient.

Additional information about type and quantity of biocidal active ingredients and co-formulants, dilution prior to use and density was collected. All products are liquid and ready-to-use (require no dilution prior to use):

Product specifications

Product	Biocidal active ingredients: concentration	Additional ingredients: concentration	Density in mg/L

Cidex OPA solution	ortho-Phthalaldehyde (643-79-8): 0.55%	Dipotassium hydrogen phosphate; Potassium dihydrogen phosphate; Benzotriazole; Citric acid; D&C Green Dye #5; N-(hydroxyethyl) -ethylenediaminetriacetic acid (HEDTA): no concentration is given	1 (assumed)
Revital OX Resert	Hydrogen peroxide (7722-84-1): 2%	2-Furancarboxylic acid (88-14-2): 3%; Potassium hydroxide (1310-58-3): 0.405%; Phosphoric acid (7664-38-2): 0,4%	1.022
Rapicide (Glut)	Glutaraldehyde (111-30-8): 2.5%	Sodium nitrite (7632-00-0): 1%	1.013
Rapicide PA (part A+part B)	Peroxyacetic acid (79-21-0): 0.105% Hydrogen peroxide (7722-84-1): 0.42%	Acetic acid (64-19-7): unknown concentration	1 (assumed)
Rapicide OPA	ortho-Phthalaldehyde (643-79-8): 0.575%	Alcohols, C9-11, ethoxylated (68439-46-3): 5%	1.01

4. Second step product benchmarking

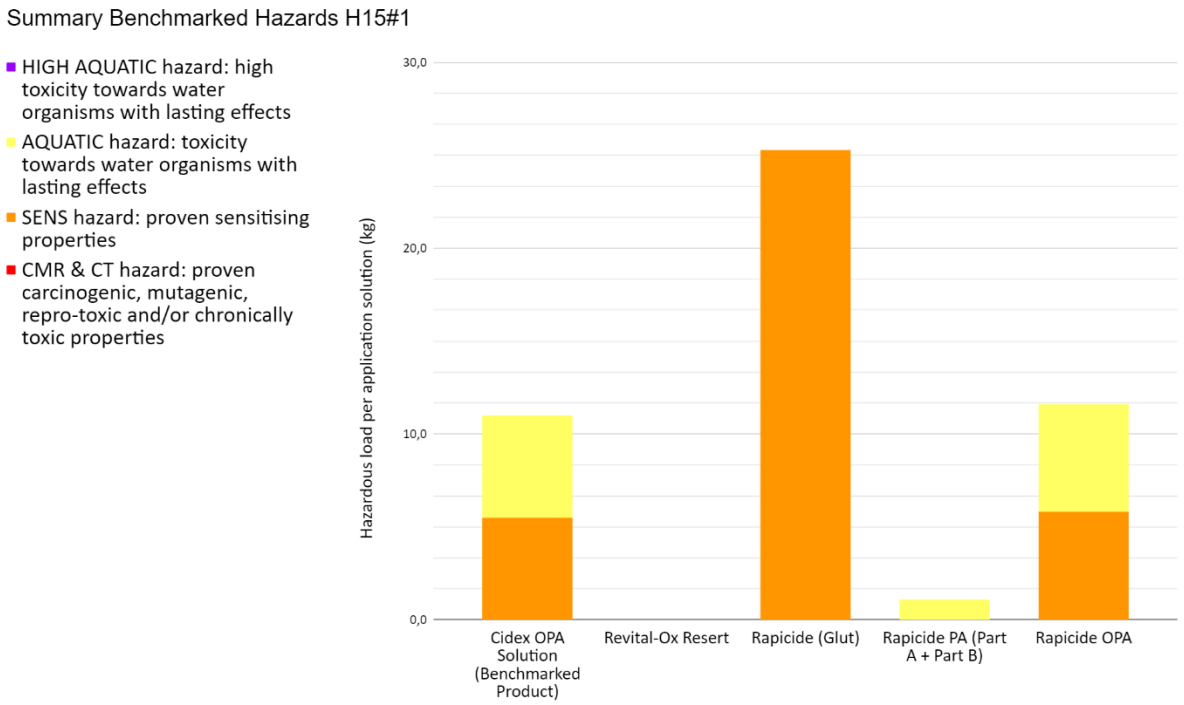
Calculation of hazardous loads (default annual amount used: 1,000L)

Since no (annual) amount used was given for Cidex OPA solution, a default value of 1,000L concentrate is assumed. All products are ready-to-use without further dilution, so the default value of 1,000L concentrate equals 1,000L of application solution.[62]

Hazardous load	**CMR & CT**	**SENS**	**AQUATIC**	**HIGH AQUATIC**
	kg / application solution			
Cidex Opa	0.0	5.5	5.5	0.0

[62] Limitations and uncertainties arising by the use of a default value of 1000L for all products are discussed in this case study.

Revital OX Resert	0.0	0.0	0.0	0.0
Rapicide (Glut)	0.0	25.3	0.0	0.0
Rapicide PA (part A+part B)	0.0	0.0	1.1	0.0
Rapicide OPA	0.0	5.8	5.8	0.0



Potential limitations: When looking at the apparently precise figures of the hazardous loads calculated for each product one should not forget that the quality of the calculation largely rely on the accuracy of the underlying information which is a.) that the chosen hazard classification correctly applies to the ingredient(s), b.) that the concentration of the ingredient in the product is correct, c.) that dilution or non-dilution of the product prior to use is correct and d.) that the quantity of the product needed to perform a service unit (in the present case: a decontamination of a flexible endoscope) is known. While sufficient accuracy can be assumed in the present case for a, b and c, there is no precise knowledge about d. This concerns the value of 1000 L application solution applied on each product for the benchmarking calculation. The problem thereby does not stem from the fact that the real use amount of the benchmarked product is unknown but instead uncertainty arises from the circumstance that the evaluator has no information about the quantity of a product needed to generate a service unit. For instance 1 L

of application solution of product A may be sufficient to decontaminate 1 endoscope, while 1 L of application solution of product B is able to decontaminate (on average) 1.3 endoscopes. Since deviations in product quantity would alter the calculated hazardous loads it is not meaningful to over-interpret the numerical values but to perceive them more as a trend.

Screening of scientific literature

Scientific literature was screened with an emphasis on adverse effects caused by occupational exposure of health-care workers to peracetic acid (PA) in combination with hydrogen peroxide (HP) and acetic acid (AA) on the one side and ortho-phthalaldehyde (OPA) on the other.

The following documents consider PA-HP:

Respiratory symptoms in hospital cleaning exposed to a product containing hydrogen peroxide, peracetic acid, and acetic acid[63]

Hospital workers using a sporicidal product containing PA, HP and AA reported work-related acute eye and upper airway symptoms, as well as chronic airway symptoms at low levels of measured exposure. The product was used as a one-step disinfectant for all surfaces throughout the hospital except floors. All full-shift Time Weight Average (TWA) for HP and AA were below established US Occupational Exposure Limits (OEL). All TWA air samples for PA were below the proposed OEL of 0.2 ppm for PPA. The authors therefore constitute a need for engineering, administrative, and/or PPE controls to reduce exposure.

Evaluation of Worker Exposures to Peracetic Acid-based Sterilant during Endoscope Reprocessing[64]

The NIOSH onsite study was conducted on request of hospital employees concerned with sterilising endoscopes with an enzymatic cleaner and Steris 20 Sterilant Concentrate in a Lab room. Health problems identified in the request were headache, shortness of breath, eye irritation, and diminished sense of smell. The NIOSH findings and conclusions were: Concentrations of peracetic acid were thought to be low, although no current levels could be measured (less than 0.2 ppm). Employees reported not using all available PPE (aprons and sleeve protectors). Employees reported periodic headaches and burning eyes that were

[63] Hawley, B., et al. (2018) Respiratory symptoms in hospital cleaning exposed to a product containing hydrogen peroxide, peracetic acid, and acetic acid. Ann Work Expo Health; 62: 28-40

[64] Sylvain, D., Gibbins, J. (2009) Evaluation of Worker Exposures to Peracetic Acid-based Sterilant during Endoscope Reprocessing. National Institute for Occupational Safety and Health. Health Hazard Evaluation Report HETA 2006-0298-3090.

more noticeable when SS1 processors[65] malfunctioned and leaked. Poor ventilation and high environmental temperatures were noted by workers. Although gloves, sleeves and aprons are provided, some workers reported not using all available PPE due to high environmental temperatures. Two workers reported prior chemical burns from occupational exposure to Steris 20 Sterilant Concentrate. Several workers reported that they had not received formal chemical hazard communication training for Steris room operations. A review of FDA CDRH data files indicated that occupational exposure to peracetic acid sterilant should be unlikely when SS1 processors are maintained and operated properly and when technicians follow the manufacturer's operating procedures. However, processor malfunctions and improper handling and disposal of Steris 20 Sterilant Concentrate containers can result in dermal or inhalation exposures. Appropriate employee training, use of adequate PPE, and routine maintenance of processors should help reduce the likelihood of worker exposures, as well as the risk of employee illness or injury if a spill or leak does occur.

Asthma caused by peracetic acid-hydrogen peroxide mixture[66]

The authors describe the case of two subjects who developed cough, wheezing and shortness of breath after being exposed to PA-HP in an endoscopy unit. Subject No.1: Five months after beginning PA-HP employment he noticed rhinorrhoea, conjunctivitis and dry cough without wheezing, whilst present at the workplace. The symptoms completely improved when the subject was off work for 3 weeks, but recurred upon return to work. Before being PA-HP exposed, he used quaternary ammonium compounds for several months. Serial monitoring of peak expiratory flow (PEF) rates for a period including work and away from work, highly suggest work-related asthma. Subject No. 2: The auxiliary nurse had to perform daily decontamination procedures for flexible endoscopes. The ventilation system for the area including the decontamination room was considered poor. After two and a half years of daily exposure, she developed chest tightness, rhinorrhoea, and conjunctivitis. These symptoms improved during weekends and completely disappeared on holidays. The positive result of the specific inhalation challenge test to PA-HP of the second subject confirms the diagnosis of occupational asthma. For the authors the following arguments suggest an irritant induced asthma IIA[67]. Thus, disinfectants belonging to the oxidant class, such as mixture of PA-HP, seem to act as occupational irritants. The authors conclude that the allergic or irritant

[65] A fully enclosed tabletop unit.
[66] Cristofari-Marquand et al. (2007) Asthma caused by peracetic acid-hydrogen peroxide mixture. J Occup Health; 49:155-158
[67] IIA or irritant-induced asthma is a subtype of occupational asthma (OA) without immunologic sensitization and includes the typical reactive airway dysfunction syndrome (RADS) and a more gradual form called not-so-sudden IIA, when onset of asthma follows repeated low-dose exposure to irritants.Outcome of IIA is considered to be as poor as occupational asthma with sensitization.

mechanism is difficult to define: low concentrations of PA-HP might increase the oxidative stress, as well as lipid peroxidation, causing the appearance of bronco-constriction.

The following documents consider ortho-Phthalaldehyde (OPA):

A case of occupational bronchial asthma and contact dermatitis caused by ortho-phthalaldehyde[68]

The authors describe the first case of occupational bronchial asthma and contact dermatitis thought to be caused by OPA exposure in an endoscopy unit. The patient had no history of bronchial asthma before the use of OPA, and her asthma corresponded to OPA exposure with a latency period of 9 months. After change of workplace (from the endoscopy unit to the emergency room) the 57-yr-old female worker experienced no further episodes of asthma and dermatitis. The authors therefore conclude that patient's asthma was occupational asthma caused by OPA exposure and that OPA may induce asthma by an immunological mechanism.

Occupational asthma after exposure to ortho-phthalaldehyde[69]

The paper describes the case of a 55-yr-old woman working in an endoscopic sterilisation service of a hospital with Cidex OPA and developing symptoms (dyspnoea, wheezing, conjunctival redness and low peak expiratory flow) after 3 weeks of exposure. The patient was referred for bronchoprovocation test with Cidex OPA. When exposed to OPA, she developed conjunctival redness and cough. A late asthmatic response was observed, with a 43% fall in forced expiratory volume (FEV_1) 4h after exposure. According to the authors this confirms OPA's potential to act as a respiratory sensitizer. OPA may enhance tissue infiltration of inflammatory cells and increase the production of allergen-specific IgE, suggesting a role as immunological adjuvant. Questionnaires administered in endoscopic units showed that 9 – 16% of workers had experienced skin, respiratory or ocular symptoms when exposed to OPA.

Allergy to ortho-phthaladehyde in the healthcare setting: advice for clinicians[70]

[68] Fujita, H., et al. (2006) A case of occupational bronchial asthma and contact dermatitis caused by ortho-phthalaldehyde. Occup Health; 48(6): 413-416
[69] Robitaille, C., Boulet LP. (2015) Occupational asthma after exposure to ortho-phthalaldehyde. Occup Environ Med; 72: 381
[70] Pala. G, Moscato, G. (2013) Allergy to ortho-phthaladehyde in the healthcare setting: advice for clinicians. Expert Rev Clin Immunol; 9: 227-234

The purpose of the study is to summarize and review available health information on OPA with particular attention is paid to possible immunological effects in the healthcare setting. The authors argue that the introduction of OPA as a safer alternative to glutaraldehyde for disinfecting heat-sensitive medical equipment was underpinned with little scientific data. The authors constitute that current literature on the topic, although scarce, suggests that OPA is a dermal and respiratory sensitizer with sensitizing potential at least comparable to that of glutaraldehyde, and may cause severe reactions, especially in patients repeatedly submitted to endoscopic procedures performed with endoscopes disinfected with OPA. The rapid onset of the reactions, along with the positivity of skin tests and the detection of specific IgE to OPA, suggest a type I response. The authors suggest air OPA levels to be as low as possible and the use of appropriate personal protective devices and end with the conclusion that *"hundreds of voluntary reports may raise the suspicion that the published papers on a dozen of cases only represent the tip of the iceberg"*.

Conclusion on substitution: The product benchmarking outcomes suggest a clear recommendation for the product Revital OX Resert, while Rapicide PA could be recommended only in replacement of ortho-phthaladehyde or glutaraldehyde. Both Revital OX Resert and Rapicife PA contain the oxidising agents hydrogen peroxide and (in the latter) peracetic acid as biocidal ingredients. The recommendation relies on the fact that for both Revital OX Resert and Rapicide PA no sensitising properties are calculated and, moreover, Revital OX Resert does not show concerning aquatic toxicity.

The literature screening indicates the occurrence of chronic airway symptoms and also of workplace related asthma for products containing peracetic acid. However, in our opinion these indications do not overrule our recommendation since the sensitising potential of the ortho-phthaladehyde as active principle in Cidex OPA and Rapicide OPA should be rated even worse in terms of sensitising potential. For decontamination of endoscopes with chemicals – be it manually or with automates – the screened literature repeatedly correlates poor working conditions with the occurrence of adverse health effects. Therefore we link our recommendation with the precondition that human exposure to any applied product in endoscope decontamination has to be reduced to a minimum.

Conclusion on comparability in antimicrobial efficacy and material compatibility: A sufficient comparability in bactericidal, yeasticidal, fungicidal and sporicidal efficacy is assumed but cannot be confirmed. In addition, no reference can be made for applicability in a distinct medical device with a specific contact time and temperature. It is up to the product applicator to review operating instructions together with claims on efficacy and material compatibility.

Proven spectrum of activity according to VAH test methodology

The following tests for Surgical Hand disinfection are obligatory:
Determination of bactericidal efficacy in the quantitative suspension test (Method 9) at 20 °C, with 50 % (final concentration in the test) and as a concentrate (in addition to the concentration required for assessment of the boundary region) using a low organic challenge at a minimum contact time of 1 min, 3 min or 5 min.
If the contact time recommended by the manufacturer differs from these test contact times, a separate, additional test has to be performed for this time.
The test product must reduce the number of test organisms of S. aureus, E. hirae, P. aeruginosa, P. mirabilis*, E. coli* (*if these have proved to be more resistant than P. aeruginosa in the qualitative suspension test) under clean conditions within the recommended contact times (1–3 min, 5 min) at 20 °C by at least 5 lg as well as of C. albicans by at least 4 lg.
Thus, each product listed has demonstrated efficacy against bacteria and yeasts (C. albicans).
Phase 2/Step 2: Surgical hand disinfection – simulated-use test with volunteers (Method 12) (DIN EN 12791). To compare the results of the test and reference procedures and evaluate the test procedure, the following requirements must be met:
> Complete results must be available for at least 18 of the 20 volunteers and
> The total mean logarithmic value of the pre-values for the reference and test procedure(s) must be at least 3.5. If the mean value of the lg reduction factor obtained for the immediate effect and the effect after 3 h of the test procedure is not significantly lower than that of the propan-1-ol-based reference procedure, the test product meets the requirements under simulated-use conditions.
The reference procedure is performed with 60vol% propan-1-ol for 3 min. The test procedure may also be tested for shorter contact times of a minimum of 1 min. If, furthermore, the mean value of the lg reduction factor obtained for the sustained effect (after 3 h) of the test procedure is significantly greater than that of the propan-1-ol-based reference procedure, the test product meets the requirements under everyday conditions for a procedure endowed with "a sustained effect" *(cited from: explanatory notes on the Test Methodology Hand disinfection – Surgical hand disinfection; VAH-List Issue: 1 June 2016, p 172).*