

ACTIVE OXYGENS FOR HEALTH CARE

Human use – Decontamination –
Pharmaceutical Synthesis

PERSYNT®
PERACLEAN®



AMERICAS



EUROPE / MEA





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Evonik is a leading supplier of H₂O₂ and Peracetic Acid with 18 production sites and an annual global capacity totaling more than one million metric tons. We are the innovative leader in high quality products and services, offering more than a century of worldwide experience to serve the megatrends of the modern society and to deliver an exceptional value for our customers. We are a global team of peroxide experts, driven by enthusiasm, dedicated to create resource efficient specialty oxidant solutions, ready for tomorrow.

Products containing hydrogen peroxide or peracetic acid are used in various applications in the pharmaceutical and medical industries due to their disinfectant properties. Such applications include dental or wound disinfection, decontamination of surgical instruments as well as treatment of contact lenses. Solutions with higher hydrogen peroxide concentration are applied as chemosterilants in specially designed machines for decontamination of heat sensitive medical devices. Hydrogen peroxide is the primary bleaching component in tooth whitening products.

HUMAN USE



Hydrogen peroxide as an Active Pharmaceutical Ingredient (API)

According to EU Directive 62/2011/EU amending Directive 2001/83/EC on the community code relating to medicinal products for human use, it is **mandatory for all producers of active substances used for medicinal products for human use to be registered at the appropriate authorities of the country of origin to prevent the entry of falsified medicinal products into the legal supply chain. Precondition for this registration is the approval of the production of the active ingredient according to GMP (Good Manufacturing Practice) guidelines.** Evonik offers the special hydrogen peroxide grade PERSYNT® 300 GMP manufactured under GMP conditions to meet the requirements of this regulation when using hydrogen peroxide as an Active Pharmaceutical Ingredient. Evonik has obtained the manufacturing authorization for PERSYNT® 300 GMP and is also listed in EudraGMDP, a database for manufacturers, which hold a GMP certificate.



HUMAN USE

Hydrogen peroxide as an Active Pharmaceutical Ingredient (API)

Furthermore, Evonik is the first and so far only holder of a Certificate of suitability to monographs of the European Pharmacopoeia, CEP, for its product PERSYNT® 300 GMP. The CEP significantly eases the management of new applications and maintenance of existing Marketing Authorizations (MA) for medicinal products.

The Evonik certificate, (RO-CEP-2018-079) can be viewed in EDQM's database under: https://extranet.edqm.eu/4DLink1/4DCGI/Web_View/mono/396.

Packaging:
PERSYNT® 300 GMP
 • 20kg, 30 kg and 65 kg can
 • IBC
 • Bulk

	GMP mandatory			
	Wound disinfection	Dental disinfection	Foot disinfection	Medical therapy
Hydrogen peroxide				
PERSYNT® 300 GMP	•	•	•	•



Certificate of suitability

DECONTAMINATION

Hydrogen peroxide and peracetic acid as sterilants and disinfectants



Depending on the manufacturer's claims (biocide or medical device), disinfectants used in the medical sector for decontamination may fall under two legislative acts of the European parliament.

Disinfectants for the control of microbiological risks related to the environment (rooms, general surfaces) are biocidal products and regulated by Biocides Regulation 528/2012. A disinfectant can be also considered as an accessory of a medical device and therefore has medical device status, if it is specifically intended for medical devices that must be disinfected before use in accordance with their instructions for use. In this case the European Medical Devices Directive (MDD) 93/42/EEC regarding medical devices is applicable. According to Directive 93/42/EEC concerning medical devices, disinfectants are regarded as medical products and must be produced according to EN ISO 13485. Evonik offers special hydrogen peroxide grades under the brand name PERSYNT® Steri and the special peracetic acid grade PERACLEAN® Steri, both produced compliant with EN ISO 13485, specifically for this use. These products allow Evonik's customers to simplify the application process for a CE label. Evonik does not hold a CE label and is not selling a medical device, but our customers can go through a conformity assessment procedure by a certified body to be qualified as a manufacturer a medical device.

	Medical devices Contact lenses, equipment and instruments	Biocides Room and surfaces
Hydrogen peroxide		
OXTERIL® 350 SPRAY		•
PERSYNT® 350 Steri	•	
PERSYNT® 500 Steri	•	
Peracetic acid		
PERACLEAN® 5 Steri	•	
PERACLEAN® 5		•

Packaging:

OXTERIL® 350 SPRAY

- 1 L Bottle
- 5 L Bottle

PERSYNT® 350 Steri

- 30 kg and 65 kg can
- IBC
- Bulk

PERSYNT® 500 Steri

- 65 kg can
- IBC
- Bulk

PERACLEAN®

- 20 kg and 30 kg can
- Drum
- IBC
- Bulk

PHARMACEUTICAL SYNTHESIS

Hydrogen peroxide and peracetic acid as oxidizing agents

Due to decades of experiences with hydrogen peroxide and peracetic acid our products meet the requirements of the pharmaceutical industry. PERSYNT® 350 LC and PERSYNT® 500 LC are high purity hydrogen peroxide grades, characterized by a very low TOC and stabilizer content. These grades are especially suited for water phase oxidation reactions in

pharmaceutical synthesis. Our highly concentrated peracetic acid grades PERACLEAN® 35 and PERACLEAN® 40 are highly effective oxidizing agents also for solvent based reactions. All grades meet the requirements of API or other fine chemical synthesis and every lot comes with a complete documentation.



API and pharmaceutical intermediates

Hydrogen peroxide

PERSYNT® 350 LC

•

PERSYNT® 500 LC

•

Peracetic acid

PERACLEAN® 35

•

PERACLEAN® 40

•

Packaging:

PERSYNT®

- 30 kg and 65 kg can
- IBC
- Bulk

PERACLEAN® 35

- 25 kg and 30 kg can
- Drum
- IBC
- Bulk

PERACLEAN® 40

- 25 kg and 30 kg can
- Bulk

PHYSICO-CHEMICAL PROPERTIES

Important physico-chemical properties of aqueous solutions of hydrogen peroxide

H ₂ O ₂ concentration	% (wt.)	30	35	50
	g (H ₂ O ₂) / kg	300	350	500
	g (H ₂ O ₂) / l	332	395	596
	mol / l	9,8	11,6	17,5
	mol %	18,5	22,2	34,6
Active oxygen content	% (wt.)	14,1	16,5	23,5
Density at 20 °C	g/ml	1,111	1,131	1,195
Density at 30 °C	g/ml	1,105	1,124	1,187
Density at 40 °C	g/ml	1,098	1,118	1,179
Density at 50 °C	g/ml	1,091	1,110	1,171
Density at 60 °C	g/ml	1,084	1,103	1,163
Density at 70 °C	g/ml	1,077	1,095	1,154
Density at 80 °C	g/ml	1,069	1,087	1,145
Freezing point	°C	-26	-33	-52
Boiling point at 1013 mbar.	°C	106	108	114
Boiling point at 2026 mbar.	°C	132	135	145
Boiling point at 3039 mbar.	°C	147	150	161
Total vapor pressure (30 °C)	mbar	33	32	24
	mm. Hg.	25	24	18
H ₂ O ₂ partial vapor pressure at 30 °C	mbar	0,3	0,4	0,8
	mm. Hg.	0,25	0,3	0,6
Specific heat at 25 °C	J*g/K	3,6	3,5	3,3
Refractive index, n _{25D} at 25 °C		1,3519	1,3554	1,3661
Viscosity at 20 °C	mPa*s	1,11	1,12	1,18
Surface tension at 20 °C	mN/m	74,2	74,5	75,7

¹⁾ The tabulated values, which are given above, describe physico-chemical properties of salt free pure aqueous solutions of hydrogen peroxide in water.

²⁾ Hydrogen peroxide concentration can be expressed in weight percent, gram of 100%-age hydrogen peroxide in 1 kg solution, gram of 100%-age hydrogen peroxide in 1L solution and as molar concentration or molar fraction of hydrogen peroxide in solution. The tabulated values for g (H₂O₂)/l and mol/l are given for the temperature of 25°C.

PACKAGING AND STORAGE

Depending on customer, grade, region and other requirements, the shipment of hydrogen peroxide and peracetic acid is made in small to large containers.

For consumers of large quantities, the installation of a storage tank is recommended. Common forms of packaging for hydrogen peroxide are:

- Plastic canister: Depending on product and concentration: 20 kg, 30 kg, 65 kg can
- Plastic drum: 200 liters/220 kg, or 55 gallons/500 lbs
- IBC (Intermediate Bulk Container): 1000-1200 kg
- Road tanker: up to 25 tonnes
- Overseas ISO container: 20 tonnes

Please check with your regional representative about the availability of desired grades and packaging systems.

Hydrogen peroxide and peracetic acid containers should be stored in roofed, fireproof rooms where they can be kept cool and protected from sunlight. Peracetic acid should be stored with good ventilation. It is important that hydrogen peroxide and peracetic acid are protected against all types of contamination, especially metal ions, alkalis and reducing agents must be avoided. Therefore, the containers should be stored unopened and in an upright position without blocking the breather vents.

Peracetic acid must be kept away from any heat sources and combustible materials, especially organic solvents. Vapors of highly concentrated peracetic acid may form explosive mixtures with air. With proper storage in the original containers or in tank installations, the products can be stored safely for a long period of time without noticeable losses in concentration. The service life of plastic containers with high strength peracetic acid is limited to 12 months.

Through the use of a tank installation for hydrogen peroxide, efficient and economical storage together with an in-plant supply to points of consumption is possible. For construction of hydrogen peroxide storage tanks, pure aluminum

and AlMg₃ can be used. Nowadays, Polyethylene (up to 60% by weight H₂O₂) or stainless steel are preferred owing to reduced corrosion problems.

Aluminum and stainless steel tanks for hydrogen peroxide can be installed horizontally or vertically, but for static reasons polyethylene containers must be installed only vertically. For safety reasons, it is advisable to install larger storage containers in a dedicated area. Stainless steel has proven most effective for piping.

Before initial filling, the storage tank and all parts in a hydrogen peroxide storage tank installation must be suitably cleaned and passivated.

Storage tanks, intermediate containers as well as dosing and reaction vessels must be fitted with venting equipment to avoid overpressure. In addition, hydrogen peroxide and peracetic acid must not remain trapped in pipes between valves because decomposition at such points could lead to pressure build-up. If ball valves are used, a vent hole must be drilled into the ball. All containers should be checked regularly. We at Evonik are happy to make available our extensive experience in the planning and construction of tank installations for hydrogen peroxide to our customers.

Our Engineering Department carries out the planning, design, construction and initial filling, including prior cleaning. As the smallest unit six cubic meter tank installations are normally built which permit delivery of the product in 5-tonnes containers. In general, such an installation is economically feasible for an annual requirement of at least 20-30 tonnes.

Applicable storage regulations for each country must be followed (for example, Gefahrstoffverordnung in Germany).

For the exact product classification as well as labelling please refer to the corresponding material safety data sheet.

LABELING AND TRANSPORTATION

Hydrogen peroxide solutions with concentration higher than 8% by weight as well as aqueous solutions of peracetic acid are dangerous substances, e.g. according to Global Harmonized System (GHS) and the European Regulation No. 1272/2008. They must be labeled and handled corre-

spondingly. The exact classification of the particular product depends on the concentration of hydrogen peroxide and peracetic acid. The table below represents the classification of the products in the pharmaceutical and medical industry. Please refer to our Material Safety Data Sheet for details.

Regulations for Labeling and Handling

Classification of aqueous hydrogen peroxide solutions and peracetic acid according to the European Regulation No. 1272/2008

PERACLEAN® 35 / PERACLEAN® 40				
Hazard statements	H242 H271 H290 H301 H331 H312 H314 H335 H410	Heating may cause a fire. May cause fire or explosion; strong oxidizer. May be corrosive to metals. Toxic if swallowed. Toxic if inhaled. Harmful in contact with skin. Causes severe skin burns and eye damage. May cause respiratory irritation. Very toxic to aquatic life with long lasting effects.		
Prevention statements	EUH071 P210 P261 P264 P273 P280	Corrosive to the respiratory tract. Keep away from heat/sparks/open flames/hot surfaces. No smoking. Avoid breathing dust/fume/gas/mist/vapors/spray. Wash hands thoroughly with soap and water after handling. Avoid release to the environment. Wear protective gloves and clothing; eye and face protection.		
PERACLEAN® 5 / PERACLEAN® 5 Steri				
Hazard statements	H242 H290 H302 H312 H332 H314 H335 H410	Heating may cause a fire. May be corrosive to metals. Harmful if swallowed. Harmful in contact with skin. Harmful if inhaled. Causes severe skin burns and eye damage. May cause respiratory irritation. Very toxic to aquatic life with long lasting effects.		
Prevention statements	EUH071 P210 P234 P273 P280	Corrosive to the respiratory tract. Keep away from heat/sparks/open flames/hot surfaces. No smoking. Keep only in original container. Avoid release to the environment. Wear protective gloves and clothing; eye and face protection.		
PERSYNT® 300 GMP				
Hazard statements	H302 H332 H318	Harmful if swallowed. Harmful if inhaled. Causes serious eye damage.		
Prevention statements	P264 P280	Wash hands thoroughly with soap and water after handling. Wear protective gloves and clothing; eye and face protection.		
OXTERIL® 350 SPRAY / PERSYNT® 350 LC / PERSYNT® 500 LC / PERSYNT® 350 Steri / PERSYNT® 500 Steri				
Hazard statements	H302 H332 H315 H318 H335	Harmful if swallowed. Harmful if inhaled. Causes skin irritation. Causes serious eye damage. May cause respiratory irritation.		
Prevention statements	P261 P280	Avoid breathing dust/fume/gas/mist/vapours/spray. Wear protective gloves and clothing; eye and face protection.		


Further information about hazards and classification can be found in the Material Safety Data Sheets (MSDS).



Regulations for Transport

Hydrogen peroxide




Hydrogen peroxide up to a concentration of 8% by weight is not subject to any transport regulations. For higher concentrations, the following classifications apply:

Product	OXTERIL® 350 SPRAY / PERSYNT® 300 GMP / PERSYNT® 350 LC / PERSYNT® 500 LC / PERSYNT® 350 Steri / PERSYNT® 500 Steri
Orange panel	3149
UN-No.	2014
IMDG-Code, RID/ADR	5.1, 8, 2014; PG.II
Labels	

National regulations may differ from one country to another, and are being revised continuously. Customers who want to transport hydrogen peroxide within particular national boundaries should refer to the applicable national regulations.

Peracetic acid

Due to transport regulations and depending on composition of the specific grade, our products are classified either as oxidizers belonging to hazard class 5.1 (UN 3149) or as organic peroxides belonging to class 5.2 (UN 3109, UN 3105) and classified as corrosive, oxidizing and harmful to the environment.

Product	PERACLEAN® 5 / PERACLEAN® 5 Steri	PERACLEAN® 35	PERACLEAN® 40
UN-No.	3149	3109	3105
IMDG-Code, ARD/RID	3149, 5.1, 8, PG.II	3109, 5.2	3105, 5.2
Labels			

HANDLING

As a consequence of the properties of hydrogen peroxide and peracetic acid and the safety aspects outlined in the previous chapters some basic rules for the handling of hydrogen peroxide and peracetic acid are summarized as follows:

Hydrogen peroxide and peracetic acid

Rule	Comment
Everybody working with H ₂ O ₂ and peracetic acid should be trained to do so.	It is our policy to avoid safety risks and incidents wherever possible. Therefore, all personnel should be familiar with all necessary precautions and properties of this chemical.
Use dedicated equipment only.	It is the easiest way to avoid unintended contamination and compatibility problems.
Only carefully pre-cleaned drums, tubes, pumps and other equipment should be used.	Even with dedicated equipment it is essential to make sure, that all surfaces which come into contact with H ₂ O ₂ and peracetic acid are cleaned carefully.
Avoid any contamination!	Any contamination with impurities like metal salts, dust, rust, wood, equipment or others is likely to accelerate the decomposition process.
Avoid higher pH-values!	Like contamination, a pH-value of 5 or above will increase the decomposition reaction. Any alkali products or caustic solutions have to be avoided.
Protect hydrogen peroxide and peracetic acid from heat, direct sunlight and UV radiation.	Heat, light and radiation can also slightly increase the decomposition process.
Never return H ₂ O ₂ and peracetic acid to its original container.	H ₂ O ₂ and peracetic acid taken out of its original storage container or tank should never be returned. The risk of unintended contamination of the whole storage volume is just too high.
Make sure that Personal Protective Equipment (PPE) is used and emergency showers are available nearby!	Every person involved in handling of H ₂ O ₂ and peracetic acid has to wear its PPE (goggles, gloves etc). Use respiratory protection with appropriate filter for highly concentrated peracetic acids. It is necessary to have immediate access to emergency showers and eye wash stations in case an incident occurs.
Have water hoses available in case of an emergency.	Besides water for personal safety it is always the method of choice to have plenty of water available for dilution or cooling in case of an emergency.
Never confine hydrogen peroxide and peracetic acid in drums, tanks, tubes etc.!	H ₂ O ₂ and peracetic acid always tends to develop overpressure. Therefore, it is mandatory to have pressure relief equipment installed in every part of your system.
Keep storage temperature under surveillance.	Increasing temperature is an excellent indicator for problems in a tank.
Make sure that only compatible working materials are used.	The most common compatible materials are glassware, polyethylene, polyvinylchloride, teflon, stainless steel, pure aluminum.
Avoid any contact with inflammable material and organic substances.	H ₂ O ₂ and peracetic acid are reactive agents and strong oxidizers. It is very likely that it reacts with combustible, inflammable or oxidizable materials, possibly resulting in a violent reaction.
Avoid spilling!	If a product is spilled during processing, it must be absorbed with inert material or diluted immediately with a large amount of water and washed away.
Use biocides safely!	If our peracetic acid products are used as biocides always read labels, MSDS and product information before use.

In case of doubt or question feel free to contact your Evonik representative for further help.



SAFETY ASPECTS

Safety has always been one of Evonik's main concerns. As we have clearly committed ourselves to the Responsible Care Program of the chemical industry, we strive for the highest possible level of safety within our own plants and laboratories as well as those of our customers. Nowadays, many risks are rather unlikely because a globally accepted technical standard exists. However, everybody should be aware of the risks and understand the necessity of certain precautions while working with hydrogen peroxide and peracetic acid.

Hydrogen peroxide is a clear colorless liquid, which resembles water. Therefore, spilled product or hydrogen peroxide in unlabeled containers could erroneously be regarded as water.

Hydrogen peroxide and peracetic acid are corrosive to the skin and eyes as well as to metal surfaces. They are strong oxidizing chemicals and, therefore, tend to react rapidly, sometimes even violently with various substances. Hydrogen peroxide solutions themselves are not flammable.

Highly concentrated hydrogen peroxide, however, can ignite inflammable materials, and the oxygen released by decomposition additionally promotes the combustion. Even at low concentrations, ignition can occur under unfavorable conditions after a gradual concentration of the hydrogen peroxide due to evaporation of water.

Explosive and shock-sensitive mixtures can be formed if concentrated hydrogen peroxide comes into contact with organic compounds. According to data in the literature, there is a general risk of detonations if the content of hydrogen peroxide in the resulting mixture is 25% by weight or above. In any case, appropriate safety precautions must be taken to avoid critical conditions.

Peracetic acid is a clear colorless liquid with a pungent odor and is miscible with water. It has a high oxidation potential and decomposes very exothermally when handled improperly. High strength peracetic acid is flammable and promotes combustion. Vapor from highly concentrated PAA can form explosive mixtures with air. While working with PAA proper care must always be taken. Protective goggles and gloves must be worn. A gas mask should be used with appropriate filter. The prerequisites for working safely with peracetic acid are adequate knowledge of the characteristics of the product and a clean working area.

FIRST AID

Response statements according to European Regulation No. 1272/2008

PERACLEAN® 35 / PERACLEAN® 40

P302+P352	IF ON SKIN: Wash with plenty of water/soap.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P311	If exposed or concerned: Call a POISON CENTER/doctor.

PERACLEAN® 5 / PERACLEAN® 5 Steri

P302+P352	IF ON SKIN: Wash with plenty of water/soap.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P311	If exposed or concerned: Call a POISON CENTER/doctor.

PERSYNT® 300 GMP

P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor.

OXTERIL® 350 SPRAY / PERSYNT® 350 LC / PERSYNT® 500 LC / PERSYNT® 350 Steri / PERSYNT® 500 Steri

P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P302+P352	IF ON SKIN: Wash with plenty of water/soap.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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