CANTEL MEDICAL

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Chemico-Pharmaceutical Industries
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Technical Data Sheet
ADASPOR PLUS®CONCENTRATE
MEDICAL DEVICE *class IIb*
CODE CODE ISA/CE/43

1. Device Name

ADASPOR PLUS CONCENTRATE®

CE 0546

2. Qualitative and quantitative composition

Activated solution (A+B)

- ISAZONE® ($C_{20}H_{20}ON_2$)	g	0.010
- Peracetic acid	g	0.180
- Co-formulants (stabilizers, buffers, anticorrosive) and purified water q.s. to	ml	100.000

3. Product presentation

Description of activated solution (A+B): concentrated, fast-acting, tuberculocidal, sporicidal, bactericidal, virucidal, fungicidal chemical cold sterilization solution compliant with Standard UNI EN ISO 14937:2009 for endoscopes and medical devices (instruments, catheters and probes, equipment for anaesthesia, inhalation therapy, haemodialysis, endoscopy, urology, dentistry, etc.). Can be used for manual and automatic cleaning of medical devices and equipment according to the manufacturer's instructions.

Packaging: 2 bottles (Sol. A: 45 ml and Sol B: 205 ml) in a box.
2 bottles (Sol. A: 180 ml and Sol B: 820 ml) in a box.

4. Activity and microbiological properties, according to UNI EN ISO 14885:2006: "Application of European standards for chemical disinfectants and antiseptics

4.1 Sterilizing Activity according to UNI EN ISO14937:2009 par 5.3.1 and in compliance with UNI EN ISO 111381:2006

Method used	**UNI EN ISO14937:2009 par 5.3.1 and UNI EN ISO 11138-1:2006**
Strains used	*Bacillus subtilis* ATCC 6633 *Bacillus atropheus* ATCC 9372 *Bacillus cereus* ATCC 12826 *Clostridium sporogenes* ATCC 19404 *Geobacillus stearothermophylus* ATCC 7953 *Mycobacterium terrae* ATCC 15755 *Candida albicans* ATCC 10231 *Aspergillus niger* ATCC16404 *Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538P *Virus lipidici e non lipidici* *Picornavirus (Coxasackie* B3*)* *Adenovirus* Type 4
Result	**sterilization time: 10' – CFU growth = 0**

4.2 Activity and microbiological properties, according to UNI EN ISO 14885:2006: "Application of European standards for chemical disinfectants and antiseptics"

4.2.1 Sporicidal Activity according to UNI EN ISO 14885:2006	
Method used	**EN 14347 - Basic sporicidal activity test** **(CBI = 10^8 - 10^9 R ≥ 4 log)**
Strains used	*Bacillus subtilis* ATCC 6633 *Bacillus cereus* ATCC 12826
Result	**contact time: 10' – CFU growth = 0** **contact time: 5' – R ≥ 4 log**
Method used	**EN 13704 - Sporicidal activity test** **(CBI = 10^6 R ≥ 3 log, in clean condition)**
Strains used	*Bacillus subtilis* ATCC 6633 *Bacillus cereus* ATCC 12826 *Clostridium sporogenes* ATCC 19404
Result	**contact time: 10 ' – CFU growth = 0, in clean condition** **contact time: 5' – R ≥ 3 log, in clean condition**

4.2.2 Mycobactericidal Activity according to UNI EN ISO 14885:2006	
Method used	**EN 1040 mod - Basic mycobactericidal activity test** **(CBI = 10^8 R ≥ 5 log)**
Strains used	*Mycobacterium terrae* ATCC 15755 *Mycobacterium avium* ATCC 15769 *Mycobacterium smegmatis* CIP 7326
Result	**contact time: 10' – CFU growth = 0** **contact time: 5' – R ≥ 5 log**
Method used	**EN 14348 - Mycobactericidal activity test in medical field** **(CBI = 10^8 R ≥ 4 log, in clean and dirty condition)**
Strains used	*Mycobacterium terrae* ATCC 15755 *Mycobacterium avium* ATCC 15769 *Mycobacterium smegmatis* CIP 7326
Result	**contact time: 10 ' – CFU growth = 0, in clean and dirty condition** **contact time: 5' – R ≥ 4 log, in clean and dirty condition**
Method used	**EN 14563 - Mycobactericidal activity test on carrier in medical field** **(CBI = 10^9 R ≥ 4 log, in clean and dirty condition)**
Strains used	*Mycobacterium smegmatis* CIP 7326 *Mycobacterium terrae* ATCC 15755 *Mycobacterium avium* ATCC 15769
Result	**contact time: 10 ' – CFU growth = 0, in clean and dirty condition** **contact time: 5' – R ≥ 4 log, in clean and dirty condition**

4.2.3 Virucidal Activity according to UNI EN ISO 14885:2006	
Method used	**EN 14476 - Virucidal activity test** **(CMI = $10^8 \div 10^9$, in clean and dirty condition)**
Strains used	*Murine norovirus (MNV) strain S99*

Result	**contact time: 10' – growth inhibition, in clean and dirty condition** **contact time: 5' – growth inhibition, in clean and dirty condition**
Method used	**EN 14476 - Virucidal activity test** **(CMI = $10^8 \div 10^9$)**
Strains used	*Picornavirus (Coxasackie B3)* *Adenovirus Type 4*
Result	**contact time: 10' – inhibits growth.** **contact time: 5'- – inhibits growth**

4.2.4 Fungicidal Activity according to UNI EN ISO 14885:2006	
Method used	**EN 1275 - Basic fungicidal activity test** **(CMI = 10^7 ufc/ml R≥ 4 log)**
strains used	*Candida albicans* ATCC 10231 *Aspergillus niger* ATCC 16404
Result	**Contact time: 10' – growth: CFU =0** **Contact time: 5' – R≥ 4 log**
Method used	**EN 1650 - Quantitative suspension test for the evaluation of fungicidal activity in the presence of interfering substances** **(CMI = 10^7 ufc/ml R≥ 4 log, in clean and dirty condition)**
strains used	*Candida albicans* ATCC 10231 *Aspergillus niger* ATCC 16404
Result	**Contact time: 10' – growth: UFC =0, in clean and dirty condition** **Contact time: 5' – R≥ 4 log, in clean and dirty condition**
Method used	**EN 13624 - Quantitative suspension test in medical field** **(CMI = 10^7 ufc/ml - R≥ 4 log, in clean and dirty condition)**
strains used	*Candida albicans* ATCC 10231 *Aspergillus niger* ATCC 16404
Result	**Contact time: 10' – growth: UFC =0, in clean and dirty condition** **Contact time: 5' – R≥ 4 log, in clean and dirty condition**
Method used	**EN 14562: Quantitative test on carrier in medical field** **(CMI = 10^7 ufc/ml R≥ 4 log, in clean and dirty condition)**
strains used	*Candida albicans* ATCC 10231 *Aspergillus niger* ATCC 16404
Result	**Contact time: 10' – growth: UFC =0, in clean and dirty condition** **Contact time: 5' – R≥ 4 log, in clean and dirty condition**

4.2.5 Bactericidal Activity according to UNI EN ISO 14885:2006	
Method used	**EN 1040 - Basic bactericidal activity test** **(CBI = 10^8 R ≥ 5 log)**
Strains used	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538P
Result	**contact time: 10' – CFU growth = 0** **contact time: 5' – R ≥ 5 log**
Method used	**EN 1276 - Bactericidal activity test in the presence of interfering substance** **(CBI = 10^8 R ≥ 5 log, in clean and dirty condition)**

Strains used	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538P *Escherichia coli* ATCC 10536 *Enterococcus hirae* ATCC 10541
Result	**contact time: 10' – CFU growth = 0, in clean and dirty condition** **contact time: 5' – R ≥ 5 log, in clean and dirty condition**
Method used	**EN 13727 - Bactericidal activity test in medical field** **(CBI = 10^8 R ≥ 5 log, in clean and dirty condition)**
Strains used	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538P *Enterococcus hirae* ATCC 10541
Result	**contact time: 10' – CFU growth = 0, in clean and dirty condition** **contact time: 5' - R ≥ 5 log, in clean and dirty condition**
Method used	**EN 14561 - Bactericidal activity test on carrier in medical field** **(CBI = 10^8 R ≥ 5 log, in clean and dirty condition)**
Strains used	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538P *Enterococcus hirae* ATCC 10541
Result	**contact time: 10' – CFU growth = 0, in clean and dirty condition** **contact time: 5' -R ≥ 5 log, in clean and dirty condition**

4.2.6 Bactericidal and Fungicidal Activity according to UNI EN ISO 14885:2006	
Method used	**UNI EN 13697 - Quantitative test on non-porous surfaces** **(CBI = 10^8 ufc/ml R≥ 4 log - CMI = 10^7 ufc/ml R≥ 3 log, in clean and dirty condition)**
Strains used	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538P *Escherichia coli* ATCC 10536 *Enterococcus hirae* ATCC 10541 *Candida albicans* ATCC 10231 *Aspergillus niger* ATCC 16404
Result	**Contact time: 10 minutes - growth: UFC =0, in clean and dirty condition** **Contact time: 5' - R≥ 4 log for bacteria and R≥ 3 log for fungi, in clean and dirty condition**

MRC evaluation for microbicidal activity (sporicide)	
Method used	**AFNOR NF-T-72-231 and EN 13704** **(CBI = 10^8/10^7 ufc/ml R ≥ 3 log/R ≥ 5 log)**
strains used	*Bacillus subtilis.* ATCC 6633
Result	**Contact time: 10' – reduction > 5 log MCR = 0.05%**

LEGEND:
CBI/CMI = Initial bacterial load/initial microbial load
R = expected reduction of bacterial/microbial load
CFU = colony-forming units

5. Directions for use

Activity: **Sterilization: 10 minutes at room temperature [EP(25±5°C)]**
High level sporicidal and disinfecting action: 5 minutes at room temperature [EP(25±5°C)]

Stability after activation/dilution: within **12 days** in covered trays. The number of cycles and the stability after activtion/dilution varies depending on the model of sterilization-disinfection machine, the type of endoscope reprocessor, on the mandatory and correct

compliance with cleaning procedures and cleaning required by guidelines and **MRC** (Minimum Recommended Concentration). The "ADASPOR PLUS" test strips can confirm that the product is always above the **MRC** of 0.05% peracetic acid solution.

Instructions and directions for use: use diluted 1:5 in water. Do not use saline solution to dilute it.
Pack of 250 ml: pour 1 litre of water in a bowl and add the solution of the two containers (solution A and solution B) or in the container of the cleaning-disinfection machine and/or automated disinfection cleaning machine according to manufacturer's instructions.
Pack of 1000 ml: pour 4 litres of water in a bowl and add the solution of the two containers (solution A and solution B) or in the container of the automated sterliziation-disinfection machine according to manufacturer's instructions.
for manual disinfection: immerse the medical devices in the activated solution, after having washed and dried them, making sure it penetrates all their cavities. Remove the disinfected devices from the tray through an aseptic procedure and rinse them with sterile water.

For use in automated sterilization and disinfection machines and ultrasonic endoscope reprocessors: fill the containers with the required amount of activated ADASPOR PLUS CONCENTRATED solution following the instructions of the manufacturers. Set the automated sterilization disinfection machine entering the appropriate contact time. The treatment plan also includes the rinsing phase.

Compatibility: the activated solution is compatible with the materials of the medical devices, especially endoscopes and automated sterilization-disinfection equipment. Data is filed with the manufacturer.

6. Toxicological Information

Solution A

DL_{50} oral rat	1540 mg/kg
DL_{50} skin rat	1410 mg/kg
Inhalation (CL_{50})	450 mg/m^3

Solution B

The composition does not justify any precautions beyond normal ones: do not ingest and avoid prolonged direct contact. ISAZONE, the component of the solution is part of a group of substances used in pharmacology given by oral path in average doses of 100 mg, 1 or 2 times a day. For these substances no toxicity value has been detected in case of contact with the skin.

Solution A + B

The acute toxicity of ADASPOR PLUS CONCENTRATE (activated solution) has been investigated on rats repeatedly administered doses of 2000 mg/kg on the skin.
No cases of mortality or clinical signs were observed due to the treatment.
These results suggest that ADASPOR PLUS CONCENTRATED has no toxic effects when administered transdermally to rats within 24 hours at doses of 2000 mg/kg. The absence of mortality indicates that its LD50 is much greater than the dose of 2000 mg/kg. The latter is considered the NOEL (NO OBSERVED EFFECT LEVEL) level for single oral doses.

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

7. Warning

For use in hospitals, and medical and dental practice. Solution A should be handled by qualified staff in compliance with effective safety regulations. Solution A and Solution B cannot be used separately.

Solution A (peracetic acid 5 %)

Warning: Danger

Symbols:

(H) Hazard statements:	(H242): Heating may cause a fire. (H290): Can 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.
(P) Precautionary statements	(P210): Keep away from heat sources, hot surfaces, sparks, open flames or other ignition sources. Do not smoke. (P234): Keep only in original container. (P260): Do not breathe vapours. (P280): Wear protective gloves/protective clothing/eye protection/face protection (faceshield with helmet or faceshield with goggles). (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 EYES: rinse continuously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. (P310): Immediately contact a POISON CENTRE. (P410+P403) Protect from sunlight. Store in a well-ventilated place.
Contains:	Peracetic Acid Hydrogen peroxide
Solution B (Isazone-Co-Formulants)	Safety data sheet available on request for professional users.
Symbols:	/
(H) Hazard statements:	/
(P) Precautionary statements	/

Keep out of reach of children. Keep in a dry place at room temperature, away from heat sources. The expiry date refers to the intact and properly stored product. Do not use after expiration date. Do not release the container to the environment after use (shown on the label with the symbol).

The product has no contraindications at the recommended dilution.

The activated and diluted product does not require additional specific safety measures for people or the environment. After use, the solutions must be disposed of in compliance with the regulations in force.

8. Physical and chemical properties

ADASPOR PLUS CONCENTRATE® upon use	**SOLUTION A+B**
aspect	clear liquid
colour	colorless and/or slightly yellowish
specific weight	1.0 ± 0.2
pH	6.0 ± 1.0
peracetic acid	0.180
Isazone®	0.010%
acceptable microbiological levels	≤ 10 cfu/ml

The above data refers to the solutions after activation/dilution.

9. Quality checks

The company operates under a fully certified quality system UNI EN ISO 9001 - UNI CEI EN 13485. Manufacturing and control processes are also compliant with the same standards (GMP-Good Manufacturing Practices) required for the manufacture of drugs.

10. Shelf-life

16 months for the product properly stored in original packaging.

12 days for the activated and diluted solutions.

11. Storage conditions

Keep in a dry place at room temperature, away from heat sources.

12. Type and capacity of containers

250 ml and 1000 ml PE bottles closed with ring-nut caps.

13. Name and address of the holder of the certification

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14. Compilation date:

Current	**Rev.**	**Date**	**REASON OF REVISIONS**	**REVISION OF PAGES**
1	0	03.04.2011	First edition	
	1	01.06.2015	Microbiological data implementation for sporicidal (EN 14347) and virucidal (MNV) activity, change of company's name/logo, adaptation to EC Regulation CLP	Integral