

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): direzionetecnica@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	SKIN.
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.

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.

 <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</p> <p>Revision no.2</p> <p>Revision date: 10.02.2017</p> <p>Page n. 10/16</p>
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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:

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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.

<u>Product.</u>	
Point	<p>3. <i>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:</i></p> <p>(a) <i>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;</i></p> <p>(b) <i>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;</i></p> <p>(c) <i>hazard class 4.1;</i></p> <p>(d) <i>hazard class 5.1.</i></p>

Contained substance.

Point.	30	<p>BORAX DECAHYDRATE Reg. no: 01-2119490790-32-0011</p> <p>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:</p> <p>— 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</p> <p>— 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</p>
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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.



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ISASPOR® SINGLE SHOT - SOL. B

Medical device class IIb
IDENTIFICATION CODE ISA/CE/43

1st Edition

Revision no.2

Revision date: 10.02.2017

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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