



Hygiene and Sanitization of Surfaces and Environments in the Pharmaceutical Industry

Industrial
Division



Hygiene and Sanitization of Open Surfaces
C.I.P. Applications
Spray Washing
Washing of the Filtration Membranes
Cleaning Floors
Hand Hygiene



In the pharmaceutical industry, as well as in the cosmetic/biotechnological and nutraceutical industry, hygiene and sanitizing operations of environments, surfaces and equipment involved in the manufacturing process, are fundamental activities to give end users the production of drugs with high quality standards, with particular reference to the absence of potential contamination of various kinds which could compromise the safety of use; in fact the pharmaceutical industry is, among the various types of industries, the one most subject to compliance with a number of sector regulations, both voluntary (EU GMP, ICH Guidelines, Management Systems) that mandatory (Directives 2001/83/EC and 2003/94/EC, HACCP, etc.), and subjected to strict controls by the institutions for the protection of public health.

The manufacturing process of a drug includes the performance of a series of activities, called validation, that have as their objective the demonstration of efficacy, of the implemented operational procedures, in ensuring the repeatability of the production process of a drug for human or veterinarian use regarding the compliance of the specifications declared by the manufacturer in the relevant ministries of the countries to which the product is marketed.

Among the different validation procedures of processes plays an important role, for approval and subsequent release of the drug on the market by the relevant authorities, the so called "**Cleaning Validation**"; representing the set of validation activities of cleaning and sanitization methods of environments, surfaces and equipment used for the production of drugs.

The Cleaning Validation, included in the *Good Manufacturing Practice* (GMP), therefore it serves to demonstrate the effectiveness of hygiene and sanitation procedures, implemented by the manufacturer, to ensure to the drug:

- the absence of contamination by particles (dust or particles suspended in manufacturing environments);
- the absence of contamination due to induced transport (contaminant particles carried by persons or things on the go inside/outside of workplaces);
- the absence of cross-contamination due to residues of the active substances or ingredients resulting from previous productions;
- the absence of contamination by pathogens.

It therefore follows that, in order to eliminate or reduce to acceptable limits these risks of contamination, it is essential that, throughout the production process, operators have cleaners and/or sanitizers able to ensure deep cleaning and sanitizing of all those environments, work surfaces, equipments and utilities used in the production of the drug, as well as to ensure the hygiene of the operator's hands for all activities performed manually.

In order to meet the needs of the cleaning in the Pharmaceutical and related sectors, AQUOS proposes itself, to operators involved, as a valid partner for the hygiene and sanitizing activities through a complete range of detergents and/or sanitizers suitable for different specific applications, as described below, which comprise: the cleaning and sanitizing of the open surfaces; recirculating washing of pasteurizers, reactors, pipes, tanks, filling plants, etc. by C.I.P. systems (Cleaning in Place); spray or immersion washing of containers, equipment and surfaces open in general; cleaning and sanitizing of equipment, floors, external of tanks and plants, storage premises; etc.



Hygiene and Sanitization of Open Surfaces


With the exception of controlled contamination environments such as the Clean Rooms, where the need to have the sterile environments requires the use of sterile detergents and/or sanitizers, for some processes which can be conducted in non-sterile areas, the choice of the products for the hygiene and sanitation of open surfaces is based on the type of contamination, which is a function of the type of products manufactured and therefore of the characteristics of the production departments.

In the pharmaceutical industry there are the following departments:

- **the "dry areas"**, in which are manufactured solid products (powders, granules, pills, tablets, etc.) where, obviously, it is preferred not to use water based detergents, but it is preferred the use of alcoholic products, that have both solvent/degreaser and sanitizing activities, both self-drying properties, allowing quick drying of treated surfaces without causing any residual effect;
- **the "damp areas"**, where are manufactured semisolid products (pomades, creams, ointments, gels, etc.), where are used cleaning and/or sanitizing solutions manually applied with cleaning cloths or mops;
- **the "wet areas"** consisting of all those productive areas where you can use, on the surfaces to be treated, the cleaners/sanitizers in aqueous solution without any difficulty by means spray washing systems.

Hygiene in the dry areas

As already mentioned, in so-called "dry areas", are realized solid products (powders, granules, tablets, etc.), for which it is preferred to avoid the use of detergents and/or sanitizers that require a subsequent rinsing stage and operate with dry cleaning systems such as vacuum cleaners, dry cloth for removal of dirt and wet cloth with hydroalcoholic products based on sanitizing agents which, while having excellent sanitizing properties, do not require subsequent rinsing with water as the alcohol component, for its high volatility, allowing quick drying of treated surfaces. **For this type of applications AQUOS proposes a self-drying alcoholic product based on isopropyl alcohol and quaternary ammonium salts:**








DRY AREAS				
Product	Features	Method	Conc. of use*	Field of application
Spectrum AT 	Sanitizer based on alcohol, quaternary ammonium salts (QAC) and organic sequestering	Rapid sanitizing	Undiluted	For applications on surfaces where it is not advisable to use water-based products. Suitable for any type of surface

* **Conc. of use** means the average concentration commonly used for the indicated applications

Hygiene in the dump areas

In the "dump areas", where are produced pomades, creams, ointments, gels, etc., are used cleaning solutions and/or sanitizers with the aid of equipment, disposable cloths, and mops with two or three buckets methodology. The choice of products depends on the surfaces (compatibility with light alloys and soft metals in general), ease of rinsing and the safety of the operators. The operating procedure consists in a first cleaning phase and a subsequent sanitizing, but, depending on the case, it is possible to operate also with the specific products that have both properties cleansing and sanitizing.







The following are the main products AQUOS suitable for the needs of dump areas:

DUMP AREAS				
Product	Features	Method	Conc. of use*	Field of application
Tensiol 390 	Concentrated neutral foaming detergent	Manual, spray and immersion washing	2 ÷ 3%	Suitable for any type of surface
TK 11 	Non-caustic degreasing detergent	Manual, with pressure washer or with dispensing at low pressure washing	2 ÷ 3%	Suitable for any type of surface
Triameen D10 	Amphoteric biocides based sanitizer	Hand washing, washing with pressure washer or with low-pressure sprinklers	1 ÷ 2%	Suitable for any type of surface
Sanybac 	Sanitizing detergent based on quaternary ammonium salts (QAC)	Manual, spray, atomization and immersion cleaning/sanitizing	1 ÷ 2%	Suitable for any type of surface
Spectrum BG 	Polibiguanide based sanitizer	Manual, spray, atomization and immersion cleaning/sanitizing	1 ÷ 2%	Suitable for any type of surface
Sanychlor 	Active chlorine based sanitizer	Manual and immersion sanitizing	0,5 ÷ 1%	Suitable for steel surfaces AISI 316 (cold), Teflon (PTFE) and plastic materials in general. It requires rinsing after use.
Liquid Top Wash 	Highly sequestering alkaline detergent	Cleaning of laboratory glassware	0,5 ÷ 2%	Suitable for glassware, equipment and labware

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The "wet areas" are characterized by the presence of large surfaces and plants that can be treated with detergents and/or sanitizers applicable through low pressure systems with lances which spray the product as a foam. The synergy between the functionality of the spraying system and the foaming character of the surfactants used in the products, allows to optimize the washing and sanitization procedures both in terms of speed of operation, both in terms of reducing consumption; moreover, the foam that clings to surfaces, increases the contact time of the products enhancing the washing and sanitizing efficacy and enabling operators to rinse with more accuracy easily recognizing the areas already treated with the product.

Below are the main foaming products that AQUOS offers for large surfaces of wet areas:

WET AREAS				
Product	Features	Method	Conc. of use*	Field of application
Aquafoam HA 	Alkaline foaming detergent	Application of the foaming detergent with low pressure systems	3 ÷ 5%	Not suitable for mild metals such as aluminum or on both plated metals (e.g. zinc plated metals)
Aquafoam MA 	Alkaline foaming detergent	Application of the foaming detergent with low pressure systems	3 ÷ 6%	Suitable for any type of surface
Cloractive FC 	Chlorinated alkaline foaming detergent (525 ppm active chlorine in 1% solution)	Application of the foaming detergent with low pressure systems	3 ÷ 6%	Not suitable for mild metals such as aluminum or on both plated metals (e.g. zinc plated metals)
Aquafoam Ampho 	Alkaline foaming sanitizing detergent	Application of the foaming detergent with low pressure systems	3 ÷ 6%	Not suitable for mild metals such as aluminum or on both plated metals (e.g. zinc plated metals)
Aquafoam Acid 	Acid foaming detergent	Application of the foaming detergent with low pressure systems	3 ÷ 5%	Not suitable for mild metals such as aluminum or on both plated metals (e.g. zinc plated metals)
Aquafoam N 	Neutral foaming detergent	Application of the foaming detergent with low pressure systems	3 ÷ 5%	Suitable for any type of surface

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C.I.P. Applications


In the pharmaceutical industry, as well as in the cosmetic and nutraceutical industry, the cleaning and sanitizing of process plants is carried out through operational methodologies called "C.I.P. cleanings", where the term C.I.P. is an acronym for "Cleaning In Place", which means "cleaning in place". This methodology consists in the automatic cleaning and sanitizing of the internal parts of equipment, containers, tanks, pipes by pumping of appropriate detergents and/or sanitizing solutions that recirculate inside the system, reaching efficiently all the surfaces to be treated.

The C.I.P. cleanings, therefore, ensure a deep cleaning and sanitization of the production plants without requiring them to be removed or transported elsewhere, thus allowing significant operational benefits in terms of efficiency and speed.

To obtain optimum results of cleaning/sanitizing process is crucial, however, that all piping and facilities involved in the production process are designed and manufactured accurately in order to avoid the presence of stagnation points, which inevitably would be difficult to sanitize.

For applications C.I.P. in the pharmaceutical industry AQUOS proposes, below, a wide range of detergents and additives which, depending on the nature of the contamination to be removed, may have alkaline/degreasing, sequestering or descaling action and sanitizers based on different active ingredients with biocidal action.











C.I.P. CLEANINGS			
Product	Features	Washing phase	Conc. of use*
Aquaflow SF 	Highly sequestering alkaline detergent	Alkaline monophase	2 ÷ 4% based on the degree of hardness
Aquaflow IG 	Sequestering and sanitizer alkaline detergent	Sanitizing alkaline monophase	2 ÷ 4% based on the degree of hardness
Aquaflow Plus 	Non-foaming caustic detergent	Highly alkaline phase	1 ÷ 3% based on the degree of contamination
Aquaflow P 	Descaler based on phosphoric acid and surfactants	Acid phase	1 ÷ 2%
		Manual descaling	0,5 ÷ 3%
Aquaflow FN 	Descaler based on phosphoric acid and nitric acid	Acid phase	1 ÷ 2%
Aquaflow N 	Descaler based on nitric acid	Acid phase	1 ÷ 2%
Osa Pharma PN 	Descaler sanitizer based on phosphoric acid and nitric acid	Sanitizing acid phase	1,5 ÷ 3%
Spectrum PA5 	Sanitizer based on stabilized peracetic acid 5% solution	Sanitizing phase	0,5 ÷ 1,5%
Spectrum PC 	Sanitizer based on satabilized percitric acid	Sanitizing phase	0,1 ÷ 1%
Aquaflow CLK 	Active chlorine based sanitizer detergent	Cleansing /sanitizing phase	0,5 ÷ 1%
Spectrum Oxy 100 	Booster based on inorganic peroxides for enhancing the phase of detergency or sanitizing	Cleansing phase or sanitizing phase	500 ÷ 1000 ppm
Aqualon SP 	Booster additive with sequestering and reducing tension action for the enhancement of alkaline phase	Alkaline phase	0,5 ÷ 1%

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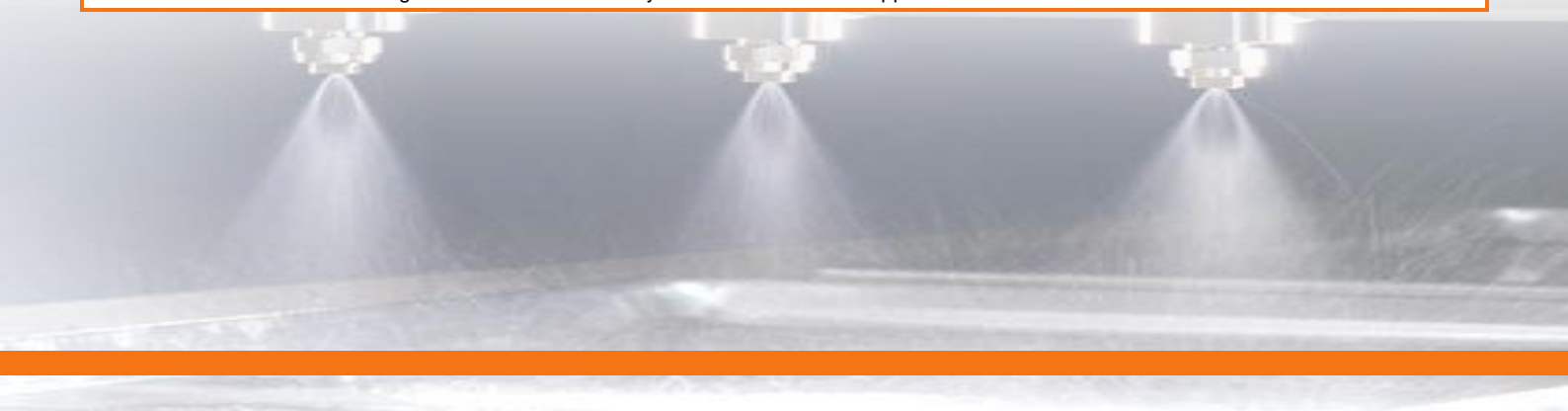


In the pharmaceutical and cosmetic industry, the production activities often requires the use of various equipment such as cassettes, various containers, trolleys, pallets, etc. These latter, together with some removable parts of the production plants and some tools, require periodic cleaning and sanitizing, which is performed by means of specific equipment which apply the technology of so-called mechanical spray washings. This type of washing provides the use of monoblock or tunnel machines that automate the washing and sanitization procedures ensuring, compared to manual washing, a greater effectiveness and especially a reduction of the operating times with a consequent economic and organizational return. Even the spray washings, as the C.I.P. cleanings, need more of an operating phase: a first step of rinsing, which uses hot water jets to remove the coarsest residues from the treated surfaces; which can be followed by an alkaline phase (if must be removed organic contaminants such as lipids or proteins) or by an acid phase (if necessary to eliminate inorganic contaminations) or both in case of particularly tenacious contaminations characterized by an organic-inorganic mixed matrix. After these phases of washing a final rinse is performed with high-temperature water (about 80 °C) to ensure a thermal sanitizing of the treated surfaces. In some cases, to strengthen the cleaning or sanitizing phase may be used based on inorganic peroxides or peracetic acid boosters.

The following table shows the AQUOS products suitable for automatic spray applications.

AUTOMATIC SPRAY WASHINGS				
Product	Features	Washing phase	Conc. of use*	Field of application
Aquaflow SF 	Highly sequestering alkaline detergent	Alkaline monophase	2 ÷ 4%	Not suitable for light alloys surfaces
Aquaflow CL 	Chlorine-active alkaline detergent with sequestering action	Sanitizing alkaline monophase	0,5 ÷ 1%	Corrosive. Use only at low temperatures (<50 °C)
TK 11 	Non-caustic alkaline detergent for aluminum and light alloys	Alkaline phase	0,5 ÷ 3%	Suitable for any type of surface
Tensiol P 	Concentrated alkaline powder detergent	Alkaline phase	0,5 ÷ 2%	Suitable for washing of laboratory glassware
Alufos 	Acid descaling detergent based on strong mineral acids	Acid phase	0,5 ÷ 3%	Suitable for aluminum. Not suitable for light alloys surfaces
Spectrum Oxy 100 	Booster based on inorganic peroxides for enhancing the phase of detergency or sanitizing	Detergent phase or sanitizing phase	According to the needs	Suitable for any type of surface
Spectrum PA 5 	Sanitizer based on stabilized peracetic acid	Sanitizing phase	0,2 ÷ 2,0%	Suitable for plastics (PE, PET, PVC, PTFE) and steel surfaces. Apply at room temperature.
Spectrum BG 	Polibiguanide based sanitizer	Sanitizing phase	0,2 ÷ 1%	Suitable for any type of surface






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Washing of Filtration Membranes

In many processes of the pharmaceutical and biotechnology industry, such as the concentration and purification of proteins, antibiotics, enzymes, pharmacological active ingredients, etc., it is essential to the use of tangential filtration technologies (microfiltration, ultrafiltration, nanofiltration, reverse osmosis and dialysis) by means filtering membranes constituted by materials different in function of the type of filtration required and of the characteristics of the solutions to be filtered.

These membranes need to be periodically regenerated in order to maintain the correct functionality and, consequently, the productivity and the yield of the filtration process; therefore, to meet the needs of operators, **AQUOS has realized a range of products, listed below, specific for washing and regeneration of the filtering membranes used in the production cycles:**

WASHING OF FILTRATION MEMBRANES				
Product	Features	Washing phase	Conc. of use*	Field of application
Aquasafe 700 K 	Highly alkaline detergent with high degreasing and sequestering action	Alkaline sequestering washing	1 ÷ 6%	Microfiltration Ultrafiltration
Aquasafe AC2 	Descaler detergent based on phosphoric acid and nitric acid	Descaler acid washing	0,5 ÷ 1%	Microfiltration Ultrafiltration Nanofiltration Reverse osmosis (no ceramic)
Aquasafe CLR 	Chlorine-active alkaline detergent	Alkaline sanitizing washing	0,5 ÷ 2%	Microfiltration Ultrafiltration
Spectrum Oxy 100 	Sanitizing additive based on inorganic peroxides	Sanitizing	0,2 ÷ 0,5%	Microfiltration Ultrafiltration
Aqualon SP 	Booster additive to enhance the sequestering action	Alkaline sequestering washing	0,5 ÷ 1%	Microfiltration Ultrafiltration Nanofiltration Reverse osmosis

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In all industrial sectors the flooring have a key role for proper performance of production processes, both for their resistance to potential static or dynamic loads that the same production activity determine on surfaces, both in terms of safety of workers during daily operations; moreover, in the case of food companies, and in particular in the pharmaceutical industry, the characteristics of the floorings must also permit a certain speed and efficiency in maintenance and cleaning operations.

In pharmaceutical companies, according to the department and activities implemented, the floors are subject to contamination of different size and nature and then require cleaning operations to be carried out manually, typically with the system with 2 or 3 buckets, or mechanically by single-disc or washer-dryer machines.

In a two-buckets system or by cleaning trolley with two tanks, both containers are filled with the detergent and/or sanitizing solution, and the mop is impregnated with detergent solution in the first tank, used for the operations of washing and then rinsed and wrung out in the second tank; in the system to three buckets or by cleaning trolley with three tanks, the third container may contain only water or the detergent solution and the mop is impregnated in the first tank, used for the cleaning of the floors, rinsed in the second tank and wrung out in the third tank.

Generally the choice of two or three tanks system depends on the entity of the contamination to be removed and by the need to perform or not even a sanitizing phase.

Both for manual and automatic applications with washer-dryer machines, AQUOS proposes, below, the main detergents suitable for all types of industrial flooring and contamination that must be removed.

FLOOR CLEANING				
Product	Features	Kind of application	Conc. of use*	Field of application
Magma K 	Solvent based degreaser detergent	Manual and mechanical	1 ÷ 3%	Suitable for the removal of heavy dirt (mineral oils, streaks of vehicle tires, etc.)
Pegaso 	Alkaline detergent	Manual and mechanical	1 ÷ 5%	Suitable for all types of floors and for each manufacturing department
Queen 890 	Non-caustic alkaline detergent	Manual and mechanical	0,5 ÷ 3%	Suitable for any type of surface

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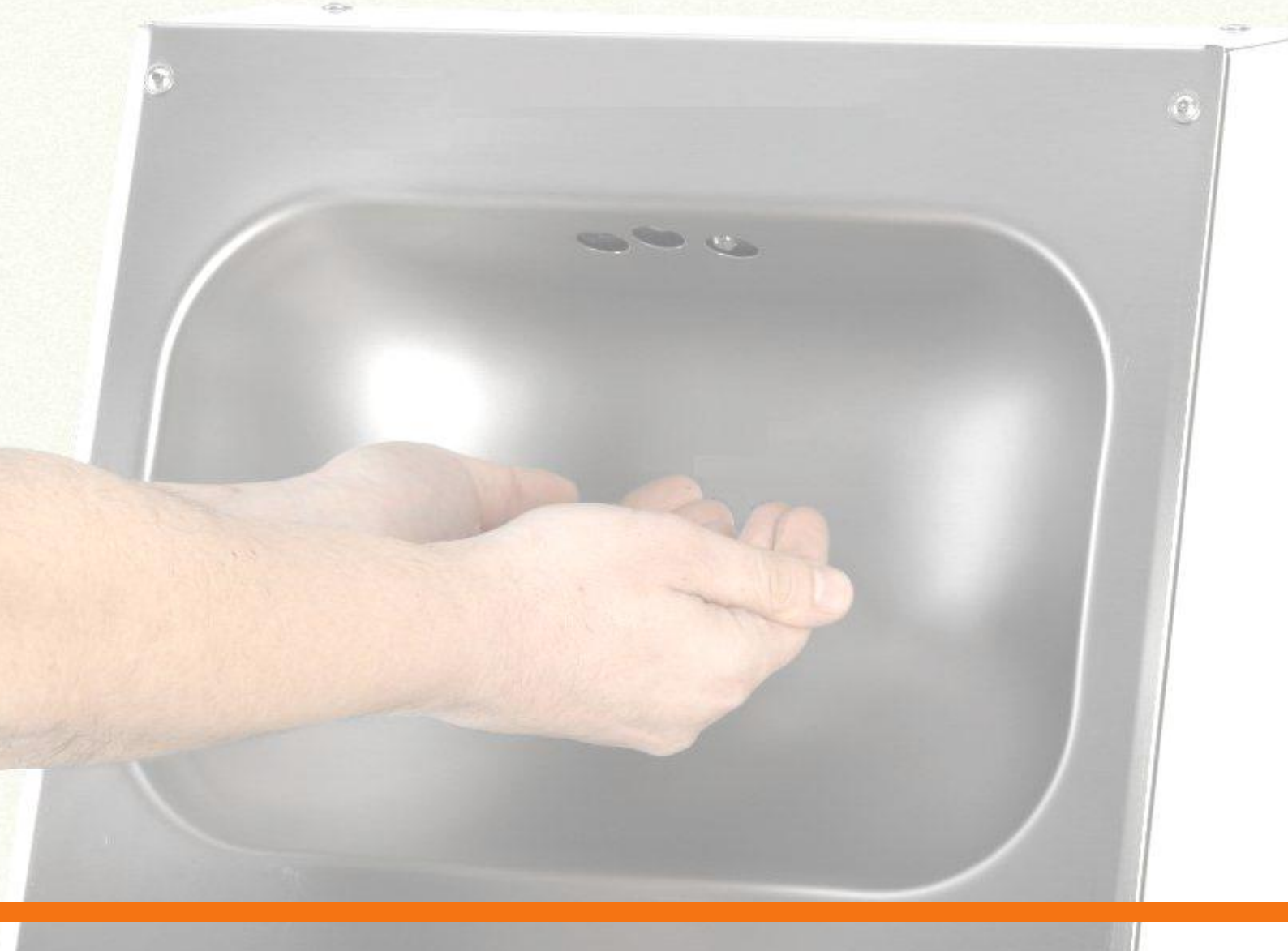
Hand Hygiene

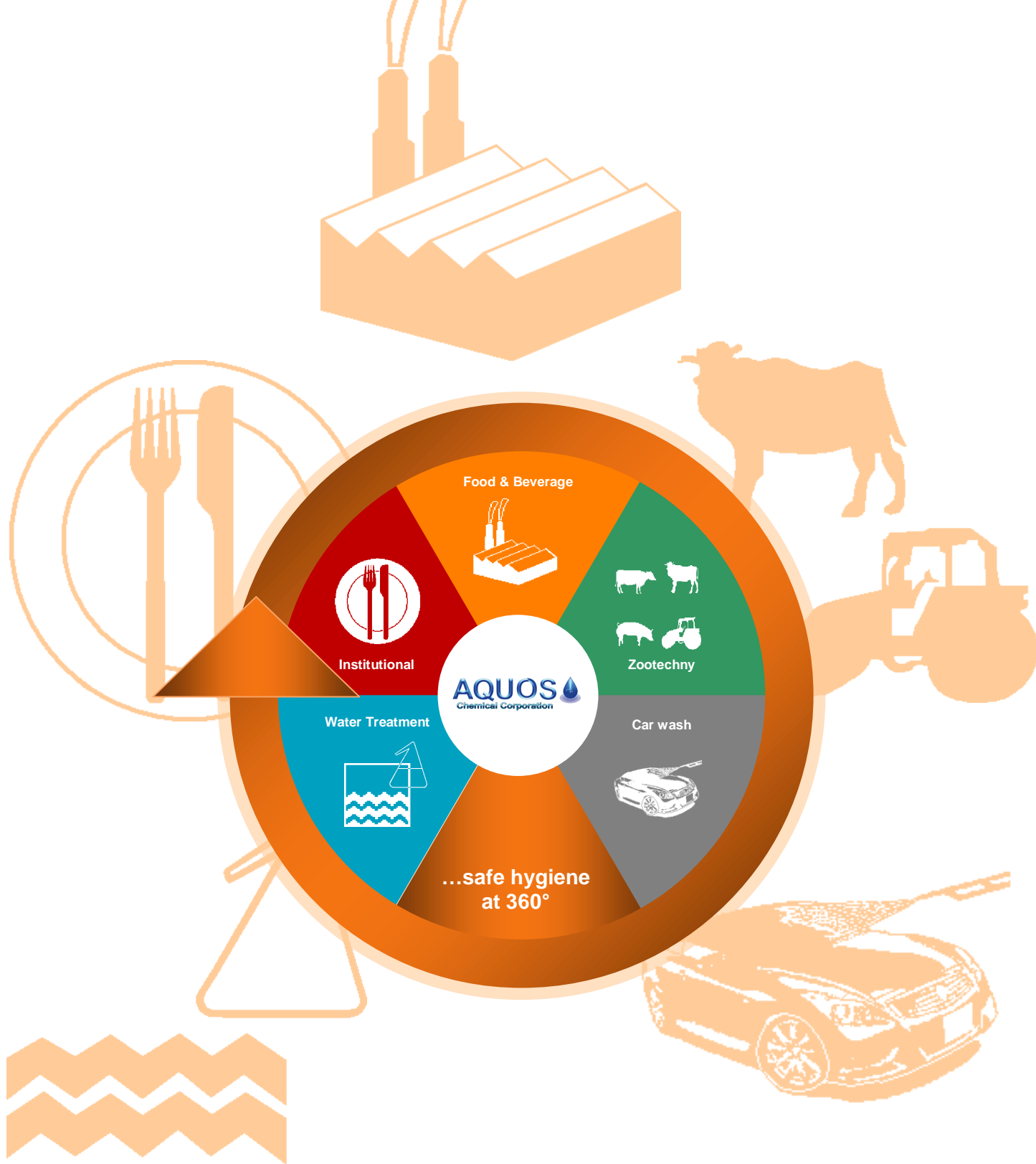
In the pharmaceutical and cosmetics industry, as well as in the food industry, the aspects related to personal hygiene are of crucial importance to ensure the control of contamination in the production departments. Particular care must be taken in the proper hygiene of the hands of operators in order to avoid cross-contamination that can contaminate the pharmaceutical or cosmetic products with possible consequences in terms of health and safety of the end users.

For these reasons should be given particular importance to the proper training of operators on hygiene and sanitation of hands procedures through the use of detergents, with sanitizing action, formulated with delicate and emollient active ingredients, capable of effectively controlling bacterial, fungal or viral contamination without causing irritation of the skin even after frequent washing.

For this particular application AQUOS offers some detergents/sanitizers based on different active ingredients, with sanitizing action, reported below:

HAND HYGIENE		
Product	Features	Kind of application
Hydra/B 	Pleasantly scented neutral detergent	Applies with any type of soap dispenser s
Dexodin 	Neutral detergent, with sanitizing action, based on chlorhexidine	Applies with any type of soap dispenser s
Spectrosol 	Alcoholic self-drying sanitizer	Applies with spray dispenser





AQUOS 
Chemical Corporation
....a little magic for a perfect clean

Piazza Regina Margherita, 24
80040 San Gennaro Vesuviano (NA) - Italy

(+39) 081 3415947

(+39) 081 3415947

(+39) 345 1116363

(+39) 392 9513074

www.aquoschemical.it

info@aquoschemical.it

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