

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 Support*)

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 Heating may cause a fire. |
| H290 | May be corrosive to metals, |
| H302 | Harmful if swallowed. |
| H314 | Causes severe skin burns and eye damage. |
| H335 | May cause respiratory irritation |
| H412 | 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 |
|-----------|------------|

HYDROGEN PEROXIDE

Threshold value.

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

TLV-ACGIH 1,4 1

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

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)

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.

-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 PEROSSIACETICO IN MISCELA STABILIZZATA

IMDG:

HYDROGEN PEROXIDE AND PEROXYACETIC ACID MIXTURE, STABILIZED

IATA:

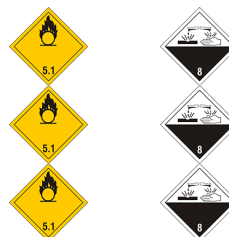
HYDROGEN PEROXIDE AND PEROXYACETIC ACID MIXTURE, STABILIZED


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)



| | | |
|---|---|---|
|  <p>Cantel Medical (Italy) S.R.L. Chemical-Pharmaceutical Company Via Laurentina 169 00071 POMEZIA (RM)</p> | <p>ISASPOR® SINGLE SHOT - SOL. A</p> <p>MEDICAL DEVICE class IIb IDENTIF. CODE ISA/CE/43</p> | <p>1st Edition Revision n. 1 Revision date 01.06.2015 Page no 13/16</p> |
|---|---|---|

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).

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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**ISASPOR® SINGLE SHOT -
SOL. A**

MEDICAL DEVICE class IIb
IDENTIF. CODE ISA/CE/43

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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. |