

**IMS srl**

Chemical and Healthcare Company

Via Laurentina 169

00040 POMEZIA (RM)

# Safety Data Sheet

## ADASPOR<sup>®</sup> SINGLE SHOT

MEDICAL DEVICE *class IIb*  
IDENTIFICATION CODE **ADA/CE/27**

Ed. 1

Rev. 5

on: 27.10.2010

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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	<b>ADASPOR<sup>®</sup> SINGLE SHOT</b> Chemical denomination: water solution of adazone and peracetic acid Medical Device classification: class 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 classifiable as dangerous product
2.2	Classification of ingredients	The active ingredient peracetic acid is a dangerous product.
2.3	Hazard identification	<b>Solution A</b> (containing peracetic acid at 5%) is corrosive and comburent. <b>The product, activated and diluted and Solution B</b> (containing Adazone and coformulants ) do not show hazard indications on the label
2.3.1	Ingestion	<b>Solution A</b> is noxious for ingestion
2.3.2	Skin contact	<b>Solution A</b> is noxious for contact with skin <b>Solution A</b> can cause sensitisation
2.3.3	Eye contact	<b>Solution A</b> is noxious if in contact with eyes
2.3.4	Inhalation	<b>Solution A is noxious for inhalation</b>
2.3.5	Effects on targeted organs	////
2.3.6	Effects on sexual reproduction	////
2.3.7	Mutagenic effects	////
2.3.8	Sensitization	End product doesn't cause sensitisation
2.4	Warnings	End product should be handled by qualified personnel with appropriated safety rules.

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### 3. COMPOSITION / INFORMATION ON INGREDIENTS

The product is made up by two tanks, each one holding 10 or 5 liters, indicated as solution A and solution B.

The Solution A tank is homologated UN 3H1/Y1.9/20(\*) – B/EM-020166 (\* last two digits represent manufacturing year)

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 breath deeply.

### 5. FIRE PREVENTION MEASURES

5.1	Extinction means	Water, foam, chemical powders, carbon dioxide
5.2	Extinction means to avoid	Organic compounds
5.3	Exposure risks from combustion and/or developed gas	Pay attention to irritating vapours 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 and 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 )

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## 7. HANDLING AND STORAGE

7.1	Handling	Avoid contact with skin, eyes and clothing. Do not breathe vapours. Use under good industrial hygiene norms and adequate safety measures.
7.2	Storage	Store in a dry and ventilated place, away from heating source and flammable substances.
7.3	Approved usage	Should be used in Automated Endoscope Reprocessors ( Medivators if single shot generator is present ). 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 limits 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	While handling solution A use protective clothes and follow the industrial hygiene and safety norms. While handling solution B no particular precautions is required. For the diluted, activated and ready to use product, no particular precautions are required.
8.2.1 a	Respiratory protection	In case of emergency use a mask for acid vapours with filter (A2B2E2K1P2)
8.2.1 b	Hands protection	Protective gloves (neoprene or rubber)
8.2.1 c	Eyes protection	Safety glasses or glasses anti-spray 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 the tray containing the solution. Exposure studies have shown that the environmental concentrations of peracetic acid are less than one half of the TLV TWA threshold the should 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	6,0 ± 1,0
	Boiling point	not applicable	> 100 °C	> 100 °C
	Flash point	> 96	> 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 g/cm <sup>3</sup>	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
	Viscosity	not calculated	30 ± 10 cP	3,0 ± 1,0 cP

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## 10. STABILITY AND REACTIVITY

10.1	Conditions to avoid	Avoid direct sunlight and heat.
10.2	Materials to avoid	Solution A: Avoid contact with products flammables, organic solvents, metals, aluminium, zinc.
10.3	Decomposition hazard products	Acetic acid and oxygen. Danger of over pressure increase 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 agents (eg. Aldehydes) 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 degradation are easily eliminated.

## 11. TOXICOLOGICAL INFORMATION

11.1	Acute toxicity	<b>Solution A</b> DL <sub>50</sub> oral on rats: 1540 mg/kg DL <sub>50</sub> cutaneous on rats: 1410 mg/kg Inhalation (CL <sub>50</sub> ) : 450 mg/m <sup>3</sup>
11.2	Primary irritation	DL <sub>50</sub> 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. Orally administrated Adazone, one of the formulation ingredients, is part of a pharmacological group of substances which can be in 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 in rabbits over a period of up to 7 days.

No irritation (erythema or oedema) was observed at treated sites (intact or abraded) following either the single 6 hours exposure to 1 ml of test 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 test item were observed during the treatment period.

On the basis of these results, the Adaspor is considered to be well tolerated following single and repeated applications to the skin of rabbits over a period of up to 7 days, due to no evidence of there being no reaction in any animal observed at treated sites.

**NOEL** (No Observed Effect Level) **2000 mg/Kg**

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### 12. ENVIRONMENTAL INFORMATION

12.1	Ecotoxicity	Toxicity on IC50 selenatrum capricornutum: ca 0.18 mg/l/120h. NOEC selenatrum capricornutum: ca 0.12 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 and earth
12.3	Persistence and degradability	Both solutions A and B have a biodegradability 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 a 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) it therefore requires disposal under the existing legislation. Behaviour in biological systems: the exhausted solution is biodegradable. <b>Class of hazard to water:</b> 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. TRANSPORT INFORMATIONS

Directions for transport and storage apply to the product being correctly stored, as indicated for any disinfectant. Transport by air, by sea and by road has to be carry 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 LABELING

National prescriptions	Follow the National directives/regulations
Labelling	Under directive CEE (91/155/CEE, 67/548/CEE and succ.mod. D.L. 65 dated 14/03/03 and further integrations.

**Solution A (Peracetic acid 5%)**

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<b>Symbols</b>	<b>Comburent (C)</b>	<b>Corrosive (C)</b>
<b>(R) Risk phrases</b>	<b>(7)</b> May cause fire - <b>(20/21/22)</b> Harmful by inhalation, it in contact with skin and if swallowed - <b>(34)</b> Causes burns <b>(36/37/38)</b> Irritating to eyes, respiratory system and skin.	
<b>(S) Safety phrases</b>	<b>(3/7)</b> Keep container tightly closed in a cool place. <b>(26)</b> In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. <b>(36/37/39)</b> Wear suitable protective clothing, gloves and eye/face protection. <b>(45)</b> In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).	

<b>Solution B</b>	
<b>Symbols</b>	<b>Irritant (Xi)</b>
<b>(R) Risk phrases</b>	<b>(43)</b> May cause irritation in contact with skin.
<b>(S) Safety phrases</b>	<b>(26)</b> In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
<b>Notices</b>	Product should be handled by qualified personnel following appropriate safety norms. Keep the recipient close in a dry place and away from heat. Expiry date refers to intact product, correctly stored. Do not use after expiry date. After use, exhaust solutions have to be disposed under the existing legislation. Do not dispose the containers in environment after use.

**PATENTS: Italy no. 01306711 - Europe no. 830229.1- 2101 - US no. 6,432,356 B1**

## 16. OTHER INFORMATION

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

**The information contained herewith are based on present knowledge, characterising the product with reference to the appropriate safety precautions.**

Ed.	Rev.	Date	STATE AND REVISION MOTIVATION
1	0	08.01.2004	First release
1	1	26.02.2007	Update to new norms
1	2	25.09.2008	Update to peracetic acid specifications
1	3	05.03.2010	Compliance to EU Directive 2007/47/EC
1	4	05.03.2010	Inactive ingredient elimination (CMK)
1	5	27.10.2010	Data upgrade

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