



Cantel Medical (Italy) S.R.L.
Industria Chimico-Farmaceutica
Via Laurentina 169
00071 POMEZIA (RM)

ISACLEAN®

MEDICAL DEVICE class IIb
IDENTIF. CODE ISAC/CE/44

1st Edition

Revision n. 5

Revision date: 09.02.2017

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Safety Data Sheet

SECTION 1. Identification of the Substance/Mixture and of the Company/Firm

1.1. Product Identifier

Name **ISACLEAN®**
Chemical name and synonyms

1.2. Relevant identified uses of the substance or mixture and uses advised against

Description/Use Isazone® solution (CAS 19066-35-4) with non-ionic and cationic surfactants.
Classification Medical Device Class IIb Directive 93/42/EEC, as amended
Decontamination solution and detergent for invasive and non-invasive medical devices and for electro-medical equipment. Professional use only.

Uses advised against None in particular.

1.3. Details of the Supplier on the Safety Data Sheet

Company Name Cantel Medical (Italy) S.R.L.
Address Via Laurentina, n. 169
Town and Country 00071 Pomezia (RM)
ITALY
telephone +39.06/9145399
E-mail: info@cantelmedical.it

email address of the person responsible,
person responsible for the safety data sheet Technical Director/Qualified Person (QP): direzionetecnica@cantelmedical.it

1.4. Emergency telephone number

Telephone numbers of the main poison centers in Italy (open 24 hours a day):

Poison Centre Niguarda Ca' Granda 02.66101029 (CAV A.O.Niguarda – Milan)

For urgent inquiries refer to Emergency telephone number of the company (24/24 hours):
tel. +39.06/9145399 (*Technical Support*)

SECTION 2. Hazards Identification.

2.1. Classification of the Substance or Mixture

The product is classified as a dangerous substance pursuant to the provisions laid within in Regulation (EC) 1272/2008 (CLP) (and subsequent amendments). The product requires therefore a safety data sheet in accordance with the provisions of Regulation (EC) 1907/2006 and subsequent amendments.

Any additional information concerning risks to health and/or environment are stated in sections 11 and 12 of this sheet.

2.1.1 Regulation 1272/2008 (CLP) and subsequent amendments.

Classification and hazard statements:

Flam. Liq. 3	H226
Acute Tox. 4	H302
Eye Dam. 1	H318
Skin Irrit. 2	H315
Aquatic Acute 3	H412

2.1.2. Directives 67/548/EEC and 1999/45/CE and subsequent amendments.

Hazard symbols: Xi

R-Phrases: 10-41

The full texts for risk phrases (R) and indications of danger (H) are specified in section 16 of this sheet.

2.2. Label elements.

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



Warnings:

Danger

H226 Flammable liquid and vapours.
H302 Harmful if swallowed.
H318 Causes serious eye injuries.
H315 Causes skin irritation.
H412 Harmful to aquatic organisms with long-term effects.
EUH208 Contains: SUBTILISIN May cause an allergic reaction.

P210 Keep away from heat sources, hot surfaces, sparks, open flames or other ignition sources. Do not smoke.
P280 Wear protective gloves / clothing / protect your eyes / face.
P305+P351+P338 IF IN EYES: rinse continuously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
P310 Immediately contact a POISON CENTRE.
P501 Dispose of the product/container in conformity with local/national/international legislation

Contains: DIDECYLDIMETHYLAMMONIUM CHLORIDE
POLY(OXY-1,2-ETHANEDIYL), .ALPHA.-TRIDECYL-.OMEGA.-HIDROXY-,BRANCHED /

2.3. Other Hazards.

Information not available.

SECTION 3. Composition/Information on Ingredients**3.1. Substances.**

Information not relevant.

3.2. Mixtures.



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Contains:

Identification.	Conc. %.	67/548/EEC Classification.	1272/2008 (CLP) Classification.
POLY(OXY-1,2-ETHANEDIYL), .ALPHA.-TRIDECYL-.OMEGA.-HIDROXY-,BRANCHED / CAS. - CE. - INDEX. - Reg. No.	18 - 19.5	Xn R22, Xi R41	Acute Tox. 4 H302, Eye Dam. 1 H318
ISOPROPANOL CAS. 67-63-0 CE. 200-661-7 INDEX. 603-117-00-0 Reg. No. -	6 - 7	R67, F R11, Xi R36	Flam. Liq. 2 H225, Eye Irrit. 2 H319, STOT SE 3 H336
DIDECYLDIMETHYLAMMONIUM CHLORIDE CAS. 7173-51-5 CE. 230-525-2 INDEX. 612-131-00-6 Reg. No. -	3.5 - 4	C R34, Xn R22, N R50	Acute Tox. 3 H301, Skin Corr. 1B H314, Aquatic Acute 1 H400 M=10
ETHANE-1,2-DIOL CAS. 107-21-1 CE. 203-473-3 INDEX. 603-027-00-1 Reg. No. 01-2119456816-28-XXXX	1 - 1.5	Xn R22	Acute Tox. 4 H302, STOT RE 2 H373
PENTASODIUM DIETHYLENETRIAMINEPENTAACETATE CAS. 140-01-2 CE. 205-391-3 INDEX. - Reg. No. 01-2119474445-33	0.3 - 0.4	Repr. Cat. 3 R63, Xn R20, Xi R36	Repr. 2 H361d, Acute Tox. 4 H332, Eye Irrit. 2 H319
SUBTILISIN CAS. 9014-01-1 CE. 232-752-2 INDEX. 647-012-00-8 Reg. No. 01-2119480434-38	0.1 - 0.2	Xn R22, Xn R42, Xi R37/38, Xi R41, N R50	Acute Tox. 4 H302, Eye Dam. 1 H318, Skin Irrit. 2 H315, STOT SE 3 H335, Resp. Sens. 1 H334, Aquatic Acute 1 H400 M=1

Note: Value exceeding the excluded range.

The full texts for risk phrases (R) and indications of danger (H) are specified in section 16 of this sheet.

T+ = Very Toxic(T+), T = Toxic(T), Xn = Harmful(Xn), C = Corrosive(C), Xi = Irritating(Xi), O = Oxidizing(O), E = Explosive(E), F+ = Extremely flammable(F+), F = Highly Flammable(F), N = Dangerous to the environment(N)

SECTION 4. First Aid Measures.



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4.1. Description of First Aid Measures.

EYES: Remove any contact lenses. Wash immediately and thoroughly with water for at least 30/60 minutes, with eyes wide open. Consult a physician immediately.

SKIN: Take off contaminated clothing. Take a shower immediately. Consult a physician immediately.

INGESTION: Drink water as much as possible. Consult a physician immediately. Do not induce vomiting unless expressly recommended by the physician.

INHALATION Seek medical advice immediately. Bring the subject outdoors, away from the place of the accident. If breathing stops, provide artificial respiration. Take adequate precautions for the first aider.

PROTECTION MEASURES FOR THE FIRST AIDERS: for the PPE needed for first aid refer to section 8.2 of this safety data sheet.

4.2. Most Important Symptoms and Effects, both Acute and Delayed.

For the symptoms and effects due to the substances contained in it, see chap. 11.

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

Information not available.

SECTION 5. Fire-Fighting Measures.

5.1. Extinguishing Media.

SUITABLE EXTINGUISHING MEDIA

Extinguishing media are carbon dioxide, foam, chemical powder. For product leaks and spills that did not cause a fire, water spray can be used to disperse the flammable vapours and protect the people involved in stopping the leakage.

UNSUITABLE EXTINGUISHING MEDIA

Do not use water jets. Water is not effective to extinguish the fire but can be used to cool close containers exposed to flames, thus preventing fires and explosions.

5.2. Special Hazards Arising from the Substance or Mixture.

DANGERS FROM EXPOSURE IN CASE OF FIRE

Excess pressure may form in containers exposed to fire with explosion hazard. Avoid breathing the combustion products.

5.3. Advice for Fire-fighters.

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear personal protection devices including fire equipment. Collect contaminated fire fighting water separately, it must not be discharged into the drains. Dispose of the contaminated water used for fire fighting and the residue of the fire according to the rules in force.

EQUIPMENT

Normal equipment for fire fighting such as self-contained breathing apparatus (EN 137), flame retardant turnout gear (EN469), flame-retardant gloves (EN 659) and boots for firemen (HO A29 or A30).

SECTION 6. Measures in Case of Accidental Release.

6.1. Personal Precautions, Protective Equipment and Procedures in Case of Emergency.

Stop leak if without risk. Wear appropriate protective devices (including the personal protective equipment referred to in section 8 of the safety data sheet) in order to prevent contamination of the skin, eyes and personal clothing. These guidelines apply to staff who work under both standard and emergency conditions.



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6.2. Environmental Precautions.

Prevent the product from entering sewers, surface waters, and groundwater.

6.3. Methods And Material For Containment And Remediation.

Suck up the spilled product into an appropriate container. Assess the compatibility of the container to use with the product, checking section 10. Absorb the remaining product with inert absorbent.

Ensure adequate ventilation of the area affected by the loss. Check any incompatibility for the material of the containers in section 7. Disposal of contaminated material must be carried out in accordance with the provisions of section 13.

6.4. References to Other Sections

Any information relating to personal protective equipment and disposal are given in sections 8 and 13.

SECTION 7. Handling And Storage.

7.1. Precautions for Safe Handling

Keep away from heat, sparks and flames, do not smoke or use matches or lighters. The vapours can be ignited with an explosion, so you must avoid accumulation holding open doors and windows and ensuring a cross ventilation. Without proper ventilation, the fumes can accumulate on the ground and ignite even from a distance, if ignited, with danger of backfiring. Avoid the accumulation of electrostatic charges. Connect to a grounded socket in the case of large packaging during the decanting process and wear anti-static shoes. The strong shaking and vigorous flow of liquid in the pipes and equipment may cause formation and accumulation of electrostatic charges. To avoid the danger of fire and explosion, never use compressed air in the movement. Open the containers with caution, because they may be pressurized. Do not eat, drink or smoke during use. Avoid release to the environment.

7.2. Conditions for Safe Storage, Including any Incompatibilities.

Keep only in original container. Keep the containers closed, in a well ventilated place, sheltered from direct sunlight. Store in a cool, well-ventilated area away from heat sources, open flames, sparks and other sources of ignition. Store containers away from any incompatible materials, refer to section 10.

7.3. Specific end uses.

No use other than those indicated in section 1.2 of this safety data sheet.

SECTION 8. Exposure controls/personal protection.

8.1. Control Parameters.

Reference Standards:

Italy	Legislative Decree April 9, 2008, n.81.
Switzerland	Valeurs limites d'exposition aux postes de travail 2012.
OEL EU	Directive 2009/161/UE; Directive 2006/15/CE; Directive 2004/37/CE; Directive 2000/39/CE.
TLV-ACGIH	ACGIH 2012



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ISOPROPANOL

Threshold value.

Type	Status	TWA/8h	STEL/15min
		mg/m3	ppm
		mg/m3	ppm
TLV-ACGIH		492	200
		983	400

ETHANE-1,2-DIOL

Threshold value.

Type	Status	TWA/8h	STEL/15min	
		mg/m3	ppm	
		mg/m3	ppm	
TLV	I	52	20	104
OEI	EU	52	20	104
TLV-ACGIH				100 (C)
				40
				SKIN
				SKIN

PENTASODIUM DIETHYLENETRIAMINEPENTAACETATE

Concentration with no predicted effect on the environment - PNEC.

Reference value for ground compartment	0.853	mg/kg
Reference value in fresh water.	6.4	mg/l
Reference value for water, discontinuous release	3.1	mg/l
Reference value in seawater	0.64	mg/l
Reference value for sediments in fresh water	23	mg/kg
Reference value for sediments in seawater	2.3	mg/kg
Reference value for STP microorganisms	51	mg/l

Health - Derived no-effect level - DNEL / DMEL

Route of Exposure	Effects on consumers.	Acute systemic	Chronic local	Chronic systemic	Effects on workers	Acute systemic	Chronic local	Chronic systemic
	Acute local				Acute local			
Inhalation.					2.5 mg/m3	2.5 mg/m3	2.5 mg/m3	2.5 mg/m3
Dermal absorption.							VND	11718 mg/kg/day

SUBTILISIN

Threshold value.

Type	Status	TWA/8h	STEL/15min
		mg/m3	ppm
		mg/m3	ppm
TLV-ACGIH			0.00006 (C)

Concentration with no predicted effect on the environment - PNEC.

Reference value for ground compartment	0.568	mg/kg
Reference value in fresh water.	0.06	microg/l
Reference value for water, discontinuous release	0.009	microg/l
Reference value in seawater	0.006	microg/l
Reference value for sediments in fresh water	NEA	
Reference value for sediments in seawater	NEA	
Reference value for STP microorganisms	65000	microg/l

Health - Derived no-effect level - DNEL / DMEL

Route of Exposure	Effects on consumers.	Acute systemic	Chronic local	Chronic systemic	Effects on workers	Acute systemic	Chronic local	Chronic systemic
	Acute local				Acute local			
Inhalation.							60 ng/m3	60 ng/m3
Dermal absorption.					0.2 mg/kg	VND		

SODIUM HYDROXIDE



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Threshold value.

Type	Status	TWA/8h mg/m3	ppm	STEL/15min mg/m3	ppm
TLV-ACGIH				2 (C)	

Health - Derived no-effect level - DNEL / DMEL

Route of Exposure	Effects on consumers. Acute local	Acute systemic	Chronic local	Chronic systemic	Effects on workers Acute local	Acute systemic	Chronic local	Chronic systemic
Inhalation.							1 mg/m3	VND

Legend:

(C) = CEILING ; INALAB = Inhalable fraction ; RESPIR = Respirable fraction ; TORAC = Thoracic fraction.
VND = danger identified but no DNEL/PNEC available ; NEA = negative exposure assessment ; NPI = no danger identified.

8.2. Exposure controls.

Considered that the use of appropriate technical measures should always prevail over personal protective devices, ensure good ventilation in the workplace using an effective local exhaust system.
The personal protective equipment should bear the CE marking to certify their compliance with applicable standards.
Provide emergency shower and eye wash facilities.

HAND PROTECTION

Protect your hands with gloves of category III (ref. standard EN 374).

Final selection of glove material must be made taking into account these factors: compatibility, degradation, permeation and time to failure.

In the case of preparations the resistance to chemical agents of gloves material should be tested before use, since unpredictable. The gloves have a wear time that depends on the duration and the mode of use.

SKIN PROTECTION

Wear long-sleeved overalls and safety footwear for professional use, Category II (ref. Directive 89/686/EEC and standard EN ISO 20344). Wash with soap and water after removing protective clothing.

Assess the opportunity to provide antistatic clothing if the work area may present a risk of explosion.

EYE PROTECTION

It is recommended to wear a faceshield with helmet or faceshield with goggles (REF. EN 166).

If there is a risk of exposure to splashes or squirts during work performed, adequate protection of the mucous membranes (mouth, nose, eyes) must be provided in order to prevent accidental absorption.

RESPIRATORY PROTECTION

If the threshold value (e.g. TLV-TWA) of the substance or of one or more of the substances present in the product is exceeded, it is recommended to wear a mask with filter type A, class 1, 2 or 3, to be chosen in relation to the concentration limit of use. (ref. standard EN 14387). In the presence of gases or vapours of a different nature and/or gas or vapours with particles (aerosols, fumes, mists, etc.) you should provide combined filters.

The use of respiratory protection is necessary if technical measures taken are not sufficient to limit the exposure of the worker to the threshold values taken into consideration. The protection provided by masks is in any case limited.

In the case where the substance in question is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in case of emergency, wear a self-contained breathing apparatus (ref. EN 137) or a respiratory device with external air intake (ref. standard EN 138). To choose the respiratory protection device correctly, refer to the standard EN 529.

ENVIRONMENTAL EXPOSURE CONTROLS.

Emissions from manufacturing processes, including those from ventilation equipment, should be controlled for the purposes of compliance with the rules and regulations on environmental protection.

The product residues should not be disposed of uncontrollably in waste water or water courses.

SECTION 9. Physical And Chemical Properties.



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9.1. Information on Basic Physical and Chemical Properties.

Physical State	clear liquid
Colour	blue
Odour	pungent
Olfactory threshold.	Not available.
pH	7.5 +-1.0
Melting o Freezing Point.	Not available.
Initial boiling point.	> 100 °C.
Boiling point.	Not available.
Flash Point.	38 °C.
Evaporation rate	Not available.
Flammability of solids and gases	Not available.
Lower Flammability Limit.	Not available.
Upper Flammability Limit.	Not available.
Lower Explosive Limit.	Not available.
Upper Explosive Limit.	Not available.
Vapor pressure.	Not available.
Vapour Density.	Not available.
Relative density.	1.0 ± 0.2 Kg/l
Solubility	soluble in water at 25°C
Partition coefficient: n-octanol/water:	Not available.
Ignition Temperature.	Not available.
Decomposition Temperature.	Not available.
Viscosity	Not available.
Explosive properties	Product not explosive considering its composition
Oxidizing properties	Product not oxidizing given its composition

9.2. Other Information.

VOC (Directive 1999/13/CE) :	7,40 % - 74,00 g/litre.
VOC (volatile carbon):	3,59 % - 35,94 g/litre.

SECTION 10. Stability and Reactivity.

10.1. Reactivity.

Under normal conditions of use there are no particular risk of reaction with other substances.

10.2. Chemical Stability.

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

10.3. Possibility of Hazardous Reactions.

None under normal and intended conditions of use. No polymerization reactions.

10.4. Conditions to Avoid.

Avoid overheating. Avoid the accumulation of electrostatic charges. Avoid any ignition source.

10.5. Incompatible Materials.

If used according to the indications, the Medical Device is compatible with regular components of the devices to be treated.

10.6. Hazardous Decomposition Products.

As a result of thermal decomposition, or in case of fire, gases and vapours dangerous to health can be released.

SECTION 11. Toxicological Information.

In the absence of the toxicological data on the experimental product itself, the possible hazards to health related to the product have been evaluated based on the properties of the substances contained, according to the criteria provided by the legislation of reference on the classification of hazardous substances. Consider therefore the concentration of the single hazardous substances eventually mentioned in sect. 3, to assess the toxicological effects arising from exposure to the product.

Acute effects: the product is harmful if swallowed and even the smallest amount ingested can cause significant disturbance to health (abdominal pain, nausea, vomiting, diarrhea).

The product will cause serious eye injury and may cause opacity of the cornea, iris lesion, irreversible coloration of the eye.

Acute effects: contact with skin may cause irritation, erythema, oedema, dryness and cracking skin. Inhalation of vapours may cause moderate irritation of the upper respiratory tract. Ingestion may cause health problems, including stomach pain and heartburn, nausea and vomiting.

11.1. Information on Toxicological Effects.

Data referring to the mixture:

ACUTE INHALATION TOXICITY: Data not available.

ACUTE ORAL TOXICITY: Harmful if swallowed due to its composition specified in section 3.2 .

ACUTE DERMAL TOXICITY: Data not available.

SKIN CORROSION/ IRRITATION: irritating to the skin due to its composition specified in section 3.2.

SEVERE EYE LESIONS/SEVERE EYE IRRITATIONS: it causes serious eye lesions due to its composition specified in section 3.2.

IRRITATION OF THE RESPIRATORY TRACT: Data not available.

RESPIRATORY OR SKIN SENSITISATION: it may trigger an allergic reaction due to SUBTILISIN (see section 3.2)

CARCINOGENICITY: Data not available.

MUTAGENICITY OF GERM CELLS: Data not available.

REPRODUCTIVE TOXICITY: Data not available.

SPECIFIC TOXICITY TO TARGET ORGANS (STOT)- SINGLE EXPOSURE: Data not available.

SPECIFIC TOXICITY TO TARGET ORGANS (STOT)- REPEATED EXPOSURE: Data not available.

DANGER IN THE CASE OF SUCTION: Data not available.

Data referred to the hazardous substances in the mixture:

ETHANE-1,2-DIOL

LD50 (Oral): 7712 mg/kg Rat (Source:site of dissemination ECHA). Harmful if swallowed as per Annex VI of Reg. 1272/2008 CLP.

ISOPROPANOL

SEVERE DAMAGE TO THE EYE/EYE IRRITATION: irritating, in vivo test on rabbit, OECD T 405;

SPECIFIC TOXICITY TO TARGET ORGANS (STOT)- SINGLE EXPOSURE: data not available;

SPECIFIC TOXICITY TO TARGET ORGANS (STOT)- REPEATED EXPOSURE: NOEC: 5000 ppm, rat, OECD TG 413.

DIDECYLDIMETHYLAMMONIUM CHLORIDE

LD50 (Oral). 238 mg/kg Rat (Method: OECD TG 401)

SKIN CORROSION/ IRRITATION: corrosive, in vivo test on rabbit (Method: OECD TG 404).

SUBTILISIN

ACUTE TOXICITY

LD50 (Oral). 1800 mg/kg Rat (Method: OECD TG 401)

SKIN CORROSION/ IRRITATION: slightly irritating to the skin, in vivo test on rabbit (Method: OECD TG 404)

SEVERE DAMAGE TO THE EYE/EYE IRRITATION: slightly irritating, in vivo test on rabbit (Method: OECD TG 405)

RESPIRATORY OR SKIN SENSITISATION: it may trigger allergic or asthmatic symptoms or difficulties in breathing if inhaled as per Annex VI of Reg. 1272/2008 CLP.

SPECIFIC TOXICITY TO TARGET ORGANS (STOT)- SINGLE EXPOSURE: it may irritate the respiratory tract as per Annex VI of Reg. 1272/2008 CLP.



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POLY(OXY-1,2-ETHANEDIYL), .ALPHA.-TRIDECYL-.OMEGA.-HIDROXY-,BRANCHED

ACUTE TOXICITY

LD50 (Oral). 500 mg/kg Rat (Method: OECD TG 423)

SKIN CORROSION/ IRRITATION: non irritating to the skin, in vivo test on rabbit (Method OECD TG 404)

SEVERE DAMAGE TO THE EYE/EYE IRRITATION: irritating, in vivo test on rabbit, (Method OECD TG 405).

SECTION 12. Ecological Information.

The product is to be regarded as dangerous for the environment and highly toxic to aquatic organisms.

12.1. Toxicity.

DIDECYLDIMETHYLAMMONIUM CHLORIDE

LC50 - Fish.

0.19 mg/l/96h Pimephales promelas (Method: US-EPA)

EC50 - Shellfish.

0.062 mg/l/48h Daphnia Magna (Method: EPA-FIFRA)

EC50 - Algae / Aquatic plants.

0.026 mg/l/96h Pseudokirchneriella subcapitata (Information available in the SDS of the supplier)

Chronic NOEC fish.

0.032 mg/l/34 d Danio Rerio (Method: OECD TG 210)

NOEC Chronic shellfish.

0.01 mg/l/21 d Daphnia Magna (Reproductive test, method: OECD TG 211)

Chronic toxicity shellfish.

NOEC = 530 mg/l

Species = Chironomus sp.

Exposure time: 28 d

Method: OECD TG 218

Toxicity to bacteria:

CE50 = 11 mg/l

Species: active fungi

Respiration inhibitor

Exposure time: 3 h

Method: OECD TG 209

Toxicity for terrestrial organisms:

NOEC >= 1000 mg/kg

Species: eisenia fetida

Exposure time: 14 d

Method: OECD TG 207

Toxicity for terrestrial plants:

CE50 = 283 -1670 mg/kg

Exposure time: 14 d

Method: OECD TG 208.

POLY(OXY-1,2-ETHANEDIYL), .ALPHA.-TRIDECYL-.OMEGA.-HIDROXY-,BRANCHED /

LC50 - Fish.

> 1 mg/l/96h Leuciscus Idus (Information available in the SDS of the supplier)

EC50 - Shellfish.

> 1 mg/l/48h Information available in the SDS of the supplier

EC50 - Algae / Aquatic plants.

> 1 mg/l/72h Information available in the SDS of the supplier

Microorganisms/Effects on active fungi:

CE10 (17 h) > 10.000 mg/l (DIN 38412 part 8).



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ETHANE-1,2-DIOL

LC50 - Fish.

72860 mg/l/96h Pimephales promelas (Source: published on the site of dissemination of the ECHA)

EC50 - Shellfish.

> 100 mg/l/48h Daphnia magna (Method: OECD Guideline 202)

ISOPROPANOL

LC50 - Fish.

9640 mg/l/96h Pimephales promelas (Equivalent method or similar to OECD TG 203)

EC50 - Shellfish.

> 10000 mg/l/48h (24h) Daphnia magna (Equivalent method or similar to OECD TG 202)

EC50 - Algae / Aquatic plants.

1800 mg/l/72h (7d) Scenedesmus quadricauda (Published on ECHA website, no reference guidelines)

SUBTILISIN

LC50 - Fish.

8.2 mg/l/96h Oncorhynchus mykiss (Method: OECD TG 203)

EC50 - Shellfish.

0.306 mg/l/48h Daphnia Magna (Method: OECD TG 202)

EC50 - Algae / Aquatic plants.

0.83 mg/l/72h Pseudokirchnerella subcapitata (Method: OECD TG 201)

12.2. Persistence and Degradability.

ISOPROPYL ALCOHOL: Rapidly biodegradable (EU Method C.5)

DIDECYLDIMETHYLAMMONIUM CHLORIDE (Information available in SDS of the supplier)

Stability in water: abiotic degradation, hydrolytically stable (Method EPA-FIFRA)

Modified Sturm essay: 72%

Rapidly degradable

Experiment duration: 28 d

Method: OECD TG 301 B

Die-Away test: 93.3%

Experiment duration: 28 d

OECD Confirmatory Test: 91%

Experiment duration: 24 - 70 d

Method: OECD TG 303 A.

OLY(OXY-1,2-ETHANEDIYL), .ALPHA.-TRIDECYL-.OMEGA.-HIDROXY-.BRANCHED

Disposal Considerations:

>= 90% bismuth active substance (Method: OECD 301E)

Analogy: assessment deriving from chemically similar products.

> 60% CO₂ formation of theoretical value (28d) (Method: OECD 301B; ISO 9439; 92/69/EEC, C.4-C)

Easily biodegradable

Analogy: assessment deriving from chemically similar products.

ETHANE-1,2-DIOL: Rapidly Biodegradable.

ISOPROPANOL: Rapidly Biodegradable.

DIDECYLDIMETHYLAMMONIUM CHLORIDE: Rapidly Biodegradable.

SUBTILISIN: Rapidly Biodegradable.

POLY(OXY-1,2-ETHANEDIYL), .ALPHA.-TRIDECYL-.OMEGA.-HIDROXY-.BRANCHED /: Rapidly Biodegradable.

12.3. Bioaccumulation Potential.



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POLY(OXY-1,2-ETHANEDIYL), .ALPHA.-TRIDECYL-.OMEGA.-HIDROXY-,BRANCHED: accumulation in organisms is not expected (Information available in the SDS of the supplier).

12.4. Mobility in Soil.

POLY(OXY-1,2-ETHANEDIYL), .ALPHA.-TRIDECYL-.OMEGA.-HIDROXY-,BRANCHED: the substance does not evaporate from the water surface in the environment. Absorption in solid soil phase is possible.

12.5. Results of PBT and vPvB Assessment.

Based on the available data, the product does not contain substances classified as PBT or vPvB in percentage greater than 0.1 %.

12.6. Other Adverse Effects

POLY(OXY-1,2-ETHANEDIYL), .ALPHA.-TRIDECYL-.OMEGA.-HIDROXY-,BRANCHED (Information available in SDS of the supplier)

Chemical oxygen demand (COD): 2100 mg/g

With correct insertion of small concentrations in suitable biological purification plants, there should be no inconveniences during the active fungi degradation activity. Do not insert the product in the water without preventive treatment.

SECTION 13. Disposal Considerations.

13.1. Methods of Waste Treatment.

Product residues should be considered special hazardous waste. The dangerousness of the wastes that contain part of this product should be evaluated according to the legislative provisions proposed in the Legislative Decree no. 152/2006 and subsequent amendments.

Disposal should be entrusted to an authorized waste management firm, in compliance with national and local regulations.

Avoid absolutely to disperse the product into the soil, in sewer systems or water courses.

Waste transportation may be subject to ADR.

CONTAMINATED PACKAGING

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

SECTION 14. Transport Information.

14.1. ONU Number

(ADR, RID, IMDG Code, ICAO): UN 2924

14.2. ONU shipping name

(ADR, RID): FLAMMABLE LIQUID, CORROSIVE, N.O.S. (ISOPROPANOL; DIDECYLDIMETHYLAMMONIUM CHLORIDE)

(IMDG Code, ICAO): FLAMMABLE LIQUID, CORROSIVE, N.O.S. (PROPAN-2-OL; DIDECYLDIMETHYLAMMONIUM CHLORIDE)

14.3. Transportation hazard classification

(ADR, RID):

Class: 3

Label: 3 (8)



(IMDG Code):

Class: 3

Label: 3 (8)



(ICAO):



Class: 3

Label: 3 (8)

For air transport, the mark of environmental hazard is compulsory only for the N. UN 3077 and 3082.

14.4. Packing group

(ADR, RID, IMDG Code, ICAO): III

14.5. Dangers for the environment : YES**14.6. Special precautions for users**

Dangerous goods must be consigned for loading/transport according to the relevant requirements depending on the chosen transport means: road (A.D.R.), rail (RID), by sea (IMDG Code), air (IATA) and the relevant national provisions. Products should be transported in their original packaging and in any case in packages that are made from materials resistant to their content and unlikely to cause dangerous reactions with it. People loading and unloading dangerous goods must be trained on all the risks deriving from the substance and on all actions to be taken in the event of emergencies.

14.7. Transport of bulk cargo according to the attachment II of MARPOL 73/78 and the IBC code

(ADR, RID, ICAO): not applicable.

(IMDG Code): not applicable.

Additional indications

(ADR, RID):

Nr. Kemler:	38
Limited Quantity.	5 L – 30 kg lordi
Code of restriction in tunnels.	(D/E)

(IMDG Code):

EMS:	F-E, S-C
Marine Pollutant.	YES
Limited Quantity.	5 L – 30 kg gross

(ICAO):

Cargo:

Packaging Instructions:	365	Maximum quantity:	60 L
Pass.:			
Packaging Instructions:	354	Maximum quantity:	5 L
Special instructions:	A3		

SECTION 15. Regulatory Information.**15.1. Standards and Legislation on Health, Safety and Environmental Specifications for the Substance or Mixture.**Seveso Category.

6. FLAMMABLE

Restrictions concerning the product or substances contained as per Annex XVII Regulation (EC) 1907/2006.



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Product:

Point.

3. *The substances or the liquid mixtures that are considered dangerous for the purposes of Directive 1999/45/CE or that match the criteria for one of the following classes or categories of danger referred to in Annex I to Council Regulation (EC) no. 1272/2008:*

a) classes of danger from 2.1 to 2.4 , 2.6 and 2.7 , 2.8 types A and B, 2.9 , 2.10 , 2.12 , 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;

b) classes of danger from 3.1 to 3.6 , 3.7 harmful effects on sexual function and fertility or development, 3.8 effects other than narcotic effects, 3.9 and 3.10;

c) hazard class 4.1 ; d) hazard class 5.1 .

Point.

40 *Substances classified as flammable gases of category 1 or 2, flammable liquids of category 1, 2 or 3, flammable solids of category 1 or 2, substances and mixtures which, in contact with water, release flammable gases of category 1, 2 or 3, pyrophoric liquids category 1 or pyrophoric solids of category 1, even if not listed in Annex VI, part 3 of Regulation (EC) n. 1272/2008.*

Candidate List Substances (Art. 59 REACH).

None.

Substances subject to authorisation (Annex XIV REACH).

None.

Substances subject to export notification Reg. (CE) 649/2012:

Substances subject to the Rotterdam Convention:

None.

Substances subject to the Stockholm Convention:

None.

Public health control.

Workers exposed to this chemical agent must undergo health checks for the health surveillance carried out in accordance with the provisions of art. 41 of Legislative Decree no. 81 of 9 April 2008, unless the risk to the safety and health of the worker has been assessed irrelevant, in accordance with art. 224 paragraph 2.

Law Decree 152/2006 and subsequent amendments.

Emissions:

TAB. D Class 3 01,40 %

TAB. D Class 4 06,00 %

Ingredients according to Regulation CE NO.648/2004

Lower 5% cationic surfactants
Between 15% and 30% non ionic surfactants



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Enzymes

15.2. Chemical Safety Assessment.

A chemical safety assessment for the mixture and substances contained therein was not prepared.

SECTION 16. Other Information.

Text of hazard indications (H) mentioned in sections 2-3 of this sheet:

Flam. Liq. 2	Flammable liquid, Category 2
Flam. Liq. 3	Flammable liquid, Category 3
Repr. 2	Reproductive toxicity, category 2
Acute Tox. 3	Acute toxicity, category 3
Acute Tox. 4	Acute toxicity, category 4
STOT RE 2	Specific target organ toxicity - repeated exposure, category 2
Skin Corr. 1B	Skin corrosion, category 1B
Eye Dam. 1	Severe eye damage, category 1
Eye Irrit. 2	Eye irritation, category 2
Skin Irrit. 2	Skin irritation, category 2
STOT SE 3	Specific target organ toxicity - single exposure, category 3
Resp. Sens. 1	Respiratory sensitization, category 1
Aquatic Acute 1	Hazardous to the aquatic environment, acute toxicity, category 1
H225	Liquid and vapors highly flammable.
H226	Flammable liquid and vapours.
H361d	Suspected that it might affect the unborn child.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H332	Harmful if inhaled.
H373	It may damage the organs in case of prolonged or repeated exposure.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye injuries.
H319	Causes severe eye irritation.
H315	Causes skin irritation.
H335	May cause respiratory irritation
H334	It may trigger allergic or asthmatic symptoms or difficulties in breathing if inhaled
H336	May cause drowsiness or dizziness.
H412	Harmful to aquatic organisms with long-term effects.

Text of risk phrases (R) mentioned in sections 2-3 of this sheet:

R10	FLAMMABLE
R11	HIGHLY FLAMMABLE.
R20	HARMFUL IF INHALED.
R22	HARMFUL IF SWALLOWED.
R34	CAUSES BURNS.
R36	IRRITATING TO THE EYES.



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R37/38	IRRITATING TO THE RESPIRATORY SYSTEM AND THE SKIN.
R41	RISK OF SERIOUS DAMAGE TO EYES.
R42	MAY CAUSE SENSITISATION BY INHALATION.
Repr. Cat. 3	Reproductive toxicity, development, category 3.
R63	POSSIBLE RISK OF HARM TO THE UNBORN CHILD.
R67	VAPOURS MAY CAUSE DROWSINESS AND DIZZINESS

Training for workers:

Training of workers must provide content, updates, and duration relating to the types of risks assigned to the specific work areas, according to the regulations laid down in Legislative Decree 81/2008.

LEGEND:

- ADR: European Agreement concerning the transport of dangerous goods by road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Concentration that has effect on 50% of the population subject to test
- CE NUMBER: Identification number in ESIS (European archive of existing substances)
- CLP: Regulation CE 1272/2008
- DNEL: Derived no effect level.
- EmS: Emergency Schedule
- GHS: Harmonized global system for the classification and labelling of chemical products
- IATA DGR: Regulation for the transport of dangerous goods of International Air Transport Association
- IC50: Concentration of immobilization of 50% of the population subject to test
- IMDG: International maritime code for transport of dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identification number in the Annex VI of the CLP
- LC50: Lethal concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational exposure level
- PBT: Persistent, bioaccumulative and toxic according to REACH
- PEC: Predictable environmental concentration
- PEL: Predictable exposure level
- PNEC: Predictable no effect concentration
- REACH: Regulation CE 1907/2006
- RID: Regulation for the international transport of dangerous goods by train
- TLV: Threshold value
- TLV CEILING: Concentration that must not be exceeded during any time of exposure during work.
- TWA STEL: Short-term exposure limit
- TWA: Weighted average exposure limit
- VOC: Volatile organic compound
- vPvB: Very persistent and very bioaccumulative according to REACH.

GENERAL BIBLIOGRAPHY:

1. Directive 1999/45/EC and subsequent amendments
2. Directive 67/548/EEC and subsequent amendments and adjustments
3. European Parliament Regulation (EC) 1907/2006 (REACH)
4. European Parliament Regulation (EC) 1272/2008 (CLP)
5. European Parliament Regulation (EC) 790/2009 (I Atp. CLP)
6. European Parliament Regulation (EC) 453/2010
7. European Parliament Regulation (EC) 286/2011 (II Atp. CLP)
8. The Merck Index. Ed. 10
9. Handling Chemical Safety
10. Niosh - Registry of Toxic Effects of Chemical Substances
11. INRS - Fiche Toxicologique
12. Patty - Industrial Hygiene and Toxicology
13. N.I. Sax - Dangerous properties of Industrial Materials-7 Ed., 1989
14. Agency ECHA website

Note for user: The information contained in this sheet are based on knowledge achieved on the date of the last version. User 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, the user must, under his own responsibility, comply with



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the current health and safety laws and regulations. We accept no liability for any unauthorised or improper use. Provide adequate training for personnel assigned to use chemical products.

Changes made since the previous revision.

Changes have been made to the following sections:

01/ 02 / 03 / 04 / 05 / 06 / 07 / 08 / 10 / 11 / 12 / 13 / 14 / 15 / 16.

Ed.	Rev.	Date	STATUS AND REASON OF REVISIONS
1	0	16.07.2010	First edition
1	1	15.07.2011	Errata corrige symbol
1	2	13.09.2011	Paragraph 3 modification
1	3	17.11.2011	Adaptation to (UE) 453/2010 Regulation
1	4	02.09.2015	Adaptation to REACH and CLP Regulation, company name change with logo
1	5	09.02.2017	Change of flashpoint

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Safety Data Sheet

SECTION 1. Identification of the substance or mixture and the company/firm

1.1. Product identification

Trade name **ISASPOR® SINGLE SHOT - SOL. A**
Chemical name and synonyms

1.2. Relevant identified uses of the substance or mixture and uses advised against

Description/Use
Solution of Isazone® (CAS 19066-35-4) and peracetic acid.
Classification Medical Device Class IIb Directive 93/42/EEC, as ammended
Cold chemical sterilizing solution for medical devices.
Professional use only.
Product to be used after mixing with ISASPOR® SINGLE SHOT - SOL. B

Uses advised against
None in particular.

1.3. Information on the supplier of the safety data sheet

Company Name
Cantel Medical (Italy) S.R.L.
Address
Via Laurentina, n. 169
Town and Country
00071 Pomezia (RM)
ITALY
telephone +39.06/9145399
E-mail : info@cantelmedical.it
email address of the person responsible,
person responsible for the safety data sheet
Technical Director/Qualified Person (QP): direzionetecnica@cantelmedical.it

1.4. Emergency telephone number

Telephone numbers of the main poison centers in Italy (open 24 hours a day):
Poison Centre Niguarda Ca' Granda Hospital +39.02/66101029 (CAV A. O. Niguarda - Milan)
For urgent inquiries refer to
Emergency telephone number of the company (24/24 hours):
telephone +39.06/9145399 (*Technical Suppor*)

SECTION 2. Identification of hazards.

2.1. Classification of substance or mixture.

The product is classified as a dangerous substance pursuant to the provisions laid within Regulation (EC) 1272/2008 (CLP) (and subsequent amendments). The product requires therefore a safety data sheet in accordance with the provisions of Regulation (EC) 1907/2006 and subsequent amendments.

Any additional information concerning risks to health and/or environment are stated in sections 11 and 12 of this sheet.

2.1.1. Regulation 1272/2008 (CLP) and subsequent amendments.

Classification and hazard statements:

Org. Perox F	H242
Corr. to metals, Cat. 1	H290
Acute Tox. 4	H302
Skin Corr. 1A	H314
STOT SE 3	H335

Aquatic Chronic 3

H413

2.1.2. Directives 67/548/EEC and 1999 /45/CE and subsequent amendments.

Hazard signs: O-C

R-Phrases: 8-20/21/22-35

The full texts for risk phrases (R) and indications of danger (H) are specified in section 16 of this sheet.

2.2. Label elements.

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



Warnings:

H242	Hazard
H290	Heating may cause a fire.
H302	May be corrosive to metals,
H314	Harmful if swallowed.
H335	Causes severe skin burns and eye damage.
H412	May cause respiratory irritation
	Harmful to aquatic organisms with long-term effects.

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P234	Keep only in original container.
P260	Do not breathe vapours.
P280	Wear protective gloves/protective clothing/eye protection/face protection
P303+P361+P353	IN CASE OF CONTACT WITH THE SKIN (or with hair): take off immediately all contaminated clothing. Rinse skin with water/shower.
P305+P351+P338	IF IN CONTACT WITH EYES: rinse thoroughly with water for several minutes. Remove any contact lenses if easy to do. Continue rinsing.
P310	Immediately contact a local POISON CONTROL CENTER.
P403+P235	Store in a cool, well-ventilated place.

Contains: PERACETIC ACID
HYDROGEN PEROXIDE

2.3. Other hazards.

Information not available.

SECTION 3. Composition/information on ingredients.

3.1. Substances.

Information not relevant.

3.2. Mixtures.

Contains:

Identification.	Conc. %.	67/548/EEC Classification.	1272/2008 (CLP) Classification.
HYDROGEN PEROXIDE			
CAS. 7722-84-1	30 - 32,5	R 5, O R 8, C R35, Xn R20/22, Note B	Ox. Liq. 1 H271, Acute Tox. 4 H302, Acute Tox. 4 H332, Skin Corr. 1A H314, STOT SE 3 H335, Aquatic Chronic 3 H412, Note B
CE. 231-765-0			
INDEX. 008-003-00-9			
Reg. No. 01-2119485845-22			
ACETIC ACID			
CAS. 64-19-7	10 - 11,5	R10, C R35, Note B	Flam. Liq. 3 H226, Skin Corr. 1A H314, Note B
CE. 200-580-7			
INDEX. 607-002-00-6			
Reg. No. 01-2119475328-30-023			
PERACETIC ACID			
CAS. 79-21-0	4-5	R10, O R 7, C R35, Xn R20/21/22, N R50, Note B D	Flam. Liq. 3 H226, Org. Perox CD H242, Acute Tox. 3 H301, Acute Tox. 3 H331, Acute Tox. 4 H312, Skin Corr. 1A H314, Eye Dam. 1 H318, STOT SE 3 H335, Aquatic Acute 1 H400 M=1, Aquatic Chronic 1 H410, Note B D
CE. 201-186-8			
INDEX. 607-094-00-8			
Reg. No. 01-2119531330-56-0004			

The full texts for risk phrases (R) and indications of danger (H) are specified in section 16 of this sheet.

T+ = Very Toxic(T+), T = Toxic(T), Xn = Harmful(Xn), C = Corrosive(C), Xi = Irritating(Xi), O = Oxidizing(O), E = Explosive(E), F+ = Extremely flammable(F+), F = Highly Flammable(F), N = Dangerous to the environment(N)

SECTION 4. First aid measures.

4.1. Description of first aid measures.

EYES: Remove any contact lenses. Wash immediately and thoroughly with water for at least 30/60 minutes, with eyes wide open. Consult a physician immediately.

SKIN: Take off contaminated clothing. Take a shower immediately. Consult a physician immediately.

INGESTION: Drink water as much as possible. Consult a physician immediately. Do not induce vomiting unless expressly recommended by the physician.

INHALATION: Seek medical advice immediately. Bring the subject outdoors, away from the place of the accident. If breathing stops, provide artificial respiration. Take adequate precautions for the first aider.

PROTECTION MEASURES FOR THE FIRST AIDERS: for the PPE needed for first aid refer to section 8.2 of this safety data sheet.

4.2. Main symptoms and effects, both acute and delayed.

The first symptoms appear on a local level, characterized by gradual tissue injury quickly penetrates in depth.

Corrosive/ irritant and harmful liquids cause, depending on the intensity of exposure, eye irritation of different severity degrees, tearing and detachment of conjunctival epithelium and stratum corneum, opacity of the cornea, oedema and ulcerations. Risk of blinding.


To skin it causes irritation and surface lesions up to ulceration and scarring.

After accidental absorption into the body, the symptoms and the clinical situation depends on the kinetic behaviour of the substance (amount of substance absorbed, the resorption time and the effectiveness of the measures undertaken for prompt elimination (first aid) / elimination-metabolism).

A specific action of the substance is not known.

After inhalation of corrosive/ irritant aerosols and mists with high solubility, irritation may occur, depending on solubility, up to necrosis of the upper respiratory tract. The first symptoms appear on a local level: irritation of the respiratory tract such as cough, burning sensation behind the breastbone, tearing, burning eyes or nose. May lead to pulmonary edema. Refer also to section 11.

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

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Information not available.

SECTION 5. Fire-fighting measures.

5.1. Extinguishing means.

SUITABLE EXTINGUISHING MEDIA

The extinguishing means are: carbon dioxide, chemical powder, foam, and water spray. For product leaks and spills that did not cause a fire, water spray can be used to disperse the flammable vapours and protect the people involved in stopping the leakage.

UNSUITABLE EXTINGUISHING MEDIA

Organic compounds (Information available in SDS of the supplier).

5.2. Special hazards arising from the substance or the mixture.

DANGERS FROM EXPOSURE IN CASE OF FIRE

The product, if involved in a fire in large amounts, may worsen it significantly. Avoid breathing the combustion products.

5.3. Advice for fire-fighters.

GENERAL INFORMATION

In the event of a fire immediately cool the containers to avoid the danger of explosions (decomposition of the product, overpressures) and the development of substances that are potentially hazardous to your health. Always wear personal protection devices including fire equipment. If possible without risk, move away from the fire containers containing the product.

Evacuate personnel to safe areas. Keep unprotected people away. Keep away unauthorized persons.

The water use to extinguish the fire should not reach the sewer systems, the ground water table or the surface waters.

Provide for the containment of the water used for extinguishment. The water use to extinguish the fire must be disposed of in accordance with the regulations in force.

The remains of the fire should be disposed of in accordance with the regulations in force.

EQUIPMENT

Normal equipment for fire fighting such as self-contained breathing apparatus (EN 137), flame retardant turnout gear (EN469), flame-retardant gloves (EN 659) and boots for firemen (HO A29 or A30).

SECTION 6. Measures in the event of accidental release.

6.1. Personal precautions, protective equipment and procedures in case of emergency.


Stop leak if without risk. Wear appropriate protective devices (including the personal protective equipment referred to in section 8 of the safety data sheet) in order to prevent contamination of the skin, eyes and personal clothing. These guidelines apply to staff who work under both standard and emergency conditions.

6.2. Environmental precautions.

Prevent the product from entering sewers, surface waters, and groundwater.

6.3. Methods and materials for containment and remediation.

Suck up the spilled product into an appropriate container. Assess the compatibility of the container to use with the product, checking section 10. Absorb the remaining product with inert absorbent. Ensure adequate ventilation of the area affected by the loss. Put damaged barrels in safety barrels in plastic (do not use metal barrels). Do not close damaged barrels hermetically, nor the safety barrels (danger of explosion due to product decomposition). Check any incompatibility of the material of the containers in section 7. Contaminated material must be disposed of in accordance with the provisions given in section 13.

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6.4. Reference to other sections.

Any information relating to personal protective equipment and disposal are given in sections 8 and 13.

SECTION 7. Handling and storage.

7.1. Precautions for safe handling.

Ensure an adequate grounding system for installations and people. Avoid contact with skin and eyes. Do not breathe vapors or mists. Do not eat, drink or smoke during use. Wash hands after use. Avoid release to the environment.
The spilled product should never be put back in the original container and reused. (Risk of decomposition.)

7.2. Conditions for safe storage, including any incompatibilities.

Store in a cool, well-ventilated area away from heat sources, open flames, sparks and other sources of ignition.
Keep only in the original container. Keep in ventilated area, away from ignition sources. Keep in hermetically sealed recipients. Keep the product in containers clearly labeled. Avoid overheating. Avoid violent blows. Store containers away from any incompatible materials, refer to section 10.

For transport, storage, handling and storage tanks, use only suitable materials (Information available in SDS of the supplier):

Suitable materials stainless steel (1.4571)
Suitable materials polyethylene, polypropylene, polyvinyl chloride (PVC),
Suitable materials polytetrafluoroethylene, glass, ceramic.
Materials not suitable mild steel, iron, copper, brass, bronze, aluminum, zinc.

Do not store together with: alkalis, reductants, metal salts (danger of decomposition).
Do not store together with: flammable substances (fire hazard).

7.3. Particular end-uses.

No use other than those indicated in section 1.2 of this safety data sheet.

SECTION 8. Control of exposure/personal protection.

8.1. Control parameters.

Reference Standards:

Italy	Legislative Decree April 9, 2008, n.81.
Switzerland	Valeurs limites d'exposition aux postes de travail 2012.
OEL EU	Directive 2009/161/UE; Directive 2006/15/CE; Directive 2004/37/CE; Directive 2000/39/CE.

TLV-ACGIH	ACGIH 2012
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HYDROGEN PEROXIDE

Threshold value.

Type	Estado	TWA/8h	STEL/15min
		mg/m3	mg/m3
		ppm	ppm



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ACETIC ACID

Threshold value.

Type	Estado	TWA/8h		STEL/15min	
		mg/m3	ppm	mg/m3	ppm
TLV	CH	25	10	50	20
OEL	EU	25	10		
TLV-ACGIH		25	10	37	15

PERACETIC ACID

Threshold value.

Type	Estado	TWA/8h		STEL/15min	
		mg/m3	ppm	mg/m3	ppm
TLV-ACGIH				1,2	0,4

Legend:

(C) = CEILING ; INALAB = Inhalable fraction ; RESPIR = Respirable fraction ; TORAC = Thoracic fraction.

8.2. Exposure controls.

Considered that the use of appropriate technical measures should always prevail over personal protective devices, ensure good ventilation in the workplace using an effective local exhaust system.
The personal protective equipment should bear the CE marking to certify their compliance with applicable standards.
Provide emergency shower and eye wash facilities.

HAND PROTECTION

Protect your hands with gloves of category III (ref. standard EN 374).

When choosing the material of safety gloves please consider the following: compatibility, degradation, break-up time and permeation.

In the case of preparations, the resistance of working gloves to chemical agents must be verified before use because it is not predictable. The gloves have a wear time that depends on the duration and the mode of use.

Information available in SDS of the supplier:

Material for gloves: polychloroprene (CR), for example: Camapren 720, Kächele-Cama Latex GmbH (KCL), Germany

Material thickness 0.65 mm

Penetration time > 480 min

Method DIN EN 374

Disposable gloves

Material for gloves Natural rubber/Natural latex (NR)

material thickness 0.22 mm

Penetration time > 480 min

Method DIN EN 374

SKIN PROTECTION

Wear work clothes with long sleeves and safety footwear for professional use of category III (Ref. Directive 89/686/EEC and standard EN ISO 20344).

Suitable materials indicated in SDS of the supplier: PVC, neoprene, nitrile rubber (NBR), rubber. Boots made of rubber or plastic.

Wash with soap and water after removing protective clothing.

Assess the opportunity to provide antistatic clothing if the work area may present a risk of explosion.


EYE PROTECTION

It is recommended to wear a faceshield with helmet or faceshield with goggles (REF. EN 166).

If there is a risk of exposure to splashes or squirts during work performed, adequate protection of the mucous membranes (mouth, nose, eyes) must be provided in order to prevent accidental absorption.

RESPIRATORY PROTECTION

If the threshold value (e.g. TLV-TWA) of the substance or of one or more of the substances present in the product is exceeded, it is recommended to wear a mask with filter type A, class 1, 2 or 3, to be chosen in relation to the concentration limit of use. (ref. standard EN 14387). In the presence of gases

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or vapors of a different nature and/or gas or vapors with particles (aerosols, fumes, mists, etc.) you should provide combined filters.

Breathing apparatus recommended in SDS of the supplier:

Breathing apparatus with combined filter A2B2E2K1P2 (Draeger)

Breathing apparatus with combined filter OV/AG (3M)

Breathing apparatus with combined Filter ABEK2P3 (3M)

If necessary: Exhaust system in the workplace.

Observe the maximum times of use of the respiratory protection system.

The use of respiratory protection is necessary if technical measures taken are not sufficient to limit the exposure of the worker to the threshold values taken into consideration. The protection provided by masks is in any case limited.

In the case where the substance in question is odorless or its olfactory threshold is higher than the corresponding TLV-TWA and in case of emergency, wear a self-contained breathing apparatus (ref. EN 137) or a respiratory device with external air intake (ref. standard EN 138). To choose the respiratory protection device correctly, refer to the standard EN 529.

ENVIRONMENTAL EXPOSURE CONTROLS.

Emissions from manufacturing processes, including those from ventilation equipment, should be controlled for the purposes of compliance with the rules and regulations on environmental protection.


SECTION 9. Physical and chemical properties.

9.1. Information on basic physical and chemical properties.

Physical State	clear liquid
Colour	colourless
Odour	pungent
Olfactory threshold.	Not available.
pH	0.6 (20°C)
Melting o Freezing Point.	About -28 °C.
Initial boiling point.	Not applicable, the product decomposes
Boiling point.	> 60°C
Flash Point.	> 80°C, methid ASTM D92-12b
Evaporation rate	Not available.
Flammability of solids and gases	Not available.
Lower Flammability Limit.	Not available.
Upper Flammability Limit.	Not available.
Lower Explosive Limit.	Not available.
Upper Explosive Limit.	Not available.
Vapor pressure.	About 27 hPa (20°C)
Vapour Density.	Not available.
Relative density.	1.120 Kg/l at 20 °C
Solubility	soluble in water
Partition coefficient: n-octanol/water	log Pow - 1.25 (calculated)
Ignition Temperature.	Not available.
Decomposition Temperature.	Not available.
Kinematic viscosity	1.19 mm ² /s (DIN 51562)
Explosive properties	Product not explosive considering its composition
Oxidizing properties	Oxidizing product considering its composition

9.2. Other information.

VOC (Directive 1999/13/CE) :	10.00 % - 112.00 g/litre.
VOC (volatile carbon):	4.00 % - 44.76 g/litre.
Surface tension :	approx. 53 mN/m(20 °C) Method: ISO 3696
Ignition temperature:	395 °C Method: DIN 51 794
Corrosive to metals:	May be corrosive to metals
Thermal decomposition	≥ 60°C (auto accelerated decomposition)

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SECTION 10. Stability and reactivity.

10.1. Reactivity.

The product is stable under normal and expected conditions of use. The product is a stabilized oxidant.

10.2. Chemical stability.

The product is stable if kept in its original container and stored according to the instructions given in section 7.2 .

10.3. Possibility of dangerous reactions.

None under normal and expected conditions of use. Danger of decomposition if subjected to heat, pollution, catalysts of the decomposition, metal salts, alkali, reducing agent; may cause self-accelerating and exothermic decomposition with release of oxygen if they are in contact with the product. Danger of overpressure and burst in the case of decomposition in close containers and pipes. Release of oxygen may promote fire.

10.4. Conditions to avoid.

Avoid overheating. Avoid the accumulation of electrostatic charges. Avoid any ignition source. Avoid transfer to containers potentially contaminated with other substances. Avoid storage near flammable products or fuels.

10.5. Incompatible materials.

Information available in SDS of the supplier:

Impurities, catalysts of decomposition, metal salts, alkali, reducing agents, metals, non ferrous metal, aluminum, zinc.

Possible dangerous reaction: decomposition

Flammable materials: possible dangerous reaction: Self-ignition

Organic Solvents: Possible dangerous reaction: Danger of explosion.

10.6. Hazardous decomposition products.


Thermal decomposition may lead to the formation of oxygen or other potentially dangerous substances.

SECTION 11. Toxicological information.

In the absence of the toxicological data on the experimental product itself, the possible hazards to health related to the product have been evaluated based on the properties of the substances contained, according to the criteria provided by the legislation of reference on the classification of hazardous substances. Consider therefore the concentration of the single hazardous substances eventually mentioned in sect. 3, to assess the toxicological effects arising from exposure to the product.

Acute Effects: the product is harmful if swallowed and even the smallest amount ingested can cause significant disturbance to health (abdominal pain, nausea, vomiting, diarrhea). The product is corrosive and causes severe skin burns and blistering, which can also appear after exposure. Burns cause strong burning sensation and pain. In contact with the eyes it causes serious injury and can cause opacity of the cornea, iris lesion, irreversible coloration of the eye. All vapors are caustic to the respiratory system and may cause pulmonary edema; symptoms may appear sometimes only after a few hours. Symptoms of exposure may include: burning sensation, coughing, asthmatic breathing, laryngitis, shortness of breath, headache, nausea and vomiting. If swallowed, it may cause burns to mouth, throat and esophagus; vomiting, diarrhea, edema, swelling of the larynx and consequent choking. Perforation of the gastrointestinal tract may also occur. The product will cause serious eye injury and may cause opacity of the cornea, iris lesion, irreversible coloration of the eye. Acute effects: contact with the eyes causes irritation; symptoms may include: redness, swelling, pain and tearing. Inhalation of vapors may cause mild irritation of the upper respiratory tract; contact with the skin may cause mild irritation. Ingestion may cause health problems, including stomach pain and heartburn, nausea and vomiting. Acute effects: Inhalation of vapors causes irritation of the lower and upper respiratory tract with cough and difficulty breathing; at higher concentrations it may also cause pulmonary edema. Ingestion may cause health problems, including stomach pain and heartburn, nausea and vomiting.

11.1. Information on toxicological effects.

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Data referring to the mixture:

ACUTE INHALATION TOXICITY: Data not available.

ACUTE ORAL TOXICITY: Harmful if swallowed due to its composition specified in section 3.2.

ACUTE SKIN TOXICITY: Data not available.

CORROSION/ SKIN IRRITATION: Causes severe skin burns due to its composition specified in section 3.2.

SEVERE EYE DAMAGE/SEVERE EYE IRRITATION: Causes severe eye damage due to its composition specified in section 3.2.

IRRITATION OF THE RESPIRATORY TRACT: Data not available.

RESPIRATORY OR SKIN SENSITISATION: Data not available.

CARCINOGENICITY: Data not available.

MUTAGENICITY OF GERM CELLS: Data not available.

REPRODUCTIVE TOXICITY: Data not available.

SPECIFIC TOXICITY TO TARGET ORGANS (STOT) - SINGLE EXPOSURE: May irritate the respiratory tract due to its composition indicated in section 3.2.

SPECIFIC TOXICITY TO TARGET ORGANS (STOT)- REPEATED EXPOSURE: Data not available.

DANGER IN THE CASE OF SUCTION: Data not available.

Data referred to the hazardous substances in the mixture:

ACETIC ACID (Data available on the site of dissemination of the ECHA)

CORROSION/ SKIN IRRITATION:

- corrosive, given to harmonized classification from Annex VI Reg. CLP.
- in vivo tests conducted on rabbits, acetic acid in a solution of 3.3 % -10% was found to be slightly irritating to the skin (Method equivalent or similar to OECD TG 404).

SEVERE DAMAGE TO THE EYE/EYE IRRITATION:

- corrosive, given to harmonized classification from Annex VI Reg. CLP.
- 10% acetic acid solution causes eye irritation on rabbit (Method equivalent or similar to OECD TG 405 (Acute Eye Irritation/Corrosion)).

HYDROGEN PEROXIDE

ACUTE TOXICITY

LD50 (Oral). 1193 mg/kg Rat (Method: US EPA Guidelines (PB82-232984, August 1982) in GLP; Source: site of dissemination ECHA)

LC50 (Inhalation). 2000 mg/m³/4h Rat (Publication: Gigiena Truda i Professional'nye Zabolevaniya. Labor Hygiene and Occupational Diseases. Vol. 21(10), Pg. 22, 1977)

CORROSION/ SKIN IRRITATION:

- corrosive, given to harmonized classification from Annex VI Reg. CLP.
- irritant (Category 2), solution to 35%, tests conducted on rabbit (Method: US EPA Guideline PB82-232984, August 1982, in GLP; Source: site of dissemination ECHA).

PERACETIC ACID

ACUTE TOXICITY

LC50 (Inhalation). 0.49 mg/l, rat, vapours such as peracetic acid (Source: Information available in SDS of supplier)

LD50 (Oral). 93 mg/kg Rat (Method: EPA OPP 81-1, GLP; Source: Site of dissemination ECHA)

LD50 (Skin). 1147 mg/kg rabbit, peracetic acid 5% (Method: EPA OPP 81-2, GLP; Source: Site of dissemination ECHA)

CORROSION/ SKIN IRRITATION: corrosive, in vivo test on rabbit (method: OECD Guideline 404 in GLP; Source: site of dissemination of ECHA)

SEVERE EYE DAMAGE/SEVERE EYE IRRITATION: corrosive, in vivo test on rabbit (method: EPA Toxic Substances Health Effects Test Guidelines (PB82-232984), in GLP; Source: site of dissemination of ECHA)

SPECIFIC TOXICITY TO TARGET ORGANS (STOT) - SINGLE EXPOSURE: may irritate the respiratory tract, given to harmonized classification in Annex VI Reg. CLP.

SECTION 12. Ecological information.

The product is considered dangerous to the environment and is toxic to aquatic organisms with long-term adverse effects on the aquatic environment.

12.1. Toxicity.

Ecotoxicological data relating to the mixture:

Daphnia magna

48 h NOEC: 4.3 mg/L

IC50: 10.2 mg/L (confidence limits 95%: 8.5 – 12.3 mg/L)

Methods:

- OECD Series on Testing and Assessment No 23 - Guidance Document On Aquatic Toxicity Testing Of Difficult Substances And Mixtures ENV/JM/MONO(2000)6. OECD Guideline No. 202. "Daphnia sp., Acute Immobilization Test", April 2004.
- Council Regulation EC 440/2008 (C.2).
- UNI EN ISO 6341:2004 "Determination of the inhibition of the mobility of Daphnia magna Straus (Cladocera, Crustacea)"

O. mykiss

96 h NOEC: 20.7 mg/L

96 h LC50: 27.4 mg/L (confidence limits 95%: 22.3 – 33.8 mg/L)

Methods:

- OECD Guideline for Testing of Chemicals, No. 203. "Fish, acute toxicity test", 1992.
- OPPTS 850.1075. "Fish acute toxicity test, freshwater and marine", EPA Ecological effects Test guidelines, 1996.

Pseudokirchneriella subcapitata

Growth rate:

72 h NOEC: 1.0 mg/L
 LOEC: 3.1 mg/L

72 h EC50: 10.3 mg/L (confidence limits 95%: 7.6 – 12.4 mg/L)

Methods:

- OECD Guideline No. 201, "Freshwater algae and cyanobacteria growth inhibition test", 2011.

Ecotoxicological data relating to the mixture:

HYDROGEN PEROXIDE

LC50 (96h) - Fish.

16.4 mg/l Pimephales promelas (Method: USEPA Toxic Substances Control Act Test Guidelines (1985), Revision of TSCA Guidelines (1987) and USEPA Methods of Measuring the Acute Toxicity of Effluents to Freshwater and Marine Organisms (1984))

EC50 (48h) - Shellfish.


2.4 mg/l Daphnia Pulex (Method: USEPA Toxic Substances Control Act Test Guidelines (1985), Revision of TSCA Guidelines (1987) and USEPA Methods of Measuring the Acute Toxicity of Effluents to Freshwater and Marine Organisms (1984).)

EC50 (72h) - Algae / Aquatic Plants.

1.38 mg/l Skeletonema costatum (Method: Paris Commission guidelines (1990) for testing of offshore chemicals and drilling muds.).

NOEC Chronic shellfish.

0.63 mg/l/21 days Daphnia magna (Method: ASTM Designation E 1193-97, 21day; Source dissemination site ECHA)

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PERACETIC ACID

LC50 - Fish.

0.53 mg/l/96h Oncorhynchus mykiss (Method: OECD Guideline 203; Source: site of dissemination ECHA)

EC50 - Shellfish.

0.5 mg/l/48h Daphnia magna (Method: OECD TG 202; Source: Information available in SDS of supplier)

EC50 - Algae / Aquatic plants.

0.16 mg/l/72h Selenastrum capricornutum (Method: EPA OPP 123-3 in GLP; Source: site of dissemination ECHA)

Chronic NOEC fish.

0.0022 mg/l/33 d Danio rerio (Method: OECD Guideline 210; Site of dissemination of ECHA)

NOEC Chronic shellfish.

0.05 mg/l Daphnia magna (Method: OECD Guideline 535.94 cm GLP; Source: site of dissemination ECHA)

Chronic NOEC Algae / Aquatic plants.

0.061 mg/l/72 h Selenastrum capricornutum (Method: EPA OPP 123-3, in GLP; Site of dissemination ECHA)

Toxicity to bacteria

CE50 Activated sludge: 5.1 mg/l/ 3 h (Method: OECD TG 209; Source: Information available in SDS of supplier).

ACETIC ACID

LC50 - Fish.

75 mg/l/96h Lepomis macrochirus (PA/Office of Pollution Prevention and Toxics)

EC50 - Shellfish.

65 mg/l/48h Daphnia magna (Janssen, CR, EQ Espiritu and G Persoone (1993).)

12.2. Persistency and degradability.

HYDROGEN PEROXIDE: easily biodegradable, degradation > 99 %. (OECD 209).

ACETIC ACID: Rapidly biodegradable.

PERACETIC ACID: easily biodegradable (Method: OECD Guideline 301 AND; Site of dissemination of ECHA)

PRODUCT (Source: Information available in SDS of supplier)

Biodegradability

Exposure Time: 28 d

Result: Rapidly biodegradable

Method: OECD TG 301 E

with non bacterio-toxic concentrations

Physico-chemical elimination

Hydrolyzing after 7 days at approx. 50 %. pH 4

Hydrolyzed after 1 day 50% about pH 7 and pH 9

AOX

The product contains no organically bound halogens.


More Information

In the environment hydrolysis, reduction or decomposition occur rapidly. The following substances form: oxygen, water, acetic acid. Acetic acid is easily biodegradable.

12.3. Bioaccumulation potential.

ACETIC ACID

Partition coefficient: n-octanol/water.

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-0,17 (CRC Press Inc. Boca Raton. USA.)

12.4. Mobility in soil.

Information not available.

12.5. Results of the PBT and vPvB evaluation.

Based on the available data, the product does not contain substances classified as PBT or vPvB in percentage greater than 0.1 %.

12.6. Other adverse effects.

PRODUCT (Source: Information available in SDS of supplier)

The product does not contain any heavy metals and compounds specified in EEC Directive 76/464 like arsenic-, lead, cadmium, mercury, organic brominated compounds, organic compounds.

SECTION 13. Disposal considerations.

13.1. Waste treatment methods.

Reuse, when possible. Product residues should be considered special hazardous waste. The dangerousness of the wastes that contain part of this product should be evaluated according to the legislative provisions proposed in the Legislative Decree no. 152/2006 and subsequent amendments. Disposal should be entrusted to an authorized waste management firm, in compliance with national and local regulations.

Avoid absolutely to disperse the product into the soil, in sewer systems or water courses.

Waste transportation may be subject to ADR.

CONTAMINATED PACKAGING

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

SECTION 14. Transport information.

14.1. UN number

ADR / RID, IMDG, IATA: UN: 3149

14.2. ONU shipping name

ADR / RID:

PEROSSIDO DI IDROGENO E ACIDO PEROSSACETICO IN MISCELA STABILIZZATA

IMDG:

HYDROGEN PEROXIDE AND PEROXYACETIC ACID MIXTURE, STABILIZED

IATA:

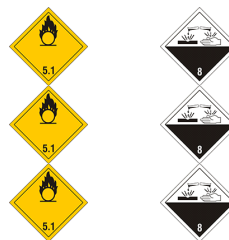
HYDROGEN PEROXIDE AND PEROXYACETIC ACID MIXTURE, STABILIZED


14.3. Transportation hazard classification

ADR / RID: Clas: 5.1 Label: 5.1 (8)

IMDG: Clas: 5.1 Label: 5.1 (8)

IATA: Clas: 5.1 Label: 5.1 (8)



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14.4. Packaging group

(ADR, RID, IMDG, IATA): II

14.5. Hazard to the environment : ADR/RID: NO

14.6. Special precautions for users

(ADR, RID):

Kemler:	58
Limited Quantity.	1 L
Code of restriction in tunnels.	(E)

(IMDG):

EMS:	F-H, S-Q
Limited Quantity.	1 L

(IATA):

Cargo:

Packaging Instructions:	554	Maximum quantity:	5 L
Pass.:			
Packaging Instructions:	550	Maximum quantity:	1 L
Special instructions:	A96		

14.7. Transport of bulk cargo according to the attachment II of MARPOL 73/78 and the IBC code not applicable.

SECTION 15. Regulatory information.

15.1. Standards and legislation on health, safety and environment specific to the substance or the mixture.

Seveso Category.

3. FLAMMABLE

Restrictions concerning the product or substances contained as per Annex XVII Regulation (EC) 1907/2006.

Product:

Point.

3. *The substances or the liquid mixtures that are considered dangerous for the purposes of Directive 1999/45/CE or that match the criteria for one of the following classes or categories of danger referred to in Annex I to Council Regulation (EC) no. 1272/2008:*

a) classes of danger from 2.1 to 2.4 , 2.6 and 2.7 , 2.8 types A and B, 2.9 , 2.10 , 2.12 , 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;


b) classes of danger from 3.1 to 3.6 , 3.7 harmful effects on sexual function and fertility or development, 3.8 effects other than narcotic effects, 3.9 and 3.10;

c) hazard class 4.1 ; d) hazard class 5.1 .

Point.

40 *Substances classified as flammable gases of category 1 or 2, flammable liquids of category 1, 2 or 3, flammable solids of category 1 or 2, substances and mixtures which, in contact with water, release flammable gases of category 1, 2 or 3, pyrophoric liquids category 1 or pyrophoric solids of category 1, even if not listed in Annex VI, part 3 of Regulation (EC) n. 1272/2008.*

Candidate List Substances (Art. 59 REACH).

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None.

Substances subject to authorisation (Annex XIV REACH).

None.

Substances subject to export notification Reg. (CE) 649/2012:

None.

Substances subject to the Rotterdam Convention:

None.

Substances subject to the Stockholm Convention:

None.

Public health control.

Workers exposed to this dangerous chemical agent must be subjected to health surveillance carried out according to the provisions of Art. 41 of Leg. decree 81 dated April 9, 2008 , unless the risk to the safety and health of the worker has been assessed as irrelevant, as provided for by Article 224 Paragraph 2.

Leg. Decree 152/2006 and subsequent amendments.

Emissions:

TAB. D Class 3 10.00 %

15.2. Chemical safety assessment.

A chemical safety assessment for the mixture and substances contained therein was not prepared.

SECTION 16. Other information.

Text of hazard indications (H) mentioned in sections 2-3 of this sheet:

Flam. Liq. 3	Flammable liquid, Category 3
Org. Perox CD	Organic Peroxide, F category
Ox. Liq. 1	Liquid oxidizer, category 1
Ox. Liq. 2	Liquid oxidizer, category 2
Acute Tox. 3	Acute toxicity, category 3
Acute Tox. 4	Acute toxicity, category 4
Skin Corr. 1A	Skin corrosion, category 1A
STOT SE 3	Specific target organ toxicity - single exposure, category 3

Aquatic Acute 1	Hazardous to the aquatic environment, acute toxicity, category 1
Aquatic Chronic 1	Hazardous to the aquatic environment, chronic toxicity, category 1
Aquatic Chronic 2	Hazardous to the aquatic environment, chronic toxicity, category 2
Aquatic Chronic 3	Hazardous to the aquatic environment, chronic toxicity, category 3
H226	Flammable liquid and vapours.
H242	Heating may cause a fire.
H271	May cause a fire or an explosion; highly combustible.
H290	May be corrosive to metals.
H301	Toxic if swallowed.
H331	Toxic if inhaled.
H302	Harmful if swallowed.
H312	Harmful in contact with the skin.
H332	Harmful if inhaled.
H314	Causes severe skin burns and eye damage.
H335	May cause respiratory irritation
H400	Very toxic to aquatic organisms.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic organisms with long-term effects.
H412	Harmful to aquatic organisms with long-term effects.

Text of risk phrases (R) mentioned in sections 2-3 of this sheet:

R 5	HEATING MAY CAUSE AN EXPLOSION.
R 7	MAY CAUSE A FIRE.
R 8	MAY CAUSE THE IGNITION OF COMBUSTIBLE MATERIAL.
R10	FLAMMABLE
R20/21/22	HARMFUL BY INHALATION, IN CONTACT WITH SKIN AND IF SWALLOWED.
R20/22	HARMFUL BY INHALATION AND IF SWALLOWED.
R35	CAUSES SEVERE BURNS.
R50	HIGHLY TOXIC TO AQUATIC ORGANISMS.

Training for workers:

Training of workers must provide content, updates, and duration relating to the types of risks assigned to the specific work areas, according to the regulations laid down in Legislative Decree 81/2008.

LEGEND:

- ADR: European Agreement concerning the transport of dangerous goods by road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Concentration that has effect on 50% of the population subject to test
- CE NUMBER: Identification number in ESIS (European archive of existing substances)
- CLP: Regulation CE 1272/2008
- DNEL: Derivative level without effect
- EmS: Emergency Schedule
- GHS: Harmonized global system for the classification and labelling of chemical products
- IATA DGR: Regulation for the transport of dangerous goods of International Air Transport Association
- IC50: Concentration of immobilization of 50% of the population subject to test
- IMDG: International maritime code for transport of dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identification number in the Annex VI of the CLP



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- LC50: Lethal concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational exposure level
- PBT: Persistent, bioaccumulative and toxic according to REACH
- PEC: Predictable environmental concentration
- PEL: Predictable exposure level
- PNEC: Predictable no effect concentration
- REACH: Regulation CE 1907/2006
- RID: Regulation for the international transport of dangerous goods by train
- TLV: Threshold value
- TLV CEILING: Concentration that must not be exceeded during any time of exposure during work.
- TWA STEL: Short-term exposure limit
- TWA: Weighed average exposure limit
- VOC: Volatile organic compound
- vPvB: Very persistent and very bioaccumulative according to REACH.

GENERAL BIBLIOGRAPHY:

1. Directive 1999/45/EC and subsequent amendments
2. Directive 67/548/EEC and subsequent amendments
3. European Parliament Regulation (EC) 1907/2006 (REACH)
4. European Parliament Regulation (EC) 1272/2008 (CLP)
5. European Parliament Regulation (EC) 790/2009 (I Atp. CLP)
6. European Parliament Regulation (EC) 453/2010
7. European Parliament Regulation (EC) 286/2011 (II Atp. CLP)
8. The Merck Index. Ed. 10
9. Handling Chemical Safety
10. Niosh - Registry of Toxic Effects of Chemical Substances
11. INRS - Fiche Toxicologique
12. Patty - Industrial Hygiene and Toxicology
13. N.I. Sax - Dangerous properties of Industrial Materials-7 Ed., 1989
14. Agency ECHA website

Note for user:

The information contained in this data sheet are based on the data available on the date of the last version. User must verify the suitability and thoroughness of the information provided 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, the user must, under his own responsibility, comply with the current health and safety laws and regulations. We accept no liability for any unauthorised or improper use.

Provide adequate training for personnel assigned to use chemical products.

Changes compared to the previous revision:

Ed.	Rev.	Date	STATUS AND REASON OF REVISIONS
1	0	07.04.2022	First edition
1	1	01.06.2015	Adaptation to REACH and CLP Regulation.

Safety data sheet

SECTION 1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name

ISASPOR® SINGLE SHOT - SOL. B

1.2. Relevant identified uses of the substance or mixture and uses advised against

Intended use

Isazone® (CAS 19066-35-4) and peracetic acid mixture.
Medical device class IIb Directive 93/42 / EEC and subsequent amendments.
Cold and sterilant chemical solution for medical devices.

Uses advised against

Professional use only. Product to use after mixing with ISASPOR® SINGLE SHOT - SOL. A
No use advised against.

1.3. Details of the supplier of the safety data sheet

Company Name

Cantel Medical (Italy) S.R.L.

Address

Via Laurentina, n. 169

Town and Country

00071 Pomezia (RM)

ITALY

telephone +39.06/9145399

E-mail : info@cantelmedical.it

email address of the person responsible,
person responsible for the safety data sheet

Technical Director/Qualified Person (QP): direzione@cantelmedical.it

1.4. Emergency telephone number

Telephone numbers of the main poison centres in Italy (open 24 hours a day):

Poison Centre Niguarda Ca' Granda Hospital +39.02/66101029 (CAV A. O. Niguarda - Milan)

For urgent inquiries refer to

Emergency telephone number of the company (24/24 hours):
telephone +39.06/9145399 (*Technical Support*)

SECTION 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 EC Regulation 1907/2006 and subsequent amendments. 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:

Eye irritation, category 2

H319

Causes serious eye irritation.

Skin irritation, category 2

H315

Causes skin irritation.

NOTE: The product isn't classified as corrosive for metals because the test described in the part III, subsection 37.4 of UN Transport of Dangerous Goods Recommendations (rif. Sec. 2.16 Annex I CLP Regulation) is resulted negative.

2.2. Label elements.

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

Hazard pictograms:



Signal words:

Warning

Hazard statements:

H319 Causes serious eye irritation.
H315 Causes skin irritation.

Precautionary statements:

P234 Keep only in original container.
P302+P352 IF ON SKIN: wash with plenty of soap and water.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 If eye irritation persists: Get medical advice / attention.
P280 Wear protective gloves and eye protection / face protection.

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%.

SECTION 3. Composition/information on ingredients.**3.1. Substances.**

Information not relevant.

3.2. Mixtures.

Contains:

Identification.	Conc. %.	Classification 1272/2008 (CLP).
PROPAN-2-OL		
CAS. 67-63-0	8 - 9	Flam. Liq. 2 H225, Eye Irrit. 2 H319, STOT SE 3 H336
EC. 200-661-7		
INDEX. 603-117-00-0		
Reg. no. 01-2119457558-25		
BORAX DECAHYDRATE		
CAS. 1303-96-4	3 - 3,5	Repr. 1B H360FD, Eye Irrit. 2 H319
EC. 215-540-4		
INDEX. 005-011-01-1		
Reg. no. 01-2119490790-32-0011		
SODIUM HYDROXIDE		

CAS. 1310-73-2

1,3 - 1,6

Met. Corr. 1 H290, Skin Corr. 1A H314

EC. 215-185-5

INDEX. 011-002-00-6

Reg. no. 01-2119457892-27-XXXX

1H-BENZOTRIAZOLE

CAS. 95-14-7

1 - 1,5

Acute Tox. 4 H302, Acute Tox. 4 H312, Acute Tox.
4 H332, Eye Irrit. 2 H319, Aquatic Chronic 3 H412

EC. 202-394-1

INDEX. -

Reg. no. -

For the substance SODIUM HYDROXIDE: below the specific limits according to Annex VI Reg. CLP:

Skin Corr. 1A; H314: $C \geq 5\%$ Skin Corr. 1B; H314: $2\% \leq C < 5\%$ Eye Irrit. 2; H319: $0,5\% \leq C < 2\%$ Skin Irrit. 2; H315: $0,5\% \leq C < 2\%$

For the substance BORAX DECAHYDRATE: below the specific limits according to Annex VI Reg. CLP:

Repr. 1B H360FD $C \geq 8,5\%$

The full wording of hazard (H) phrases is given in section 16 of the sheet.

SECTION 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 30-60 minutes, opening the eyelids fully. Get medical advice/attention.

SKIN: Remove contaminated clothing. Rinse skin with a shower immediately. Get medical advice/attention.

INGESTION: Have the subject drink as much water as possible. Get medical advice/attention. Do not induce vomiting unless explicitly authorised by a doctor.

INHALATION: Get medical advice/attention immediately. Remove victim to fresh air, away from the accident scene. If the subject stops breathing, administer artificial respiration. Take suitable precautions for rescue workers.

PROTECTIVE MEASURES FOR THE FIRST RESCUE WORKERS: for PPE (personal protection equipment) required for first aid refer to section 8.2 of this safety data sheet.

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

For symptoms and effects caused by the contained substances, see chap. 11.

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

Information not available.

SECTION 5. Firefighting measures.

5.1. Extinguishing media.**SUITABLE EXTINGUISHING EQUIPMENT**

Extinguishing substances are: carbon dioxide, foam, 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**

Excess pressure may form in containers exposed to fire at a risk of explosion. Do not breathe combustion products.

5.3. Advice for firefighters.**GENERAL INFORMATION**

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

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).

SECTION 6. Accidental release measures.**6.1. Personal precautions, protective equipment and emergency procedures.**

Block the leakage if there is no hazard.

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 into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

Make sure the leakage site is well aired. Check incompatibility for container material in section 7. 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.

SECTION 7. Handling and storage.

7.1. Precautions 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.

Storage class TRGS 510 (Germany):
10

7.3. Specific end use(s).

No use other than specified in Section 1.2 of this safety data sheet.

SECTION 8. Exposure controls/personal protection.

8.1. Control parameters.

Regulatory References:

BGR	България	МИНИСТЕРСТВО НА ТРУДА И СОЦИАЛНАТА ПОЛИТИКА МИНИСТЕРСТВО НА ЗДРАВЕОПАЗВАНЕТО НАРЕДБА No 13 от 30 декември 2003 г
CZE	Česká Republika	Nařízení vlády č. 361/2007 Sb. kterým se stanoví podmínky ochrany zdraví při práci
DEU	Deutschland	MAK-und BAT-Werte-Liste 2012
DNK	Danmark	Graensevaerdier per stoffer og materialer
ESP	España	INSHT - Límites de exposición profesional para agentes químicos en España 2015
EST	Eesti	Töökeskkonna keemiliste ohutegurite piirnormid 1. Vastu võetud 18.09.2001 nr 293 RT I 2001, 77, 460 - Redaktsiooni jõustumise kp: 01.01.2008
FRA	France	JORF n°0109 du 10 mai 2012 page 8773 texte n° 102
GBR	United Kingdom	EH40/2005 Workplace exposure limits
GRC	Ελλάδα	ΕΦΗΜΕΡΙΣ ΤΗΣ ΚΥΒΕΡΝΗΣΕΩΣ -ΤΕΥΧΟΣ ΠΡΩΤΟ Αρ. Φύλλου 19 - 9 Φεβρουαρίου 2012
HRV	Hrvatska	NN13/09 - Ministarstvo gospodarstva, rada i poduzetništva
HUN	Magyarország	50/2011. (XII. 22.) NGM rendelet a munkahelyek kémiai biztonságáról
ITA	Italia	Decreto Legislativo 9 Aprile 2008, n.81
LTU	Lietuva	DĖL LIETUVOS HIGIENOS NORMOS HN 23:2007 CHEMINIŲ MEDŽIAGŲ 2007 m. spalio 15 d. Nr. V-827/A1-287

LVA	Latvija	Ķīmisko vielu aroda ekspozīcijas robežvērtības (AER) darba vides gaisā 2012
NLD	Nederland	Databank of the social and Economic Concil of Netherlands (SER) Values, AF 2011:18
NOR	Norge	Veiledning om Administrative normer for forurensning i arbeidsatmosfære
POL	Polska	ROZPORZĄDZENIE MINISTRA PRACY I POLITYKI SPOŁECZNEJ z dnia 16 grudnia 2011r
SVK	Slovensko	NARIADENIE VLÁDY Slovenskej republiky z 20. júna 2007
SVN	Slovenija	Uradni list Republike Slovenije 15. 6. 2007
SWE	Sverige	Occupational Exposure Limit Values, AF 2011:18
	TLV-ACGIH	ACGIH 2014

PROPAN-2-OL

Threshold Limit Value.

Type	Country	TWA/8h		STEL/15min	
		mg/m3	ppm	mg/m3	ppm
TLV	BGR	980		1225	
TLV	CZE	500		1000	
AGW	DEU	500	200	1000	400
MAK	DEU	500	200	1000	400
TLV	DNK	490	200		
VLA	ESP	500	200	1000	400
TLV	EST	350	150	600	250
VLEP	FRA			980	400
WEL	GBR	999	400	1250	500
TLV	GRC	980	400	1225	500
GVI	HRV	999	400	1250	500
AK	HUN	500		2000	
RD	LTU	350	150	600	250
RV	LVA	350		600	
OEL	NLD	650			
TLV	NOR	245	100		
NPHV	SVK	500	200	1000	
MV	SVN	500	200		
MAK	SWE	350	150	600	250
TLV-ACGIH		492	200	983	400

Predicted no-effect concentration - PNEC.

Normal value in fresh water	140,9	mg/l
Normal value in marine water	140,9	mg/l
Normal value for fresh water sediment	552	mg/kg
Normal value for marine water sediment	552	mg/kg
Normal value for water, intermittent release	140,9	mg/l
Normal value of STP microorganisms	2251	mg/l
Normal value for the food chain (secondary poisoning)	160	mg/kg
Normal value for the terrestrial compartment	28	mg/kg

Health - Derived no-effect level - DNEL / DMEL

Health	Derived no effect level: DNEL/ DMEL					Derived no effect level: DNEL/ DMEL		
Route of exposure	Effects on consumers. Acute local	Acute systemic	Chronic local	Chronic systemic	Effects on workers Acute local	Acute systemic	Chronic local	Chronic systemic
Inhalation.							VND	500 mg/m3

Skin. VND 888 mg/kg bw/d

BORAX DECAHYDRATE
Threshold Limit Value.

Type	Country	TWA/8h mg/m3	ppm	STEL/15min mg/m3	ppm
TLV	DNK	2			
VLA	ESP	2		6	
TLV	EST	2		5	SKIN.
VLEP	FRA	5			
WEL	GBR	5			
TLV	GRC	10			
GVI	HRV	5			
OEL	ITA	2		6	
RD	LTU	2		5	SKIN.
RV	LVA	2		5	
OEL	NLD	5			
TLV	NOR	5			
NDS	POL	0,5		2	
MAK	SWE	2		5	SKIN.
TLV-ACGIH		2		6	

Predicted no-effect concentration - PNEC.

Normal value in fresh water	202	mg/l
Normal value in marine water	2,02	mg/l
Normal value for water, intermittent release	13,7	mg/l
Normal value of STP microorganisms	10	mg/l
Normal value for the terrestrial compartment	54	mg/kg

Health - Derived no-effect level - DNEL / DMEL

Route of exposure	Effects on consumers. Acute local	Acute systemic	Chronic local	Chronic systemic	Effects on workers Acute local	Acute systemic	Chronic local	Chronic systemic
Inhalation.					17,04 mg/m3	VND	17,04 mg/m3	6.7 mg/m³
Skin.							VND	316.4 mg/kg bw/day

SODIUM HYDROXIDE
Threshold Limit Value.

Type	Country	TWA/8h mg/m3	ppm	STEL/15min mg/m3	ppm
TLV-ACGIH				2 (C)	


Health - Derived no-effect level - DNEL / DMEL

Route of exposure	Effects on consumers. Acute local	Acute systemic	Chronic local	Chronic systemic	Effects on workers Acute local	Acute systemic	Chronic local	Chronic systemic
Inhalation.							1 mg/m3	VND

PROPAN-2-OL: Biological exposure indices (BEI): Acetone in urine 40 mg/L. Time of sampling: end of shift, end working week (Source ACGIH 2014).

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.

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

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. 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

Protect hands with category III work gloves (see standard EN 374).

The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

SKIN PROTECTION

Wear category II 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 airtight protective goggles (see standard EN 166).

RESPIRATORY PROTECTION

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type A filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.

If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

ENVIRONMENTAL EXPOSURE CONTROLS.

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

SECTION 9. Physical and chemical properties.

9.1. Information on basic physical and chemical properties.

Appearance	clear liquid
Colour	colourless
Odour	spirit
Odour threshold.	Not available.
pH.	11
Melting point / freezing point.	Not available.
Initial boiling point.	> 100 °C.
Boiling range.	Not available.
Flash point.	> 100 °C.
Evaporation Rate	Not available.
Flammability of solids and gases	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.	1,0 ± 0,2
Solubility	soluble in water
Partition coefficient: n-octanol/water	Not available.
Auto-ignition temperature.	Not available.
Decomposition temperature.	Not available.
Viscosity	30 +- 10 cP
Explosive properties	Product is not explosive based on the composition
Oxidising properties	Product is not explosive based on the composition

9.2. Other information.

No data available.

SECTION 10. Stability and reactivity.**10.1. Reactivity.**

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

SODIUM HYDROXIDE: The contact with metals generates flammable hydrogen gas. Contact with strong acids may cause violent reactions and explosions. Potential danger for exothermic reactions. corrosiveness to the metals.

BENZOTHAZOLE decomposes at 160°C.

10.2. Chemical stability.

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

10.3. Possibility of hazardous reactions.

None under normal and expected conditions of use. Polymerization reactions do not take place.

10.4. Conditions to avoid.

Avoid overheating. Avoid bunching of electrostatic charges. Avoid all sources of ignition. Avoid contact with oxidants and strong reducing agents, strong acids, strong bases.

BORAX DECAHYDRATE: keep away from strong reducing agents to avoid the development of explosive gas like hydrogen.


10.5. Incompatible materials.

Oxidants and strong reducing agents, strong acids, strong bases.

SODIUM HYDROXIDE: It can react violently with: acids, halogenated organic substances, in particular trichlorethylene, aluminum and other very reactive aldehydes metals, anhydrides, nitriles, especially acrylonitrile, alcohols and phenols, cyanohydrin, hydroquinone, organic nitro compounds, phosphorus, tetrahydrofuran

10.6. Hazardous decomposition products.

In the event of thermal decomposition or fire, gases and vapours that are potentially dangerous to health may be released.

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SODIUM HYDROXIDE: Decomposes on heating, developing toxic fumes including sodium oxide.
BORAX DECAHYDRATE: boron oxides, sodium oxides.
BENZOTHAZOLE: nitric oxides.

SECTION 11. Toxicological information.

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.

Acute effects: stinging eyes. Symptoms may include: rubescence, edema, pain and lachrymation. Ingestion may cause health problems, including stomach pain and sting, nausea and sickness.

Acute effects: contact with skin may cause: irritation, erythema, edema, dryness and chapped skin. Ingestion may cause health disorders, including stomach pain and sting, nausea and sickness.

11.1. Information on toxicological effects.

Data refers to the mix:

ACUTE TOXICITY: No data available.

SKIN CORROSION/IRRITATION: the product is irritating to the skin on the basis of the composition indicated in Section 3.2 of this safety data sheet;

SERIOUS EYE DAMAGE/IRRITATION: The product is irritating to eyes on the basis of the composition indicated in Section 3.2 of this safety data sheet;

RESPIRATORY OR SKIN SENSITISATION: No data available

GERM CELL MUTAGENICITY: No data available

CARCINOGENICITY: No data available

REPRODUCTIVE TOXICITY: No data available

STOT SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE: No data available

STOT SPECIFIC TARGET ORGAN TOXICITY -REPEATED EXPOSURE: No data available

ASPIRATION HAZARD: No data available:

Data relating to substances hazardous mixture:

PROPAN-2-OL

ACUTE TOXICITY:

LD50 (Oral).5840 mg/kg (Rat; equivalent or similar to OECD Guideline 401)

LD50 (Dermal).16,4 ml/kg (Rabbit; equivalent or similar to OECD Guideline 402)

LC50 (Inhalation).> 10000 ppm/6h (Rat,vapours, equivalent or similar to OECD Guideline 403 GLP Test)

SERIOUS EYE DAMAGE/IRRITATION: It causes serious eye irritation (Rabbit; equivalent or similar to OECD Guideline 405)

STOT SPECIFIC TARGET ORGAN TOXICITY -SINGLE EXPOSURE: It may cause drowsiness or dizziness (Rat; OECD Guideline 426, GLP Test)

SODIUM HYDROXIDE

The substance should not be available at the systemic level and the effects should be due to pH variations.

SKIN CORROSION/IRRITATION: corrosive, (Rabbit, equivalent or similar to OECD TG 404). The substance causes chemical burns whose severity depends on the concentration of the solution, the importance of the contamination and the duration of contact. Depending on the depth of the damage it is observed warm and painful erythema, blisters and necrosis. Evolution can complicate with infections.

SERIOUS EYE DAMAGE/IRRITATION: sodium hydroxide 2% solutions are irritant (Rabbit, OECD TG 405). At eye level the effects are immediate pain, tearing, conjunctival hyperemia, conjunctival adhesions, corneal opacities, cataracts, glaucoma and even blindness.

BORAX DECAHYDRATE

SERIOUS EYE DAMAGE/IRRITATION: irritating to eyes (OECD Guideline 405).

REPRODUCTIVE TOXICITY: Method: equivalent or similar to two-generation OECD 416 studies.

Dose: 0; 34 (5.9); 100 (17.5); and 336 (58.5) mg of boric acid (B mg) / kg body weight / day; and 0; 50 (5.9); 155 (17.5); and 518 (58.5) mg of borax decahydrate (mg B) / kg body weight / day)

Exposure routes: oral

Results: The dose with no observed adverse effect level (NOAEL) in rats in terms of effects on fetal development, including the loss of fetal weight and skeletal variations in the minimum is 55 mg boric acid / kg of body weight acid or 9,6 B mg / kg; equivalent to 64.7 mg of disodium tetraborate pentahydrate / kg body weight.

Method: occupational studies for the evaluation of sensitive parameters to sperm in highly exposed workers to the borates. They were conducted epidemiological studies investigating environmental exposures to boron and the effects on the development of individuals. (Culver, BD & al. (1995) Inorganic Boron Health Effects in Humans: An Aid to Risk Assessment and Clinical Judgment. Trace Elements in Experimental Medicine 9(4):175-184.)

Species: Human

Dose: a subset of workers were exposed to 125 mg B/day.

Exposure routes: oral and inhalation combined

Results: no adverse effect on fertility of male workers. Epidemiological studies of the effects on human development have shown an absence of effects in workers exposed to borates and in populations living in areas with high environmental levels of boron.

1H-BENZOTRIAZOLE

TOSSICITÀ ACUTA LD50 (Oral). 500 mg/kg Rat (OECD Guideline 423, GLP test)

LD50 (Dermal).450 mg/kg Rat (data available in the supplier's SDS)

SERIOUS EYE DAMAGE/IRRITATION: irritant (Rabbit, OECD TG 405).

SECTION 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 HYDROXIDE, short term effects:

Fish (*Gambusia affinis*) CL50-96 ore: 125 mg/l (EU, 2007; OECD, 2002, Wallen (1957));

Crustacea (*Ceriodaphnia* sp.) CE50-48 ore: 40 mg/l (EU, 2007; OECD, 2002, (Warne et al, 1999));

Microorganismi (*Photobacterium phosphoreum*) CE50-15 min: 22 mg/l (EU, 2007; OECD, 2002, (Bulich et al. 1990)).

Long Term Effects: No data available.

PROPAN-2-OL

LC50 - for Fish.

9640 mg/l/96h (*Pimephales promelas*, not stated method)

EC50 - for Crustacea.

9714 mg/l/(24h) (*Daphnia magna*, equivalent or similar to OECD Guideline 202)

EC50 - for Algae / Aquatic Plants.

1800 mg/l/(7d) (*Scenedesmus quadricauda*, not stated method)

BORAX DECAHYDRATE

LC50 - for Fish.

74 mg B/L, *Limanda limanda* (Taylor et al. (1985) *Aquat Toxicol*, 7, 135-144).

EC50 - for Algae / Aquatic Plants.

30 mg/L 21 d *Lampsilis siliquoidea* (read-across from substance CAS 10043-35-3, ASTM E 2455-6 (2006). Standard guide for conducting laboratory toxicity tests with freshwater mussels)

1H-BENZOTRIAZOLE

LC50 - for Fish.

180 mg/l/96h *Danio rerio* (OECD 203)

EC50 - for Crustacea.

158 mg/l/48h *Daphnia galeata* (OECD 202)

EC50 - for Algae / Aquatic Plants.

75 mg/l/72h *Selenastrum capricornutum* (OECD 201)

12.2. Persistence and degradability.

PROPAN-2-OL:

Rapidly biodegradable, 53% in 5 days (method equivalent or similar to EU Method C.5)


SODIUM HYDROXIDE:

Instantly hydrolyzed in water with pH increase, in the air it is neutralized by atmospheric carbon dioxide (data available in the supplier's SDS).

BORAX DECAHYDRATE:

The biodegradation is not an endpoint applicable since the product is an inorganic substance (data available in the supplier's SDS).

1H-BENZOTRIAZOLE:

 <p>Cantel Medical (Italy) S.R.L. Industria Chimico-Farmaceutica Via Laurentina 169 00071 POMEZIA (RM)</p>	<p>ISASPOR® SINGLE SHOT - SOL. B</p> <p>Medical device class IIb IDENTIFICATION CODE ISA/CE/43</p>	<p>1st Edition Revision no.2 Revision date: 10.02.2017 Page n. 12/16</p>
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Biodegradation was not observed during the tests conducted (OECD 302A)

12.3. Bioaccumulative potential.

SODIUM HYDROXIDE: BCF Non applicable

BORAX DECAHYDRATE

Partition coefficient: n-octanol/water: Log Pow = - 0,7570 a 25°C (according to boric acid, Cordia et al. (2003) Unpublished report no: PML 2002-C42r to Borax decahydrate Europe,Ltd.).

BENZOTHAIAZOLE: no appreciable bioaccumulation potential (log Ko/w 1-3).

PROPAN-2-OL

Partition coefficient: n-octanol/water. 0,05 Log Kow (CRC Handbook of Chemistry and Physics)

12.4. Mobility in soil.

SODIUM HYDROXIDE:

Considering the high mobility in soil and high solubility, it can be dissolved after the rain and seep into the soil. (data available in the supplier's SDS).

BORAX DECAHYDRATE:

The product is soluble in water. The adsorption in soil or sediment is irrelevant (data available in the supplier's SDS).

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.

SECTION 13. Disposal considerations.

13.1. Waste treatment methods.

Reuse, when possible. 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.

Waste transportation may be subject to ADR restrictions.

CONTAMINATED PACKAGING

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

SECTION 14. Transport information.

NOTE: The product isn't classified as corrosive for metals because the test described in the part III, subsection 37.4 of UN Transport of Dangerous Goods Recommendations (rif. Sec. 2.16 Annex I CLP Regulation) is resulted negative.

SECTION 15. Regulatory information.

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture.

Seveso category.

None.

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

Product.

Point

3. *Liquid substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:*
(a) *hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;*
(b) *hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;*
(c) *hazard class 4.1;*
(d) *hazard class 5.1.*

Contained substance.

Point.

30

BORAX DECAHYDRATE Reg. no:
01-2119490790-32-0011

Substances which appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 classified as toxic to reproduction category 1° or 1B (Table 3.1) or toxic to reproduction category 1 or 2 (Table 3.2) and listed as follows:

— Reproductive toxicant category 1A adverse effects on sexual function and fertility or on development (Table 3.1) or reproductive toxicant category 1 with R60 (May impair fertility) or R61 (May cause harm to the unborn child) (Table 3.2) listed in Appendix 5

— Reproductive toxicant category 1B adverse effects on sexual function and fertility or on development (Table 3.1) or reproductive toxicant category 2 with R60 (May impair fertility) or R61 (May cause harm to the unborn child) (Table 3.2) listed in Appendix 6

Substances in Candidate List (Art. 59 REACH).

BORAX DECAHYDRATE

Reg. no: 01-2119490790-32-0011

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.

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

WGK 1: Low hazard to waters

15.2. Chemical safety assessment.

A chemical safety assessment has been performed for the following contained substances:

SODIUM HYDROXIDE Nr Reg. 01-2119457892-27-XXXX

PROPAN-2-OL, Nr Reg. 01-2119457558-25

BORAX DECAHYDRATE Nr Reg. 01-2119490790-32-0011

SECTION 16. Other information.

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

Flam. Liq. 2	Flammable liquid, category 2
Met. Corr. 1	Substance or mixture corrosive to metals, category 1
Repr. 1B	Reproductive toxicity, category 1B
Acute Tox. 4	Acute toxicity, category 4
Skin Corr. 1A	Skin corrosion, category 1A
Skin Corr. 1B	Skin corrosion, category 1B
Skin Corr. 1C	Skin corrosion, category 1C
Eye Dam. 1	Serious eye damage, category 1
Eye Irrit. 2	Eye irritation, category 2
Skin Irrit. 2	Skin irritation, category 2
STOT SE 3	Specific target organ toxicity - single exposure, category 3
Aquatic Chronic 3	Hazardous to the aquatic environment, chronic toxicity, category 3
Aquatic Chronic 4	Hazardous to the aquatic environment, chronic toxicity, category 4
H225	Highly flammable liquid and vapour.
H290	May be corrosive to metals.
H360FD	May damage fertility. Suspected of damaging the unborn child.
H302	Harmful if swallowed.
H312	Harmful in contact with skin.

H332	Harmful if inhaled.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H336	May cause drowsiness or dizziness.
H412	Harmful to aquatic life with long lasting effects.
H413	May cause long lasting harmful effects to aquatic life

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EU) 1907/2006 (REACH) of the European Parliament
 2. Regulation (EU) 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
- 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
 - ECHA website

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.



Cantel Medical (Italy) S.R.L.
Industria Chimico-Farmaceutica
Via Laurentina 169
00071 POMEZIA (RM)

ISASPOR® SINGLE SHOT - SOL. B

Medical device class IIb
IDENTIFICATION CODE ISA/CE/43

1st Edition

Revision no.2

Revision date: 10.02.2017

Page n. 16/16

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.

Changes to previous review:

The following sections were modified: 02 / 03 / 08 / 10 / 11 / 12 / 13 / 14 / 15 / 16 / Exposure scenario

Classification according to Regulation (EC) Nr. 1272/2008

Eye irritation, category 2

Skin irritation, category 2

Classification procedure

Calculation method

Calculation method

Changes made since the previous revision.

Ed.	Rev.	Date	STATUS AND REASON OF REVISIONS
1	0	07.04.2011	First edition
1	1	01.06.2015	Adaptation to REACH and CLP Regulation.
1	2	10.02.2017	Riclassification of the mixture in compliance with the EC Regulation CLP N. 1272/2008 for the change of formulation of the solution B



CERTIFICATO CE - SISTEMA COMPLETO DI GARANZIA DI QUALITÀ
EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

APPROVAZIONE DEL SISTEMA DI QUALITÀ ATTUATO DA
APPROVAL OF THE QUALITY SYSTEM OPERATED BY

CANTEL MEDICAL (ITALY) S.R.L.

IT - 00071 POMEZIA (RM) - VIA LAURENTINA 169

SITI / SITES

IT - 00071 POMEZIA (RM) - VIA LAURENTINA 169

PER I SEGUENTI DISPOSITIVI O GRUPPI DI DISPOSITIVI / FOR THE FOLLOWING DEVICES OR GROUPS OF DEVICES

Disinfettanti per dispositivi medici

Disinfectants for medical devices

Certiquality S.r.l., Organismo Notificato n° 0546, certifica che il sistema di qualità

Certiquality S.r.l., Notified Body n°0546, certifies that the quality system

è conforme ai requisiti della Direttiva 93/42/CEE, Allegato
is in compliance with the requirements of Directive 93/42/EEC, Annex

II

ad esclusione del punto 4
excluding section 4

RAPPORTO DI AUDIT N°
AUDIT REPORT NO. **24884**

CERTIFICATO N.
CERTIFICATE N. **24884**

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CONCESSIONE E IL MANTENIMENTO DELL'APPROVAZIONE DI SISTEMA QUALITÀ AI SENSI DELLA DIRETTIVA 93/42/CEE

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE REGULATIONS FOR AWARDED AND MAINTENANCE OF QUALITY SYSTEM APPROVAL IN ACCORDANCE WITH DIRECTIVE 93/42/EEC

IL SISTEMA QUALITÀ E' SOGGETTO A SORVEGLIANZA PERIODICA
THE QUALITY SYSTEM IS SUBJECT TO PERIODICAL SURVEILLANCE

LA VERIFICA DEL SISTEMA QUALITÀ E' LIMITATA AGLI ASPETTI DELLA FABBRICAZIONE CONCERNENTI LA CONFORMITÀ AI REQUISITI METROLOGICI PER I DISPOSITIVI DI CLASSE I CON FUNZIONE DI MISURA E AGLI ASPETTI DELLA FABBRICAZIONE CHE RIGUARDANO IL RAGGIUNGIMENTO E IL MANTENIMENTO DELLO STATO STERILE PER I DISPOSITIVI DI CLASSE I STERILE

THE AUDIT OF THE QUALITY SYSTEM IS RESTRICTED TO THE ASPECTS OF MANUFACTURE CONCERNED WITH THE CONFORMITY OF THE DEVICES WITH METROLOGICAL REQUIREMENTS FOR DEVICES IN CLASS I WITH MEASURING FUNCTION AND WITH SECURING AND MAINTAINING STERILE CONDITIONS FOR DEVICES IN CLASS I IN STERILE CONDITION

IL PRESENTE CERTIFICATO NON E' DA RITENERSI VALIDO SE NON ACCOMPAGNATO DAL RELATIVO ALLEGATO
THIS CERTIFICATE IS NOT VALID WITHOUT THE RELEVANT ANNEX

PRIMA EMISSIONE
FIRST ISSUE **08/04/1998**

EMISSIONE CORRENTE
CURRENT ISSUE **12/07/2017**

DATA DI SCADENZA
EXPIRY DATE **11/07/2022**


CERTIQUALITY S.r.l.



ORGANISMO NOTIFICATO N° 0546

NOTIFIED BODY N° 0546

ALLEGATO AL CERTIFICATO N.
ANNEX TO CERTIFICATE N.

24884

Pagina / Page 1/1

CANTEL MEDICAL (ITALY) S.R.L.

SITI / SITES

IT - 00071 POMEZIA (RM) - VIA LAURENTINA 169

ELENCO PRODOTTI / PRODUCT LIST

ADASPOR, ADASPOR ERS, ADASPOR M, ADASPOR MONODIE, ADASPOR PENTADIE, ADASPOR SINGLE SHOT, PROLYSTICA AUTO PAA, BLUESTERIL ALCOLICO, BLUSTERIL FERRI CE, CLOREXAN FERRI, NEO PROTEOZIM PLUS 500, PROTEOZIM PLUS 400, PROTEOZIM PLUS 1000, PROTEAZONE, PROTEAZONE ERS, PROTEAZONE OD, SPOREX, SPOREX OPA, SPOREXIN PLUS DS, SPOREXIN PLUS OD, SPOREXIN PLUS SALVIETTE, SPOREXIN PLUS VACUUM, SPORIDOX, SPORIDOX PLUS, ISASPOR, ISASPOR MONODIE, ISASPOR SINGLE SHOT, ISACLEAN, BACTRYL SPRAY, BACTRYL WIPES, ADASPOR PLUS PRONTO, ADASPOR PLUS CONCENTRATO, ADASPOR PLUS MONODIE, ADASPOR PLUS SINGLE SHOT, ISASPOR M, ISASPOR PENTADIE, ISASPOR ERS, ADASPOR PLUS M, ADASPOR PLUS PENTADIE, ADASPOR PLUS ERS, ISACLEAN SPRAY, SPOREXIN SPRAY, SPOREXIN VACUUM, SPOREXIN WIPES

IL PRESENTE ALLEGATO NON E' DA RITENERSI VALIDO SE NON ACCOMPAGNATO DAL RELATIVO CERTIFICATO
THIS ANNEX IS NOT VALID WITHOUT THE RELEVANT CERTIFICATE

PRIMA EMISSIONE <i>FIRST ISSUE</i>	08/04/1998
EMISSIONE CORRENTE <i>CURRENT ISSUE</i>	12/07/2017
DATA DI SCADENZA <i>EXPIRY DATE</i>	11/07/2022


CERTIQUALITY S.r.l.

DICHIARAZIONE DI CONFORMITA CE EC DECLARATION OF CONFORMITY

Nome del Fabbricante Manufacturer's Name	Cantel Medical (Italy) S.r.l.
Indirizzo del Fabbricante Manufacturer's address	Via Laurentina, 169-00071 Pomezia (Roma)-Italy
Nome del Dispositivo Medico Name of the Medical Device	ISACLEAN®
Codice Identificativo Identification code	ISAC/CE/44
Classe del prodotto Device Class	II b
Destinazione d'uso Fields covered	Soluzione decontaminante e detergente per dispositivi medici Disinfectant and detergent solution for medical devices
Sistema di Qualità Quality System	UNI EN ISO 9001-UNI CEI EN ISO 13485 Ultime revisioni Direttiva 93/42/CEE e s.m.i. UNI EN ISO 9001-UNI CEI EN ISO 13485 Recent revisions Directive 93/42/CEE and next renewals
Organismo Notificato Notified Body	CERTIQUALITY Srl Via Gaetano Giardino, 4-20123 Milan – (Italy)
Numero Certificato A Q Q A Certificate no.	No. 995/CE001 rilasciato in data 08.04.1998 e successivi rinnovi No. 995/CE001 released on 08.04.1998 and next renewals

La Società Cantel Medical (Italy) S.r.l. dichiara che il Dispositivo Medico **ISACLEAN®** è conforme ai requisiti essenziali dell'allegato I della Direttiva 93/42/CEE e modifiche apportate dalla Direttiva 2007/47/CE e che il Sistema di Gestione della Qualità è conforme all'allegato II della Direttiva 93/42/CEE approvato dall'Organismo notificato Certiquality n. 0546.

Dichiara, altresì, che **ISACLEAN®** rientra nella famiglia dei disinfettanti per Dispositivi Medici così come descritto nel Certificato n. 995/CE/001 rilasciato in data 08.04.1998 dall'Istituto di certificazione "Certiquality" e successivi rinnovi.

The undersigned Co Cantel Medical (Italy) S.r.l. company declares that the Medical Device **ISACLEAN®** conforms with the Essential Requirements of the attachment I of the Directive no. 93/42/EEC, and modifications within Directive 2007/47/EC and that the Quality System conform with attachment II of the Directive no. 93/42/EEC, approved by the Notified Body Certiquality no. 0546.

Cantel Medical (Italy) Srl declares also that **ISACLEAN®** is part of the Medical Device disinfectant family as indicated in the Certificate no. 995/CE/001 released on 08.04.1998 by Certiquality Notified Body and successive renewals.

Data/date 27.01.2017

GIORNO/DAY - MESE/MONTH - ANNO/YEAR

AMMINISTRAZIONE

CEO
VINIT MARK SUPEKAR

DICHIARAZIONE DI CONFORMITA CE EC DECLARATION OF CONFORMITY

Nome del Fabbricante Manufacturer's Name	Cantel Medical (Italy) S.r.l.
Indirizzo del Fabbricante Manufacturer's address	Via Laurentina, 169 – 00071 Pomezia (Roma) - Italy
Nome del Dispositivo Medico Name of the Medical Device	ISASPOR - ISASPOR MONODIE - ISASPOR SINGLE SHOT - ISASPOR M - ISASPOR PENTADIE- ISASPOR ERS
Codice Identificativo Identification code	ISA/CE/43
Classe del prodotto Device Class	IIb
Destinazione d'uso Fields covered	Sterilizzanti chimici a freddo per dispositivi medici Conformi alla norma UNI EN ISO 14937: 2009- 5.3.1 Cold chemical sterilant solutions for medical devices conforming to UNI EN ISO 14937: 2009- 5.3.1
Sistema di Qualità Quality System	UNI EN ISO 9001– UNI EN ISO 13485 Ultime Revisioni Directive 93/42/CEE - Directive 2007/47/CE
Organismo Notificato Notified Body	CERTIQUALITY Srl Via Gaetano Giardino, 4 – 20123 Milan – (Italy)
Numero Certificato A Q Q A Certificate no.	No. 995/CE001 rilasciato in data 08.04.1998 e successivi rinnovi No. 995/CE001 released on 08.04.1998 and next renewals

La Società Cantel Medical (Italy) S.r.l. dichiara che i Dispositivi Medici **ISASPOR, ISASPOR MONODIE, ISASPOR SINGLE SHOT, ISASPOR M, ISASPOR PENTADIE e ISASPOR ERS** sono conformi ai requisiti essenziali dell'allegato I della Direttiva 93/42/CEE e modifiche apportate dalla Direttiva 2007/47/CE e, che il Sistema di Gestione della Qualità è conforme all'allegato II della Direttiva 93/42/CEE approvato dall'Organismo notificato Certiquality n. 0546.

Dichiara, altresì, che i Dispositivi Medici **ISASPOR, ISASPOR MONODIE, ISASPOR SINGLE SHOT, ISASPOR M, ISASPOR PENTADIE e ISASPOR ERS** rientrano nella famiglia dei disinfettanti per Dispositivi Medici così come descritto nel Certificato n. 995/CE001 rilasciato in data 08.04.1998 dall'Istituto di certificazione "Certiquality" e successivi rinnovi.

The undersigned Co Cantel Medical (Italy) S.r.l. declares that the Medical Devices **ISASPOR, ISASPOR MONODIE, ISASPOR SINGLE SHOT, ISASPOR M, ISASPOR PENTADIE and ISASPOR ERS** conforms with the Essential Requirements of the attachment I of the Directive no. 93/42/EEC and modifications within Directive 2007/47/EC, and that the Quality System conform with attachment II of the Directive no. 93/42/EEC, approved by the Notified Body Certiquality no. 0546.

Cantel Medical (Italy) S.r.l. declares also that the Medical Devices **ISASPOR, ISASPOR MONODIE, ISASPOR SINGLE SHOT, ISASPOR M, ISASPOR PENTADIE and ISASPOR ERS** are part of the Medical Device disinfectant family as indicated in the Certificate no. 995/CE001 released on 08.04.1998 by Certiquality Notified Body and successive renewals.

Data/date 01.06.2015

Amministratore/CEO

GIORNO/DAY - MESE/MONTH - ANNO/YEAR

VINIT MARK SUPEKAR

