

Safety Data Sheet

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

1.1. Product identification

Trade **ADASPOR® PLUS M CONCENTRATE- SOL. B**

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 amended
Cold chemical sterilizing solution for medical devices.
Professional use only.
Product to be used after mixing with ADASPOR® PLUS M CONCENTRATE- SOL. A

Uses advised against None in particular.

1.3. Information on the supplier of the safety data sheet

Company Name Autonomous production laboratory.
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: 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. Identification of hazards.

2.1. Classification of substance or mixture.

The product is not classified as a dangerous substance pursuant to the provisions laid down in Regulation (EC) 1272/2008 (CLP) (and subsequent amendments). The product, however, containing dangerous substances in concentration so as to be declared in section 3, requires a safety data sheet with appropriate information, in accordance with Regulation (EC) 1907/2006 and subsequent modifications.

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

Classification and hazard statements:

2.2. Label elements.

Hazard signs:

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Warnings: --

Hazard indications:

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Safety phrases:

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Safety data sheet available on request for professional users.

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.
BORAX DECAHYDRATE CAS. 1303-96-4 CE. 215-540-4 INDEX. 005-011-01-1 Reg. No. -	7,5 - 8,4	Repr. Cat. 2 R60, Repr. Cat. 2 R61	Repr. 1B H360FD
ISOPROPANOL CAS. 67-63-0 CE. 200-661-7 INDEX. 603-117-00-0 Reg. No. -	7 - 8	R67, F R11, Xi R36	Flam. Liq. 2 H225, Eye Irrit. 2 H319, STOT SE 3 H336
1H-BENZOTRIAZOLE CAS. 95-14-7 CE. 202-394-1 INDEX. - Reg. No. -	1 - 1,5	R52/53, Xn R22, Xi R36	Acute Tox. 4 H302, Eye Irrit. 2 H319, Aquatic Chronic 3 H412

The full texts of 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 15 minutes, with eyes wide open. Consult a doctor if the problem persists.

SKIN: Take off contaminated clothing. Wash immediately and thoroughly with water. If the irritation persists, consult a physician. Wash contaminated clothing before reuse.

INHALATION: Bring the subject out to open air. If breathing is difficult, call a physician immediately.

INGESTION: Consult a physician immediately. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person unless authorized by your doctor.

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.

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 means.

SUITABLE EXTINGUISHING MEDIA

The extinguishing means 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 the 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 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 works 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. Check any incompatibility for the material of the containers in section 7. The disposal of the contaminated material must be made in accordance with the provisions of point 13.

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.

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 the 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. Control of exposure/personal protection.

8.1. Control parameters.

Reference Standards:

Italy	Legislative Decree April 9, 2008, n.81.
Switzerland	Limit values for exposure at workplace 2012.
OEL EU	Directive 2009/161/UE; Directive 2006/15/CE; Directive 2004/37/CE; Directive 2000/39/CE.
TLV-ACGIH	ACGIH 2012

BORAX DECAHYDRATE**Threshold value.**

Type	Estado	TWA/8h		STEL/15min	
		mg/m3	ppm	mg/m3	ppm
TLV-ACGIH		2		6	

ISOPROPANOL**Threshold value.**

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

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.

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.

SKIN PROTECTION

Wear work clothes with long sleeves and safety footwear for professional use of category I (Ref. Directive 89/686/EEC and standard EN ISO 20344). Wash with soap and water after removing protective clothing.

EYE PROTECTION

It is recommended that you wear protective goggles (ref. standard EN 166).

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.

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	slightly alcoholic
Olfactory threshold.	Not available.
pH	10.5 ± 0.5
Melting o Freezing Point.	Not available.
Initial boiling point.	> 100 °C.
Boiling point.	Not available.
Flash Point.	> 100 °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.
Vapour pressure.	Not available.
Vapour Density.	Not available.
Relative density.	1 ± 0.2 Kg/l
Solubility	soluble in water
Partition coefficient: n-octanol/water	Not available.
Ignition Temperature.	Not available.
Decomposition Temperature.	Not available.
Viscosity	30 ± 10 cP
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) :	7.85 % - 78.50 g/litre.
VOC (volatile carbon):	4.70 % - 47.02 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.
1H-BENZOTRIAZOLE: decomposes at 160 °C.

10.2. Chemical stability.

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

10.3. Possibility of dangerous reactions.

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

10.4. Conditions to avoid.

Avoid overheating. Avoid the accumulation of electrostatic charges. Avoid any ignition source.
Avoid contact with oxidizing agents and strong reducing, strong acids, strong bases.

10.5. Incompatible materials.

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

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.

BORAX: oxides of boron, oxides of sodium.
1H-BENZOTRIAZOLE: nitrogen oxides.

SECTION 11. Toxicological information.

11.1. Information on toxicological effects.

There are no known incidents of damage to health due to exposure to the product. In any case it is recommended to operate in compliance with the rules of good industrial hygiene. The preparation can, in particularly sensitive subjects, cause minor health effects after exposure upon inhalation and/or absorption through skin and/or contact with the eyes and/or ingestion.

Data referring to the mixture:

ACUTE INHALATION TOXICITY: Data not available.
ACUTE ORAL TOXICITY: Data not available.
ACUTE SKIN TOXICITY: Data not available.
CORROSION/ SKIN IRRITATION: Data not available.
SEVERE EYE DAMAGE/SEVERE EYE IRRITATION: Data not available.
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: 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:

BORAX DECAHYDRATE

REPRODUCTIVE TOXICITY: May affect fertility and the unborn child, as per harmonized classification in Annex VI Reg. CLP.

ISOPROPANOL

SEVERE DAMAGE TO THE EYE/EYE IRRITATION: irritating, in vivo test on the rabbit (Method equivalent or similar to OECD TG 405; Site of dissemination of ECHA)

SPECIFIC TOXICITY TO TARGET ORGANS (STOT) - SINGLE EXPOSURE: May cause drowsiness or dizziness as per harmonized classification in Annex VI Reg. CLP.

1H-BENZOTRIAZOLE

ACUTE TOXICITY LD50 (Oral). 500 mg/kg Rat (Method: OECD Guideline 423 in GLP; Site of dissemination of ECHA)

SEVERE DAMAGE TO THE EYE/EYE IRRITATION: irritating, in vivo test on the rabbit (Method: OECD TG 405; Site of dissemination of ECHA)

SECTION 12. Ecological information.

There is no specific data on the preparation, use according to the good working practices, so as to avoid releasing the product to the environment. Avoid absolutely to disperse the product into the soil, in sewer systems or water courses. Alert the relevant authorities if the product has reached water courses or sewers or if it has contaminated soil or vegetation. Take measures to minimize the effects on ground water.

12.1. Toxicity.

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/7d Scenedesmus quadricauda (Published on ECHA website, no reference guidelines)

12.2. Persistence and degradability.

ISOPROPANOL

Readily biodegradable (EU Method C.5, Site of dissemination ECHA)

12.3. Bioaccumulation potential.

1H-BENZOTRIAZOLE: no relevant bioaccumulation potential (log Ko/w 1- 3).

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.

Information not available.

SECTION 13. Disposal considerations.

13.1. Waste treatment methods.

Reuse, when possible. The residues of the product which are to be considered as non-hazardous waste. 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.

The product is not to be considered dangerous under the provisions for transport of dangerous goods by road (A.D.R.), rail (RID), by sea (IMDG Code) and by air (IATA).

SECTION 15. Regulatory information.

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

Seveso Category. None.

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

Contained substances.

BORAX DECAHYDRATE

Point. 30

Substances listed in part 3 of the annex VI of Regulation (EC) no. 1272/2008 Classified as toxic to reproduction (category 1A or 1B (table 3.1) or toxic to reproduction in category 1 or 2 (table 3.2), reported as

follows:

— toxic to reproduction in category 1A with harmful effects on sexual function and fertility or development (table 3.1) or toxic to reproduction in category 1 with R60 (May reduce fertility) or R61 (may harm the unborn child) (table 3.2) listed in Appendix 5,

— toxic to reproduction in category 1B with harmful effects on sexual function and fertility or development (table 3.1) or toxic to reproduction in category 2 with R60 (may reduce fertility) or R61 (may harm the unborn child) (table 3.2) listed in Appendix 6.

Candidate List Substances (Art. 59 REACH).

BORAX DECAHYDRATE

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.

Information not available.

Leg. Decree 152/2006 and subsequent amendments.

Emissions:

TAB. D Class 4 07,85 %

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
Repr. 1B	Reproductive toxicity, category 1B
Acute Tox. 4	Acute toxicity, category 4

Skin Corr. 1A	Skin corrosion, category 1A
Eye Irrit. 2	Eye 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
H360FD	May impair fertility. May harm the unborn child.
H225	Liquid and vapours highly flammable.
H319	Causes severe eye irritation.
H336	May cause drowsiness or dizziness.
H302	Harmful if swallowed.
H412	Harmful to aquatic organisms with long-term effects.
H290	Can be corrosive to metals.
H314	Causes severe skin burns and eye damage.

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

R11	HIGHLY FLAMMABLE.
R22	HARMFUL IF SWALLOWED.
R36	IRRITATING TO THE EYES.
R52/53	HARMFUL TO AQUATIC ORGANISMS, MAY CAUSE LONG-TERM ADVERSE EFFECTS TO THE AQUATIC ENVIRONMENT.
Repr. Cat. 2	Reproductive toxicity, fertility, category 2.
R60	MAY REDUCE FERTILITY.
Repr. Cat. 2	Reproductive toxicity, development, category 2.
R61	MAY HARM 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: 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
- LC50: Lethal concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational exposure level
- PBT: Persistent, bio accumulative and toxic according to REACH
- PEC: Predictable environmental concentration
- PEL: Predictable exposure level
- PNEC: Predictable no effect concentration



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

**ADASPOR® PLUS M
CONCENTRATE- SOL. B**

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

1st Edition
Revision no.1
Revision date 01.06.2015
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- 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 bio accumulative according to REACH.
- WGK: Aquatic hazard class (Germany).

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. European Parliament Regulation (EC) 618/2012 (II Atp. CLP)
9. The Merck Index. Ed. 10
10. Handling Chemical Safety
11. Niosh - Registry of Toxic Effects of Chemical Substances
12. INRS - Fiche Toxicologique
13. Patty - Industrial Hygiene and Toxicology
14. N.I. Sax - Dangerous properties of Industrial Materials-7 Ed., 1989
15. 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 made since the previous revision.

Ed.	Rev.	Date	STATUS AND REASON OF REVISIONS
1	0	18.09.2012	First issue
1	1	01.06.2015	Adaptation to REACH and CLP Regulation, changing company's name and logo