
Health Care
Without Harm
Promoting
safer disinfectants
in the healthcare sector
SAICM 2.0
FINAL
REPORT

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CONTENTS

ABBREVIATIONS USED IN THIS REPORT

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

BPR
Biocidal Products Regulation

CAS
Chemical Abstracts Service

CLP
EU Regulation on classification, labelling and packaging of chemical substances and mixtures

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

ECHA
European Chemicals Agency

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 levels of toxicity towards aquatic organisms with lasting effects (M≥100)

IARC
International Agency for Research on Cancer

ICAN
Infection Control Africa Network

ISO
International Organisation for Standardisation

MRSA
Methicillin resistant

NSG
National Substitution Group

OT
Operating theatre

PHMB
Polyhexamethylene biguanides

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 sensitising 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

THE SAICM 2.0 PROJECT AND THE WIDES DATABASE

Health Care Without Harm (HCWH) Europe coordinated Strategic Approach to International Chemicals Management (SAICM) 2.0 project, a two-year pilot project which aims to raise awareness of, and combat potential environmental and health hazards of disinfectants, by promoting safer, more environmentally friendly products without compromising hygienic or occupational health standards. The project builds on the successful experience of the WIDES database. This database has been developed by the Vienna City Administration to directly address the difficulties in choosing appropriate disinfectants, while at the same time considering wider health and environmental impacts. During the implementation of the SAICM 2.0 project, the WIDES database was systematically applied to provide the most recent ingredients classification from EU legislation and to identify lack of knowledge or data insecurity with respect to the hazard potential of ingredients. Furthermore, the database was occasionally applied to exclude unsuitable alternatives, since it provides hazard categorisation for biocidal active ingredients. Since the database provides a considerable pool of products with proven efficacy – recommendations for product selection strategies for distinct applications, as well as shortlists to support selection of recommendable products, were created from the content and integrated in the final report.

SURVEY ON THE PROCUREMENT AND USE OF DISINFECTANTS

HCWH Europe launched a survey aimed at gathering information on the practices of procurement and application of disinfectants within healthcare organisations. The survey, made available in five languages between January and April 2019, collected 87 responses from 19 countries across the globe.

The majority of respondents are environmental protection and/or infection prevention and control employees with more than ten years of experience from large public teaching or general hospitals. The survey questions covered their level of awareness on disinfectant use and potential hazards, the policies and measures adopted to minimise such hazards, and whether these are reflected in the organisations' procurement practices. It is important to consider that the majority of participating organisations are either members of HCWH or one of its strategic partners, who have made a commitment to sustainability and might be more aware of environmental issues compared to their peers. In addition, the majority of participating organisations from outside Europe are also involved in the **Sustainable Health in Procurement Project** (SHiPP).[1] According to the survey results, respondents considered safety data sheets (SDSs) to be the primary source of information on disinfectant product hazard properties. However, approximately half of the participants either struggled to obtain disinfectant SDSs for HCWH Europe's hazard analysis or confused SDSs with product technical sheets. This was especially the case for participants from Latin America and Asia.

Overall, there are considerable regional differences in the level of knowledge on the Global Harmonized System of Classification and Labelling of Chemicals (GHS). Nevertheless, there is a substantial level of awareness on the potential health and environmental hazards related to the use of disinfectants, with the majority of responding organisations having hygiene plans and disinfectant disposal protocols in place, as well as training in the use and disposal of disinfectants. However, given the lower rate of awareness on GHS, further research is needed on the waste management plans in place.

Although participants demonstrate a good level of awareness and efforts to reduce disinfectant 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.

Although two thirds of 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 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.

HAZARD ANALYSIS (ABC CATEGORISATION)

The first step hazard analysis investigated the environmental and health hazards of 172 disinfectants. Product ingredients were identified via the SDSs by means of CAS numbers. Ingredient hazard information was complemented by the hazard statements provided in the WIDES database, which consider the most relevant and recent classification provided by EU chemicals legislation.

Ingredient hazard statements are differentiated according to the "ABC categorisation" that presumes that hazards can be reasonably differentiated in terms of severity and duration.

Category A covers long-lasting, difficult to control and/or irreversible hazards on human health and/or the aquatic environment. Category A hazards affecting human health relate to proven mutagenic, carcinogenic, reprotoxic or chronically toxic properties, as well as allergic skin reactions and asthma. Category A hazards to the aquatic environment are long-lasting and/or already occur in extremely low concentration. Category B covers hazards which still have a significant or rather unpredictable impact. Therefore, ingredients which are suspected of being mutagenic, carcinogenic and reprotoxic belong to category B. If a substance is not adequately investigated to exclude certain hazards it is also assigned to category B expressing data uncertainty. Category C covers irritating and corrosive properties to skin and airways. Hazards allocated to category C are of minor concern and not further indicated in the hazard analysis. The ABC categorisation disregards hazardous incidents that mainly arise due to improper handling, and it presumes proper working conditions (ventilation), as well as the use of personal protective equipment (PPE).

The hazard analysis was carried out for all participating hospitals and 37 hospitals received final evaluation documents. In cases where the disinfectant contains at least one category A ingredient, a "substitution demand" is stated. This means we recommend a search for less hazardous product alternatives and the carrying out of product benchmarking. If the disinfectant contains two or more category B ingredients a "limited substitution demand" is stated. This means that we do not perceive an urgent need for substitution, but recommend product alternatives are considered on a case by case basis. If the disinfectant contains only category C ingredients, no substitution demand is indicated and we recommend the application of such a product. We wish to emphasise that conclusions drawn at this stage of the hazard analysis solely consider ingredient hazards independently of concentration.

Nine hospitals were invited to search for potential alternatives for substitution, six of which agreed to continue their participation in the project. The criteria for selecting these hospitals were a minimum of analysed products (> 5) and balanced geographical distribution.

PRODUCT BENCHMARKING

While the first step hazard analysis provides an initial orientation and is primarily intended to identify candidates for substitution, the subsequent second step of the analysis – product benchmarking – is thought to identify less hazardous product alternatives for such candidates. For proper benchmarking, knowledge on dangerous ingredients and their concentration is needed. Differing or insufficient antimicrobial efficacy or material compatibility may be a reason to reject the alternative.

Product benchmarking includes the following steps: Either alone, or in cooperation with the evaluator, the participant screens the market for product alternatives. The ABC categorisation scheme is useful for this preselection phase - if a potential alternative contains category A substances it is rejected, while an alternative solely with category C ingredients is preferred. After a product alternative has been selected, a "hazardous load" (synonym for dangerous material cargo) is calculated based on consumption volume, both for benchmarked products and product alternatives. If the consumption volume is unknown, a default volume is applied. In any case, the quantity of calculated application solution of the benchmarked product and the product alternative(s) must be equal. Another important step in benchmarking is the grouping of hazards. Therefore, hazard statements are grouped to sum up hazards with a comparable degree of adverse impact. Therefore, we routinely group together proven carcinogenic (H350), mutagenic (H340), repro-toxic and chronically toxic hazards to a "CMR & CT" hazard. Accordingly, skin sensitising hazards (H317) and hazards for the induction of asthma (H334) are grouped as "SENS" hazards. Finally, hazards to the aquatic environment are grouped as "HIGH AQUATIC" and "AQUATIC respectively, depending on hazard statements H400 and H410, with accompanying M-factors (indicating the "strength" of aquatic toxicity).

Product benchmarking is the main focus of the case studies carried out in 6 hospitals located in Brazil, Colombia, Germany, Iceland, South Africa, and the United States. The feedback document contains the results of the grouped hazardous load calculation in kg per litre of application solution, conclusions on comparable antimicrobial efficacy, material compatibility and

recommendations for substitution. Feedback may further include barriers to replacing products as given by participants or justifications by the evaluator as to why proposed alternatives were rejected. If the results of benchmarking are ambiguous, scientific literature on indications for occupational problems may also be consulted to draw conclusions. Product benchmarking, as documented in the case studies, is less schematic, but more profound and extensive than the first step hazard analysis (ABC Categorisation).

RECOMMENDATIONS

The recommendations presented in this report reflect many of the challenges and areas for improvement identified in the project, beginning with assisting hospitals to identify safer product alternatives with equivalent efficacy.

The recommendations also highlight current policy gaps. Stronger regulations for biocides and disinfectants, as well as better implementation of existing regulations are urgently needed and should involve a multi-stakeholder and multi-sectoral approach. The Strategic Approach to International Chemicals Management (SAICM), a policy framework to promote chemical safety around the world, should be a vehicle to establish a global policy framework for that. Through legal and regulatory frameworks supported by SAICM, covering both occupational health and the environment, the impact of the full life cycle of biocides/disinfectants and waste on human health and environment should be minimised. Firstly, we recommend a world-wide implementation of the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and an international standardisation of hazard communication and documentation. We want to emphasise the importance of a hazard-based assessment as a guiding principle, as only this really complies with the precautionary approach. Regulatory actions should ensure mandatory best practice (reducing the use of biocidal products to a minimum and use of alternatives, as well as non-chemical products) and include mandatory training and further education and equipment for the application of biocides.

Looking at the demand side, procurers are encouraged to leverage their purchasing power to demand safer and more environmentally friendly products. Hospitals should have a sustainable procurement policy that protects their patients, employees and the environment. Multidisciplinary procurement project teams can support the implementation of such a strategy and are better equipped to set procurement criteria in line with the organisation's sustainability policy.

Lastly, maintaining dialogue with suppliers and manufacturers is equally important to spark innovation of more environmentally friendly and efficient products. Open dialogue and transparency from the supply side is essential to create trust. This project demonstrates that there is a market for safer and more environmentally 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.

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. HCWH Europe coordinated the SAICM 2.0 project, a pilot 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.

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 disinfection. The SAICM 2.0 project, financed by the German Environmental Agency, builds upon the pioneering work of the Viennese Database for Disinfectants (WIDES)[2] and aims to broaden its application worldwide.

NOTES CONCERNING THE COVID-19 PANDEMIC

The SAICM 2.0 project started in 2018 prior to the COVID-19 pandemic. Although disinfectant 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"[3] (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 an alternative for when suitable commercial products are either unavailable or too costly. The formulations are, according to today's knowledge, effective against coronaviruses.
- The WHO document Cleaning and disinfection of environmental surfaces in the context of COVID-19 (cited in the section "Policy recommendations") provides guidance for healthcare professionals, public health professionals and health authorities that are developing and implementing policies and standard operating procedures (SOP) on the cleaning and disinfection of environmental surfaces in the context of COVID-19.

THE HAZARD OF DISINFECTANTS TO HEALTH AND ENVIRONMENT

Recent studies indicate that biocidal active substances pose potential occupational health hazards, environmental threats, and can contribute to the spread of antimicrobial resistance (AMR) – a global health threat.[4] 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[5] (disinfectants can be sensitising or irritant), asthma and chronic obstructive pulmonary disease (COPD), skin problems, eye irritation, migraine, or other neurologic symptoms.[6 7] Some disinfectant ingredients are also allergenic[8] and have been identified as CMR (carcinogenic, mutagenic, and repro-toxic)[9 10] or endocrine disrupting.[11 12]

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.[13]

In terms of **environmental impact**, disinfectants may have adverse effects on aquatic systems due to high aquatic toxicity,[14 15] bioaccumulation and/or low biodegradability.[16] Additionally, disinfectants entering into wastewater from hospitals potentially disturb the wastewater treatment process and the microbial ecology in surface waters.[17]

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 in **resistance to antimicrobial disinfectants** commonly used to prevent them from spreading.[i 18]

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[19]) 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.[20] Furthermore, it can be difficult to easily identify and choose chemical disinfectants that are less harmful to human health and the environment, as biocides cannot be awarded the EU Ecolabel (Art. 6.6).[ii]

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

i Bacteria such as Enterococcus faecium and Staphylococcus aureus are resistant 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

ii 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).

programme ("Eco Purchase")[21] to support purchasing decisions. Among the tools provided is the **WIDES disinfectants database**, a user-friendly information system, which helps procurers choose the most suitable product for specific requirements, by comparing the hazard profiles of frequently used disinfectants available on the Austrian market. It lists about 200 ingredients of disinfectants and includes published human toxicological and ecotoxicological data and hazard statements of substances. In addition, it hosts around 300 market-based products for hygienic hand wash, hand disinfection, skin antisepsis, surface, instrument and linen disinfection.

Use of the WIDES database is mandatory for the Vienna Hospital Association, all buildings of the Vienna City Administration, kindergartens, schools, and public baths in the city when procuring disinfectant products. By 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.[22]

HCWH Europe, together with the technical support of Manfred Klade (Chemist and Environmental Engineer at TB Klade),[23] used the WIDES database throughout the implementation of the SAICM 2.0 project and disseminated the database worldwide.

SAICM 2.0 PROJECT

GOALS OF THE PROJECT

This two-year pilot 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 on the environmental burden of disinfectants, and a more sustainable use of disinfectants within the healthcare institutions.

In the longer term, the project will encourage transparent disclosure of disinfectant ingredients 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 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 offered support throughout the implementation of the project as an advisory body. The 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 Global
- 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 Programme - HCWH US
- Susan Wilburn, International Sustainability Director - HCWH Global

Survey: The first step involved surveying healthcare facilities to identify obstacles in using safer and more environmentally friendly 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 final report.

Product hazard analysis: Half of the organisations that replied to the survey 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 hazard analysis, 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.

Interview – Case studies: For a more in-depth analysis, HCWH followed up with six selected surveyed facilities that agreed to start the chemical substitution process. 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 report presents these case studies highlighting their challenges and opportunities in substituting disinfectants.

Product benchmarking: Product alternatives were then benchmarked against the products to be replaced and savings in hazard emissions were estimated (more detailed information about benchmarking can be found in annexes).

Interim report: The objective of the interim report was to present the preliminary project results and recommendations, and to gather feedback from experts and relevant stakeholders. The report remained available online for public consultation from 28 April until 17 May 2020.

Workshop: 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 the interim report and advance 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 and made use of this opportunity to:

- 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;
- Share experience and lessons learned in replacing disinfectants with safer, effective products.

International policy call: To provide further input from experts for improving the current policy and regulatory framework, a dedicated call was organised in June 2020. The feedback and suggestions from participants are included in the "Policy recommendations" section.

Publication: The outcomes of the projects and input received in the public consultation, workshop and international policy call are integrated in this final project report.

Dissemination: The outcomes of the project and the publications are presented at several high-level international events e.g. Biocides Europe, the International Conference on Chemicals Management (ICCM5), CleanMed conferences, as well as webinars.

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

THE PROCUREMENT AND USE OF DISINFECTANTS IN HEALTHCARE SETTINGS: SURVEY RESULTS

INTRODUCTION

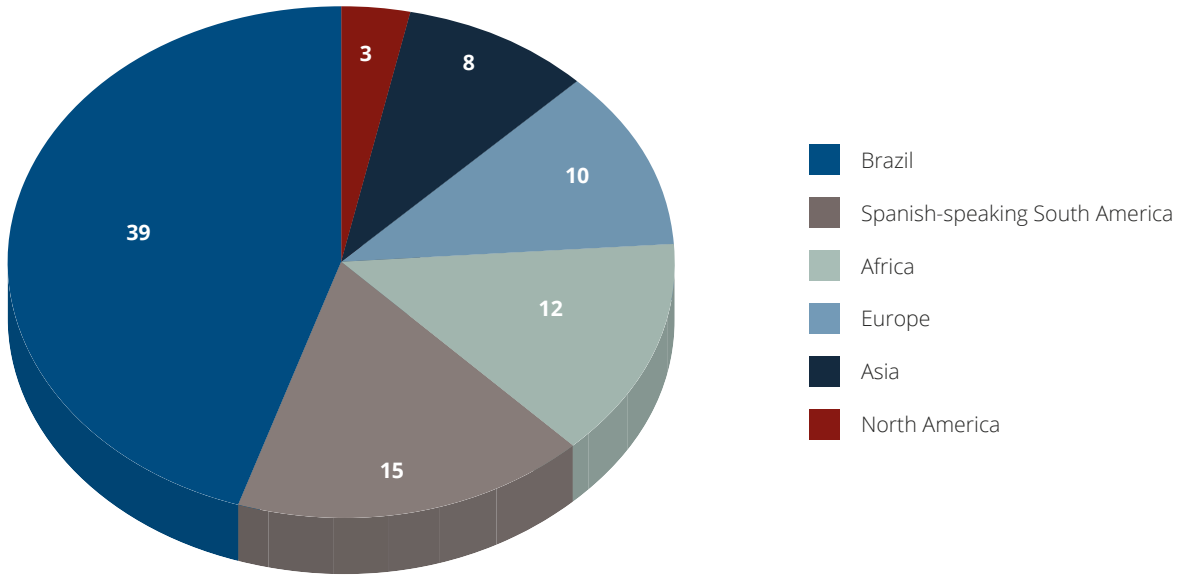
HCWH Europe launched a survey aimed at gathering information on the practices of procurement and application of disinfectants within healthcare organisations. The survey, carried out between 6 January 2019 and 30 April 2019, was available in five languages (English, German, Mandarin, Portuguese and Spanish) and was targeted at employees of hospitals and health organisations who have detailed insight into the procurement and application of disinfectants. The survey questions covered level of awareness on disinfectant use and potential hazards, the policies and measures adopted to minimise such hazards, and whether these are reflected in the organisations' procurement practices. It is important to consider that the majority of participating organisations are either members of HCWH or one of its strategic partners, who have made a commitment to sustainability and might be more aware of environmental issues compared to their peers. In addition, the majority of participating organisations from outside Europe are also involved in the Sustainable Health in Procurement Project (SHiPP).[1]

PARTICIPANT AND RESPONDENT PROFILES

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, 5 India, 1 Philippines)
- 15 in Spanish-speaking South America (3 Argentina, 2 Chile, 9 Colombia, 1 Costa Rica)
- 39 in Brazil

Geographical representation of survey participants



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, in addition to hospitals, there are also several companies that run hospital cleaning services and were asked to answer the survey on behalf of the hospitals that they serve.

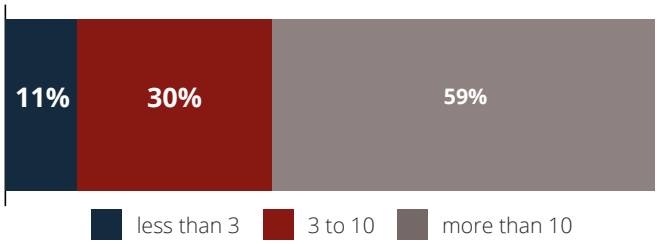
Participating hospitals represent different types of healthcare practice. The biggest groups are specialist or teaching hospitals (36%) and general hospitals (36%), while almost a fifth belong to a hospital network (18%). Only a small percentage of participants represent primary care centres or health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

Regarding the size[iii] 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.

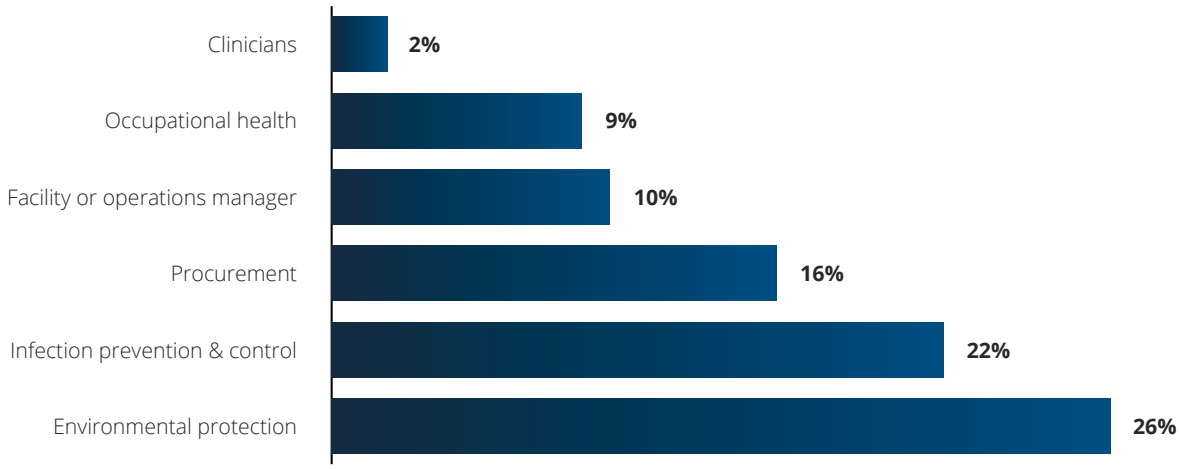
Among the other mentioned functions, some of the respondents are contract managers or work in Corporate Social Responsibility (CSR) and strategic planning. It is worth noting that almost two thirds of respondents (59%) have more than 10 years of experience in their role, while 30% have between three and nine years and only a minority (11%) have less than three years of experience.

Years of experience



iii 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

Position/Department



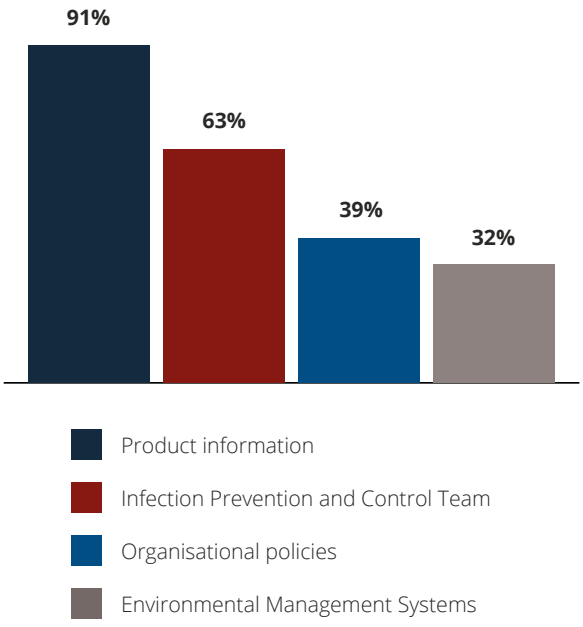
AWARENESS OF DISINFECTANT USE AND POTENTIAL ADVERSE EFFECTS

SOURCES OF INFORMATION

The survey assessed participants' knowledge of the issues related to the application of disinfectants and asked about 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. Organisational policies (39%) and Environmental Management Systems (e.g. ISO 14001, EMAS) (32%), are also relevant, while other sources such as employers, colleagues or professional associations and networks, as well as education and scientific papers were selected by less than a quarter of participants.

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

Most relevant source of information regarding chemicals and their hazardous properties



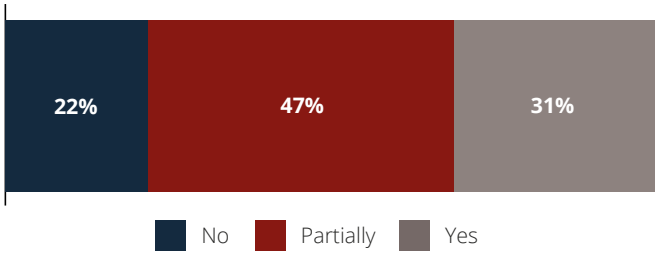
DISINFECTANT SAFETY DATA SHEETS (SDS)

The large majority of respondents (93%) stated that they either always (73%), or at least occasionally (20%), consulted the disinfectant SDS. Only one respondent stated that they did not consult it, while five respondents did not consider this relevant for their roles. However, this trend was not reflected in reality when the HCWH team collected disinfectant SDSs from participating hospitals - at least half of them did not have products SDSs, particularly in Latin American and Asia. Although the majority of hospitals were able to get the information from their suppliers, this process took several months and some participants were unable 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 are, however, different degrees of awareness about the types of hazards posed by these products.

Do you believe the use of disinfectants in your organisation poses a hazard to human health and/or the environment?



Respondents stress the value of disinfectants in healthcare settings and the need to carry out cost benefit analyses on the use of these essential products, due to the harm that they can cause to people and the environment. Some respondents further explained 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".[iv]

The most frequently mentioned causes of risk are: mishandling and incorrect disposal of disinfectants; lack of adequate safety information provided by the product

iv 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)

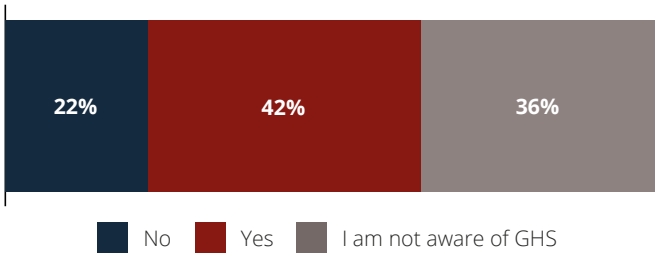
manufacturer; lack of adequate personnel training and PPE, and the presence of active ingredients that are carcinogenic and corrosive.

Some of the respondents shared their challenges in finding products that do not pose difficulties for breathing and do not have negative effects on the skin of employees and patients exposed to disinfectants. They emphasise their willingness to purchase safer products, but point out to a lack of (widespread) availability of such products for the healthcare market.

ADOPTION OF THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS)

Some of the challenges related to lack of information could be overcome by implementing 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 stated that they used 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, 67% recognised 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 manufacturers, importers or downstream users of substances or mixtures to classify, label and package their hazardous chemicals appropriately before placing them on the market.

Does your organisation use the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) classification?



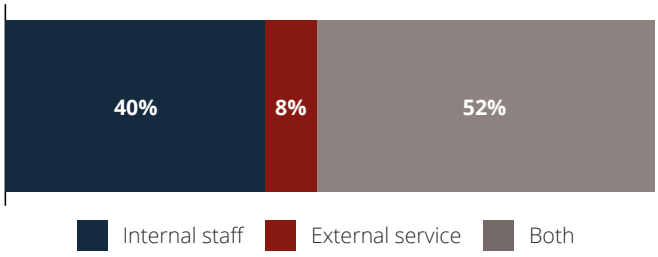
DISINFECTANT APPLICATION AND DISPOSAL

APPLICATION

All the organisations except one stated that they have hygiene plans and disinfection protocols. In addition, 51.2% have already identified areas where the use of disinfectants can be safely minimised or eliminated, such as non-critical and non-clinical common areas, especially where patients do not normally have access (administration offices, corridors, some kitchens, pharmacy, laboratories and warehouses). A few respondents stated that they have reduced the use of disinfectants for clinical procedures such as endoscopies. Amongst the other examples, one institution has replaced 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, as studies have shown that their use is not necessary.

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

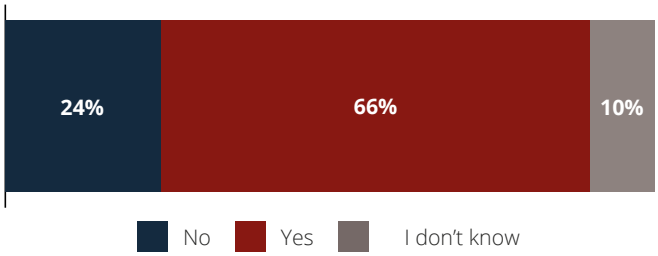
Who performs disinfection?



DISPOSAL

66% of the organisations surveyed have disposal/waste management protocols for disinfectants. Around a quarter of 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 on GHS, further research is needed on the waste management plans in place.

Are there waste management protocols for disinfectants?



TRAINING PROVISION

The majority of participating health organisations (77%) provide training in the use and disposal of disinfectants. The frequency of such training varies across organisations and it is often based on the level of employee experience (e.g. new employees receive it more often) and departmental needs (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 such as hygienists, facility managers and infection control managers. Around 10% of the organisations also invite suppliers and service providers to deliver the training. A few of the organisations opt for online training or induction and orientation on the job.

Sixty-one organisations provided further details about the frequency of this training. 19% organise training at least twice a year; eight organisations have quarterly training, two bimonthly, and eleven of them hold monthly training. 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 and existing employees and adapt the training needs accordingly.

DATA COLLECTION AND MONITORING

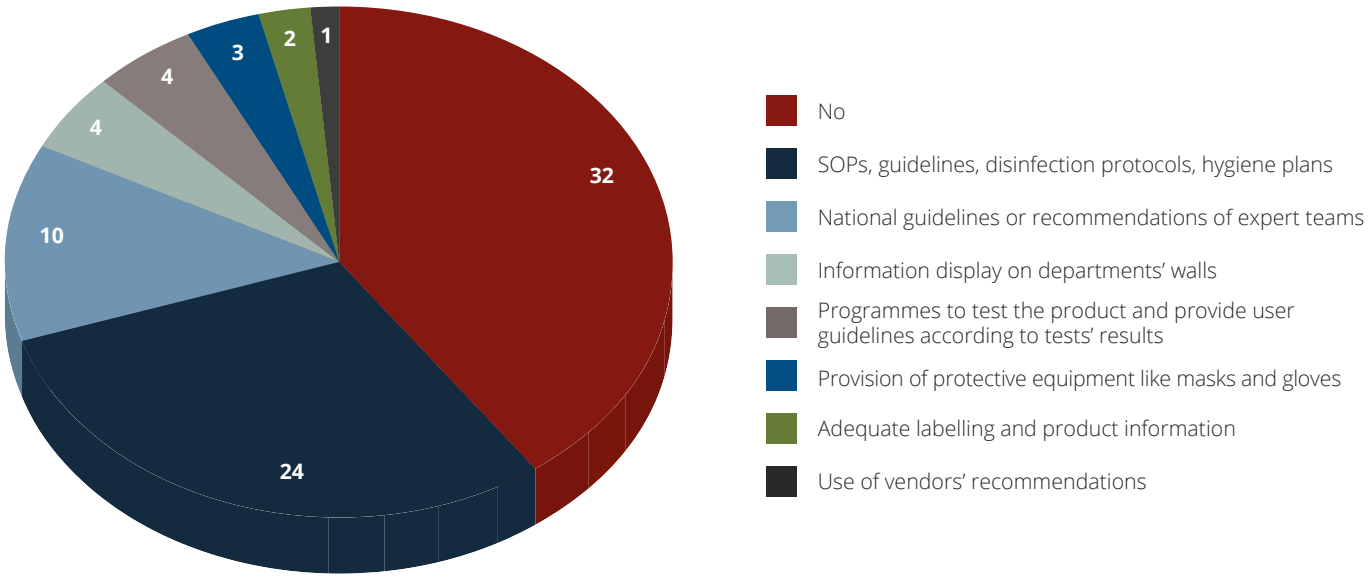
The majority of participating organisations (60%) state that they collect data on the quantities of disinfectants used. They were asked at what level they collect such data and were given the following options: department, clinic, hospital, hospital group, 'data are not collected', and 'I do not know'.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

OCCUPATIONAL HEALTH AND SAFETY AND ENVIRONMENTAL PROTECTION

The large majority of respondents (95%) state 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.

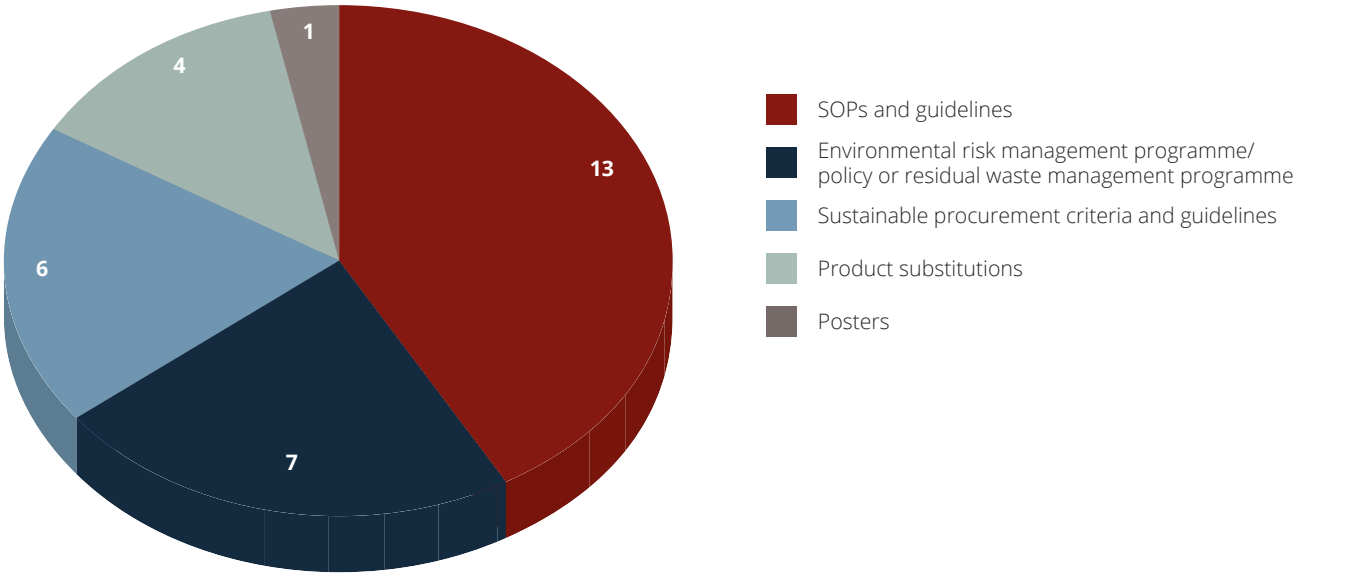
Almost two thirds of the organisations (61%) provide employees with tools, rules and guidance to minimise or avoid disinfectants/substances that pose a **threat to human health**. Among them, the majority of respondents (24) list the following measures: adoption of Standard Operating Procedures (SOPs), 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 departmental walls to ensure that guidelines are constantly visible to employees (4), programmes to test the product and the provision of user guidelines (4), provision of personal protective equipment such as masks and gloves (3), adequate labelling and product information (2) and the use of supplier recommendations (1).

Are tools and guidance to reduce the hazard of disinfectants to human health provided?



Similarly, more than half of the respondents (55%) state that they provide tools, rules and recommendations to reduce or avoid the application of disinfectants that pose a **threat to the environment**. Apart from training, these tools mainly consist of SOPs and guidelines (e.g. Global Green and 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) explained how they substituted certain products, especially for the disinfection of toilets and laundry cleaning to avoid the most hazardous substances entering the sewage systems. Other hospitals use posters and treat empty disinfectant containers as hazardous waste.

Tools and guidance provided to reduce disinfectants' hazard to the environment



PROCUREMENT AND TENDERING PROCESSES

THE BODY 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 explained 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 require disinfectants are directly responsible for purchasing them. In Brazil, one hospital has a Commission for the Standardisation of Medical-Hospital Materials in charge of procuring disinfectants.

INITIATORS

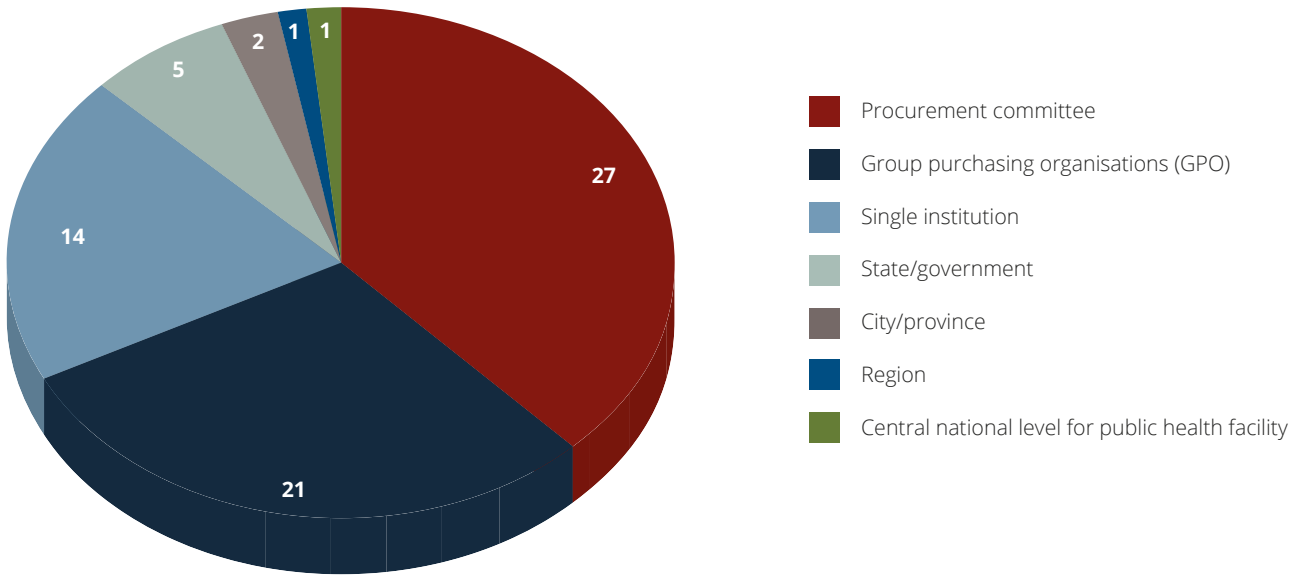
Seventy-three hospitals provided more information about who highlights the need for disinfectants (initiators). In half of the hospitals (51%), the main initiator is the Infection Prevention and Control Department, and in almost half of these cases, the department assesses the need for the product in cooperation with other units and colleagues. The units and roles mentioned vary across hospitals: pharmacy, cleaning/hygiene, environmental and waste units, sterilisation 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%), clinical staff (12%) or the head of each department (8%). The remainder of the respondents gave different answers such as 'interdisciplinary commission' or 'external providers'. In addition, in one hospital, any of the employees can highlight the need for disinfectant.

SUSTAINABLE PROCUREMENT

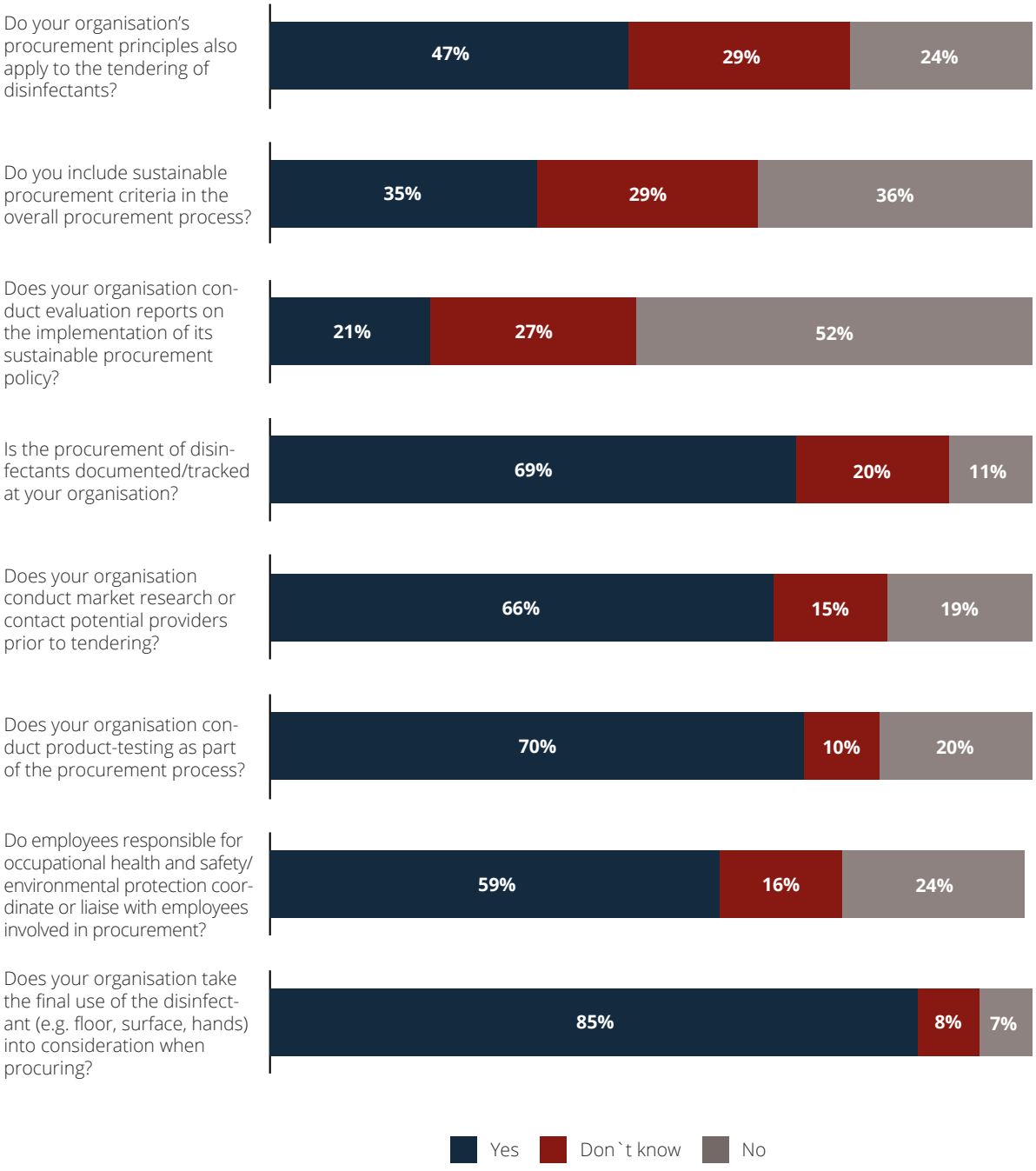
For almost half of the respondents (47%), procurement principles also apply to the tendering of disinfectants, but fewer organisations (35%) include sustainable procurement criteria in the overall procurement process. In addition to this, more than half of the organisations (52%) do not conduct evaluation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

Who is responsible for the procurement of disinfectants at your organisation?



A majority of organisations (69%) document the procurement of disinfectants and conduct product testing as part of the procurement process. However, participants did not share any further 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.

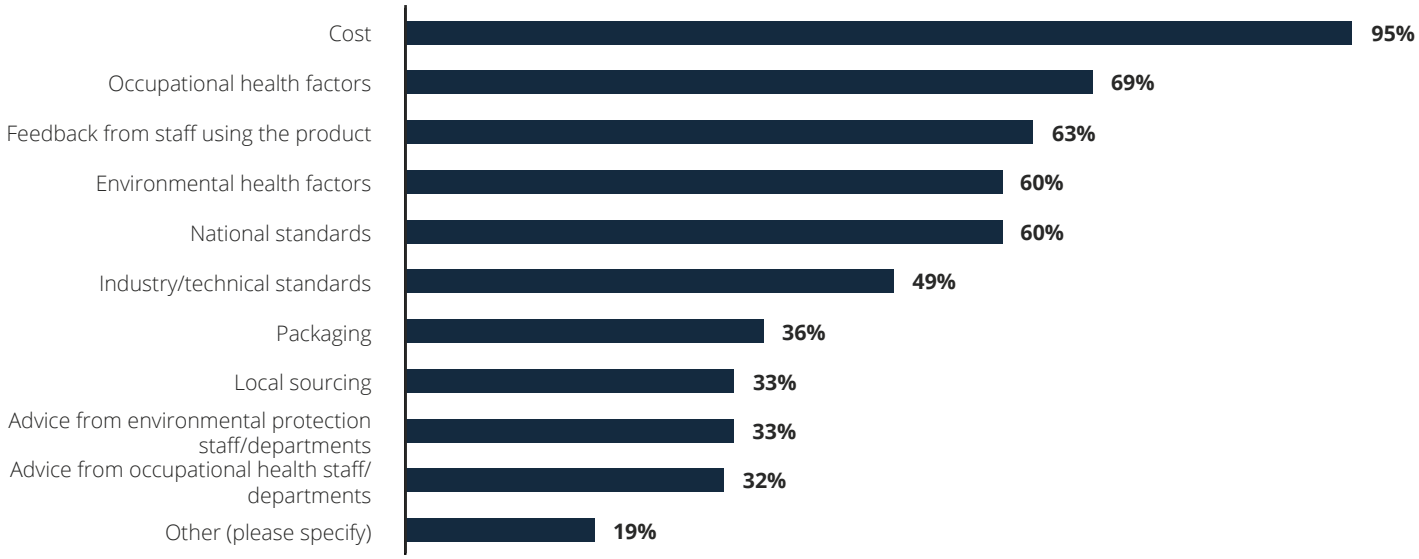


OTHER FACTORS CONSIDERED WHEN PROCURING DISINFECTANTS

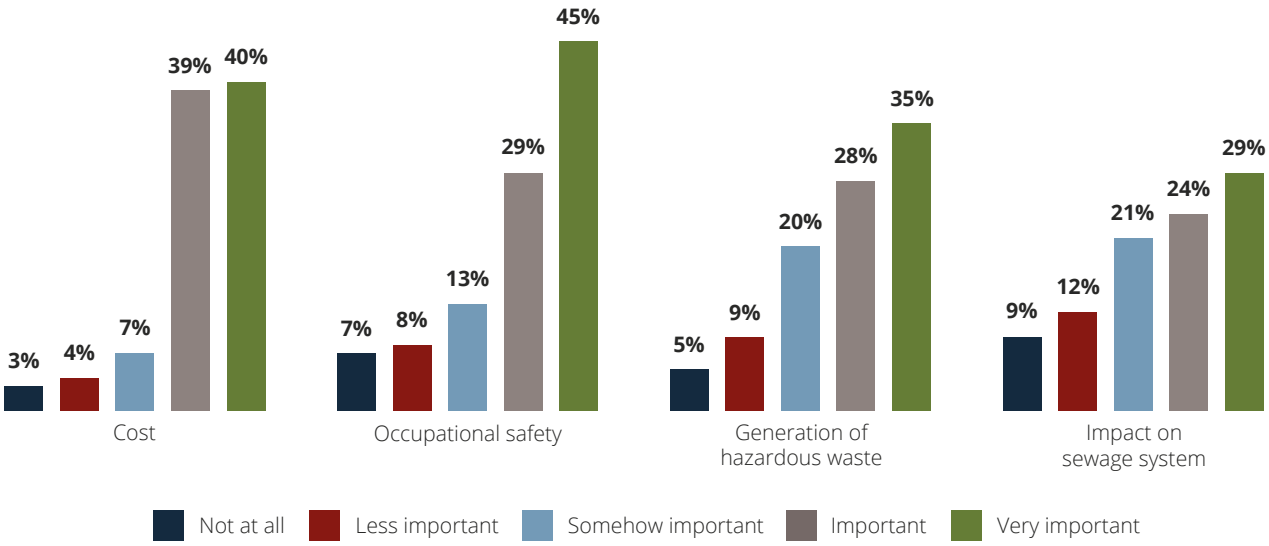
Seventy-five respondents provided more information about other factors considered when procuring disinfectants. Almost all respondents (95%) consider the price of the product. The vast majority state that they also take into consideration occupational health factors (69%) and feedback from employees using the disinfectant products (63%). While national standards and environmental factors seemed to be equally considered (60%), only a third of respondents state that they consider the advice from occupational health (32%) 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 such as the generation of hazardous waste or the impact on the sewage system are considered either very important or important by fewer participants.

Other factors considered when procuring disinfectants



Importance of the following factors when procuring disinfectants

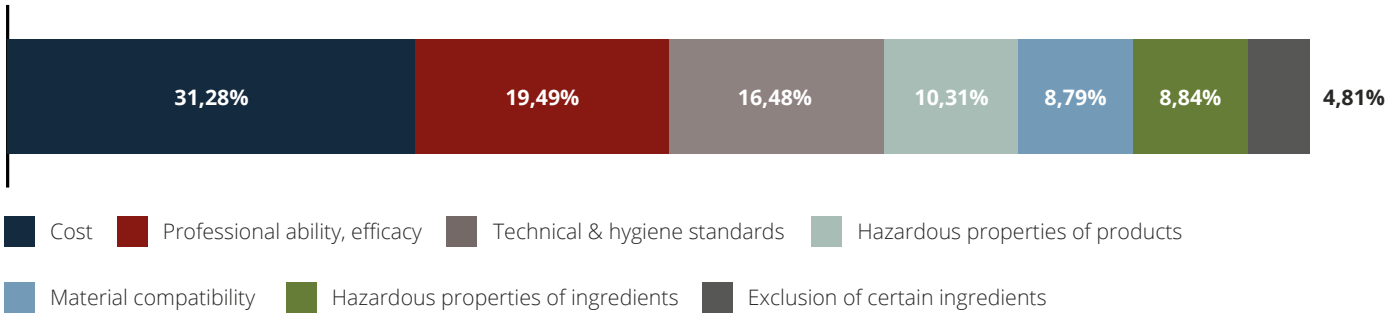


Participants were asked to give an estimated award criteria percentage attributed to different factors in their organisation's procurement of disinfectants (the total sum of award criteria should equal 100%). Sixty-seven participants replied to this question. On average, product price is the criteria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

tion prevention and control professionals are responsible for defining the needs for disinfectant products and this emphasises the need to raise awareness of potential hazards, not only among procurers, but also among healthcare staff.

Half of the organisations have procurement committees or are part of group purchasing organisations (GPOs). GPOs can be good intermediaries for leverag-

Estimated award criteria percentage attributed to each of the following factors when procuring disinfectants



CONCLUSIONS

Overall, there is a substantial 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. However, it is important to acknowledge that the majority of participating organisations made a commitment to sustainability by becoming HCWH members and might therefore be more aware of environmental issues compared to their peers.

Nevertheless, greater attention is given to patient and occupational health and safety compared to environmental protection and this trend is reflected both in the procurement process and in the application protocols in place. Two thirds of the organisations have disinfectant disposal management protocols and provide tools and guidance to minimise the threat to human health. However, given the lower rate of awareness on GHS, further research is needed on the waste management plans in place.

Although participants show a good level of awareness and make the effort to reduce disinfectants hazards, it is important to recognise that 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.

Each organisation described very different procurement processes, but for half of the respondents, infec-

ing the purchasing power of the healthcare providers and give a signal to the market by introducing sustainability demands in their tenders.

Two thirds of the respondents stated that infection control, occupational health and environmental managers are involved in the procurement process. Such multidisciplinary teams should promote consideration of both environmental and human health concerns in the procurement process. However, 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 feedback, prove to be decisive factors for most of the hospitals involved in the project.

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

HAZARD ANALYSIS OF DISINFECTANT PRODUCTS

This section presents the aggregated results of the hazard analysis. As illustrated in the table below, 40 organisations wanted to participate in the hazard analysis, but only 37 shared the SDS or technical information of the products used. These organisations were subsequently given a hazard analysis of their products from project technical lead TB Klade. We received 273 documents with information on 276 products: 172 were analysed, while the remaining 104 products were not considered for this study, as they were classified as products with no disinfecting properties (as they were mostly cleaning products). Based on the responses, nine organisations were offered the opportunity to continue with the second step of product benchmarking and received tailored support for identifying safer disinfectants.

Overview of participants - those selected for the second step (Product Benchmarking) are highlighted.

Hospital Code	# Documents received	Identified Products	Identified as disinfectants	Disinfectants not considered (mostly 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

Hospital Code	# Documents received	Identified Products	Identified as disinfectants	Disinfectants not considered (mostly cleaning products)	Second step - product benchmarking
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	(+supplement)	21	18	3	recommended
40	21	20	19	1	recommended
Total	273	276	172	104	9

The Hazard analysis results table (available on the HCWH Europe website) summarises the results of the product hazard analysis and indicates if a product is recommended for substitution according to the methodology explained in the annex (Hazard analysis: Methodology). Products are listed in alphabetical order.

In the European Union, regulation on chemicals in general and on disinfectants in particular (REACH regulation (EC) No 1907/2006 and the Biocidal Products Regulation (EU) 528/2012 (BPR), respectively) is in place and data concerning hazards and efficacy of disinfectants are available.

The hazard analysis in the SAICM 2.0 project mainly relies on classifications and data sets included in the WIDES database.

These data are based on the outcomes of the European chemicals REACH regulation (EC) No 1907/2006 and the Biocidal Products Regulation (EU) 528/2012 (BPR). The BPR oversees the staggered evaluation and authorisation of biocidal active substances used in disinfectants with direct human contact (Product type 1) and non-direct human contact (Product type 2). The WIDES database, as the main data source for substance information in SAICM 2.0, utilises the classifications and data sets of the BPR assessment reports published on the

ECHA webpage.[24] If an evaluation is not completed and assessment reports are not available, REACH dossiers are utilised as an alternative both for active substances and co-formulants to derive the most reliable classification and data for the determination (or exclusion) of hazards.

Since key topics of the SAICM 2.0 project - comparative assessment and substitution - are also present in the BPR regulation, similarities and differences will be discussed. Depending on certain criteria the BPR review programme may designate an active substance as a candidate for substitution. The criteria are specified in article 10 and inter alia concern CMR properties, respiratory sensitisation, potential for endocrine-disruption as well as high ecotoxicity, persistence or bioaccumulation. In essence, the first step of the hazard analysis of the SAICM 2.0 project is similar to this. However, the criteria are partly identical (CMR properties, respiratory sensitisation), and partly divergent (skin sensitisation, chronic toxicity).

If an active substance has been designated as a candidate for substitution in the BPR, a comparative assessment must be carried out by the competent authority for biocidal products including such a substance. Article 23 defines a potential alternative: for the uses specified in the application, another authorised biocidal product or a non-chemical control or prevention method already exists which presents a significantly lower overall risk for human health, animal health and the environment, is sufficiently effective and presents no other significant economic or practical disadvantages. For comparative assessment, technical guidance exists.[25] High complexity and in particular, a risk-based instead of a hazard-based approach, are the main reasons why this concept was not included in the SAICM 2.0 project. Although the product benchmarking of the SAICM 2.0 project has a significant analogy to comparative assessment it relies "only" on hazards. Instead, the hazard analysis covers all (known) ingredients of the disinfectant.

Moreover, a consideration of non-chemical alternatives – as foreseen in the comparative assessment – is not part of the benchmarking. This would afford a systemic view on the application and increase complexity.[v] Like the comparative assessment, product benchmarking requires specification of application and (presumes) a comparable antimicrobial efficacy between product and product alternative. Nevertheless, a detailed evaluation of efficacy is to be carried out by the applicator.

In conclusion, a comparative assessment in the BPR is to a significant extent risk-driven while the product benchmarking of the SAICM 2.0 relies on the evaluation of substance hazards. While comparative assessment is a complex procedure for regulatory purposes within the EU, the product benchmarking of SAICM 2.0 is designed as a participatory tool for applicators in the healthcare sector concerned with product selection and procurement decisions.

v Non-chemical alternatives however are thought to be promising additional options for the healthcare sector. Therefore a reference is made to the topic Chemical leasing and probiotic cleaners in the chapter *Non-chemical alternatives [page 83]*.

PRODUCT BENCHMARKING: CASE STUDIES

Nine hospitals were selected for the second step of the hazard analysis, namely product benchmarking. They were offered tailored support to identify less hazardous disinfectant alternatives. Selection criteria took into consideration hospital location (to have a balanced geographical representation), their product portfolio (at least 5 products), 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.

Five of these hospitals have advanced in the identification of less hazardous alternatives and received the results of the product benchmarking. A sixth case study (from the US) has been produced without the hospital testing the alternative products as detailed in the case study description. More information on product benchmarking can be found in the annexes.

Based on the outcomes of this second step, this report contains case studies from Brazil, Colombia, Germany, Iceland, South Africa, and the United States.

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

Table: Hospitals selected for the second step of 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

HOSPITAL 25 (H25): BRAZIL

SUMMARY

The Brazilian hospital selected for the case study is a medium size general hospital, with approximately 300 beds, an average of approximately 1,317 inpatients per month and 443 urgency and emergency patients 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 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, there remain risks of material incompatibility related to the use of the products on the acrylic material of the incubators. In March 2020, the hospital decided to test two other products for the disinfection of incubators, neither product contained category A ingredients. After testing and a cost-benefits analysis, the hospital's standardisation committee chose one of these latter alternatives.

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 due to the fact 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


Santa Joana
Hospital e Maternidade
Santa Joana
Hospital e Maternidade
Estacionamento
Visitantes
450

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 along with H317 are classified as potentially causing allergic skin reactions (category A). For Divosan S1, no further product benchmarking was considered, because the product has been rarely used and the hospital stopped 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 statement category A
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 H372 Causes damage to organs through prolonged or repeated exposure
We categorised all of these hazard statements under A, meaning that they are of high concern. It is therefore recommended that Surfic is replaced with a product containing other biocidal active substances.	

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

- Improved 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)
- Improved 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 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 didecyldimethylammonium 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 didecyldimethylammonium chloride (CAS N° 7173-51-5: 25 mg/g) and N-(3-Aminopropyl)-N-dodecylpropan-1,3-diamin (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 contain active substances with category A hazard properties.

4. Second step product benchmarking

Product benchmarking was carried out between Surfic and Oxivir Five 16 Concentrate as a potential alternative. In January 2020 the hospital delivered data concerning use amount and dilution.

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.

Use amount of Oxivir Five 16/Surfic

Period	Product	Pres-entation	Total amount used in the period	Average consump-tion per month	Dilution used	Total yield of diluted product in the month	Total yield of diluted product in the year
01/01/18 to 28/10/19	Surfic (Qua-ternary Ammonium + PHMB)	1L Bottle	846L	39L	1/200	7,800L/month	93,600L/year
01/11/19 to 17/01/20	Oxivir Five 16 (Hydrogen peroxide)	1.5L Bottle	216 x 1.5 = 324L	(324/78 days) x 30 = 125L	1/64	8,000L/month	96,600L/year

Amount of Surfic (Concentrate) used: Between 1 January 2018 and 28 October 2019, an amount of 846L concentrate was used, resulting in an annual amount of 468L of Surfic used. 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 2020, a monthly amount of 125L concentrate was used by the hospital, 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

Conclusion on substitution: Oxivir Five 16 Concentrate can be recommended as a product alternative to Surfic.

Conclusion on comparability of antimicrobial efficacy: 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 of material compatibility: The information gathered on the product and its alternative does not enable a final conclusion, it is recommended that compatibility is tested with the materials concerned.

Antimicrobial efficacy & material compatibility

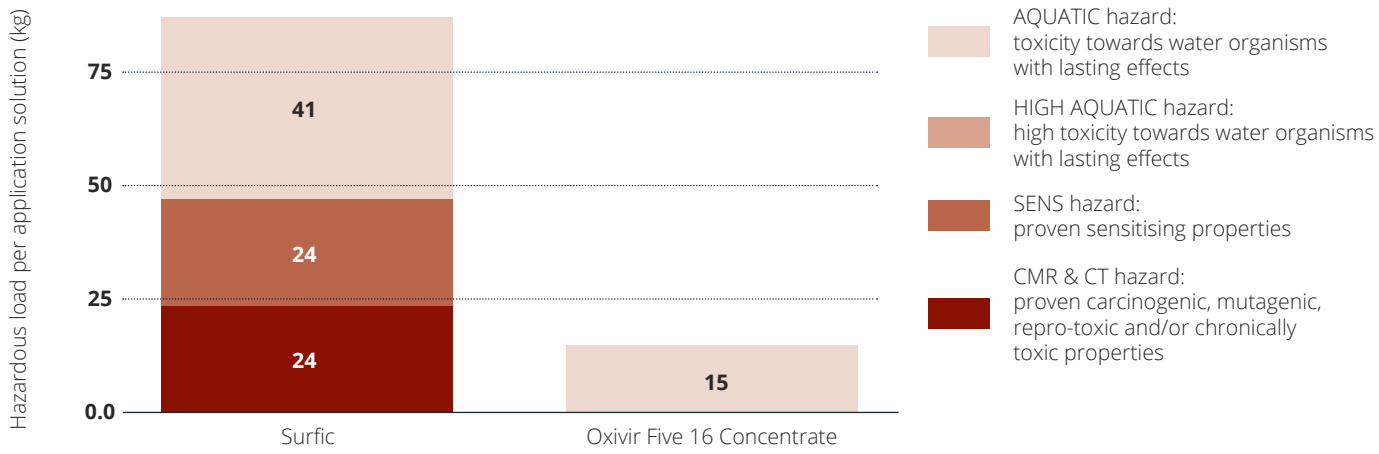
Claims for	Surfic	Oxivir Five 16 Concentrate (product data sheet*)
Antimicrobial efficacy	No information received or made available.	...effective against a wide variety of pathogenic microorganisms including viruses, bacteria, antibiotic-resistant bacteria, fungi, mould and mildew...
Material compatibility	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

Summary Benchmarked Hazards H25#1



5. Learning outcomes

In light of this process, the standardisation committee of H25 had to decide between the alternatives Oxivir Five Concentrate, Surfanios Premium NPC, and Surfa'Safe.

The hospital started to test Oxivir Five Concentrate in November 2019, but despite its good cleaning and disinfection results, some employees complained about its strong odour. Initially, the hospital also tested the product on incubators, which had been turned off, for a couple of months and obtained positive results. However, in March 2020, the hospital decided against testing the product with incubators that were switched on, as there was a risk of opacifying the acrylic material of the incubator and therefore damaging it. Subsequently, the hospital carried out further tests, together with the supplier, using the products Surfanios Premium NPC and Surfa'Safe. In June 2020, after completing testing, the hospital standardisation committee chose Surfanios Premium NPC as the main product to disinfect floors, walls of critical areas, equipment and non-critical medical products, while Oxivir Five Concentrate was included in the hospital contingency plan if there was a lack of Surfanios Premium NPC.

The choice was motivated by the following factors:

- Material compatibility: the product disinfects incubator material without damaging it
- Practicality: the product is easy to store, comes with automatic dispensers, and a single dilution 0.25% (2.5 ml/L) and an action time of five minutes
- Employee feedback/satisfaction: employees do not perceive any odour
- Benefits: the product represents an improvement in terms of reducing toxicity compared to Surfic
- Costs: the product costs less compared to Oxivir Five Concentrate and Surfic.

HOSPITAL 11 (H11): COLOMBIA, NUESTRA SEÑORA DEL CARMEN HOSPITAL

SUMMARY

With 18 beds, and an average of 45 inpatients and 2,250 outpatients per month, the Colombian hospital selected for the case study is a first level 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 product concerned is used 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; several different steps were taken: market research to identify products containing the active substances recommended from the WIDES database, supplier survey conducted 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 category A ingredients) but with strong limitations due to unidentifiable ingredients. Subsequently, two other alternatives were proposed by the hospital, which, according to the results of the benchmarking, were considered suitable product alternatives.

Thanks to this process, the hospital is now aware of GHS international chemical classification systems and of the potential risks to human and environmental 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. The hospital also began migration to the use of safer alternatives by engaging with the product supplier and by using them in some areas of the facility. As of July 2020, the hospital still needed to complete the migration process but hopes to finalise this procedure and replace the product shortly.

1. Conclusion on the outcomes of first step hazard analysis

It can be stated that the hospital's overall product portfolio presents a considerable satisfying standard in terms of occupational and environmental safety. The products used 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 the 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	
Used to disinfect instruments in the area of emergency care, hospitalisation and dentistry.	
Active ingredient	Hazard statement category A
Glutaraldehyde	H317 May cause an allergic skin reaction
	H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled
Formaldehyde	H317 May cause an allergic skin reaction
	H350 May cause cancer
We categorised all of these hazard statements under A, meaning that they are of high concern. It was therefore recommended that Quiruger Plus is replaced with a product containing other biocidal active substances.	

Hospital's reasons for using the product

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

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

- It is environmentally friendly: Does not have components such as nonylphenol that represent a H400 and H410 risk, which are very toxic to aquatic life with lasting effects on it
- Does not cause harm to employees, contractors or to external customers: It should not contain risk category A compounds (glutaraldehyde and formaldehyde)
- Has high level of efficacy in cleaning and disinfection of hospital microbial activity: Bactericidal, mycobactericidal, virucidal, fungicidal, sporicidal and sterilising
- Easy to use

Indications for use

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.

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

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 any products containing the active substances recommended by the consultant on the local market. 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 carrying out a supplier survey of their members to identify a company that would be able to provide suitable alternatives.

The hospital proposed replacing Quiruger Plus with two products, one for surface disinfection (Madacide-1) and another one for instrument disinfection (Alkazyme). Their use 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 request more information about the fragrance used and asked about the possibility to obtain the product fragrance-free, but this was not possible. The same process was undertaken to request whether 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 which 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 product benchmarking was performed.

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 (cited from received document*)	Percentage	Ingredient (assigned WIDES ingredient entry**)
Cloruro de n-Alquil (60% C14, 30% C16, 5% C12, 5% C18) dimetil bencil amonio	0.105%	Alkyl (C12-18) dimethylbenzyl ammonium chloride (ADBAC (C12-18)); CAS 68391-01-5; **Category B**
Cloruro de n-Alquil (68% C12, 32% C14) dimetil etil-bencil amonio	0.105%	Quaternary ammonium compounds, C12-18-alkyl[(ethylphenyl)methyl]dimethyl, chlorides; CAS 68956-79-6; **Category B**
EDTA	4.210%	Tetrasodium ethylene diamine tetraacetate; CAS 64-02-8; **Category B**
Neutronyx 656	0.526%	Substance assigned to ECHA entry "nonylphenol, 4-, Branched, ethoxylated (CAS 127087-87-0). "Substance of very high concern (SVHC)" due to suspected endocrine disrupting properties requiring authorisation (Annex XIV of REACH): No WIDES entry exists; **Category B (provisional)**
Sodiometasilicato·5H2O	0.263%	Disodium metasilicate; CAS 6834-92-0; **Category C**
Dietilenglicolbutileter	8.0%	2-(2-butoxyethoxy) ethanol; CAS 112-34-5; **Category C**
Fragancia	0.2%	Not assignable. Several fragrances have skin sensitising properties (H317) and **category A**

*Ficha tecnica Madacide-1 (LP advanced Medical S.A.S; www.lpadvancedmedical.com)

**The assignment to a WIDES ingredient is not unequivocal since no CAS number is given in the received document. Therefore ingredient identification was supported by a Google search.

Pre-screening of proposed alternatives Madacide-1 and Alkazyme

On 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 on ingredient identity (fragrance) and ingredient properties (Neutronyx 656).

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. No conclusion can be made as to whether the product is comparable in terms of efficacy (this would require 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 Quiriger Plus for Alkazyme is questionable.

Alkazyme

In the received product information sheet, Alkazyme is indicated to be suitable 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 an in-depth interpretation and comparison to Quiruger Plus would require more information. Therefore the evaluation and given conclusions are limited to the ingredients indicated in the product information sheet and the SDS.

Product information

Ingredient (cited from received documents*)	Percentage	Ingredient (assigned WIDES ingredient entry**)
Enzimas proteolíticas	0.6%	Not assignable. A proteolytic enzyme listed in WIDES is subtilisin (CAS 9014-01-1); **Category A**
Agentes absorbentes del calcáreo	32%	Decalcifiers: not assignable; **Category C** (provisional)
Agentes tensoactivos no iónicos	8.75%	Non-ionic surfactants: not assignable; **Category** C (provisional)
Cloruro de didecildimetilamonio	-	Didecyldimethylammonium chloride (DDAC); CAS 7173-51-5; **Category B**

Safety data sheet

Carbonato de sodio (CAS 497-19-8)	25-50%	Sodium carbonate, CAS 497-19-8; **Category C**
Alcohol etoxilado C16-C18 (CAS 68439-49-6)	2.5-10%	Alcohols, C16-18, ethoxylated (1 - 2.5 moles ethoxylated); CAS 68439-49-6; **Category C**
Alcohol etoxilado C10 (CAS 26183-52-8)	2.5-10%	Decan-1-ol, ethoxylated; CAS 26183-52-8; **Category C**
Cloruro de didecildimetilamonio (CAS 7173-51-5)	2.5-10%	Didecyldimethylammonium chloride (DDAC); CAS 7173-51-5; **Category B**
Propan-2-ol (CAS 67-63-0)	< 2.5%	Propan-2-ol; CAS 67-63-0; **Category C**

*...product data sheet for "Alkazyme" ALKAMEDICA S.A.S; www.alkamedica.com; safety data sheet for alkazyme (revision date: 4 February 2019) SODEL - Gamme ALKAPHARM; www.sodel-sa.eu / www.alkapharm.fr

**The assignment to a WIDES ingredient is not unequivocal since no CAS number is given in the received document. Therefore ingredient identification was supported by a Google search.

4. Second step product benchmarking

Based on the hospital's second proposal, 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 hospital 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. The density of application solutions is assumed to be 1. Annual application solution of Quiruger Plus was calculated based on the annual amount of the concentrate (109L) used 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 solution use of Oxivir Five 16 Concentrate.

Antimicrobial efficacy & material compatibility

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

Claims for	Quiruger Plus	Oxivir Five 16 Concentrate (product data sheet)
Microbial efficacy	Disinfectant with bactericidal, mycobactericidal, virucidal, fungicidal, sporicidal and sterilising activity	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

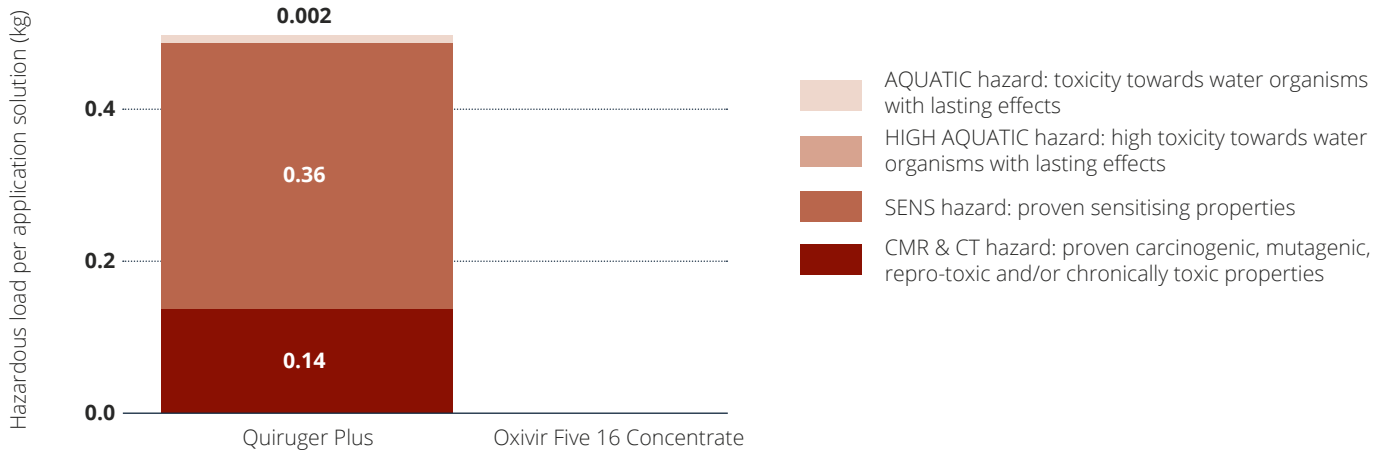
The hospital (represented by research group GESPSS) in conjunction with the provider SES Diagnostics started a clinical study comparing the use of Quiruger Plus and Oxivir Five 16 Concentrate for surface disinfection and medical instruments. The study is composed of two phases: a clinical phase and a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

As of March 2020, the hospital has finished the clinical phase during which they performed the sampling, culture, and counting of bacteria and fungi from different hospital areas and instruments that were subsequently disinfected with Quiruger Plus, generating a new culture, and subsequently disinfecting with Oxivir Five 16 Concentrate, with a final culture. The clinical phase showed adequate performance of Oxivir Five 16 Concentrate. The laboratory phase is underway where Oxivir Five 16 Concentrate's ability to destroy highly pathogenic microorganisms is being measured.

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

Hazardous load	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

Summary Benchmarked Hazards H11#1a



Conclusion on substitution: Oxivir Five 16 Concentrate is recommended as a 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. Sufficient comparability in bactericidal and fungicidal efficacy is assumed, but cannot be finally confirmed. It is left up to the hospital to review the available data and decide if their requirements are met.

Conclusion on comparability of material compatibility: Information on material compatibilities of both the benchmarked product and the product alternative does not allow for conclusions to be drawn on full comparability. It is recommended that compatibility with the materials concerned is tested.

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. The 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

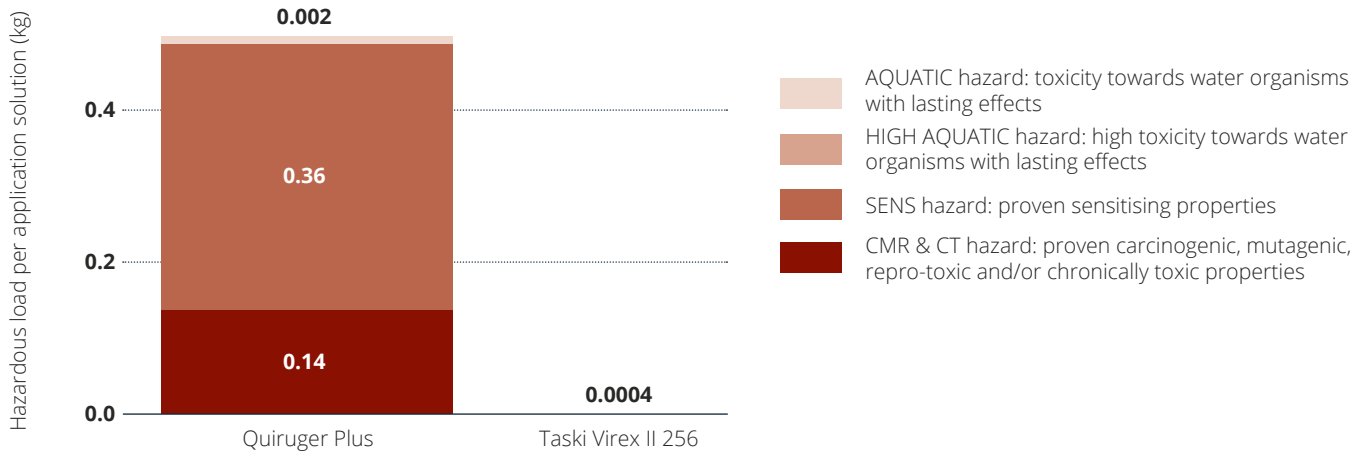
With respect to microbial efficacy and material compatibility, the following information was found in the delivered documents (own translation from Spanish):

Claims for	Quiruger Plus	Taski Virex II 256 (product data sheet)
Microbial efficacy	Disinfectant with bactericidal, mycobactericidal, virucidal, fungicidal, sporicidal, sterilising activity	**Bactericidal at 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 and Enterococcus faecalis - Resistencia Vancomycin according to AOAC method. **Fungicidal at 1:256 against:** Tricophyton mentagrophytes, Candida albicans and Aspergillus niger. Virucidal at 1:256 against: HIV (AIDS virus), Influenza A2/J305, Herpes Simplex Tipo 1, Herpes Simplex Tipo 2, Adenovirus Tipo 2, Virus New Castle disease, Avian influenza and Pseudorabies virus
Material compatibility	No information received	Compatible with surfaces

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

Hazardous load	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

Summary Benchmarked Hazards H11#1b



Conclusion on substitution: Taski Virex II 256 is a recommended 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 on comparability in terms of microbial efficacy. It is left up to the hospital to review the available data and decide if their requirements are met.

Conclusion on comparability of material compatibility: The information about material compatibilities for both the benchmarked product and the alternative product does not allow for conclusions to be drawn on full comparability. It is recommended that compatibility with the materials concerned is tested.

5. Learning outcomes

The hospital is now aware of international chemical classification systems and of the potential risks to human health and the environment 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 academic experts. They already have results for aerobic mesophylls and fungi and yeasts on surfaces and instruments. The next step is to complete migration to the use of Oxivir Five 16 Concentrate and ensure that other hospitals have all the necessary information to improve their use of disinfectants. As of July 2020, the hospital started a dialogue with the suppliers of Oxivir Five 16 Concentrate and have already started using the product in some areas of the facility. However, changing provider completely and completely replacing Quirurger Plus will require an additional series of steps (e.g. calculating the volume required to meet hospital needs), but they hope to finalise this procedure and replace the products shortly.

Disinfection personnel would welcome the substitution of Quirurgel Plus with Oxivir Five 16 Concentrate; the latter does not require rinsing, surfaces dry quicker, and they can easily use smaller products amounts without having to activate the entire product as with Quirurger Plus.

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

HOSPITAL 39 (H39): GERMANY, KLINIK FACHKLINIK GAISSACH

SUMMARY

The hospital from Germany is a medium size hospital of approximately 250 beds specialised in treating 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 such as 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, the use of which 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.

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

Eighteen disinfectant products have been analysed. It can be stated that the overall product portfolio of the hospital reflects a 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-Alkylaminopropylglycine, which is classified as causing chronic tox-

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

icity and therefore categorised as 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.

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-Alkylaminopropylglycine (category A).

Microbac Forte	
Intended use: Surface disinfection (bactericidal and yeasticidal with mechanical action) at a dilution of 0.5% (60 min). The *Disinfection plan* does not specify if there is a need to combat high organic load (i.e. dirty conditions).	
Ingredients	Hazard
Substitution demand relies on 3 allergenic fragrances (R)-p-Mentha-1,8-dien, citronellol, hexyl cinnamal mentioned in SDS (21 June 2019; Hartmann-Bode).	H317 May cause an allergic skin reaction (category A)
Biocidal active substances: Benzyl-C12-18-Alkyldimethylammonium chloride & N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine	Category B does not constitute a substitution demand. It would be 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
Substitution demand relies on the active substance N-Alkylaminopropylglycine	H372 Chronic toxic (Category A) according to an EU-Assessment Report.[26] The substance is also suspected to be reprotoxic (H361)

Apesin SDR San	
Intended use: In the *Disinfection plan* Apesin SDR is indicated as a phased-out product and substituted by Kiehl-AciDes. If there is a substitution demand for Kiehl-AciDes, alternatives will be proposed.	
Ingredients	Hazard
Substitution demand 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 (category A). Butylphenyl methylpropional is also suspected of damaging fertility or the unborn child (H361)
Biocidal active substances: Lactic acid & phosphoric acid	Category C

Kiehl-AciDes	
Intended use: In the *Disinfection plan* 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).[27]	
Ingredients	Hazard
Substitution demand relies on 2 allergenic fragrances, namely limonene & benzyl salicylate, mentioned in SDS (04 May 2017; Kiehl KG).	H317 May cause an allergic skin reaction (category A)
Lactic acid (active substance)	Category C
Didecyldimethylammonium chloride (active substance)	Category B does not constitute a substitution demand. It would be sufficient to choose a product without allergenic fragrances.

Eltra (60°C)	
Intended use: In the *Disinfection plan* application is indicated for laundry. According to VAH, Eltra is applied at 60°C with bactericidal, yeasticidal, tuberculocidal, mycobactericidal and fungicidal efficacy.	
Ingredients	Hazard
Substitution demand relies on 3 allergenic fragrances butylphenyl methylpropional, hexyl cinnamal and limonene mentioned in SDS (18 March 2019; Ecolab).	H317 May cause an allergic skin reaction (category A). Butylphenyl methylpropional is also suspected of damaging fertility or the unborn child (H361).
Biocidal active substances: generates peracetic acid	Category B does not constitute a substitution demand. It would be sufficient to choose a product without allergenic fragrances.

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

Barriers to replacing products

- The hospital is subject 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 hospital) an alternative has to fulfil (in terms of efficacy, material compatibility, price)

- Some products should be legally authorised for preventing epidemic diseases and therefore be listed in Robert Koch Institute's guidelines
- Some disinfectants must have the German VAH certification for efficiency (e.g. Eltra 60°C)
- Proposed alternatives 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 the products used
- 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 bathe. 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: Granules/active substance: Magnesium monoperoxyphthalate hexahydrate (CAS 84665-66-7)/VAH listed/provider: Bode	Mikro Quat Extra: Liquid – Concentrate/active substances: Benzalkonium chloride (CAS 68424-85-1); Didecyldimethylammonium chloride/VAH listed/provider: Ecolab
Apesin AP 100: Granules/active substance: Magnesium monoperoxyphthalate hexahydrate (CAS 84665-66-7)/VAH listed/provider: Tana	Incidin Pro: Liquid – Concentrate/active substances: Benzalkonium chloride (CAS 68424-85-1); N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamin/VAH listed/provider: Ecolab
Descogen F: Granules/active substance: Pentapotassium bis(peroxymonosulfate) bis(sulfate)/VAH listed/provider: Antiseptica	Cleanisept: Liquid – Concentrate/active substances: Benzalkonium chloride (CAS 68424-85-1); Didecyldimethylammonium chloride/VAH listed/provider: Dr. Schuhmacher GmbH

Bacillol 30 Tissues	
According to VAH, Bacillol 30 Tissues can be used 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 surface disinfection universal tissue: Tissue – rtu/active substances: Benzalkonium chloride, didecyldimethylammonium chloride:/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 fragrance (clean conditions)	**Acid based alternatives with non-allergenic fragrances (clean conditions)**
No comparable acid based alternatives without fragrance could be found.	Disinfectant cleaner AF: Concentrate/active substances: Benzalkonium chloride, didecyldimethylamonium chloride; Citric acid/VAH listed/provider: Schülke
	Budenat azid plus D587: Concentrate/active substances: Benzalkonium chloride, didecyldimethylamonium chloride; 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 and 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 in clean conditions (low organic load). The following is a limited selection of alternatives.
Alternative (clean conditions): Laudamonium: Concentrate/active substance: Benzalkonium chloride/VAH listed/provider: Ecolab

4. Second step product benchmarking

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 are replaced with Descosept Sensitive Wipes

As summarised in the table below, 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.

Benchmarking: Bacillol 30 Tissues and Descosept Sensitive Wipes

Ingredient concentrations and classified hazards were gathered from safety data sheets, the VAH List and the WIDES database. Density of application solution is 0.96 for Bacillol 30 Tissues and 0.93 for Descosept Sensitive Wipes. The 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.

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 (part) substitution	Reduction of sensitising hazard load (not quantifiable)
Kiehl-Aci Des	Allergenic fragrance	-	Phased out	
Eltra (60°C)	Allergenic fragrance	130 kg	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

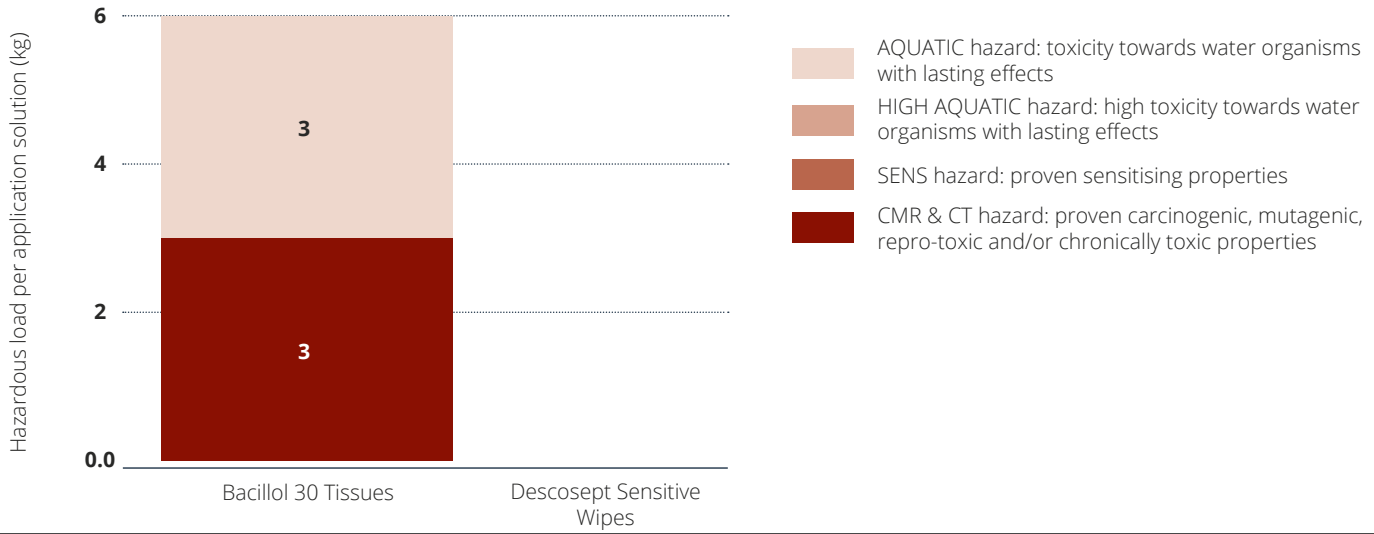
Antimicrobial efficacy & material compatibility

Claims for	Bacillol 30 Tissues	Descosept Sensitive Wipes
Antimicrobial efficacy	VAH is listed as: bactericidal (not Mycobacteria), yeasticidal, works in dirty conditions and mechanical action in 5 minutes	VAH is listed as: bactericidal (not Mycobacteria), yeasticidal, works in dirty conditions and mechanical 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/annual application solution			
Bacillol 30 Tissues	3	0	3	0
Descosept Sensitive Wipes	0	0	0	0

Summary Benchmarked Hazards H39#1



Conclusion on substitution: Descosept Sensitive Wipes are a recommended product alternative for Bacillol 30 Tissues.

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

Conclusion on comparability of material compatibility: The hospital requirements together with information about the product alternative are cited. Since it does not enable a final conclusion, it is recommended that compatibility is tested with the 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.[28] The density of application solutions is assumed to be 1. The application solution is derived from the annual use amount of 130kg for Eltra (60°C), an application concentration of 7g/L (RKI) and a liquor ratio of 1:5. Both Eltra (60°C) and Lavo Des 60 Kompakt are included in the RKI list for chemo-thermal laundry disinfection, with both of them having a disinfecting temperature of 60°C and a liquor ratio of 1:5. While the exposure time is 20 minutes for Eltra (60°C), for Lavo Des 60 Kompakt it is 15 minutes.

Antimicrobial efficacy & material compatibility

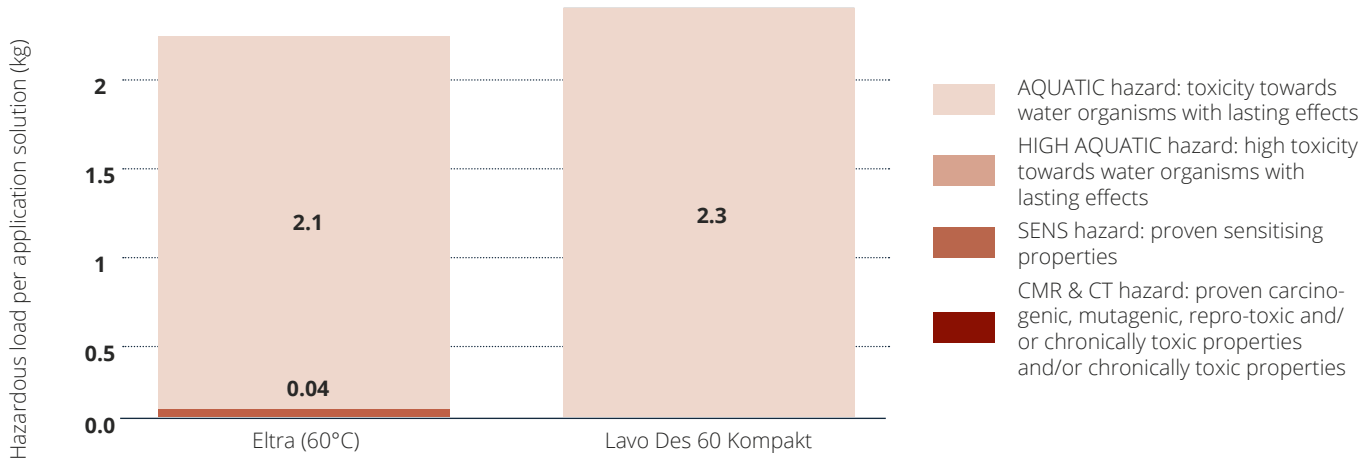
Claims for	Eltra (60°C)	Lavo Des 60 Kompakt
Antimicrobial efficacy	RKI list: AB*	RKI list: AB*
Material compatibility	Not indicated	Not indicated

*Bactericidal (including mycobacteria), fungicidal and virucidal

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

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

Summary Benchmarked Hazards H39#2



Conclusion on substitution: Lavo Des 60 Kompakt is a recommended 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 that of Lavo Des 60 Kompakt, but this difference does not outweigh the avoidance of proven sensitising loads.

Conclusion on comparability of antimicrobial efficacy: The hospital requirements 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 of 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

Although the hospital is still testing the alternative products, the lessons learned 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 20 (H20): LANDSPÍTALI - THE NATIONAL UNIVERSITY HOSPITAL OF ICELAND

SUMMARY

The hospital from Iceland is a large general hospital with 631 beds and an average of 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. While product testing was still ongoing, a second step product benchmark has been performed for four products showing the savings in hazardous loads. The chemical substitution process has been delayed by the lack of supply of the chosen alternative on the Icelandic market and by the COVID-19 pandemic. As of July 2020, the hospital is using a safer alternative in one of the four OT departments and is aiming to use the products in all the departments in autumn 2020.

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 hospital 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, 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(peroxymonosulphate) bis(sulphate) (CAS 70693-62-8), which is category C and therefore recommended 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 are classified as a 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 chlorhexidine digluconate (CAS 18472-51-0), which is also classified as a 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 polyhexamethylene biguanide 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).

Hospital's reasons for using the products

- Rely+On Virkon Tablets are used to clean and disinfect patient rooms, toilets and equipment, as well as operating theatres (OT). 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 OT between operations and at the end of the day after the last operation, the anaesthesia side of the OT, as well as 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 OT, 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 detergent 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 OT. 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, such as blood pressure cuffs 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 replacing products

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 headaches and the bad odour when using chlorine products (Chlor-clean 1000ppm).
Surfa'Safe Premium and Wip'Anios Excel	The cleaning staff like this product. It makes their job easier - it does not have a bad odour and does not leave any stains behind.
Aniosurf ND Premium	There are no particular barriers to replacing this product. The staff do not like it, because of its bad odour and the warnings written on the container. Therefore, some people refuse to use it.
Clinell Universal Sanitising Wipes	This product is widely used at the facility and the staff like using this product.

Conditions (received from the hospital) 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 any strong odour. • It needs, of course, to be compatible with all kinds of materials that are used in patient rooms and WCs, such as 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 should not affect the substance/product activity. • Does not leave any residue behind that needs to be cleaned afterwards. • Must be free from any strong odour. • It has to be compatible with all kind of materials used in the OT, 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 should not affect the substance/product activity. • Dries out without residue. • Must be free from any strong odour. • Compatible with vinyl.
Clinell Universal Sanitising 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. Further information on product efficacy requirements, availability of alternatives and testing were exchanged via e-mail over four months. The following decisions have been made about the six products:

- TB Klade did not further recommend choosing Rely+On Virkon Tablets (and Virkon S) for product benchmarking for the following reasons: The product's main active ingredient is the biocide pentapotassium bis(peroxymonosulphate) bis(sulphate) which is category C and therefore does not pose severe concern. In addition, the hospital staff are very satisfied with the product.
- The hospital decided to prioritise the replacement of Surfa'Safe Premium spray and Wip'Anios Excel. The hospital chose the products Incidin Oxy Foam S and Incidin Oxy Wipes S. As they were not available on the local market, H20 contacted 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 such as Clinell Universal Sanitising Wipes, TB Klade recommended considering product alternatives with quaternary ammonium compounds but without the category A ingredient polyhexamethylene biguanide (PHMB). Thus, the product was benchmarked against 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 themselves.
- 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 category A	394.5L	Planned substitution**	19.8
Wip'Anios Excel	Biocidal active ingredient with category A	222.3L*	Planned substitution***	11.2
Clinell Universal Sanitising Wipes	Biocidal active ingredient with category A	Default value: 100L	Use reduction****	0.7*****
Aniosurf ND Premium	Biocidal active ingredient with category 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).

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

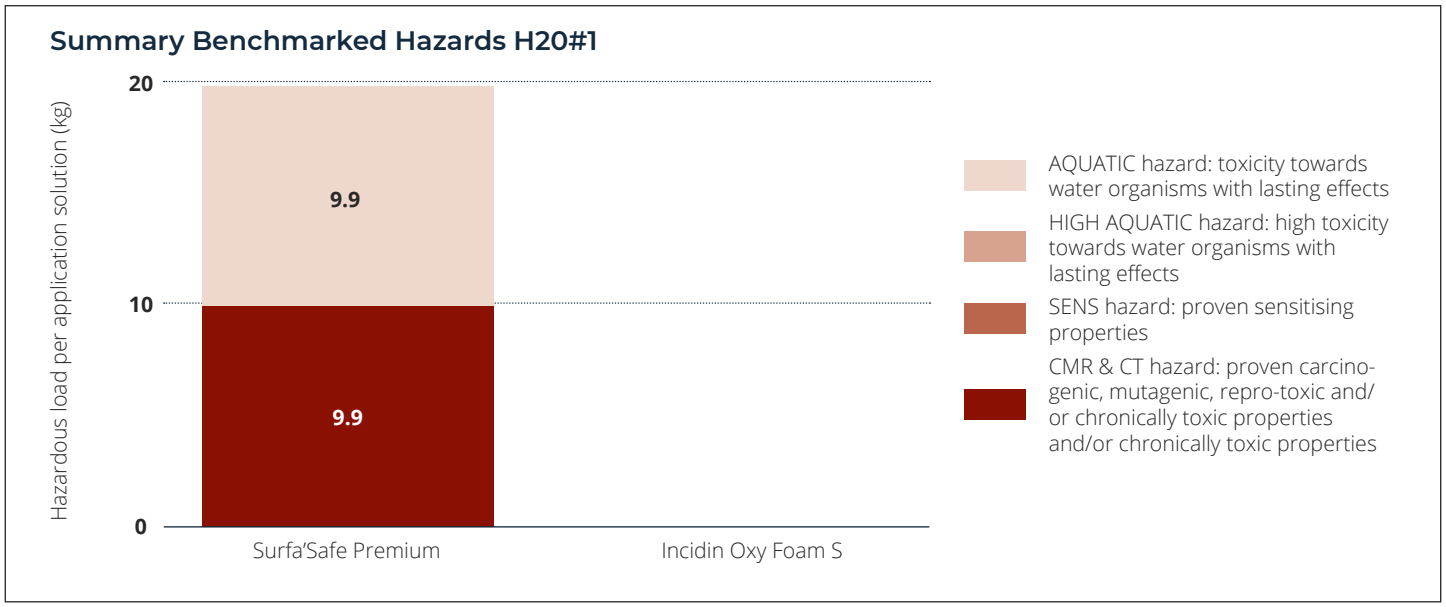
Conclusion on comparability of antimicrobial efficacy: The hospital requirements for antimicrobial efficacy are cited together with the basic claims for the product alternative. Sufficient comparability in bactericidal, yeasticidal and fungicidal efficacy is assumed, but cannot be confirmed in detail.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

Antimicrobial efficacy & material compatibility

Claims for	Surfa'Safe Premium	Incidin Oxy Foam S (product data sheet)
Antimicrobial efficacy	Hospital demands efficacy as follows: Has to kill/destroy common bacteria, viruses and fungi, but not spores. Organic materials should not affect activity.	Bactericidal, yeasticidal & fungicidal with high organic load in 5 min.
Material compatibility	Hospital demands compatibility as follows: Has to be compatible with all kinds of material used in the operating theatre.	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 comparability of material compatibility: The hospital requirements together with information about the product alternative are cited. Since it does not enable a final conclusion, it is recommended that compatibility is tested with the 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. The 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.

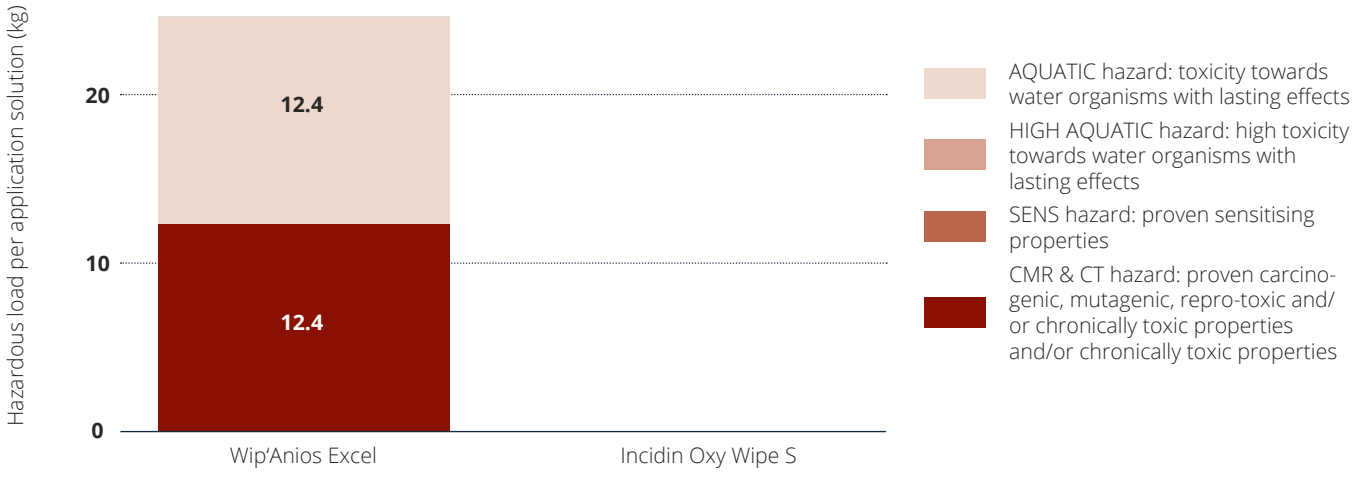
Antimicrobial efficacy & material compatibility

Claims for	Wip'Anios Excel	Incidin Oxy Wipe S (product data sheet)
Antimicrobial efficacy	Hospital demands are as follows: Has to kill/destroy common bacteria, viruses and fungi, but not spores. Organic materials should not affect activity.	Bactericidal, yeasticidal & fungicidal with high organic load in 5 min.
Material compatibility	Hospital demands are as follows: Has to be compatible with all kinds of material used in the operating theatre.	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	12.4	0	12.4	0
Incidin Oxy Wipe S	0	0	0	0

Summary Benchmarked Hazards H20#2



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

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

Conclusion on comparability of material compatibility: The hospital requirements, together with information about product alternatives are cited. Since it does not enable a final conclusion, it is recommended that compatibility is tested with the materials concerned.

Benchmarking Clinell Universal Sanitising Wipes and Sani Cloth Active

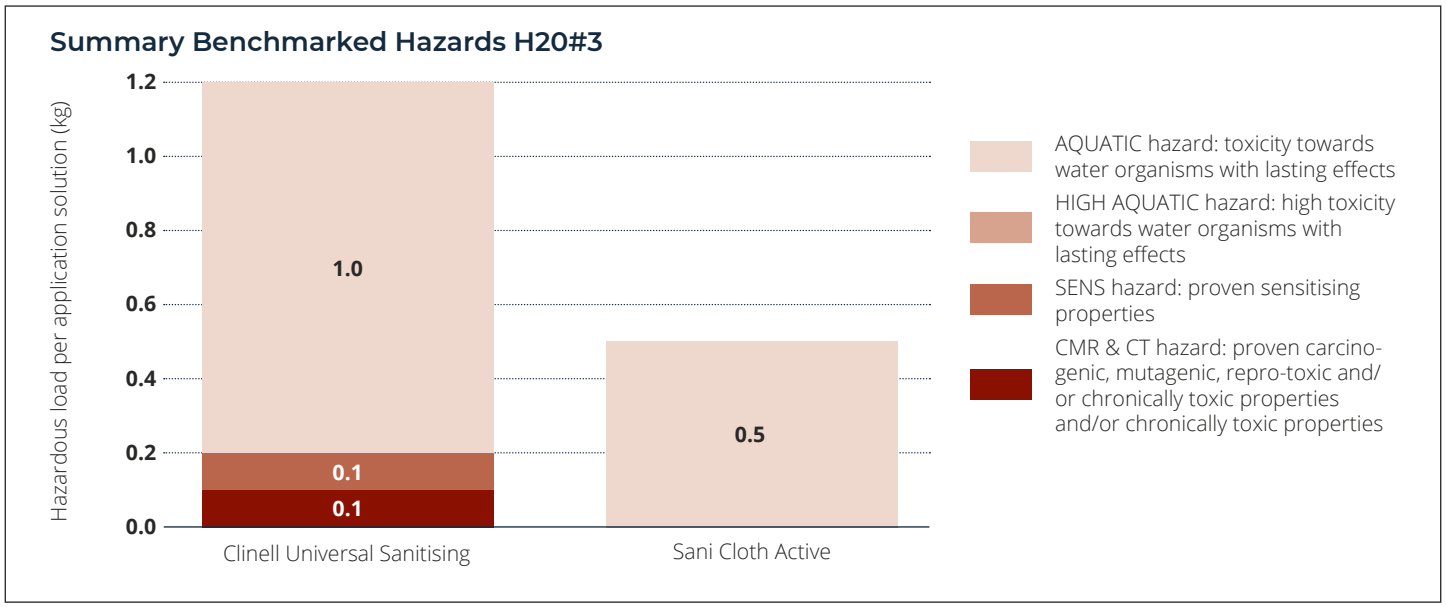
Ingredient concentrations and classified hazards were gathered from the SDS and the WIDES database. The density of application solutions is assumed to be 1. The annual use amount of Clinell Universal Sanitising Wipes is unknown, therefore a default value of 100L applica-

Antimicrobial efficacy & material compatibility

Claims for	Clinell Universal Sanitising Wipes	Sani Cloth Active (product data sheet)
Antimicrobial efficacy	Hospital demands are 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	Hospital demands are 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



tion solution (i.e. impregnating lotion for wet wipes) is assumed. An equal amount is therefore assumed for Sani Cloth Active.

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

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

Conclusion on comparability of material compatibility: The hospital requirements together with information about the product alternative are cited. Since it does not enable a final conclusion it is recommended that compatibility is tested with the materials concerned.

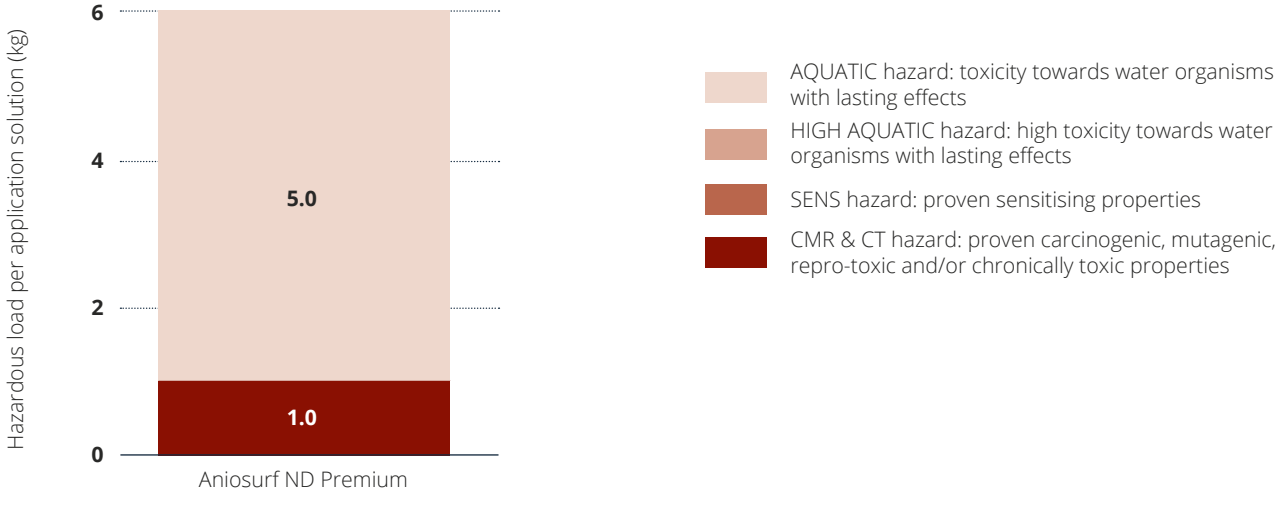
Avoidance of hazardous loads calculation – Aniosurf ND Premium

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

Avoidance of Hazardous Loads Calculation H20#4



5. Learning outcomes

The hospital tested the alternatives for several months with promising results. As of July 2020, the hospital was using Incidin Oxy Foam S in one of its four OT departments and hoped to be able to use the products in all the departments in autumn 2020. The substitution process was first delayed by the lack of supply on the Icelandic market and then by the COVID-19 pandemic.

The hospital also hopes to further simplify their use of disinfectant products by narrowing down the product portfolio. Based on the lessons learned from this project, preference is given to return to the use of alcohol whenever possible, as they have been doing for many decades.


STOFA 6
Hafdis
LANDSPÍTALI
Hafdís
Sjúkraliði

HOSPITAL 16 (H16): SOUTH AFRICA, SEBOKENG HOSPITAL

SUMMARY

The hospital from South Africa is a large regional hospital with 800 beds, an average of 736 inpatients and 25,000 outpatients. 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. However, the substitution requires changing the policy of the provincial government that manages the hospital's procurement contracts. To support the change in 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 provincial policy for future procurement of routine hand disinfectants.

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.

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 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,[3] 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.[29] As a result, the hospital was encouraged to substitute these products with alcohol-based disinfectants.

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	-

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,[30] 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. It is an antiseptic 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:

- The book "Wallhäußer" from 2008 (available only in German) represents a standard reference for disinfection methods and ingredients in industrial and medical applications. Therein the field of application of chlorhexidine gluconate (CAS 18472-51-0) is reviewed mentioning the following areas: antiseptic for 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, skin tolerability is reduced. Considering the unknown long-term risks of chlorhexidine and the questionable benefit of the addition of chlorhexidine to alcoholic products for long-standing application, it is recommended that alcoholic products are selected that do not contain chlorhexidine. When applying chlorhexidine containing products, the risk of an anaphylactic reaction has to be taken into account.*[31]
- The World Health Organization (WHO) recommends handrub formulations.[3] 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 replacing products

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

Conditions (received from the hospital) 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.

3. Identification and assessment of potential alternatives

To support the change in 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 products listed are available on the local market. As indicated above, the WHO provides a recipe for an alcohol hand rub that can be produced in the hospital pharmacy, together with recommendations on hand rub formulations.[3]

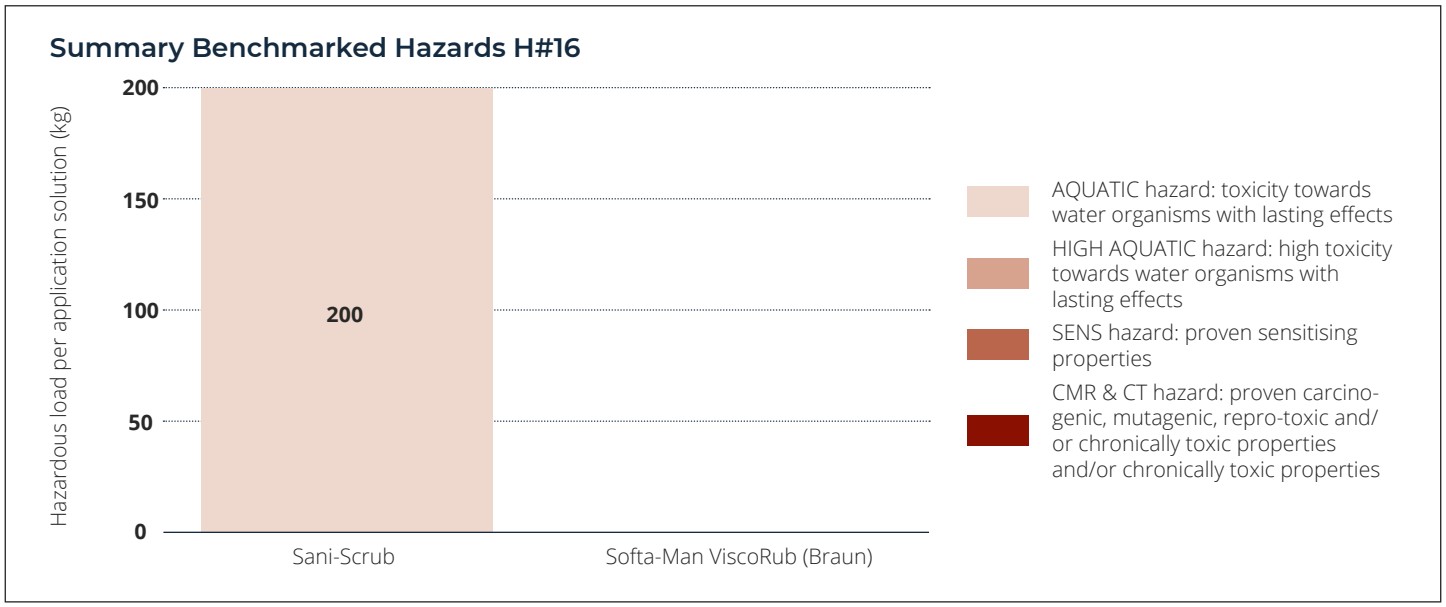
4. Second step product benchmarking

To further support the hospital in their decision-making, product benchmarking is performed for Sani-Scrub with Softa-Man ViscoRub as alternative. The alternative Softa-Man ViscoRub is a random choice of a product listed in the WIDES database for disinfectants. The product alternative is marketed in Europe and there is no knowledge as to whether 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 as 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. The 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 for an application solution of 5,000L.

dient compositions with typical concentrations have been given to the hospital to support the selection of appropriate alternatives. Future procurement decisions should take into consideration this evidence and recommendations. It is, however, up to the hospital

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



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

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

5. Learning outcomes

Without taking into account the specific requirements of the participating hospital for the performance of the 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 ingre-

and provincial government to check efficacy of the product alternatives by questioning 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 15 (H15): UNITED STATES

SUMMARY

The participant from the United States is a large hospital network. 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 a literature review.

After carrying out 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.

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

This case study will have a different structure compared to the others because the hospitals that provided the data discontinued their participation in the project.

The disinfectants listed by the participant, however, are widely used among HCWH US members, so product benchmarking and further research were conducted without the participant.

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 a category A hazard ingredient.

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

In addition to 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 had 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 employees and the environment.

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-phthalaldehyde (643-79-8), which has proven sensitising 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

Product benchmarking for Cidex OPA solution representing both Cidex OPA Concentrate and Metricide OPA Plus was carried out. The benchmarking included 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 websites):

- Cidex OPA solution[32] is a high level disinfectant for reprocessing heat sensitive reusable semi-critical medical devices, for which sterilisation 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[33] 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)[34] is a high level disinfectant when used or reused, in a legally marketed Automated Endoscope Reprocessor.
- Rapicide PA High-Level Disinfectant[35] is a single-use, peracetic acid-based solution (...) with proven material 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[36] 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 sterilisation.

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

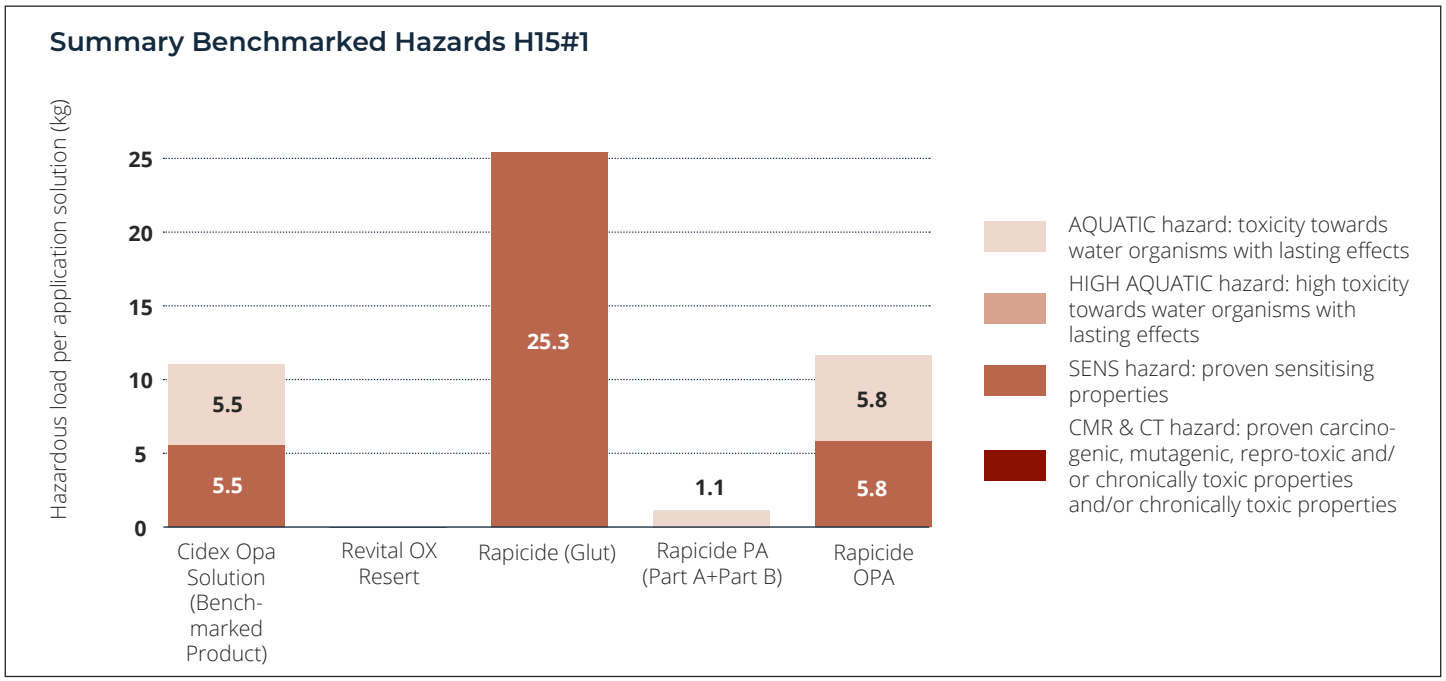
4. Second step product benchmarking

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.[vi]

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 1,000L application solution applied on each product

Hazardous load	CMR & CT	SENS	AQUATIC	HIGH AQUATIC
	kg/application solution			
Cidex Opa	0.0	5.5	5.5	0.0
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 it is important to consider that the quality of the calculation largely relies on the accuracy of the underlying information namely: a) that the chosen hazard classification correctly applies to the ingredient(s); b) that the concentration of the ingredient in

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 1L of application solution of product A may be sufficient

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

to decontaminate 1 endoscope, while 1L 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 healthcare workers to peracetic acid (PA) in combination with hydrogen peroxide (HP) and acetic acid (AA) on the one hand, and ortho-phthalaldehyde (OPA) on the other.

The following documents consider PA-HP:

- *Respiratory symptoms in hospital cleaning staff exposed to a product containing hydrogen peroxide, peracetic acid, and acetic acid*[37]

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 suggest a need for engineering, administrative, and/or PPE controls to reduce exposure.

- *Evaluation of Worker Exposures to Peracetic Acid-based Sterilant during Endoscope Reprocessing*[38]

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 that 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), and also reported periodic headaches and burning eyes that were more noticeable when SS1 processors[vii] 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 exposure. 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*[39]

The authors describe the case of two subjects who developed a 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 three 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 rates for a period including work and away from work, are highly suggestive of 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.[viii] Thus, disinfectants belonging to the oxidant class, such as mixtures of PA-HP, appeared to act as occupational irritants. The authors conclude that the allergic or irritant mechanism is difficult to define – low concentrations of PA-HP might increase oxidative stress, as well as lipid peroxidation, causing the appearance of bronco-constriction.

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vii IIA or irritant-induced asthma is a subtype of occupational asthma (OA) without immunologic sensitisation 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 sensitisation.

viii A fully enclosed tabletop unit.

The following documents consider ortho-phthalaldehyde (OPA):

- *A case of occupational bronchial asthma and contact dermatitis caused by ortho-phthalaldehyde*[40]

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 prior to using OPA, and her asthma corresponded to OPA exposure with a latency period of nine months. After change of workplace (from the endoscopy unit to the emergency room) the 57-year-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*[41]

The paper describes the case of a 55-year-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 three 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 (FEV1) four hours after exposure. According to the authors this confirms OPA's potential to act as a respiratory sensitiser. 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*[42]

The purpose of the study is to summarise and review available health information on OPA with particular attention 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 sensitiser with sensitising 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 as a replacement to 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 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 the 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.

SUGGESTIONS FOR PRODUCT SELECTION STRATEGY (BASED ON THE WIDES DATABASE)

STRENGTHS AND LIMITATIONS OF ABC CATEGORISATION AND 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 ABC categorisation 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 ABC categorisation 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 that 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.[2] 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 central European Market, they may be available worldwide. Their efficacy is certified by the German Association for Applied Hygiene (VAH)[27] 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 carried out 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 they 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 avoiding products containing category A ingredients (see 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) Dihydroxydioxahexane (B) Formaldehyde (A)	Heat-sensitive and heat-resistant instruments	Yes	Low & high
2	Korsolex extra (Hartmann/ Bode)	Dihydroxydioxahexane (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)	Glucoprotamine (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 GmbH)	Amines, N-C12-14-alkyltrimethylenedi- (A) 2-Propanol (C)	For medical instruments and rigid endoscopes	No	Low & high

No	Product (Manufacturer)	Active ingredients (Category)	Application (manufacturer claim)	Flexible endoscopes	Organic load
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 tetra hydro-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-alkyltrimethylenedi- (A) N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine (B)	For medical instruments and rigid endoscopes	Yes	High
14	Korsolex plus (Hartmann/ Bode)	Didecyldimethylammonium chloride (B) N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine (B)	Reprocessing of heat-sensitive and heat-resistant instruments	Yes	High
15	Cidex OPA solution**	Phthalaldehyde (CAS 643-79-8) (A)	High level disinfectant for reprocessing heat sensitive reusable semi-critical medical devices.	Yes	High

*Recommended by Robert Koch Institute Germany 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 with only 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 peroxide with acid in aqueous solution. The most concerning human health hazard is with respect to 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 the data.
3. **Glucoprotamin (8):** Glucoprotamin is exclusively offered by one manufacturer and data provision is limited. According to WIDES, glucoprotamine 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-dodecylpropane-1,3-diamine (14):** Didecyldimethylammonium chloride is – due to H301 - category B with no data gaps. N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine 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-dodecylpropane-1,3-diamine (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-dodecylpropane-1,3-diamine 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[ix], 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 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 used peracetic acid solution into the aquatic environment is avoided.

Additionally, the following ingredients could be found in the shortlist cited above: glucoprotamine (category B), reaction product based on tetrahydro-2,5-dimethoxyfuran (category B), amines, N-C12-14-alkyltrimethylenedi- (category A), N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine (category B) and phthalaldehyde (CAS 643-79-8). As long as an ingredient is category B, it can be considered equivalent to peracetic acid and serve as a potential alternative 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 in enough detail 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 *Recommendations of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI, Germany) and the German Federal Institute for Medicinal Products and Medical Devices (BfArM):*[43]

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. Preparation in a closed system facilitates reprocessing and standardises the preparation process, therefore machine processing is preferable. [p. 1289]*

Concerning the disinfection of endoscopes that takes place after cleaning and rinsing:

> *Insufficient cleaning and intolerances of detergent residues and disinfectants may affect the efficacy of disinfection. Disinfectants with proven efficacy are listed in the VAH disinfectant list for the manual disinfection of medical instruments.*[27] *For machine disinfection, the efficacy of the disinfectant must be demonstrated by the manufacturer using expert opinion. 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 should be used. The concentration and time of the disinfectant*

ix To avoid category A ingredients as far as application conditions allow.

must be strictly adhered to in accordance with the manufacturer specifications [...] Since there is an increase in the load of air with disinfectant vapours in the treatment room, the possibility of adequate ventilation or a separate extraction option must be given for reasons 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-resistant gloves and liquid-tight protective coats must be worn. Tubs for instrument disinfection must be covered. Disinfection of flexible endoscopes and any additional endoscopic instruments should preferably be carried out as part of the integrated system of cleaning equipment in order to protect personnel from contact with the disinfectant medium. Treatment of 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.[44]]

This chapter concerns products applied for hand disinfection. Application covers hygienic hand disinfection (carried out on dry hands as a rub-in procedure without the addition of water) and surgical hand disinfection (carried out prior to 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 ingredients or combination of ingredients used. For some of these, additionally, limited virucidal activity is claimed.[x] Certification is by either VAH (for bactericidal and yeasticidal efficacy) or – in the case of limited virucidal efficacy – by the manufacturer themselves, by VAH or RKI. Unless otherwise stated, testing fulfils or is at least equal to the norms in the table below:

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 product selection criteria and on 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 table on page 77 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. "Limited virucidal" efficacy is needed to safely combat the enveloped COVID-19 virus.

	Bactericidal	Yeasticidal	Limited virucidal
Hygienic handrub/hygienic hand disinfection	EN 13727[xi]	EN 13624[xii]	DVV, RKI 2015[xiii] EN 14476[xiv]
Surgical handrub/surgical hand disinfection	EN 13727 EN 12791[xv]	EN 13624	DVV, RKI 2015 EN 14476

x "Limited virucidal" efficacy is needed to safely combat Corona virus COVID-19

xi 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).

xii 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).

xiii DVV/RKI (2015). Guidelines 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.

xiv 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).

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

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

*... according to manufacturer claim;
** ...for disinfection measures related to the novel coronavirus (SARS-CoV-2) disinfectants with proven efficacy against enveloped viruses are to be used: this range of action is referred to as „limited virucidal". Tested products can be found in the VAH list (https://vah-liste.mhp-verlag.de/en/) or – for government-ordered disinfection – in the RKI list according to Federal Health Bl. 2017; 60:1274-1297.

STRATEGY FOR PRODUCT SELECTION:

First of all, product selection has to assure the antimicrobial efficacy requested by the applicator. All products in the table above are certified in their efficacy against (defined) bacteria and fungi. Some are additionally effective against enveloped viruses (e.g. against SARS-CoV-2), either by manufacturer claim and/or by independent certificate. Secondly, the active ingredients should be screened in terms of category. The table above provides only one disinfectant with a category B ingredient (#5; 2-Biphenylol). Alternatives may be #1, #5 and #7 with no category B product. The product list above only comprises a small selection of disinfectants predominantly offered on the (central) European market. It can only be seen as an example of the general procedure for product selection in terms of efficacy and ingredient category avoidance.

The WHO document "WHO-recommended Handrub Formulations"[3] 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. There are two formulations proposed for hand disinfection (see table on page 78).Investigations indicate that the WHO-recommended hygienic hand disinfection formulations based on 80% v/v Ethanol or 75% v/v 2-propanol do not meet bactericidal efficacy requirements according to EN 1500[xvi] with 3ml in 30s.[45] However, if the formulations are used 2x with 3ml each over 30 seconds each, i.e. 6ml in 60s, they have sufficient bactericidal efficacy. Since this type of application, which deviates from the standard, is not practicable in the health sector for routine operation due to time constraints, it has been proposed that the active ingredient content is modified in order to improve the bacterial efficacy for hygienic hand disinfection.

xvi Chemical disinfectants and antiseptics – Hygienic handrub – Test method and requirements (phase 2/step 2). (1997a)

Composition of the original WHO formulations for hygienic hand disinfection and modified formulations

WHO Formulation I		WHO Formulation II	
Original	Modified	Original	Modified
80% v/v Ethanol	80% w/w Ethanol*	75% v/v Isopropyl alcohol	75% w/w Isopropyl alcohol**
1.45% Glycerin	1.45% Glycerin (for routine hand disinfection) 0.725% Glycerin (for surgical hand disinfection)	1.45% Glycerin	1.45% Glycerin (for routine hand disinfection) 0.725% Glycerin (for surgical hand disinfection)
0.125% Hydrogen Peroxide	0.125% Hydrogen Peroxide	0.125% Hydrogen Peroxide	0.125% Hydrogen Peroxide

*corresponds to 85.5% v/v ethanol (calculated); **corresponds to 81.3% v/v Isopropyl alcohol.

Since the WHO formulations were also unable to meet the efficacy requirements for surgical hand disinfection in 3min or 5min, it was proposed to modify them with respect to active substance content and glycerin content for this use in order to improve their bactericidal efficacy.[46]

Apart from a high content of alcohol, 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 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 recommendations given for product selection.

There is strong indication that in terms of efficacy, tolerability and cost-effectiveness, solely alcohol containing disinfectants can be recommended 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 cases, 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.

During the final discussion of the product benchmarking results (see also case study H16) the question arose as to whether the addition of remanent-acting[xvii] 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)[47] (own translation from German) supports our assumption that this is not the case – at least not for daily routine hand disinfection:

- *The aim of hygienic hand disinfection is rapid sufficient reduction of transient flora (not belonging to the single skin flora), so that the hands do not pose a risk of spreading potential pathogens after known or contaminated contamination. If the alcohol-based formulations do not have an effective antimicrobial additive with remanent action, the effect of the alcohols ceases after their evaporation. However, there is no evidence that by the addition of 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 digluconate, octenidine hydrochloride, polyhexanide, 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.*

xvii Remanence is the ability of a disinfectant to suppress the propagation of germs during a certain period of time after use


CAUTION
WET FLOOR

SURFACE DISINFECTANTS

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

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

a. a dilution prepared from a concentrate

b. a ready-to-use liquid

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 ingredients or combination of ingredients applied as 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 product selection criteria and on 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, mechanical action; Exposure time: 1h

	Ingredient combination	Product (Manufacturer) (random example)
1	Didecyldimethylammonium chloride N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine	Pursept AF (Schülke)
2	Benzalkonium chloride (CAS 68424-85-1) Glutaraldehyde Didecyldimethylammonium chloride	Antiseptica Kombi Flächendesinfektion (Antiseptica)
3	Didecyldimethylammonium chloride Polyhexamethylene biguanide hydrochloride (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	Glucoprotamine	Incidin plus (Ecolab)
7	Peracetic acid	Ultrasol active (Schumacher)
8	2-Phenoxyethanol Benzalkonium chloride (CAS 68424-85-1), Aminoalkylglycine (CAS 139734-65-9)	Terralin protect (Schülke)
9	Didecyldimethylammonium chloride Glutaraldehyde Formaldehyde Dihydroxydioxahexane	Kohrsolin extra (Hartmann)
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	Pentapotassium bis(peroxymonosulfate) bis(sulfate)	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-dodecylpropane-1,3-diamine	Apesin rapid (Tana)
5	Magnesium monoperoxyphthalate hexahydrate (CAS 84665-66-7)	Dismozon plus (Hartmann)
7	Tosylchloramide sodium trihydrate	Clorina (Lysoform)
8	Benzalkonium chloride (CAS 68424-85-1) Glucoprotamine	Incidin extra N (Ecolab)
9	Didecyldimethylammonium chloride Glutaraldehyde Formaldehyde Dihydroxydioxahexane	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, mechanical action; Exposure time: 0.5 - 15min

	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 - 15min

	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	Polyhexamethylene biguanide hydrochloride (CAS 27083-27-8 or 32289-58-0) 2-Propanol Ethanol	Biguacid liquid (Antiseptica)	No
4	2-Propanol, Glucoprotamine Benzalkonium chloride (CAS 68424-85-1)	Incidin foam (Ecolab)	No
5	Didecyldimethylammonium chloride 1-Propanol	Meliseptol rapid (Braun)	No
6	1-Propanol Ethanol	Purades decaWipes XL (Prisman)	Yes
7	1-Propanol 2-Propanol Ethanol N-alkylaminopropylglycine (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 avoiding 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 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 cases, 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.

NON-CHEMICAL ALTERNATIVE SOLUTIONS AND INNOVATION IN THE FIELD OF SUSTAINABLE DISINFECTION PRACTICES

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.[48] 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;[49] the use of UV light systems is becoming more widely used in healthcare facilities for disinfecting patient and operating rooms.[19] 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.[50]

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 high-level disinfection also include hot-water disinfection (pasteurisation) or steam (e.g. autoclaving at lower temperature).[51]

While the scope of the SAICM 2.0 project is limited to solely chemical based disinfectants, we want to emphasise that a holistic view on the overall practice of disinfection and decontamination in hospitals may also include non-chemical "solutions". The options below cited constitute systemic interventions and may generate desirable secondary-effects (e.g. reduction of hospital acquired infection rates). We therefore want to mention them notwithstanding the fact that they are still within the trial phase.

CHEMICAL LEASING

Chemical leasing is a service-oriented business model that aims to shift the focus from selling quantities (of chemicals) to selling the function (of chemicals).[52] The model is therefore use-oriented and does not account for consumption quantities. This should help to optimise the quantities of chemicals used. It is generally considered for biocides[53], as well as for disinfection in particular[54] and a case study has already been carried out in a hospital together with a service supplier and scientific advisory.[55] To outline the extent and outcomes of service implementation the only available case study is extensively cited. The aim was to find out how the cooperation of suppliers of disinfectants and their users in hospitals can contribute to a sustainable, low-risk use of disinfectants. The following applications have been considered: surface disinfectants, skin and hand disinfectants, instrument disinfectants and disinfection cleaners.

Reduction of disinfectant consumption was not the only aim, other important objectives were improving hygiene status, improving the level of knowledge of all hygiene-relevant employees, reducing antibiotic use, environmental impact analysis, as well as ensuring or increasing occupational safety. Suggestions for optimisation in use, such as improved hand disinfection, were part of the process, as their positive effect on the reduction of nosocomial infections is proven. A daily routine disinfection of soils was advised against, as their efficacy has not yet been demonstrated. Alternatively, the use of maintenance cleaners was recommended. The service provider carried out inspections, analysed the hygiene status (microbiological examinations), developed hygiene plans and carried out staff training. They also contributed to the selection of hygiene-relevant procedures and products and to the monitoring of hygiene practices. The following disinfection measures have been recommended or implemented: improvement of infection protection through more hand sanitisers and moderately more instrument sanitisers; halving of alcoholic surface sanitisers (spray disinfection) and replacement by wipes; reduction of disinfectant cleaners used in sanitary areas; quarterly lap-down attempts; infection rate recording and surveillance programme for OTs and intensive care units as an indicator of performance and; instructions for personnel in the safe handling of disinfectants.

In order to determine the success of the implementation additional data collection was carried out two years after the first data collection and the results were compared with the initial data. Consumption of surface disinfectants was reduced by 14.3% for concentrates and 41.6% for ready-to-use products. The decrease is mainly due to the increasing use of wiping disinfection from concentrates instead of alcoholic spray sanitisers. Consumption of hand sanitisers increased by 38%,

which significantly improved the hygiene status at the hospital. The additional costs of about €10,000 per year could be offset by costs avoided in the treatment of nosocomial infections. Consumption of instrument disinfectants was 28% higher in 2010 than in 2008, at 5.9L per bed. This has made it easier to ensure hygiene requirements for treated medical devices. Consumption of disinfectant cleaners has been reduced by 28.6%, with no negative impact on hygiene status expected. Total annual consumption of disinfectants increased by 18.5%. The objective of reducing the total consumption of disinfectants and the resulting costs could not be achieved. This result is ultimately attributed to the fact that improving hygiene status was a priority objective. According to the report, environmental or waste water pollution could be reduced. The increased use of instrument disinfectants is more than compensated for, for example, by savings in surface disinfectants and disinfectant cleaners. The environmental relevance of the emission of alcoholic hand sanitisers is considered to be rather low.

MICROBIAL BASED CLEANING

Microbiological cleaners (Microbial-Based Cleaning Products or MBCPs) are products with microorganisms as an active principle of action. They are used as an alternative to purely chemical agents in domestic and especially commercial cleaning, for example for degreasing and odour improvement. The effect is justified, among other things, when the spores released during application develop into viable microorganisms, colonise surfaces, use existing contaminants as a food source and thus compete with undesirable microorganisms in the long term. Through the production and extracellular release of proteases, cellulases, amylases and ureases, the probiotic microorganisms are able to break down high molecular weight organic molecules[56]. The majority of products contain different species of the genus Bacillus in the form of spores. The advantage of Bacillus spores is its years of storage in liquid. The cleaning performance of the microorganisms can be supported or improved by added surfactants and enzymes.

The possibility of controlling nosocomial infections by probiotic bacteria was first formulated as a hypothesis by Falagas & Makris in 2009.[57] This is based on the assumption that probiotic microorganisms counteract the growth of nosocomial pathogens on inanimate surfaces. From this, the authors derive the idea of considering the use of microorganisms (probiotic bacteria) and corresponding products (biosurfactants) to prevent nosocomial infections, since the colonisation of surfaces and medical devices with pathogenic germs plays an essential role.

The hypothesis of Falagas & Makris was first tested in hospitals in Italy and Belgium in field trials using microbiological cleaners in the form of floor, bath and interior cleaners.[58] At three locations, microbiological cleaners were compared with conventional disinfectant cleaners or cleaned with the same hygiene protocol. The microbiological cleaners contained spores of Bacillus subtilis, Bacillus pumilus and bacterium megaterium. Generally, after the start of cleaning with microbiological products, a different, but at least significant reduction of the coliform germs occurred after approximately two weeks. The reduction over the observation period averaged 74% for total coliform germs and 89% for E.coli. In general, the field tests were able to prove that when microbiological cleaners are used on solid surfaces, the colonisation with germs changes after two weeks. With the exception of Clostridium difficile, a significant decrease in all potentially pathogenic germs was observed, with the number of germs remaining at a consistently low level after two weeks. If the use of microbiological cleaners was discontinued, the germ counts of the potentially pathogenic germs returned to initial values. The authors conclude that on the one hand, the decline of pathogenic germs is causally related to the application of microbiological cleaners, whilst on the other hand a constant reduction of potentially pathogenic germs causes a continuous application of probiotic microorganisms. The bacterial strains used (Bacillus subtilis, Bacillus pumilus, Bacillus megaterium) are classified by the manufacturer as not hazardous to humans or are produced according to certified methods. No evidence of the incorporation of resistance genes in the Bacillus strains could be found.[59]

Recently a multicentre study on this topic in five Italian hospitals lasting for 18 month was finished and published.[60] In the hospitals, conventional sanitation was replaced by a microbial based sanitation strategy which was associated with remodulation of hospital microbiota and a reduction of healthcare-associated infections (HAI). The authors conclude that the spread of antimicrobial resistance in the hospital environment can be limited by the use of microbial-based sanitation methods to re-modulate microbiota. An overall reduction of -52.1% of HAI incidence was statistically proven. Recent work is investigating the ability of bacteriophages in removing HAI-associated pathogens from hard surfaces.[61]

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 the need of hospitals and procurers to identify safer alternatives
2. Improve the current regulatory and policy framework
3. Promote sustainable procurement practices
4. Encourage responsible business practices
5. Foster innovation in the field of sustainable disinfection practices

1) HOW TO SELECT PRODUCT ALTERNATIVES IN THE WIDES DATABASE 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 substance or to other ingredients. It should be noted that the assignment 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 and ABC categorisation 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 at 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 can be excluded. Products with category C ingredients should be preferred as far as possible.

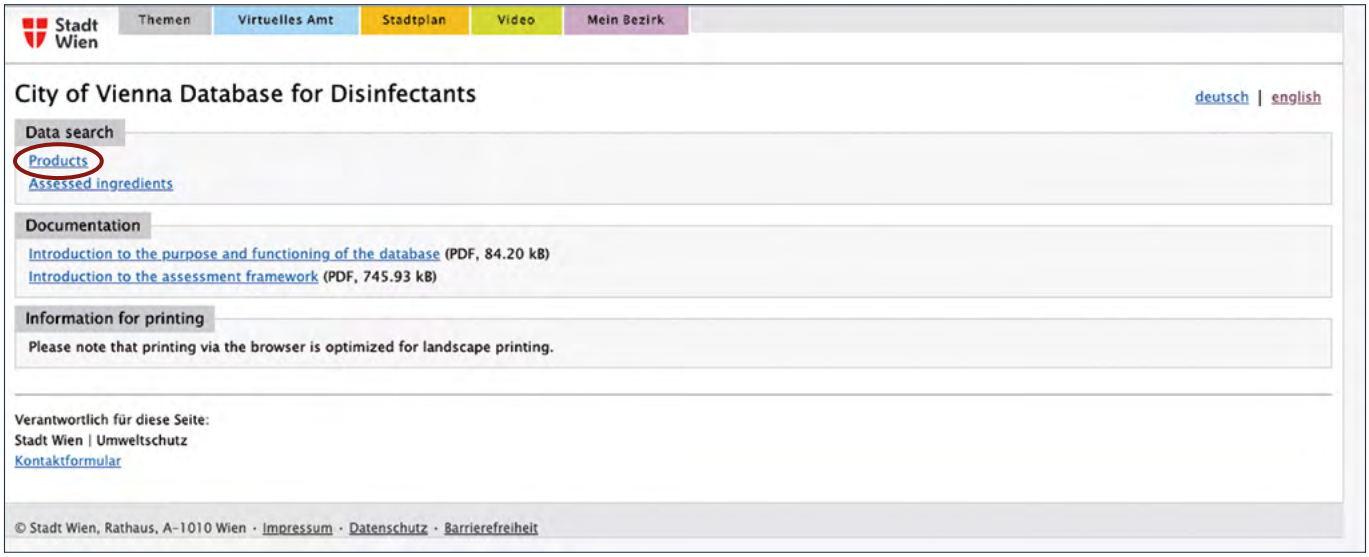
Generally ABC categorisation provides an initial orientation for the applicator and does not take into account substance concentration. It is primarily applicable to identify ingredients with high hazards to further avoid and/or substitute the corresponding disinfectant.

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

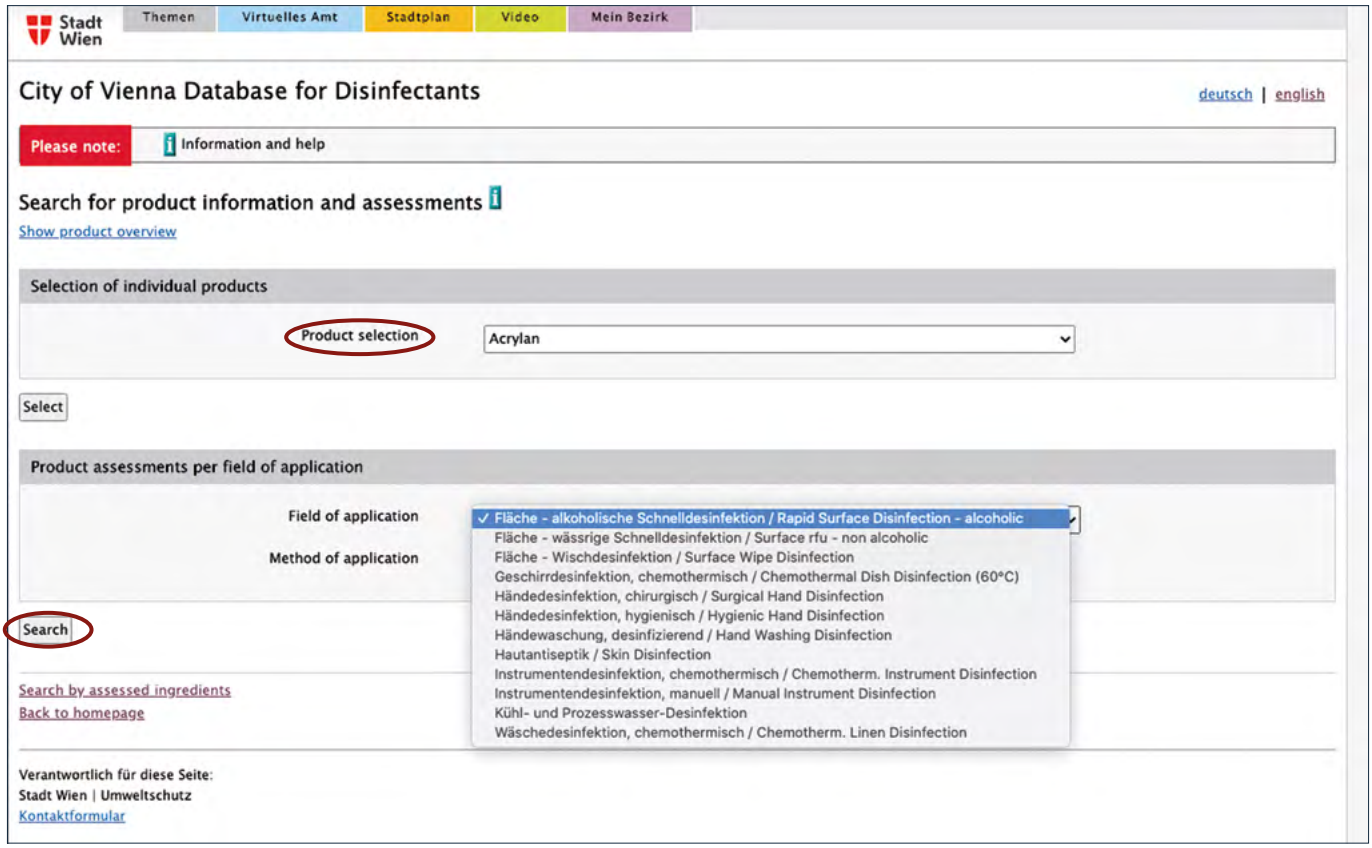
For such screening, the user can follow the instructions below to generate a list of all ingredients with name, CAS number, synonyms and – in the right column – the substance category. The "i" button provides basic information about the categorisation scheme. More detailed explanations regarding the ABC categorisation and the WIDES product assessment can be found in the "Introduction to the assessment framework".[2]

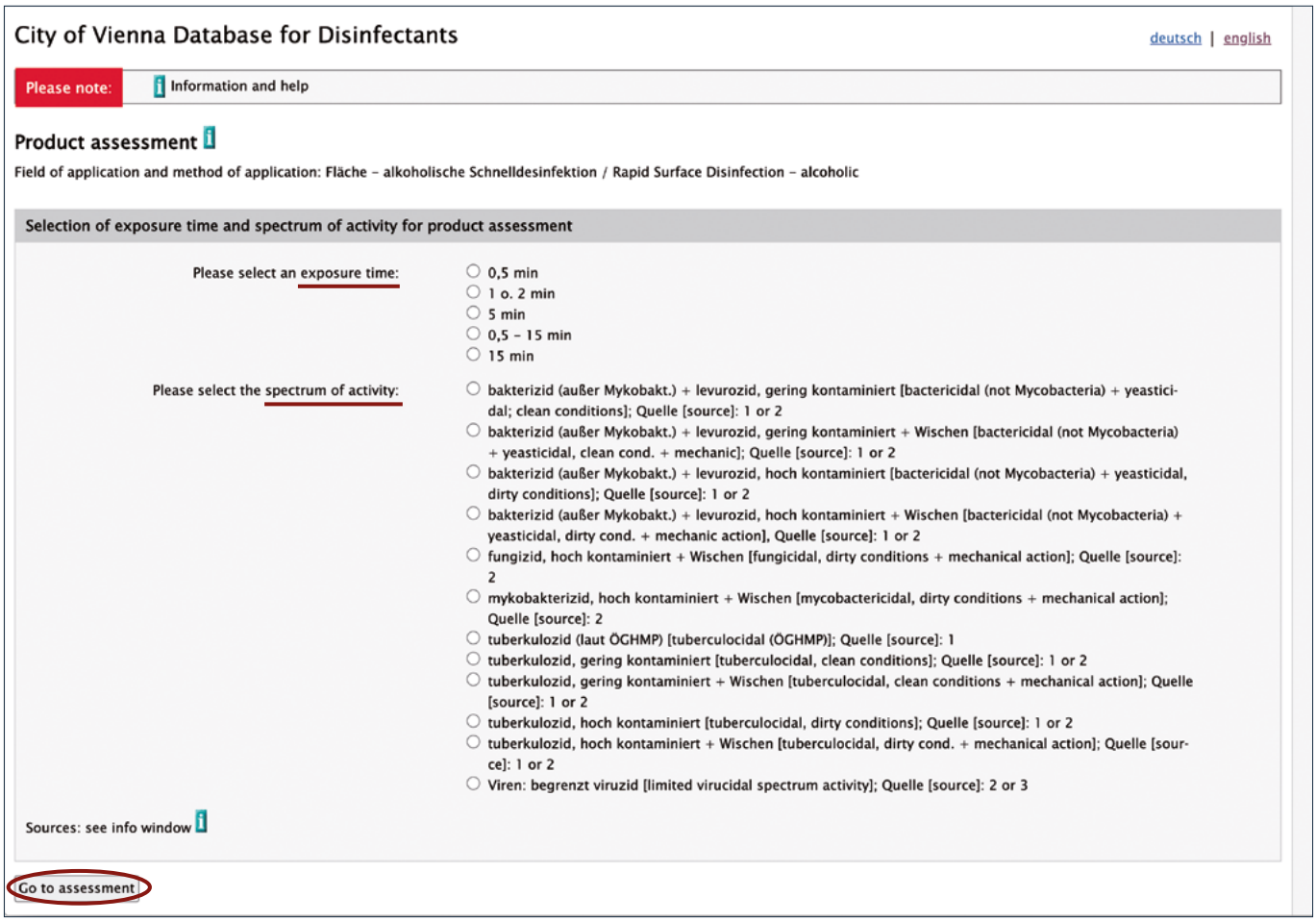
The right column can be sorted by clicking on the button on the right to "substance category". It is generally recommended that biocidal active ingredients (and co-formulants) indicated with category A (red) are avoided and the use of biocidal active ingredients (and co-formulants) indicated with category C (white) is preferred. 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 colour field (red, yellow, white).



- To generate a list of comparable products: A selection function with field of application, exposure time and spectrum of activity.





City of Vienna Database for Disinfectants

deutsch | english

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

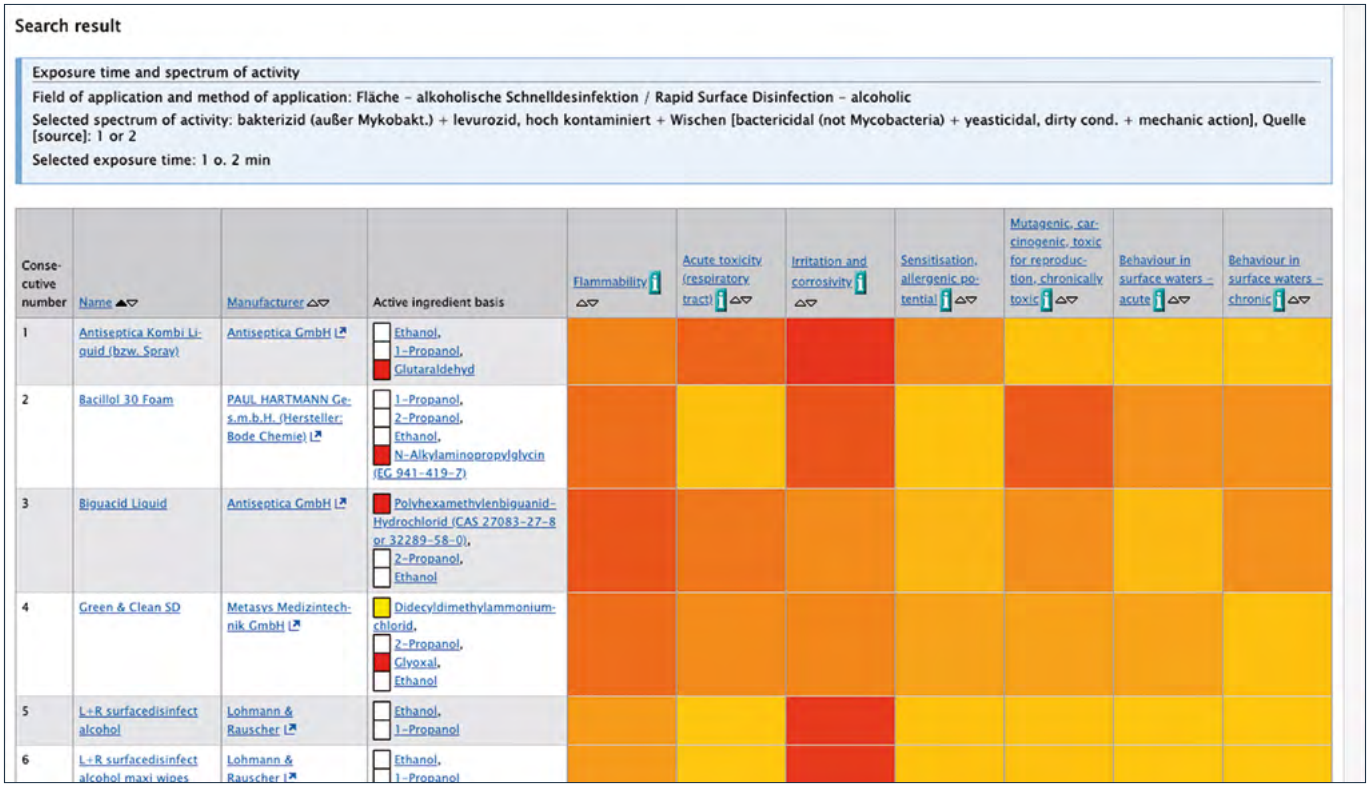
Please select the spectrum of activity:

- 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

- To exclude products with specified hazardous properties from a list of comparable products: A predefined or programmable filter function.



Search result

Exposure time and spectrum of activity

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

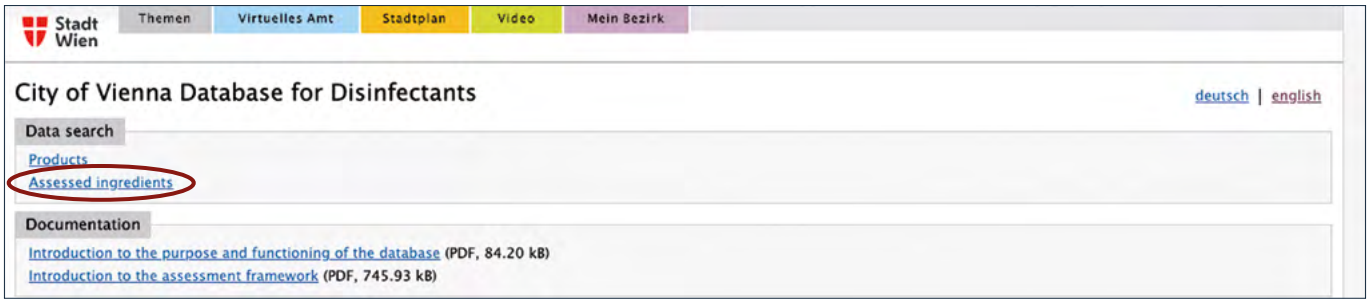
Selected spectrum of activity: bakterizid (außer Mykobakt.) + levurozid, hoch kontaminiert + Wischen [bactericidal (not Mycobacteria) + yeasticidal, dirty cond. + mechanic action], Quelle [source]: 1 or 2

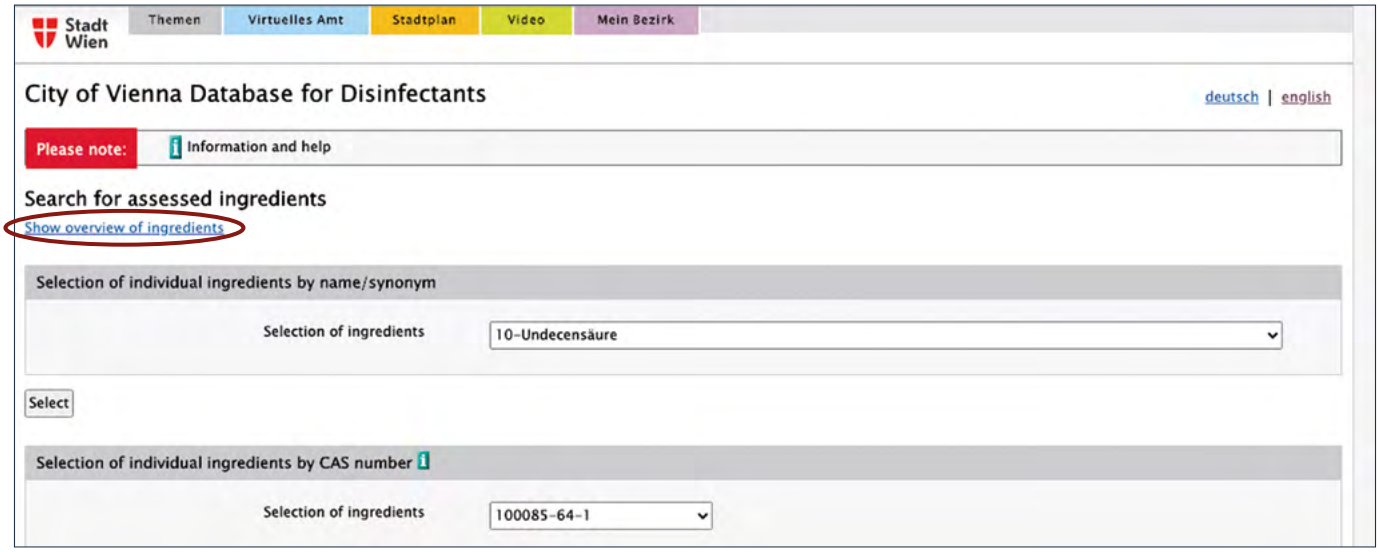
Selected exposure time: 1 o. 2 min

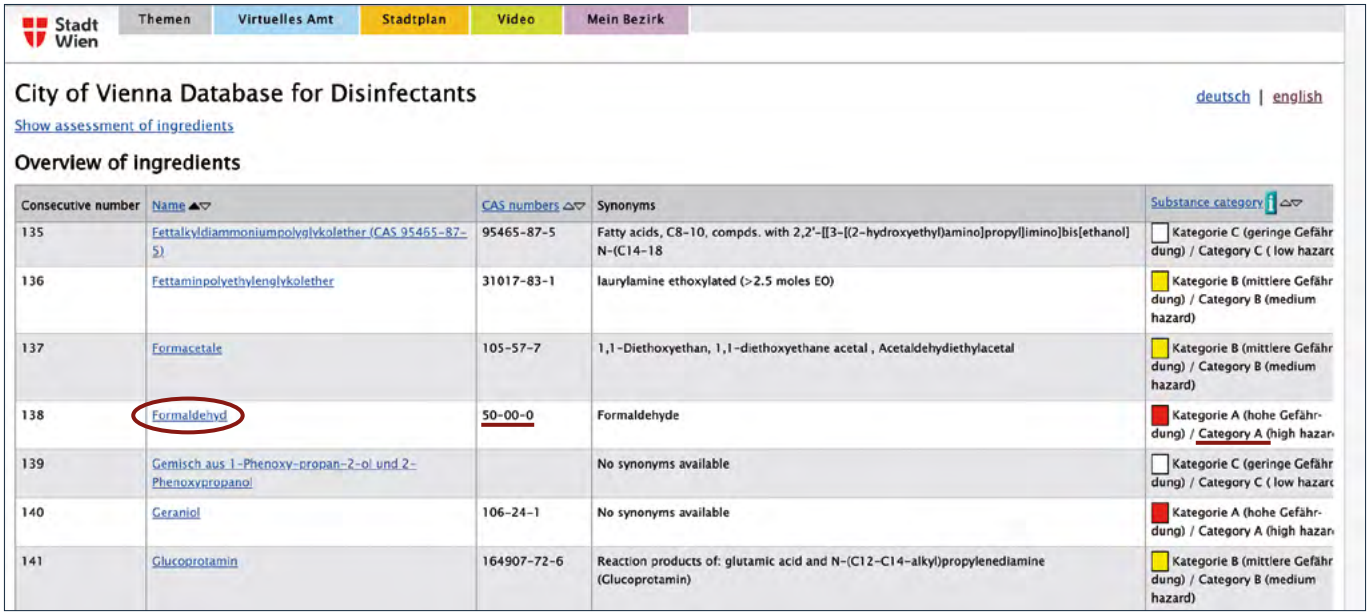
Consecutive number	Name	Manufacturer	Active ingredient basis	Flammability	Acute toxicity (respiratory tract)	Irritation and corrosivity	Sensitisation, allergenic potential	Mutagenic, carcinogenic, toxic for reproduction, chronically toxic	Behaviour in surface waters – acute	Behaviour in surface waters – chronic
1	Antiseptica Kombi Liquid (bzw. Spray)	Antiseptica GmbH	Ethanol, 1-Propanol, Glutaraldehyd							
2	Bacillol 30 Foam	PAUL HARTMANN Ges.m.b.H. (Hersteller: Bode Chemie)	1-Propanol, 2-Propanol, Ethanol, N-Alkylaminopropylglycin (EG 941-419-7)							
3	Biguacid Liquid	Antiseptica GmbH	Polyhexamethylenbiguanid-Hydrochlorid (CAS 27083-27-8 or 32289-58-0), 2-Propanol, Ethanol							
4	Green & Clean SD	Metasys Medizintechnik GmbH	Didecyldimethylammoniumchlorid, 2-Propanol, Glyoxal, Ethanol							
5	L+R surfacedisinfect alcohol	Lohmann & Rauscher	Ethanol, 1-Propanol							
6	L+R surfacedisinfect alcohol maxi wipes	Lohmann & Rauscher	Ethanol, 1-Propanol							

Hospitals can assess the hazards of products or gauge the feasibility of substitution by following these steps

1. Use the chosen disinfectant product's SDS and/or Technical Fact Sheet (SDS preferable) to find all the ingredients' names and CAS numbers.[xviii]
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.







xviii A unique identifier regardless of differing regional product names

2) POLICY RECOMMENDATIONS

2.1. Hazard communication

It is important to distinguish here between biocides (i.e. active substances that can be used across a wide range of applications) and disinfectants (products with a specific formulation, designed to inactivate or destroy microorganisms on surfaces, for which step-by-step use instruction is needed to ensure best practise).

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

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 a system is still lacking. As of 2018, more than 120 countries had not yet implemented the GHS.[62] The GHS ensures that information on physical hazards and toxicity from chemicals is available and communicated, including labels and safety data sheets.

In general, urgent action is needed towards the achievement of Sustainable Development Goal 12 on responsible consumption and production, which should include policies that improve resource efficiency, and reduce waste and mainstream sustainability practices across all sectors of the economy. There is a need for global standards and harmonised regulation, linked to very specific, concrete actions and guidance.

2.2. Testing and information disclosure

Globally, there are still biocides and disinfectants on the market that have not yet been sufficiently investigated (referred to in this report as "data gaps" and "data insecurity"). Missing knowledge regarding both human safety and environmental hazards hinders the making of an informed choice towards truly safer alternatives. Data on the risks and efficacy of disinfectants is only available in regions where specific regulations on disinfectants are in place.

In the EU, a biocidal product authorisation application requires a technical dossier containing information on the properties of all active substances as well as the co-formulants, information on the properties and uses of the product, its efficacy and stability as well as a risk assessment for all uses. Within the process of evaluation of dossiers for biocidal products, as specified in Annex VI of the BPR, the possibility of cumulative or synergistic effects (i.e. expected effects are higher) should also be taken into account.

There is mandatory data-sharing of data on vertebrates and mandatory data sharing of all toxicological and environment data for the approved suppliers, listed in order, to reduce the need for new testing and to ensure the costs of data are fairly shared. 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.[xix] 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/risk assessment protocols, prioritising consideration on health or environmental impact and harm caused, and strengthening the science-policy interface.

The SAICM 2.0 project provides a participatory tool for hazard identification, product selection and procurement decision which is thought to be applicable worldwide. Ideally, a selection of the "best performing disinfectants" in terms of health and environmental impact is achievable with a fixed minimum of data input. We recommend considering SAICM 2.0 as a contribution and stimulus for the assessment and substitution of products for decontamination purposes in the healthcare sector. We are recommending a world-wide implementation of the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and an international standardisation of hazard communication and documentation. Finally, we want to emphasise the importance of a hazard-based assessment, as only this really complies with the precautionary approach.

xix Commission Delegated Regulation (EU) No 2017/2100 and Commission Regulation (EU) No 2018/605

2.3. Sustainable use

For biocidal products, sustainable use can be defined 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.

The correct and sustainable use of biocidal substances should be preceded by thorough cleaning. Cleaning helps to remove pathogens or significantly reduce their load on contaminated surfaces and is an essential first step in any disinfection process. Cleaning with water, soap (or a neutral detergent) and some form of mechanical action (brushing or scrubbing) removes and reduces dirt, debris and other organic matter which can impede direct contact of a disinfectant to a surface and inactivate the germicidal properties or mode of action of several disinfectants.[63]

Poor cleaning can also jeopardise sterilisation of medical tools - vaporised hydrogen peroxide failed to completely sterilise surgical tools 76% of the time when the tools were soiled with salts or blood and not cleaned prior to sterilisation, according to a new study.[64]

A recent study compared the occurrence of AMR between surfaces in highly controlled clinical settings and other "less clean" environments. Results showed that more-controlled environments had just as many bacteria as less-controlled ones, but had less variety of bacterial species. The study highlights that the loss of microbial diversity correlates with an increase of resistances, indicating that these populations might be burdened by antibiotic-resistant organisms. Therefore, the overall use of antimicrobials in hospitals needs to be carefully considered, and human exposure to almost sterile environments should be limited to operating theatres or specific industrial processes in cleanrooms.[65]

The overall aim of sustainable use is that biocides are only used where deemed truly necessary. A very good example of real-life application of this principle was the reasoning of the US FDA for banning of triclosan from soap - the manufacturers were not able to prove the added value of adding this disinfectant.[66]

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 the sustainable use of biocides.[53] We agree with the German Environmental Agency, that even though a lot of information on the use of biocides is still missing, this is not an argument that there is no need for action.

2.4. Next steps on national, European and global levels

A better regulation for biocides and disinfectants is needed, and should involve a multi-stakeholder approach (experts working on the occupational health, environment, efficacy, etc.). Currently, the **national authorities** perform risk assessment and grant authorisation of disinfectants, but every country can decide which agency is involved and responsible for such assessment (i.e. it can be the public health authority, or the authority with competence in environmental aspects; however, they do not necessarily cooperate). In Germany for example, all leading sectors are involved.

Authorities and healthcare managers should ensure better reporting and monitoring on the application of disinfectants in order to increase the evidence base and the 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 the use of alternatives, also non-chemical ones), including mandatory training and further education and equipment for the application of biocides.

Of the utmost importance is adherence to best practices in the use of biocides of less concern. **In the EU**, the Biocidal Products Regulation 528/2012 provides mechanisms to phase out the use of high and very high concern substances. In addition, this creates the incentive 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.

In 2014, the German Federal Environmental Agency (UBA) proposed a concerted European approach towards the sustainable use of biocides.[53] The document advocates for the inclusion of biocides in the Directive 2009/128/EC, establishing a framework for community action to achieve the sustainable use of pesticides, or the creation of an independent framework on the sustainable use of biocides. We recommend this document as an excellent source of information and recommendations on measures required for the sustainable use of biocides from an environmental perspective, that are equally important on a global level such as, among others, mandatory best practice and use of alternatives, mandatory training and education, and establishment of independent advisory services.

Regarding the environment, chemical pollution, including from chemicals and waste, is one of the key drivers of global biodiversity loss. Protecting biodiversity is vital for human health and well-being. This has been recently addressed by EU policy makers who adopted the new EU Biodiversity Strategy for 2030 and an associated Action Plan (annex)[67] - a comprehensive, ambitious, long-term plan for protecting nature and reversing the degradation of ecosystems, which also places a strong emphasis on reducing chemical pressures. As part of the Commission's Zero Pollution Ambition for a toxic-free environment, a new EU Chemicals Strategy for Sustainability will be put forward along with a Zero Pollution Action Plan for Air, Water and Soil. There is certainly a place within those strategies and plans to address the sustainable use of biocides and promoting safer alternatives for disinfection.

The Strategic Approach to International Chemicals Management (SAICM), a policy framework to promote chemical safety around the world, should be a vehicle to establish a **multi-stakeholder and multi-sectoral global approach to biocides and disinfectants**. Through legal and regulatory frameworks supported by SAICM, covering both occupational health and the environment, the impact of the full life cycle of biocides/disinfectants and waste on human health and environment should be minimised. Having such an international framework/code of conduct in chemicals management to move towards a legally binding instrument is particularly needed in many countries outside the EU. Enforcement of regulation is also a global issue, especially when there is a fragmentation of legislation and no clear responsibility/competency is linked to the implementation.

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 the effort 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 and existing employees to adapt the need of training accordingly.

The development of standards, combined with a certification process, can also be used to ensure the proper and sustainable use of biocidal products, for example by demonstrating 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 used without equipment or the equipment used is mainly items like gloves and other personal protective equipment. The use of appropriate dosing equipment designed to be fit for purpose and to minimise exposure and avoid overdosing (e.g. calibrated sprayers) should be considered and promoted whenever possible.

2.5. The role of the healthcare sector

The healthcare sector gained high visibility and recognition during the current pandemic, and is hoping to become more involved in the process of setting up model policies and practices related to disinfectants.

An example of healthcare commitment to transform the sector and foster a healthy, sustainable future is the dedicated Global Green and Healthy Hospitals (GGHH)[68] network, having over 1,350 members in 72 countries who represent the interests of more than 43,000 hospitals and health centres.

In more concrete terms, the healthcare sector may use its long-standing expertise on the topics to advocate for a broad implementation of best practices and sustainable use of biocides. With the engagement of progressive leaders, the healthcare sector can facilitate cooperation and build up a coalition that would give more visibility to the topic and could lead the way in addressing policy-related demands.

3) SUSTAINABLE PROCUREMENT

As explained above, an adequate regulatory framework is certainly crucial to support procurers to leverage their purchasing power to demand safer and environmentally friendly products. However, the hospitals involved in the project, and procuring authorities in general, should have an organisational sustainable procurement policy and a strategy to implement it. Given the wide use of disinfectants in healthcare facilities, hospital sustainable procurement strategies 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.[69] 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.[70]

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 disinfectant manufacturer showed interest in developing and testing a product that could meet the hospital's sustainability criteria and potentially increase the offer of these type of products on the local market.

4) SUPPLIERS' SUSTAINABILITY PRACTICES

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 of chemicals provided by the supplier 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 minimising the hazardous nature of their products.

This project demonstrates that there is a market for safer and more environmentally 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.

ANNEXES

HAZARD ANALYSIS: METHODOLOGY

The hazard analysis for each hospital was carried out as follows:

1. DATA EVALUATION

In the 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). Participants received a summary of the data evaluation 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.

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 provided in the third paragraph of the safety data sheet (CAS number, product concentration, H-phrasing) was transfered to an excel sheet. This information is complemented with the corresponding name and classification given in the WIDES database (right-hand columns).[xx] 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 the column "WIDES data gap", overall knowledge about potential hazards of the ingredient is rated as follows:

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

xx In the case in which the WIDES does not already include the product component, an anonymous entry for this component is created - including classification and assessment data. In such cases, the WIDES name is not underlined.

Identified ingredients	CAS#	%	H-phrase according to SDS	WIDES name	WIDES classification	WIDES data gap
Benzalkonium chlorides	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
Polyhexamethylene biguanides (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

In the 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 H310 H330 H301 H311 H331	H341 H351 H361 H362	H373	EUH029 EUH031 EUH070 H370	Data gap	H400 (M≥1000) H410 (M≥100)	H400 (M≥10) H410 (M≥1)	Data gap
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, H400M10), H411	0												
polyhexamethylene biguanide hydochloride (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 this is the Globally Harmonized System of Classification and Labelling of Chemicals (GHS System), which provides standardised phrases - 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 carried out by means of the classification (i.e. a set of hazard statements) of the dangerous ingredient.[xxi]

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, 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.

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 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)[xxii]	Very toxic to aquatic life and M-factor equal to or higher than 1000
H410 (M≥100)[xxii]	Very toxic to aquatic life with long-lasting effects and M-factor equal to or higher than 100

xxi This approach has 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 hand, 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 that the categorisation is a compromise. But, on the other hand, we try to "hide" all cases where an adverse effect is completely reversible or a consequence of improper handling, accident, poor working conditions (e.g. proper ventilation) or insufficient personal protective equipment.

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)	
H400 (M≥10)[xxii]	Very toxic to aquatic life and M-factor equal to or higher than 10
H410 (M≥1)[xxii]	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.	

xxii M-factor stands for multiplying factor for substances that are highly toxic to the aquatic environment (i.e. LC50 or EC50 < 1mg/l). When classifying a substance as acute aquatic toxicity category 1 or chronic aquatic toxicity category 1 under GHS, it is usually necessary to indicate an appropriate M-factor. This is mandatory under CLP regulation. The purpose of applying M-factor is to give an increased weight to highly toxic components.

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. Under 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 state 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 page 99).
- 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 cases the product is recommended for product benchmarking. The overall aim is to identify products ("product alternatives") that are recommendable for substitution. For 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 is advised: the participant searches for product alternatives using the ABC categorisation for preselection – if the product contains category A substances, it cannot be an alternative. Participants may additionally consult the WIDES database for hand, skin, surface, instrument and laundry disinfectants. The potential alternative has to have comparable biocidal efficacy. Lacking material comparability may be a reason to reject the potential alternative. After a product alternative is selected, product benchmarking starts with calculation steps.

Equal application solution: It is a prerequisite for correct benchmarking that the quantity of application solution of the benchmarked product and the product alternative are equal. There are two types of application: without dilution (product is "ready-to-use") and; after dilution with water (product is a "concentrate"). The following example may serve as an illustration for dealing with concentrates: the benchmarked product is a concentrate and should be diluted before use to 0.5%. Therefore, 1,000L of concentrate results in 200,000L of application solution. If the potential alternative is also a concentrate and diluted to 1%, 2,000L of product alternative are required to generate the same amount of 200,000L of application solution.

Hazardous load (kg): The term "hazardous load" is synonymous with dangerous material cargo. The hazardous load is calculated based on the consumption volume of the product. Alternatively, a default consumption value may be applied. For the calculation, the following information is required:

- Concentration of ingredients for both the benchmarked product and the product alternative(s): This information can be found in the SDS, product information sheet and/or the WIDES database.
- Application concentration for the benchmarked product and the product alternative(s): This information is required to calculate the quantity of application solution.

The following example shows the optimum information provided for a benchmarked product (BP) applied for disinfection of hard surfaces:

Category A or B ingredient	Classification	%
Didecydimethylamoniumchlorid	H301, H400(M10), H411	0,53
Aminoalkylglycin	H302, H314, H361f, H372, H400(M10), H410(M1)	0,5
Polyhexamethylenbiguanid-HCL	H302, H317, H318, H330, H351, H372, H400(M10), H410(M10)	0,12

Density (kg/l)	1
Consumption volume (litres)	1000
Application Concentration (%)	100 (ready-to-use)
Spectrum of activity	bactericidal (not Mycobacteria) + yeasticidal, dirty conditions + mechanical activation
Exposure time (min)	0,5 - 15

In order to ensure comparability, the product alternatives (PA) should have the same use and a comparable spectrum of efficacy. After the research, four products were selected for benchmarking with partly corresponding, partly diverging active ingredients:

- PA1: Didecyldimethylammonium chloride; Benzalkonium chloride
- PA2: Hydrogen peroxide
- PA3: Didecyldimethylammonium chloride; Benzalkonium chloride; N-Alkyl-N-ethylbenzyl-N,N-dimethylammonium chloride
- PA4: Didecyldimethylammonium chloride

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 proven carcinogenic, mutagenic repro-toxic and chronic toxicity hazards respectively have their H-phrases summed up and grouped to hazard "CMR & CT hazard". The precautionary principle is particularly strongly emphasised here. If alternatively, only proven carcinogenic, mutagenic repro-toxic and chronically toxic hazards or their H-phrases were considered, the grouped hazard would not contain the hazard phrases H341, H351, H361, H362 and H373.

		Health Hazards									Aquatic Hazards		
		Category A				Category B					Category A	Category B	
Grouped hazards	Shortcut	H340 H350 H360	H372	H334	H317	H300 H310 H330 H301 H311 H331	H341 H351 H361 H362	H373	EUH029 EUH031 EUH070 H370	WIDES data gap	H400 (M≥1000) H410 (M≥100)	H400 (M≥10) H410 (M≥1)	WIDES data gap
Proven and/or suspected carcinogenic, mutagenic, repro-toxic and/or chronically toxic hazard	CMR & CT	H340 H350 H360	H372				H341 H351 H361 H362	H373					
Proven sensitising hazard	SENS			H334	H317								
Hazard to be aquatic environment	AQUATIC										H400 (M≥1000) H410 (M≥100)	H400 (M≥10) H410 (M≥1)	

The hazardous load for each ingredient is calculated according to the following formula:

$$Hazardous\ load\ (Kg) = Conc.i(\%)\ x\ \frac{Cons.Vol.1(l)}{100}\ x\ Density\ \frac{kg}{l}\ x\ \frac{App.Conc.(\%)}{100}$$

Adapted Hazardous Load: Per definition, one ingredient can contribute only once to a grouped hazard or hazardous load respectively. The hazardous load has been adapted to this specification as follows:

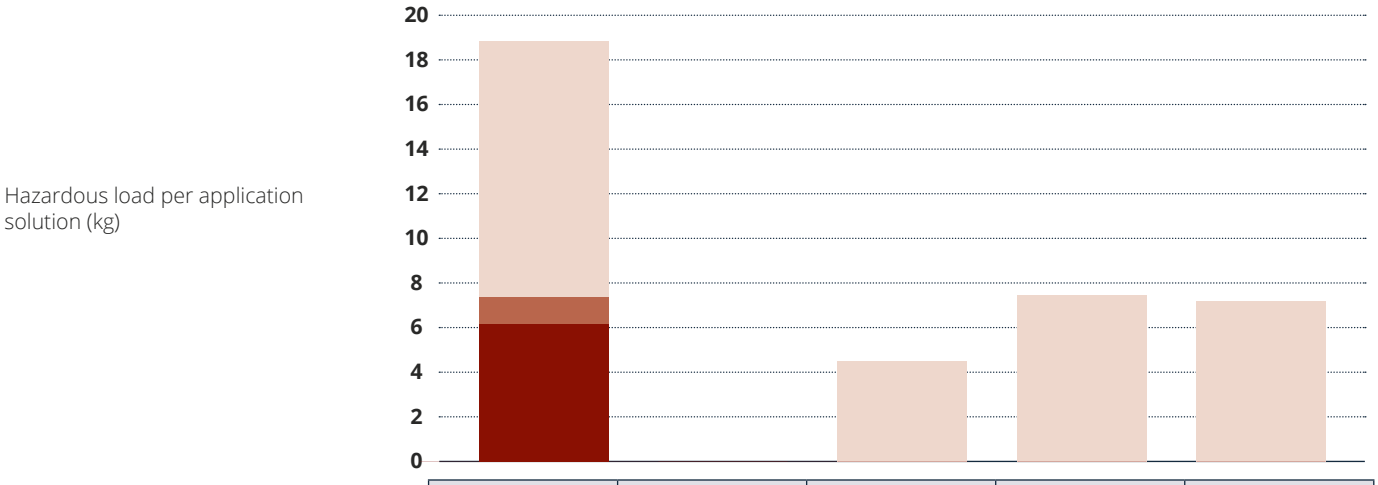
$$Adapted\ Hazardous\ load\ (Kg) = \frac{Hazardous\ load\ (kg)}{number\ of\ H-prhases\ contributing\ to\ the\ grouped\ hazard}$$

H361 and H372 of aminoalkylglycine each cause 5kg and a total of 10kg of hazardous load. The adapted load for grouped hazard CMR & CT is 5kg. H351 and H372 of polyhexamethylene biguanide each cause 1.2kg and a total of 2.4kg of hazardous load. The adapted load for grouped hazard CMR & CT is 1.2kg.

BP			Health Hazards									Aquatic Hazards			Adapted Hazardouz Load (kg)		
			Category A				Category B					Category A	Category B				
Ingredient	H-phrases	%	H340 H350 H360	H372	H334	H317	H300 H310 H330 H301 H311 H331	H341 H351 H361 H362	H373	EUH029 EUH031 EUH070 H370	WIDES data gap	H400 (M≥1000) H410 (M≥100)	H400 (M≥10) H410 (M≥1)	WIDES data gap	CMR & CT	SENS	AQUA-TIC
Didecy-dimethyl-amonium-chlorid	H301, H314, H400(M10), H411	0,53					5,3				#		5,3				5,3
Aminoalky-lglycin	H302, H314, H361f, H372, H400(M10), H410(M1)	0,5		5				5					5		5		5
Polyhex-amethyl-enbigua-nid-HCL	H302, H317, H318, H330, H351, H372, H400 (M10), H410 (M10)	0,12		1,2		1,2	1,2	1,2					1,2		1,2	1,2	1,2
														Overall	6,2	1,2	11,5

Benchmarking result: For BP the benchmarking for an assumed use amount of 1,000L concentrate gives an overall adapted hazardous load of 18.9kg. This load consists of 6.2kg containing a proven or suspected CMR & CT hazard, 1.2kg containing a proven sensitising hazard and 11.5kg load with hazard to the aquatic environment. The products PA1, PA2, PA3, PA4 were selected as potential alternatives and hazardous loads were calculated analogously: PA1, PA2, PA3 and PA4 contain 0kg load with proven or suspected CMR & CT hazard and 0kg load with sensitising hazard. However, PA2 contains 4.5kg, PA3 contains 7.2kg and PA4 contains 7.5kg of load with a hazard to the aquatic environment. Viewed together all are recommended product alternatives, with a preference for PA1.

Product Benchmarking



	BP	PA1	PA2	PA3	PA4
AQUATIC hazard: high toxicity towards water organisms with lasting effects	11,5	0	4,5	7,5	7,2
SENS hazard: proven skin sensitation and/or asthma induction via inhalation	1,2	0	0	0	0
CMR & CT hazard: Proven or suspected carcinogenic, mutagenic, repro-toxic and/or chronically toxic properties	6,2	0	0	0	0

In the SAICM project the following set of grouped hazards is applied, which is different from those used in the example above:

- HIGH AQUATIC hazard: 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 to 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: 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 to 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
- CMR & CT hazard: 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: 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

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