BIOCIDES

Hydrogen peroxide and
peracetic acid for disinfection

OXTERIL®
CLARMARIN®
PERACLEAN®
VIGOROX®

EVONIK
Leading Beyond Chemistry

HOW OUR BIOCIDES REACH THE EUROPEAN MARKET

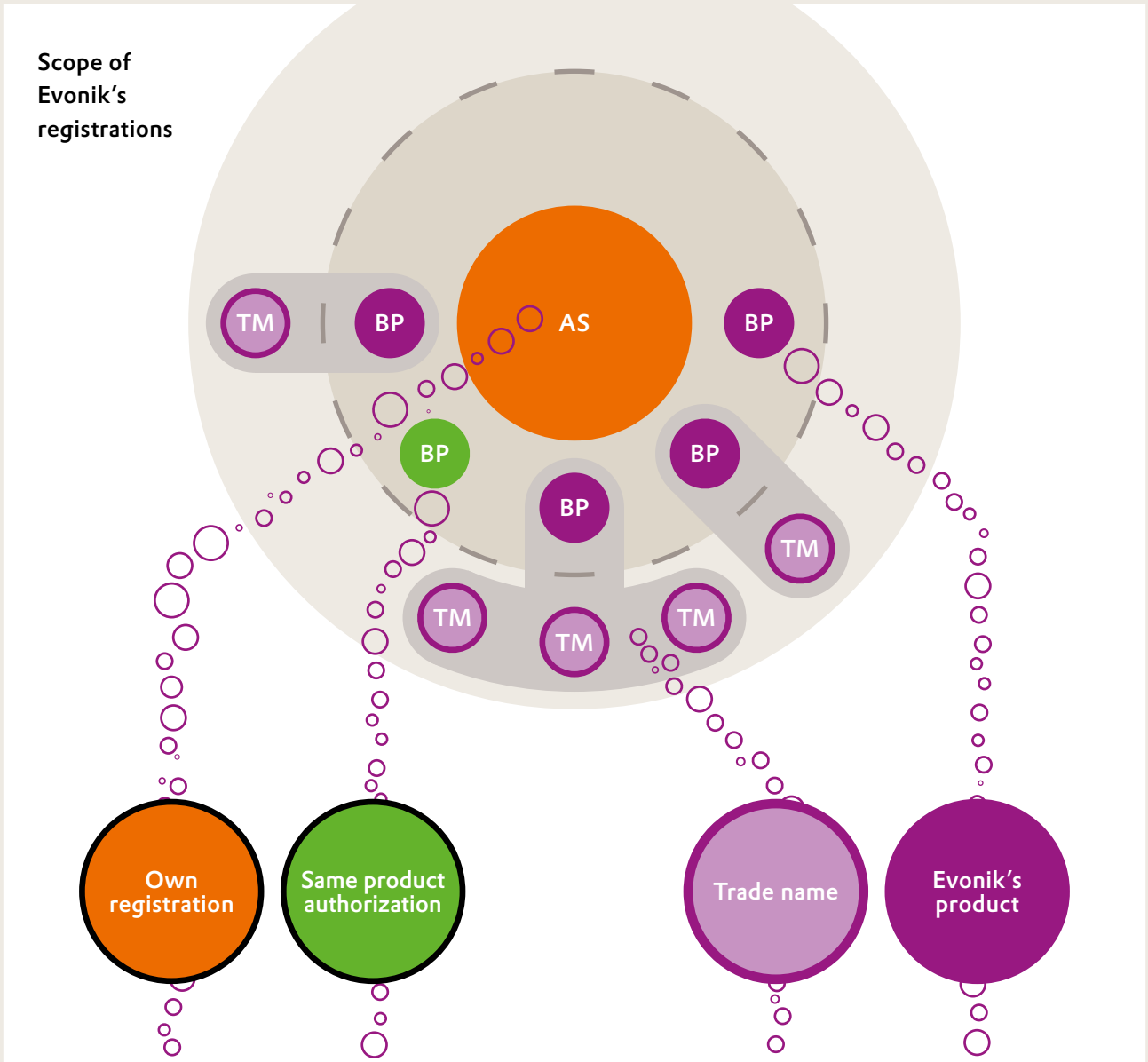
The European Biocidal Product Regulation (BPR) will replace old national regulations for hydrogen peroxide as of late 2022 and peracetic acid approximately one year later. The BPR defines the marketing authorization procedure for biocidal products. Only authorized products are allowed to be sold on the market. The main rule of the BPR: no authorization – no market.

- Evonik is a supplier of active substances hydrogen peroxide and peracetic acid.
- Evonik also offers its own portfolio of biocidal products under the brand names OXTERIL® and CLARMARIN® as our hydrogen peroxide solutions and PERACLEAN® and VIGOROX®as our peracetic acid-based biocides. They are designed to be used by end users as well as service providers.
- Evonik offers to include the private labels of service providers into its dossiers (Trade Name Model). The trade name (TM) biocides have the same formulation and proven efficacy as corresponding biocidal products from Evonik. The marketing authorization holder (MAH) of the private labels is Evonik.
- As a default, Evonik does not offer the same product authorization model to service providers. Evaluation is performed on a case-by-case basis.
- As a co-owner of the active substance dossier, Evonik supports service providers in their own BPR registration procedure and issues Letters of Access Active Substance Hydrogen Peroxide and Peracetic Acid.

EVONIK IS A MEMBER OF H_2O_2 BPR TF AND PAR GROUPS AND PROVIDES A FULL SPECTRUM OF SERVICES FOR MARKET ACCESS STRATEGIES

EVONIK PARTICIPATES ACTIVELY IN REGISTRATION OF HYDROGEN PEROXIDE AND PERACETIC ACID AS ACTIVE SUBSTANCES AND BIOCIDAL PRODUCTS UNDER THE BPR

HOW OUR BIOCIDES REACH THE EUROPEAN MARKET



Marketing authorization holder: Customer

Value for the customer:
Higher degree of operational freedom

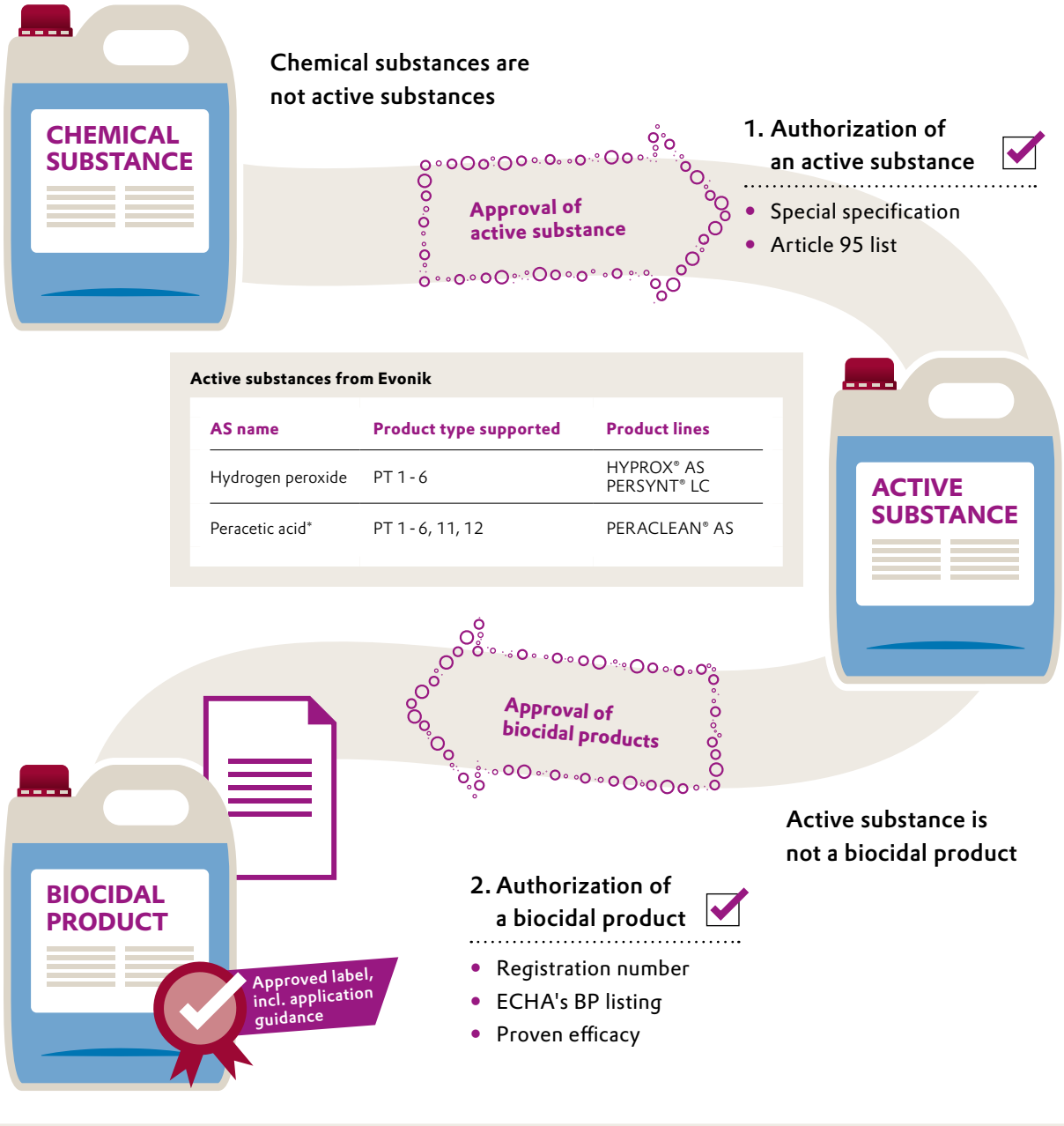
Marketing authorization holder: Evonik

Value for the customer:
No BPR-related effort

AS – Active substance
BP – Customer's biocidal product

TM – Customer's trade name
BP – Evonik's biocidal product

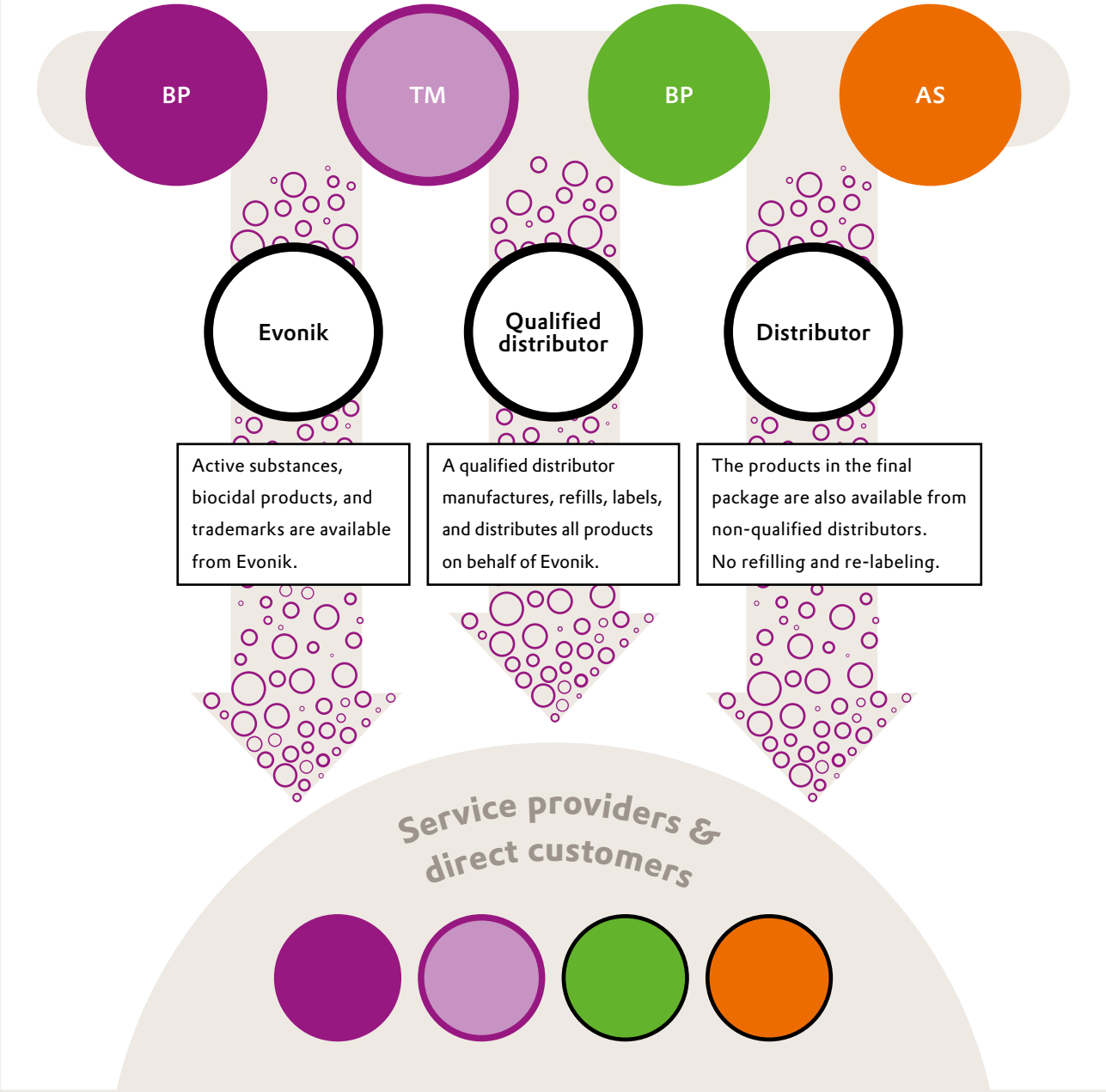
ACTIVE SUBSTANCES & BIOCIDAL PRODUCTS



For a chemical to become an **active substance,** successful approval via active substance authorization is required. Only Article 95 listed suppliers are allowed to place active substance on the market.

A **biocidal product** contains an active substance as an ingredient to take action against harmful organisms. The efficacy of the entire biocidal product formulation must be proven in its specific application field, grouped into product types (PT). Biocidal products undergo biocidal product authorization and can be offered on the market after successful registration only. An active substance itself cannot be used in place of biocidal product.

SUPPLY CHAIN CONCEPT



Evonik has established a Distributor Qualification Program. For detailed options on participation in the Distributor Qualification Program, including other supply chain relevant questions, please contact your regional sales representative.

BP – Biocidal product from Evonik
TM – Trade name of a customer
BP – Biocidal product from a customer
AS – Active substance

FOOD AND BEVERAGE

Disinfectants

Biocide

Disinfection of various surfaces and equipment usually falls into the scope of the BPR. Typical examples are the disinfectants used in cleaning-in-place programs.

BPR

Food processing aid

Disinfectants used in direct contact with foods or food additives fall under the Food Safety Regulations. Disinfection of sugar liquor during the extraction step exemplifies a non-biocidal application.

Food Safety Law

Disinfectants for use in food production fall into the scope of either the biocides regulation or corresponding Food Safety Law regulations. The exact assignment of a product to the related regulatory field is realized on a case-by-case basis and depends on the intended purpose as well as the claims made for the product concerned. In the case of ambiguity, **please contact us.**

FOOD AND BEVERAGE

Aseptic packaging

Aseptic packaging is used to protect food and beverages all along the supply chain and to guarantee a high quality of the packed foods along with long shelf life. Hydrogen peroxide and peracetic acid are utilized for disinfection of diverse packaging materials. Various technologies have been developed for aseptic filling: bath, spray, vapor, and rinse. Bath and spray technologies are mainly used for carton-based packages. Vapor and rinse methods are utilized for PET material.

OXTERIL® 350 SPRAY, OXTERIL® 350 BATH, OXTERIL® 350 SPRAY S, OXTERIL® 350 COMBI, PERACLEAN® 5 FB, PERACLEAN® 15 FB

Cleaning-in-place

Cleaning-in-place (CIP) is an integral part of the total hygiene conception in food & beverage facilities. CIP is a multistep procedure for thoroughly cleaning all items in plant or pipeline circuits under closed-system conditions without dismantling. Peracetic acid and hydrogen peroxide are widely used in the disinfection step and reduce the total number of microorganisms to a harmless level.

OXTERIL® 350 BATH, OXTERIL® 350 SPRAY, OXTERIL® 350 SPRAY S, OXTERIL® 350 LRD, PERACLEAN® 5 FB, PERACLEAN® 15 FB

FOOD AND BEVERAGE

Industrial and institutional cleaning in food processing

Among the most important aspects in food manufacturing is the need to clean and disinfect the food processing plant and equipment sufficiently to produce food free of physical, allergenic, chemical, and microbiological hazards. Disinfection of food-contact surfaces substantially reduces the number of undesirable microorganisms. Due to their ecologically benign character, peroxygens are becoming the first choice as disinfectants in the food area.

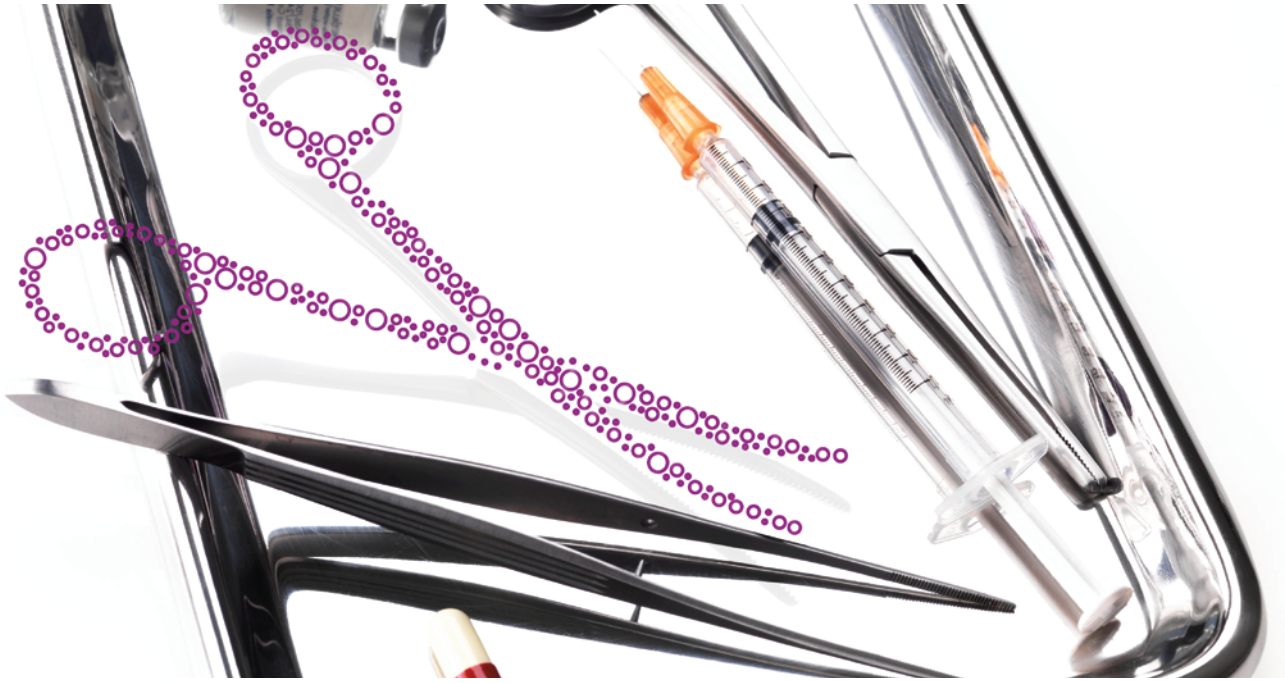
CLARMARIN® 350, CLARMARIN® 500, PERACLEAN® 5 FB

Drinking water distribution systems

Tap water intended for human consumption is subject to stringent microbiological and chemical standards, which make sure it can be consumed safely on a daily basis. Along with the preparation of drinking water itself, installation, piping, and tank maintenance, which includes cleaning and disinfection, is of crucial importance. Biocidal agents like hydrogen peroxide are utilized to ensure hygienically clean conditions in the installation.

OXTERIL® 350 BATH, OXTERIL® 350 SPRAY, PERACLEAN® 5 FB, PERACLEAN® 15 FB

MEDICAL APPLICATIONS



Medical disinfectants

Medical device

For a disinfectant to be a medical device, it must be designed and claimed specifically for the disinfection of another medical device. Peracetic acid solutions for manual endoscope reprocessing are examples of medical devices.

MDR

General purpose disinfectants

Disinfectants with a medical use are biocidal products and are subject to the BPR. These are general-purpose disinfectants for rooms, hard surfaces, devices, and hands, as well as disinfection of hospital laundry.

BPR

Medicinal product

A medicinal product is a disinfectant which is used on humans to treat or prevent diseases. A 3 % hydrogen peroxide solution for wound disinfection falls under the medicinal product regulations.

EudraLex

Exact assignment of a product to the related regulatory field is realized on a case-by-case basis. In the case of ambiguity, **please contact us.**

Disinfectants for use in the medical field fall into the scope of either the biocides or the medical device regulations, or the regulations covering medicinal products for human use. The exact applicability of the corresponding law depends on the intended purpose as well as the claims made for the product concerned.

MEDICAL APPLICATIONS

Industrial and institutional cleaning

Clinically relevant pathogens often persist on inanimate surfaces for weeks or even months. That is why, in healthcare settings, cleaning and disinfecting surfaces is part of the multi-barrier system for preventing hospital-acquired infection. Proper risk assessment is the basis for applying disinfection procedures. Here, focus is on those surfaces that are directly touched by personnel and patients and are exposed to frequent contamination. Cleaning and disinfecting the floors and walls of buildings, hospital rooms, and laboratories, as well as various equipment, is an integral part of numerous cleaning protocols across medical areas. Active oxygen compounds are often the choice of various service providers.

PERACLEAN® 5 HC, PERACLEAN® 15 HC

Laundry care

In the chemo-thermal disinfection of laundry, especially originating from hospitals, nursing homes, and other medical care institutions, peracetic acid and hydrogen peroxide are used in the washing stage as a disinfectant and bleaching agent. The primary goal for laundry treatment is to prevent possible pathogen transfer among patients. Disinfectant is usually added in the main wash cycle and targets the elimination of spores and viruses. Sometimes, the disinfection step is carried out after applying detergents and prior to the dewatering cycle. Textile disinfection is essential for infection prophylaxis for patients and staff in numerous medical facilities.

CLARMARIN® 350, PERACLEAN® 5 LD, PERACLEAN® 10 LD, PERACLEAN® 15 LD

VHP process

The bio-decontamination of surfaces contaminated with microorganisms within critical enclosed areas is an important consideration for pharmaceutical and other facilities. A safe and reliable way to disinfect equipment such as isolators, laminar flow cabins, and whole cleanrooms involves exposing the surface to gas-phase hydrogen peroxide. Vaporized hydrogen peroxide disinfection, as a low-temperature process, is also commonly used to treat various heat-sensitive devices. Hydrogen peroxide containing air is generated by means of special equipment. Depending on the cycle parameters, hydrogen peroxide is present in form of vapor, condensed vapor, or a mist.

OXTERIL® 350 VHP

(*) products to be launched

ANIMAL HYGIENE

Animal housing

Proper housing is integral to animal welfare. Hygienic conditions help avoid bacterial, viral, and parasitic infection and related illness in animals. Dry cleaning and washing usually precede the disinfection procedure. During the first two steps, gross contamination, various sorts of organic material (e.g., soil, manure, bedding, feed, exudates) are removed from production areas or equipment. Disinfecting solutions are then applied by means of special thermofogging equipment or by high-pressure cleaners. Biocides based on peracetic acid are widely used in sanitation procedures in preparing premises for new livestock.

PERACLEAN® 5 AH, PERACLEAN® 5.1 AH, PERACLEAN® 15 AH, PERACLEAN® 17 AH

Animal drinking water

A clean, safe water supply is essential in animal husbandry. Oftentimes, drinking water is also used as a carrier for various feed supplements and medicines, which can also lead to the formation of biofilms and bacteria growth in water. Microbial contamination above acceptable levels in drinking water directly affects animal health and farm performance. Reducing the bacteria level in the drinking water keeps animals healthier by preventing the pathogens from traveling from one animal to another. Peracetic acid and hydrogen peroxide are secondary disinfecting agents utilized in animal drinking water management.

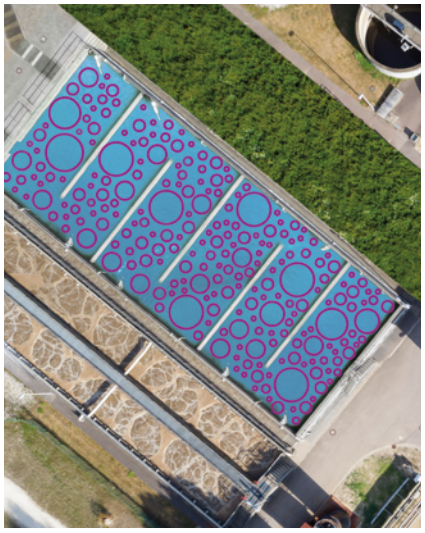
PERACLEAN® 5 AH, PERACLEAN® 5.1 AH, PERACLEAN® 15 AH, PERACLEAN® 17 AH

Equipment

Equipment cleaning and disinfection (e.g., of animal transport vehicles, footwear, and more) is an integral part of farm biosecurity. The key objective of numerous hygiene protocols, response plans, and management systems is to prevent the transfer of pathogens from animals to humans and to reduce the spreading of animal diseases within the logistical network. Oxidizing disinfectants based peracetic acid are highly effective against many viruses and other pathogens and remains active over a long period of time.

PERACLEAN® 5 AH, PERACLEAN® 5.1 AH, PERACLEAN® 15 AH, PERACLEAN® 17 AH

WATER TREATMENT



Sewage and wastewater

The overall quality of effluent streams from sewage treatment plants is often subject to numerous European and national regulations, which define the ecological status of the treated water. Effluents are of good ecological quality if they fulfill specific requirements. An environmental permit is generally required to discharge liquid sewage effluent into the environment. Sometimes, the treated wastewater is used for agricultural irrigation, where certain acceptance criteria also apply.
A post-disinfection procedure is applied to wastewater if it is necessary to reduce or control the microbiological load. Due to its efficacy against a number of fecal coliforms and its high deactivation efficacy, peracetic acid is frequently dosed to the effluent streams. What is more, peracetic acid leaves no harmful chemical residues in the environment, as it breaks down solely into water, oxygen, and vinegar.

PERACLEAN® 2 WT, PERACLEAN® 5 WT, PERACLEAN® 15 WT, VIGOROX® WWT II

Irrigation water

Drip irrigation increases average crop productivity by 30-50% and saves up to 50% water vs. surface irrigation. Peracetic acid is used to remove slime and algae from drip irrigation systems. The regular addition of peracetic acid to irrigation water prevents the growth of biofilm in pipes and lines, reducing the blockage of lines and emitters and the frequency to replace them. Oxygen produced by decomposition to hydrogen peroxide will further help in oxygenating the roots of the plant.

OXYPURE® C50, VIGOROX® AGRO

WATER TREATMENT

Cooling water

Liquid cooling is an essential component of numerous industrial processes. Water from natural sources is commonly used for this purpose. Cooling towers, heat exchangers, or chill water systems often suffer from corrosion phenomena as well as the formation of deposits, including extensive microbiological growth. Unless special precaution measures are taken, this can lead to flow restrictions, reduced operating efficiency, higher maintenance costs, and unscheduled outages. Peracetic acid solutions are used as a preservative to assure micro-biologically clean water and prevent biofouling in the cooling cycle. This increases the overall reliability and performance of the cooling systems of various industrial facilities.

PERACLEAN® 2 WT, PERACLEAN® 5 WT, PERACLEAN® 15 WT

Slimicides

Slime formation is a common negative phenomenon associated with the paper manufacturing process. Polysaccharides leached from the pulp act as nutrients and can favor microbial growth. The formation of microbial slime causes critical failures in the papermaking process and a reduction in paper quality. Uncontrolled slime growth can also result in breakages in paper mass and, as a consequence, a stoppage of the production line. It is therefore necessary to treat process water of papermaking machines to prevent microbial contamination of the water cycle. Use of peracetic acid as a disinfectant and slimicide reduces microbiological activity and prevents slime-related interruptions of the manufacturing process.

PERACLEAN® 2 WT, PERACLEAN® 5 WT, PERACLEAN® 15 WT

NEW RULES FOR BIOCIDAL PRODUCTS

1. **Biocidal products are regulated by the biocidal product regulation. No unauthorized products can be used as biocidal products.**

2. **No registration – no market.**

3. **A biocidal product must be registered for each single application and can be used only for those applications stated on its label.**

4. **The label of a biocidal product is a part of the authorization procedure and contains all relevant application-specific information, including directions for use.**

5. **A biocidal product is defined by its registration number.**

6. **A biocidal product has a marketing authorization holder, who is responsible for its claims and placing it on the market.**

7. **A biocidal product can be sold under multiple trade names. The trade name of a biocidal product must refer to one registration number only.**

USES OF HYDROGEN PEROXIDE & PERACETIC ACID

Approved products

PT	Active substance	Biocidal use	
PT2	H_2O_2	Laundry disinfection	CLARMARIN® 350/500
	H_2O_2	Surface disinfection by VHP process	OXTERIL® 350 VHP, OXTERIL® 350 SPRAY
PT4	H_2O_2	Aseptic packaging	OXTERIL® 350 BATH, OXTERIL® 350 SPRAY, OXTERIL® 350 SPRAY S, OXTERIL® 350 COMBI, OXTERIL® 350 LRD
	H_2O_2	Disinfection of non-porous hard surfaces and equipment by immersion(*)	OXTERIL® 350 BATH, OXTERIL® 350 SPRAY, OXTERIL® 350 SPRAY S, OXTERIL® 350 COMBI, OXTERIL® 350 LRD, CLARMARIN® 350/500
	H_2O_2	Surface disinfection by VHP process	OXTERIL® 350 SPRAY
	H_2O_2	Cleaning-in-Place (CIP)	OXTERIL® 350 BATH, OXTERIL® 350 SPRAY, OXTERIL® 350 SPRAY S, OXTERIL® 350 COMBI, OXTERIL® 350 LRD, CLARMARIN® 350/500
	H_2O_2	Disinfection of drinking water distribution systems	OXTERIL® 350 BATH, OXTERIL® 350 SPRAY, OXTERIL® 350 SPRAY S, OXTERIL® 350 COMBI, OXTERIL® 350 LRD, CLARMARIN® 350/500

Products under evaluation

PT	Active substance	Biocidal use
PT1	H_2O_2	Hand disinfection(*) (***)
PT2	PAA	Laundry disinfection
	PAA	Disinfection of sewage and wastewater
	PAA	Disinfection of non-porous hard surfaces and equipment(**)
	PAA	Cleaning-in-place (CIP)
	PAA	Treatment reverse osmosis membranes
	PAA	Disinfection of ion exchangers
	PAA	Disinfection by open-plant cleaning(*)
	PAA / H_2O_2	Disinfection of drip irrigation water and equipment(*)
PT3	PAA	Disinfection of animal housing (4 applications)
	PAA	Disinfection of transport trucks (3 applications)
	PAA	Disinfection of fish farms(*)
	PAA	Disinfection of boots in footbaths in animal production(*)
	PAA	Disinfection of animal feet (hoof disinfection)(*)
	PAA	Disinfection of equipment by dipping(*)
PT4	PAA	Aseptic packaging
	PAA	Disinfection of non-porous hard surfaces and equipment(**)
	PAA	Disinfection of drinking water distribution systems
	PAA	Disinfection of milking parlours(*)
	PAA	Disinfection by open-plant cleaning(*)
	H_2O_2	Disinfection of cork stoppers(*)
PT5	PAA	Drinking water for animals
	H_2O_2	Drinking water for animals and humans(*)
PT11	PAA	Preservation of cooling water in once-through systems(*)
	PAA	Preservation of cooling water in recirculating cooling systems(*)
	PAA	Disinfection of water in thermal power plants (zebra mussel)(*)
PT12	PAA	Slimicide in pulp and paper industry(*)

(*) Application will be available only in limited number of countries

(**) By wiping, by low pressure spraying, by foaming, by dipping and immersion

(***) Only available after BPR approval

Way to GO_2

At Active Oxygens, sustainability is at the core of futurizing our business. Discover more about how we are expanding our beneficial handprint and eliminating our environmental footprint: **active-oxygens.com/sustainability**

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