Edited in accordance with attachment II of the Regulation N. 1907/2006 of the European Parliament and Committee (Official European Journal L 136/84 dated 29.05.2007)

1. IDENTIFICATION OF SUBSTANCE OR PRODUCT AND COMPANY/MANUFACTURER

1.1	**Identification of product**	**ADASPOR® READY TO USE - ADASPOR® CONCENTRATE** Chemical denomination: water solution of adazone and peracetic acid Medical Device classification: classe IIb - Directive 2007/47/EC
1.2	**Use of the product**	Cold chemical sterilant solution for Medical Devices
1.3	**Company identification**	IMS srl - Via Laurentina, n. 169 – 00040 Pomezia (RM), Italy
1.4	**Emergency phone**	Italy: +39 - 06/9145399

2. HAZARD IDENTIFICATION

2.1	**Classification of dangerousness**	End product is not classificable as dangerous product
2.2	**Classification of ingredients**	The active ingredient peracetic acid is a dangerous product.
2.3	**Hazard identification**	**Solution A** (containing peracetic acid 5%) is corrosive and comburent. **The pruduct, activated and diluted and Solution B** (containing Adazone and coformulants) does not show hazard indications on the label
2.3.1	**Ingestion**	**Solution A** is noxious for ingestion
2.3.2	**Skin contact**	**Solution A** is noxious for contact with skin **Solution A** can cause sensitation
2.3.3	**Eye contact**	**Solution A** is noxious if in contact with eyes
2.3.4	**Inhalation**	**Solution A is noxious for inhalation**
2.3.5	**Effects on target organ**	/////
2.3.6	**Effects on sexual reproduction**	/////
2.3.7	**Mutagenic effects**	/////
2.3.8	**Sensitisation**	End product does not cause sensitisation.
2.4	**Notes**	End product should be handled by qualified personnel with appropriated safety rules.

3. COMPOSITION / INFORMATION ON INGREDIENTS

The product is made up by two bottles indicated as Solution A and Solution B. (Container with volume lower than 1 litre)

SOLUTION	INGREDIENTS/CONTENT	NO. CAS	RATE	CLASSIFICATION	RISK PHRASES
A	Peracetic acid	79-21-0	4-6	**O-C**	7-10-20/21/22-35-50
	Hydrogen peroxyde	7722-84-1	20 - 30	**O-C**	8-34
	Acetic acid	64-19-7	6 - 10	**O-C**	10-35
B	Adazone	263768-83-8	<1	///	///
	Coformulants (stabilisers,buffers, anticorrosives) and purified water	///	///	///	///

4. FIRST AID MEASURES

4.1	**Skin**	Wash immediately with plenty of water.
4.2	**Eyes**	Wash immediately with plenty of water for at least 10 minutes and call immediately a physician specialist.
4.3	**Ingestion**	Drink water in small quantities (dilution effect), but do not induce vomiting. Do not give active coal danger of hydrogen peroxide release.
4.4	**Inhalation**	Go outdoors and breathe deeply.

5. FIRE PREVENTION MEASURES

5.1	**Extinction means**	Water, foam, chemical powders, carbon dioxide
5.2	**Extinction means to avoid**	Organic compound
5.3	**Exposure risks from combustion and/or developed gas**	Pay attention to irritating vapors of acetic acid
5.4	**Special equipment for fire extinguishment**	Protect the respiratory ways. Use visors and gloves.

6. MEASURES IN CASE OF ACCIDENTAL SPILLAGE

6.1	**Individual caution**	Use gloves and protective clothes. Protect eyes.
6.2	**Environment caution**	In case of accidental spillage, the product resulting from mixing both solutions presents no toxicity issues. In case of spillage of Solution A alone, make sure it doesn't reach water courses, surface water or earth.
6.3	**Drainage method**	In case of spillage absorb with inert materials (diatomite, universal absorbing), pick up and dispose of safely. Clean the contaminated surfaces with water.
6.4	**Other suggestions**	Spilled product should not be poured in the original flask/tank for its reuse (decomposition hazard).

7. HANDLING AND STORAGE

7.1	**Handling**	Avoid contact with skin, eyes and clothing. Do not breathe vapours. Use under good industrial higene norms and adequate safety measures.
7.2	**Storage**	Store in a dry and ventilated place, away from heating source and flammable substances. Do not smoke
7.3	**Approved usage**	For hospitals, medical and dental surgeries and anywhere requiring sterilization and/or high level disinfection of medical devices.Only the concentrate solution A has to be handled by trained personnel following the safety norms indicated at point 8.

8. INDIVIDUAL PROTECTION AND EXPOSURE CONTROL

8.1	**Exposure limit** **Solution A**	Peracetic acid: TLV-TWA = 25 mg/mc (10 ppm) - TLV-STEL = 37 mg/mc (15 ppm). Mean olfactory threshold: 24,3 ppm Hydrogen peroxide: TLV-TWA = 1 ppm
	Solution B	//
8.2	**Exposure control**	
8.2.1	**Professional exposure control**	To handle solution A use protective clothes and follow the industrial hygiene and safety norms. To handle solution B no particular precautions is required. For the diluted activated and ready to use product, no particular precautions are required.
8.2.1a	**Respiratory protection**	In case of emergency use a mask for acid vapors with filter (A2B2E2K1P2)
8.2.1 b	**Hands protection**	Protective gloves (neoprene or rubber)
8.2.1 c	**Eyes protection**	Safety glasses or anti-spray glasses with mask and visor
8.2.1 d	**Skin protection**	Use acid resistant clothes (PVC, Neoprene, NBR, rubber) to protect the skin

8.3	**Environment exposure control**
Normal safety precautions should be observed during the mixing, opening and closing of Solution A. Exposure studies have shown that the environmental concentrations of peracetic acid are less than one half of TLV TWA for several minutes at a distance of one meter from the open tray/ tank .	

9. CHEMICAL AND PHYSICAL PROPERTIES

9.1	**General Informations**	**Solution A**	**Solution B**	**Solutions A + B**
Appearance		Clear liquid	Clear liquid	Clear liquid
Colour		Clear	Clear	Clear and/or slightly yellow
Odour		Pungent	Slightly alcohol	Pungent
9.2	**Important informations concerning health, safety and the environment**			
pH		0,5 ± 0,5	12,5 ± 1,0	6,0 ± 1,0
Boiling point		not applicable	> 100°C	> 100°C
Flammable point		> 96°C	> 100°C	> 100°C
Explosive properties		No data	No data	No data
Combustion properties		YES	NO	NO
Vapour pressure		27 mbar	not calculated	not calculated
Relative density		1,12 ± 0,2 kg/lt	1,0 ± 0,2	1,0 ± 0,2
Solubility in water at 25°C.		Complete	Complete	Complete
Distribution coefficient: n-octanol/water		log Pow – 1,25	not calculated	not calculated

10. STABILITY AND REACTIVITY

10.1	**Conditions to avoid**	Avoid direct sunlight and heat.
10.2	**Materials to avoid**	Solution A: avoid the contact with products flammables, organic solvents, metals, aluminium, zinc.
10.3	**Decomposition hazard products**	Acetic acid and oxygen. Danger of over pressure in case of decomposition.
10.4	**Incompatibility**	If used according to instructions, the product is compatible with all common components of which instruments are constituted. Simultaneous use of other medical devices is not envisaged. Anyway, contact with oxidant (eg. Chloro-derivatives) or reducing (eg. Aldehydes) agents is to avoid. Both solution A and B contain stabilizers. The dilution in water does not cause an exothermic reaction and the products formed by the degradation are easily eliminated. Do not mix with chlorinated products

11. TOXICOLOGICAL INFORMATIONS

Toxicological informations concerning active ingredients are the following:

11.1	**Acute toxicity**	**Solution A** DL_{50} oral on rats: 1540 mg/kg DL_{50} cutaneous on rats: 1410 mg/kg Inhalation (CL_{50}) (CL_{50}): 450 mg/m^3
11.2	**Primary irritation**	DL_{50} cutaneous on rats: 1410 mg/kg
11.3	**Ingestion**	Nausea and vomit, if ingested

Solution B
The composition does not require any precautions other than not ingesting and avoiding direct prolonged contact.

Adazone, one of the formulation ingredients, is part of a pharmacological group of substances which can be orally administered with a medium dose of 100 mg, 1 or 2 times daily. For these substances no toxicity value has been established for skin contact.

Solution A + B

The local tolerance of Adaspor following single and repeated dermal administration to both abraded and intact skin was investigated on rabbits over a period of up to 7 days.
No irritation (erythema or oedema) was observed at treated sites (intact or abraded) after either the single 6 hours exposure to 1 ml of product per contact site or the 7 days repeated dose with 0.5 ml of Adaspor.
No indications of a systemic effect (clinical signs) of the product were observed during the treatment period.
On the basis of these results, Adaspor is considered to be well tolerated after single and repeated application to the skin of rabbits over a period of up to 7 days, due to no evidence of reaction in any animal observed at treated sites.
NOEL (No Observed Effect Level) **2000 mg/Kg**

12. ENVIRONMENTAL INFORMATION

12.1	**Ecotoxicity**	Toxicity on IC50 selenatrum capricornutum: ca 0.18 mg/l/120h. NOEC selenatrum capricornutum: ca 0.20 mg/l/120h.
12.2	**Mobility**	In case of accidental spillage, the product resulting from mixing both solutions presents no toxicity issues. In case of spillage of Solution A alone, make sure it doesn't reach water courses, surface water or earth
12.3	**Persistence and biodegradability**	Both solutions A and B have a degradability grade of over 99%. Evaluation: high degradability Testing method: closed bottle test Analysis method: COD determination Behaviour in biological plants: 99% biodegradable
12.4	**Bio-accumulation potential**	No component has bio-accumulation potential
12.5	**Others adverse effects**	Not known.

13. DISPOSAL

13.1	**Product disposal**	As a disinfectant is considered a special waste (toxic) and therefore it requires disposal under existing legislation. Behaviour in biological systems: the exhausted solution is biodegradable. **Class of hazard to water:** WGK: 2 (classified according to German legislation).
13.2	**Disposal of bottles and packing**	After a thorough rinsing, bottles can either be recycled or disposed of as urban waste. Anyway, do not dispose of in the environment after use

14. TRANSPORTATION INFORMATIONS

Directions for transportation and storage apply to the product being correctly stored as indicated for any disinfectant.
Transportation by air, by sea and by read has to be carried out in respect of National and International legislation in force.

Proper shipping name	HYDROGEN PEROXIDE AND PEROXYACETIC, MIXTURE, STABILIZED
Air transportation	UN 3149 - Class 5.1 - Packing group II
Sea transportation	UN 3149 - HYDROGEN PEROXIDE AND PEROXYACETIC, MIXTURE, STABILIZED 5.1 (8), PG II
Road transportation	UN 3149 - HYDROGEN PEROXIDE AND PEROXYACETIC, MIXTURE, STABILIZED 5.1 (8), II

15. INFORMATION ON REGULATORY AND LABELLING

Labelling	Under directive CEE (91/155/CEE, 67/548/CEE and further modifications. D.L. 65 dated 14.03.2003 and further integrations.

Solution A (Peracetic acid 5%)

Symbols	Comburent CO	Corrosive C
(R) Risk phrases	**(7)** May cause fire - **(20/21/22)** Harmful by inhalation, in contact with skin and if swallowed - **(34)** Causes burns **(36)** Irritating to eyes	
(S) Safety phrases	**(36/37/39)** Wear suitable protective clothing, gloves and eye/face protection.	

Solution B				
Symbols	None			
(R) Risk phrases	None			
(S) Safety phrases	None.			
Warnings	The product should be handled by trained personnel following dedicated safety procedures keep in a dry place and at room temperature, away from heat sarces. Expiry date refers to intact product, correctly stored. Do not use after expiry date. After use exhausted solutions should be disposed under existing legislation. Do not dispose the containers in the environment after use.			

16. OTHER INFORMATION

Informations contained in this safety data sheet are based on our current knowledge and are supported by a considerable bibliographical documentation.They are applicable to the product under the state and conditions in which it is provided. The use of the product in association with any other product or under different conditions than those reported on the label, is of exclusive responsability of the user.

This safety data sheet has been compiled exclusively for storage, transportation and safety use of the product. This sheet illustrates the procedures to be followed in case of accidental spillage of the solution.
It is recommended to follow instructions on the label and/or the instruction sheet. Any other use of the product in combination with other products or in other processes is at users own risk and peril.

PATENTS: Italy no. 01306711 - Europe no. 830229- - US no. 6,432,356 B1

The information contained herewith is based on present knowledge. They characterise the product with reference to the appropriate safety precautions.

Ed.	Rev.	Date	STATE AND REVISION MOTIVATION
2	0	12.03.2004	pH variation for the reaty to use solution; More precise information about indications of use in “stability after activation/dilution”
2	1	20.09.2004	Date update
2	2	26.02.2007	Update to new norms
2	3	25.09.2008	Update to peracetic acid specifications.
2	4	15.10.2009	Update new norms
2	5	05.03.2010	Compliance to EU Directive 2007/47/EC
2	6	27.10.2010	Data update

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