

According to Regulation (EC) No. 1907/2006/, n.1272/2008, n.830/2015

Revision date: 25.08.2016

1. Identification of the substance/preparation and of the company/undertaking

Product details :

1.1. Trade name

STERICOLD

1.2. Application of the substance / the preparation Filler/ Extender

Disinfectant medical device

1.3. Manufacturer/Supplier

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1.4. Information in case of emergency

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Ospedali Riuniti - Bergamo 800 883300

Ospedale Careggi - Firenze 055 7947819

Policlinico Umberto I - Roma 06 49978000

Ospedale Cardarelli - Napoli 081 74728702

2.Hazards identification

2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2015/830. Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Acute toxicity, category 4

H302 Harmful if swallowed.

Serious eye damage, category 1

H318 Causes serious eye damage.

2.2. Label elements

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:

Signal words:

Danger

Hazard statements:

H302 Harmful if swallowed.

H318 Causes serious eye damage.

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P264 Wash with water thoroughly after handling.
P280 Wear eye protection / face protection.
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 / . . .

Contains:

Sodium percarbonate

Anionic surfactants

tetrasodium (1-hydroxyethylidene) bisphosphonate

Ingredients according to Regulation (EC) No. 648/2004

Less than 5% : phosphonates, non-ionic surfactants, phosphonates, non-ionic surfactants

5% or over but less than 15% : phosphates, anionic surfactants, phosphates, anionic surfactants

enzymes, enzymes

2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

3. Composition/information on ingredients

3.1. Description/CAS No./Dangerous components

Information not relevant

3.2. Mixture

Identification	Conc. %	Classification
Sodium percarbonate CAS 15630-89-4 EC 239-707-6 INDEX - Reg. no. 01-2119457268-30	$40 \leq x < 44,65$	Ox. Sol. 3 H272, Acute Tox. 4 H302, Eye Dam. 1 H318
Anionic surfactants CAS - EC 932-051-8 INDEX - Reg. no. 01-2119565112-48-0000	$5 \leq x < 7,5$	Eye Dam. 1 H318, Skin Irrit. 2 H315, Aquatic Chronic 3 H412
Tetrasodium (1-hydroxyethylidene) bisphosphonate CAS 3794-83-0 EC 223-267-7 INDEX - Reg. no. 2119510382-52-000	$1 \leq x < 3$	Acute Tox. 4 H302, Eye Irrit. 2 H319

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4.First aid measures

4.1. Description of first aid measures

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.

SKIN: Remove contaminated clothing. Rinse skin with a shower immediately. Wash contaminated clothing before using it again.

INHALATION: Remove to open air. If the subject stops breathing, administer artificial respiration.

Get medical advice/attention immediately.

INGESTION: Get medical advice/attention immediately. Do not induce vomiting. Do not administer anything not explicitly authorised by a doctor.

4.2. Most important symptoms and effects, both acute and delayed

Specific information on symptoms and effects caused by the product are unknown.

4.3. Indication of any immediate medical attention and special treatment needed

Information not available

5. Fire-fighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT

Extinguishing substances are: carbon dioxide and chemical powder.

For product loss or leakage that has not caught fire, water spray can be used to disperse flammable vapours and protect those trying to stem the leak.

UNSUITABLE EXTINGUISHING EQUIPMENT

Do not use jets of water.

Water is not effective for putting out fires but can be used to cool containers exposed to flames to prevent explosions.

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

If large quantities of the product are involved in a fire, they can make it considerably worse. Do not breathe combustion products.

5.3. Advice for firefighters

GENERAL INFORMATION

In the case of fire, use jets of water to cool the containers to prevent the risk of explosions (product decomposition and excess pressure) and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Remove all containers containing the product from the fire, if it is safe to do so.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

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6.Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

If there are no contraindications, spray powder with water to prevent the formation of dust. Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up

Collect the leaked product and place it in containers for recovery or disposal. If the product is flammable, use explosion-proof equipment. If there are no contraindications, use jets of water to eliminate product residues. Make sure the leakage site is well aired. Evaluate the compatibility of the container to be used, by checking section 10. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

7.Handling and storage

7.1. Information for safe handling

Ensure that there is an adequate earthing system for the equipment and personnel. Avoid contact with eyes and skin. Do not breathe powders, vapours or mists. Do not eat, drink or smoke during use. Wash hands after use. Avoid leakage of the product into the environment.

7.2. Conditions for safe storage, including any incompatibilities

Store only in the original container. Store in a ventilated and dry place, far away from sources of ignition. Keep containers well sealed. Keep the product in clearly labelled containers. Avoid overheating. Avoid violent blows. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s)

Information not available

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8. Exposure controls and personal protection

8.1. Control parameters

Regulatory References:

Sodium percarbonate								
Threshold Limit Value								
Type	Country	TWA/8h		STEL/15min				
		mg/m ³	ppm	mg/m ³	ppm			
TLV-ACGIH		10				INHAL		
TLV-ACGIH		3				RESP		
Predicted no-effect concentration - PNEC								
Normal value in fresh water				0,035		mg/l		
Normal value in marine water				0,035		mg/l		
Health - Derived no-effect level - DNEL / DMEL								
	Effects on consumers				Effects on workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Chronic local	Acute local	Acute systemic	Chronic systemic
Inhalation							5 mg/m ³	VND
Skin	6,4 mg/cm ²	VND	6,4 mg/cm ²	VND	12,8 mg/cm ²	VND	12,8 mg/cm ²	VND
Anionic surfactants								
Predicted no-effect concentration - PNEC								
Normal value in fresh water				0,268		mg/l		
Normal value in marine water				0,0268		mg/l		
Normal value for fresh water sediment				8,1		mg/kg		
Normal value for marine water sediment				8,1		mg/kg		
Normal value of STP microorganisms				5,6		mg/l		
Normal value for the terrestrial compartment				35		mg/kg		
Health - Derived no-effect level - DNEL / DMEL								
	Effects on consumers				Effects on workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Chronic local	Acute local	Acute systemic	Chronic systemic
Oral			VND	0,425 mg/kg				
Inhalation			VND	1,5 mg/m ³			VND	6 mg/m ³
Skin			VND	42,5 mg/kg			VND	85 mg/kg
tetrasodium (1-hydroxyethylidene) bisphosphonate								
Predicted no-effect concentration - PNEC								
Normal value in fresh water				0,136		mg/l		
Normal value in marine water				0,0136		mg/l		
Normal value of STP microorganisms				20		mg/l		
Health - Derived no-effect level - DNEL / DMEL								
	Effects on consumers				Effects on workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Chronic local	Acute local	Acute systemic	Chronic systemic
Oral			VND	6,5 mg/kg			VND	13 mg/kg

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ;

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THORA = Thoracic Fraction.

VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified.

During the risk assessment process, it is essential to take into consideration the ACGIH occupational exposure levels for inert particulate not otherwise classified (PNOC respirable fraction: 3 mg/m³; PNOC inhalable fraction: 10 mg/m³). For values above these limits, use a P type filter, whose class (1, 2 or 3) must be chosen according to the outcome of risk assessment.

8.2. Exposure controls

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration. When choosing personal protective equipment, ask your chemical substance supplier for advice. Personal protective equipment must be CE marked, showing that it complies with applicable standards. Provide an emergency shower with face and eye wash station.

HAND PROTECTION

In the case of prolonged contact with the product, protect the hands with penetration-resistant work gloves (see standard EN 374). Work glove material must be chosen according to the use process and the products that may form. Latex gloves may cause sensitivity reactions.

SKIN PROTECTION

Wear category I professional long-sleeved overalls and safety footwear (see Directive 89/686/EEC and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION

Wear a hood visor or protective visor combined with airtight goggles (see standard EN 166). In the presence of risks of exposure to splashes or squirts during work, adequate mouth, nose and eye protection should be used to prevent accidental absorption.

RESPIRATORY PROTECTION

Use a type P filtering facemask, whose class (1, 2 or 3) and effective need, must be defined according to the outcome of risk assessment (see standard EN 149).

ENVIRONMENTAL EXPOSURE CONTROLS

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

9. Physical and chemical properties

9.1. General Information

Appearance powder

Colour Not available

Odour typical

Odour threshold Not available

pH (sol 20 g/l): 8,5±0,3

Melting point / freezing point Not available

Initial boiling point Not available

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Boiling range Not available
Flash point Not available
Evaporation rate Not available
Flammability (solid, gas) Not available
Lower inflammability limit Not available
Upper inflammability limit Not available
Lower explosive limit Not available
Upper explosive limit Not available
Vapour pressure Not available
Vapour density Not available
Relative density +/- 0,05
Solubility soluble in water
Partition coefficient: n-octanol/water Not available
Auto-ignition temperature Not available
Decomposition temperature Not available
Viscosity Not available
Explosive properties Not available
Oxidising properties Not available

9.2. Further informations
Information not available

10. Thermal decomposition / conditions to be avoided

Do not mix with other products.

10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

The powders are potentially explosive when mixed with air.

10.4. Conditions to avoid

Avoid environmental dust build-up.

10.5. Incompatible materials

Information not available

10.6. Hazardous decomposition products

Information not available

11. Toxicological information

11.1. Acute toxicity

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In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification. It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

11.1. Information on toxicological effects

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

LC50 (Inhalation) of the mixture: Not classified (no significant component)

LD50 (Oral) of the mixture: 1786 mg/kg

LD50 (Dermal) of the mixture: Not classified (no significant component)

Sodium percarbonate

LD50 (Oral) 893 mg/kg rat female

LD50 (Dermal) > 2000 mg/kg rabbit

LC50 (Inhalation) 700 mg/m³ rat

tetrasodium (1-hydroxyethylidene) bisphosphonate

LD50 (Oral) 940 mg/kg rat

LD50 (Dermal) > 2000 mg/kg rabbit

Tetraacetylenediamine

LD50 (Oral) > 2000 mg/kg rat

LD50 (Dermal) > 2000 mg/kg rat

LC50 (Inhalation) > 2,08 mg/l rat

Anionic surfactants

LD50 (Oral) 2000 mg/kg rat

LD50 (Dermal) > 2000 mg/kg

POTASSIUM ACID PHOSPHATE

LD50 (Oral) 1700 mg/kg Mouse

LD50 (Dermal) > 4640 mg/kg Rabbit

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

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SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye damage

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

12. Ecological information

No specific data are available for this product. Handle it according to good working practices. Avoid littering. Do not contaminate soil and waterways. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation. Please take all the proper measures to reduce harmful effects on aquifers.

12.1. Toxicity

Sodium percarbonate

LC50 - for Fish 70,7 mg/l/96h Pimephales promelas

EC50 - for Crustacea 4,9 mg/l/48h Daphnia pulex

EC50 - for Algae / Aquatic Plants 8 mg/l/72h Alga anabaena

Chronic NOEC for Fish 7,4 mg/l Pimephales promelas

Chronic NOEC for Crustacea 2 mg/l Daphnia pulex

tetrasodium (1-hydroxyethylidene) bisphosphonate

LC50 - for Fish > 200 mg/l/96h Poecilia reticulata

EC50 - for Crustacea > 370 mg/l/48h Daphnia magna

Tetraacetylenediamine

LC50 - for Fish > 500 mg/l/96h Zebra fish

EC50 - for Crustacea > 1000 mg/l/48h Daphnia magna

EC50 - for Algae / Aquatic Plants > 1000 mg/l/72h Desmodesmus subspicatus

Anionic surfactants

LC50 - for Fish > 1 mg/l/96h Cyprinus carpio

EC50 - for Crustacea > 1 mg/l/48h Daphnia magna

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Chronic NOEC for Fish > 0,1 mg/l Oncorhynchus mykiss

12.2. Persistence and degradability

Degradability

Sodium percarbonate : information not available

tetrasodium (1-hydroxyethylidene) bisphosphonate : Entirely degradable

Tetraacetylenediamine : Rapidly degradable

Anionic surfactants : Rapidly degradable

potassium acid phosphate : Solubility in water > 10000 mg/l Degradability: information not available

12.3. Bioaccumulative potential

Information not available

12.4. Mobility in soil

Information not available

12.5. Results of PBT and vPvB assessment

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

12.6. Other adverse effects

Information not available

13. Disposal considerations

13.1. Waste treatment methods

Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations. Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

The exhausted solutions must be disposed of in accordance with local regulation. The spent solutions as the wastewater can be conveyed in authorized sewage network in accordance with legal standards.

14. Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

15.Regulations

15.1.Labelling according to EU guidelines

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Seveso Category - Directive 2012/18/EC: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006 :

None

Substances in Candidate List (Art. 59 REACH):

On the basis of available data, the product does not contain any SVHC in percentage greater than 0,1%.

Substances subject to authorisation (Annex XIV REACH) :

None

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Healthcare controls :

Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

Regulation (EC) No. 648/2004:

Ingredients according to Regulation (EC) No. 648/2004

EU regulation on the classification of substances hazardous to water (VwVwS 2005)

WGK 1: Low hazard to waters

15.2. Chemical safety assessment

No chemical safety assessment has been processed for the mixture and the substances it contains.

16. Other information

Note for users: The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product. This document must not be regarded as a guarantee on any specific product property. The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses. Provide appointed staff with adequate training on how to use chemical products.

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Ox. Sol. 3 Oxidising solid, category 3

Acute Tox. 4 Acute toxicity, category 4

Eye Dam. 1 Serious eye damage, category 1

Eye Irrit. 2 Eye irritation, category 2

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Skin Irrit. 2 Skin irritation, category 2

Aquatic Chronic 3 Hazardous to the aquatic environment, chronic toxicity, category 3

H272 May intensify fire; oxidiser.

H302 Harmful if swallowed.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H315 Causes skin irritation.

H412 Harmful to aquatic life with long lasting effects.

GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
 2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
 3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
 4. Regulation (EU) 2015/830 of the European Parliament
 5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
 6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
 7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
 8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
 9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
 10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
 11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
 12. Regulation (EU) 2016/1179 (IX Atp. CLP)
 13. Regulation (EU) 2017/776 (X Atp. CLP)
- The Merck Index. - 10th Edition
 - Handling Chemical Safety
 - INRS - Fiche Toxicologique (toxicological sheet)
 - Patty - Industrial Hygiene and Toxicology
 - N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
 - IFA GESTIS website
 - ECHA website
 - Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy