

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form	: Mixture
Trade name	: exeol sept first
UFI	: 6SF9-70M0-T00R-S6F7
Product code	: 3422-112-1
Type of product	: Detergent, Medical devices for cleaning or disinfection
Product group	: Trade product

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses

Main use category	: Professional use
Use of the substance/mixture	: Neutral pH disinfectant detergent Solution to be diluted for cleaning and disinfection by immersion of invasive and non-invasive reusable medical devices before sterilisation or final disinfection

1.3. Details of the supplier of the safety data sheet

Manufacturer

SODEL
190 rue René Barthélemy
FR 14100 LISIEUX
FRANCE
T +33(0)2 31 31 10 50, F +33(0)2 31 31 80 60
info@sodel-sa.eu, www.sodel-sa.eu

1.4. Emergency telephone number

Country/Area	Organisation/Company	Address	Emergency number	Comment
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals- 24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER	+44 20 7188 7188	
United Kingdom	National Poisons Information Service (Newcastle Centre) Regional Drugs and Therapeutics Centre	16/17 Framlington Place Newcastle-upon-Tyne NE2 4AB Newcastle	0344 892 0111	Only for healthcare professionals

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin corrosion/irritation, Category 1, Sub-Category 1B	H314
Serious eye damage/eye irritation, Category 1	H318
Hazardous to the aquatic environment – Acute Hazard, Category 1	H400
Hazardous to the aquatic environment – Chronic Hazard, Category 3	H412
Full text of H- and EUH-statements: see section 16	

Adverse physicochemical, human health and environmental effects

Causes severe skin burns and eye damage. Causes serious eye damage. Very toxic to aquatic life. Harmful to aquatic life with long lasting effects.

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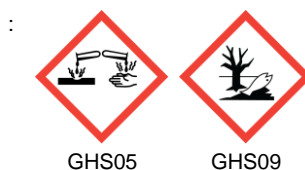
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2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



Signal word (CLP) : Danger

Contains : didecyldimethylammonium chloride; methanesulphonic acid; Alcohols, C9-11, ethoxylated

Hazard statements (CLP) : H314 - Causes severe skin burns and eye damage.
H410 - Very toxic to aquatic life with long lasting effects.

Precautionary statements (CLP) : P273 - Avoid release to the environment.
P280 - Wear protective gloves, protective clothing, eye protection, face protection.
P301+P330+P331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with 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.
P310 - Immediately call a POISON CENTER, a doctor.
P391 - Collect spillage.
P501 - Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards

Contains no PBT and/or vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

Component	
Substance(s) not meeting the PBT criteria of REACH regulation, in accordance with Annex XIII	didecyldimethylammonium chloride (7173-51-5)
Substance(s) not meeting the vPvB criteria of REACH regulation, in accordance with Annex XIII	didecyldimethylammonium chloride (7173-51-5)

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or substance(s) are not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
didecyldimethylammonium chloride	CAS-No.: 7173-51-5 EC-No.: 230-525-2 EC Index-No.: 612-131-00-6 REACH-no: 01-2119945987-15	$\geq 10 - < 20$	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Skin Corr. 1B, H314 Eye Dam. 1, H318 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 2, H411
Alcohols, C9-11, ethoxylated	CAS-No.: 68439-46-3	$\geq 5 - < 10$	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Eye Dam. 1, H318

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Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
propan-2-ol	CAS-No.: 67-63-0 EC-No.: 200-661-7 EC Index-No.: 603-117-00-0 REACH-no: 01-2119457558-25	$\geq 1 - < 5$	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336
methanesulphonic acid	CAS-No.: 75-75-2 EC-No.: 200-898-6 EC Index-No.: 607-145-00-4 REACH-no: 01-2119491166-34	$\geq 1 - < 5$	Met. Corr. 1, H290 Acute Tox. 4 (Oral), H302 (ATE=649 mg/kg bodyweight) Acute Tox. 4 (Dermal), H312 (ATE=1000 mg/kg bodyweight) Skin Corr. 1B, H314 Eye Dam. 1, H318 STOT SE 3, H335
N-Alkyl (C12-C14)-1,3-diaminopropane	CAS-No.: 90640-43-0 EC-No.: 292-562-0 REACH-no: 01-2119957843-25	$\geq 0.1 - < 1$	Acute Tox. 3 (Oral), H301 (ATE=100 mg/kg bodyweight) Skin Corr. 1B, H314 STOT RE 1, H372 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410
Diphenyl ether substance with a Community workplace exposure limit	CAS-No.: 101-84-8 EC-No.: 202-981-2	< 0.1	Eye Irrit. 2, H319 Aquatic Acute 1, H400 Aquatic Chronic 3, H412

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Call a physician immediately. Never give anything by mouth to an unconscious person. As a general rule, in case of doubt or if symptoms persist, always call a doctor.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Rinse skin with water/shower. Take off immediately all contaminated clothing. Call a physician immediately.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a physician immediately.
First-aid measures after ingestion	: Rinse mouth. Do not induce vomiting. Call a physician immediately.
First-aid measures for first aider	: First aid workers will be equipped with suitable personal protective equipment.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after skin contact	: Burns.
Symptoms/effects after eye contact	: Serious damage to eyes.
Symptoms/effects after ingestion	: Burns.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Water spray. Dry powder. Foam. Carbon dioxide.
Unsuitable extinguishing media	: Do not use a heavy water stream.

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5.2. Special hazards arising from the substance or mixture

Fire hazard	: Not flammable.
Explosion hazard	: No direct explosion hazard.
Hazardous decomposition products in case of fire	: Toxic fumes may be released. Do not breathe in smoke.

5.3. Advice for firefighters

Firefighting instructions	: Fight fire from safe distance and protected location. Do not enter fire area without proper protective equipment, including respiratory protection.
Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Stop leak if safe to do so. Notify authorities if product enters sewers or public waters. Absorb spillage to prevent material damage.
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For non-emergency personnel

Protective equipment	: Wear recommended personal protective equipment.
Emergency procedures	: Ventilate spillage area. Avoid contact with skin and eyes.

For emergency responders

Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
Emergency procedures	: Evacuate unnecessary personnel. Stop leak if safe to do so.

6.2. Environmental precautions

Avoid release to the environment. Prevent entry into storm water systems or watercourses.

6.3. Methods and material for containment and cleaning up

For containment	: Collect spillage. Stop leak without risks if possible.
Methods for cleaning up	: Take up liquid spill into absorbent material.
Other information	: Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed	: Not expected to present a significant hazard under anticipated conditions of normal use.
Precautions for safe handling	: Ensure good ventilation of the work station. Avoid contact with skin and eyes. Wear personal protective equipment.
Hygiene measures	: Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures	: Keep in a cool, well-ventilated place away from heat.
Storage conditions	: Store locked up.
Storage temperature	: 5 – 25 °C
Storage area	: Store away from heat.
Special rules on packaging	: Store in a closed container. Keep only in original container.

7.3. Specific end use(s)

No additional information available

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

National occupational exposure and biological limit values

propan-2-ol (67-63-0)	
Ireland - Occupational Exposure Limits	
Local name	Isopropyl alcohol [Propan-2-ol]
OEL TWA	200 ppm
OEL STEL	400 ppm
Regulatory reference	Chemical Agents Code of Practice 2021
Ireland - Biological limit values	
Local name	2-Propanol
Regulatory reference	Biological Monitoring Guidelines (HSA, 2011)
United Kingdom - Occupational Exposure Limits	
Local name	Propan-2-ol
WEL TWA (OEL TWA)	999 mg/m ³
	400 ppm
WEL STEL (OEL STEL)	1250 mg/m ³
	500 ppm
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE
sodium hydroxide (1310-73-2)	
Ireland - Occupational Exposure Limits	
Local name	Sodium hydroxide
OEL STEL	2 mg/m ³
Regulatory reference	Chemical Agents Code of Practice 2021
United Kingdom - Occupational Exposure Limits	
Local name	Sodium hydroxide
WEL STEL (OEL STEL)	2 mg/m ³
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE
citral (5392-40-5)	
Ireland - Occupational Exposure Limits	
Local name	Citral
OEL TWA	5 ppm IFV (Inhlabl Fraction and Vapour)
Regulatory reference	Chemical Agents Code of Practice 2021
Diphenyl ether (101-84-8)	
EU - Indicative Occupational Exposure Limit (IOEL)	
Local name	Diphenyl ether
IOEL TWA	7 mg/m ³
	1 ppm
IOEL STEL	14 mg/m ³

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Diphenyl ether (101-84-8)	
	2 ppm
Regulatory reference	COMMISSION DIRECTIVE (EU) 2017/164
Ireland - Occupational Exposure Limits	
Local name	Diphenyl ether (vapour)
OEL TWA	7 mg/m ³
	1 ppm
OEL STEL	14 mg/m ³
	2 ppm
Remark	IOELV (Indicative Occupational Exposure Limit Values)
Regulatory reference	Chemical Agents Code of Practice 2021
United Kingdom - Occupational Exposure Limits	
Local name	Diphenyl ether
WEL TWA (OEL TWA)	7 mg/m ³
	1 ppm
WEL STEL (OEL STEL)	14 mg/m ³
	2 ppm
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:

Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure good ventilation of the work station.

Personal protection equipment

Personal protective equipment:

Wear recommended personal protective equipment.

Personal protective equipment symbol(s):



Eye and face protection

Eye protection:

Safety glasses. Use eye protection according to EN 166, designed to protect against liquid splashes. In the event of high danger, protect the face with a face shield. Avoid contact with eyes. Prescription glasses are not considered as protection. Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure

Eye protection			
Type	Field of application	Characteristics	Standard
Safety glasses		With side shields	EN 166

Skin protection

Hand protection:

Chemical resistant gloves (according to European standard ISO 374-1 or equivalent). Gloves must be selected according to the application and duration of use at the workstation

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Hand protection					
Type	Material	Permeation	Thickness (mm)	Penetration	Standard
Disposable gloves, Reusable gloves					EN 374

Other skin protection

Materials for protective clothing:

Wear protective clothing. Avoid contact with skin. Grossly contaminated clothing should be removed and the skin washed with soap and water or a proprietary skin cleaner. Work clothing worn by personnel shall be laundered regularly. In the event of a risk of splashing, wear protective clothing against chemical risks (type 6) in accordance with EN13034 to prevent skin contact. In the event of substantial spatter, wear liquid-tight protective clothing against chemical risks (type 3) in accordance with EN14605 to prevent skin contact

Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

Other information:

Use personal protective equipment that is clean and has been properly maintained. Store personal protective equipment in a clean place, away from the work area. You must check the condition of the protections before each use. Used at the recommended dosage dose on the label, the product is not classified and does not require the use of PPE. The solution remains a chemical to be handled with care.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Blue.
Appearance	: Clear.
Odour	: Synthetic scent. lemon.
Odour threshold	: Not available
Melting point	: Not applicable
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: > 93 °C
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: 7.1 – 8.1
pH solution concentration	: 100 %
Viscosity, kinematic	: Not available
Viscosity, dynamic	: < 50 mPa·s
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: 1.008 – 1.012 g/ml
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

9.2. Other information

Other safety characteristics

VOC content	: 3.92 % (EU Directive 2010/75)
Refractive index	: 1.3705 – 1.3725

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SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

didecyldimethylammonium chloride (7173-51-5)

LD50 oral rat	329 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 401 (Acute Oral Toxicity)
LD50 oral	329 mg/kg bodyweight
LD50 dermal rat	> 1000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 402 (Acute Dermal Toxicity), Guideline: EU Method B.3 (Acute Toxicity (Dermal))
LD50 dermal	3342 mg/kg bodyweight
LC50 Inhalation - Rat (Dust/Mist)	70 mg/l

propan-2-ol (67-63-0)

LD50 oral rat	5840 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 401 (Acute Oral Toxicity)
LD50 oral	4396 mg/kg bodyweight
LD50 dermal	12800 mg/kg bodyweight
LC50 Inhalation - Rat (Dust/Mist)	46600 mg/l

methanesulphonic acid (75-75-2)

LD50 oral	649 mg/kg bodyweight
LD50 dermal rabbit	> 1000 mg/kg bodyweight Animal: rabbit, Guideline: OECD Guideline 402 (Acute Dermal Toxicity), Guideline: other:49 CFR 173.132
LD50 dermal	> 1000 mg/kg bodyweight
LC50 Inhalation - Rat	> 1.3 mg/l 330ppm 6h

Alcohols, C9-11, ethoxylated (68439-46-3)

LD50 oral rat	> 2000 mg/kg
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Alcohols, C9-11, ethoxylated (68439-46-3)	
LD50 dermal rat	> 2000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 402 (Acute Dermal Toxicity)
LC50 Inhalation - Rat	> 1.6 mg/l air Animal: rat, Guideline: OECD Guideline 403 (Acute Inhalation Toxicity)
Diphenyl ether (101-84-8)	
LD50 oral rat	2830 mg/kg bodyweight Animal: rat, Animal sex: female, 95% CL: 2,49 - 3,21
Skin corrosion/irritation	: Causes severe skin burns. pH: 7.1 – 8.1
didecyltrimethylammonium chloride (7173-51-5)	
pH	6.8 – 6.9 Temp.: 25 °C Concentration: 1 other:% (w/w) tel quel and active ingredient
Serious eye damage/irritation	: Causes serious eye damage. pH: 7.1 – 8.1
didecyltrimethylammonium chloride (7173-51-5)	
pH	6.8 – 6.9 Temp.: 25 °C Concentration: 1 other:% (w/w) tel quel and active ingredient
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
propan-2-ol (67-63-0)	
STOT-single exposure	May cause drowsiness or dizziness.
methanesulphonic acid (75-75-2)	
STOT-single exposure	May cause respiratory irritation.
STOT-repeated exposure	: Not classified
N-Alkyl (C12-C14)-1,3-diaminopropane (90640-43-0)	
NOAEL (oral, rat, 90 days)	0.4 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity Study in Rodents), Guideline: EU Method B.26 (Sub-Chronic Oral Toxicity Test: Repeated Dose 90-Day Oral Toxicity Study in Rodents)
STOT-repeated exposure	Causes damage to organs through prolonged or repeated exposure.
Alcohols, C9-11, ethoxylated (68439-46-3)	
NOAEL (oral, rat, 90 days)	≥ 500 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents)
Diphenyl ether (101-84-8)	
LOAEL (dermal, rat/rabbit, 90 days)	100 mg/kg bodyweight Animal: rat
NOAEL (dermal, rat/rabbit, 90 days)	1000 mg/kg bodyweight Animal: rat
Aspiration hazard	: Not classified
didecyltrimethylammonium chloride (7173-51-5)	
Viscosity, kinematic	24.5 mm²/s Temp.: '20°C' Parameter: 'kinematic viscosity (in mm²/s)'
methanesulphonic acid (75-75-2)	
Viscosity, kinematic	7.86 mm²/s Temp.: 'other:25.0°C' Parameter: 'kinematic viscosity (in mm²/s)'
Diphenyl ether (101-84-8)	
Viscosity, kinematic	2.419 mm²/s

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11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Very toxic to aquatic life. Harmful to aquatic life with long lasting effects.
Hazardous to the aquatic environment, short-term (acute) : Very toxic to aquatic life.
Hazardous to the aquatic environment, long-term (chronic) : Harmful to aquatic life with long lasting effects.

didecyldimethylammonium chloride (7173-51-5)

LC50 - Fish [1]	0.49 mg/l
LC50 - Fish [2]	0.49 mg/l Test organisms (species): Danio rerio (previous name: Brachydanio rerio)
EC50 - Crustacea [1]	0.057 mg/l Test organisms (species): Daphnia magna
EC50 - Crustacea [2]	0.029 mg/l Test organisms (species): Daphnia magna
EC50 - Other aquatic organisms [1]	0.057 mg/l waterflea
EC50 - Other aquatic organisms [2]	0.156 mg/l
LOEC (chronic)	0.047 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC (chronic)	0.021 mg/l Test organisms (species): Daphnia magna Duration: '21 d'

propan-2-ol (67-63-0)

LC50 - Fish [1]	9640 mg/l
LC50 - Fish [2]	9640 mg/l Test organisms (species): Pimephales promelas
EC50 - Other aquatic organisms [1]	13299 mg/l waterflea
EC50 - Other aquatic organisms [2]	> 1000 mg/l

N-Alkyl (C12-C14)-1,3-diaminopropane (90640-43-0)

LC50 - Fish [1]	0.148 mg/l Test organisms (species): Danio rerio (previous name: Brachydanio rerio)
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methanesulphonic acid (75-75-2)

LC50 - Fish [1]	73 mg/l
EC50 - Crustacea [1]	260 mg/l Test organisms (species): Daphnia magna
EC50 - Crustacea [2]	70 mg/l Test organisms (species): Daphnia magna
EC50 - Other aquatic organisms [1]	> 10 mg/l waterflea
EC50 - Other aquatic organisms [2]	> 12 mg/l
EC50 72h - Algae [1]	12 – 24 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)
EC50 96h - Algae [1]	7.2 – 20 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)

Alcohols, C9-11, ethoxylated (68439-46-3)

LC50 - Fish [1]	5 – 7 mg/l Test organisms (species): Oncorhynchus mykiss (previous name: Salmo gairdneri)
EC50 - Crustacea [1]	2.5 mg/l Test organisms (species): Daphnia magna
EC50 96h - Algae [1]	1.4 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)

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Diphenyl ether (101-84-8)

LC50 - Fish [1]	4.2 mg/l Test organisms (species): Oncorhynchus mykiss (previous name: Salmo gairdneri)
EC50 - Crustacea [1]	1.96 mg/l Test organisms (species): Daphnia magna

12.2. Persistence and degradability

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Persistence and degradability	The surfactant(s) contained in this preparation complies(comply) with the biodegradability criteria as laid down in Regulation (EC) No. 648/2004 on detergents. Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them, at their direct request or at the request of a detergent manufacturer.
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didecyldimethylammonium chloride (7173-51-5)

Persistence and degradability	Readily biodegradable (OECD).
Biodegradation	> 70 % (Activated Sludge) (OECD 301 D)

propan-2-ol (67-63-0)

Persistence and degradability	Readily biodegradable (OECD).
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N-Alkyl (C12-C14)-1,3-diaminopropane (90640-43-0)

Persistence and degradability	Readily biodegradable (OECD).
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methanesulphonic acid (75-75-2)

Persistence and degradability	Not rapidly degradable
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Alcohols, C9-11, ethoxylated (68439-46-3)

Persistence and degradability	Readily biodegradable (OECD).
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Diphenyl ether (101-84-8)

Persistence and degradability	Readily biodegradable (OECD).
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12.3. Bioaccumulative potential

didecyldimethylammonium chloride (7173-51-5)

Partition coefficient n-octanol/water (Log Pow)	0.4
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propan-2-ol (67-63-0)

Partition coefficient n-octanol/water (Log Pow)	0.05
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methanesulphonic acid (75-75-2)

Partition coefficient n-octanol/water (Log Pow)	-2.38
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Alcohols, C9-11, ethoxylated (68439-46-3)

Partition coefficient n-octanol/water (Log Pow)	2.86 – 3.76
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12.4. Mobility in soil

No additional information available

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12.5. Results of PBT and vPvB assessment

Component

Substance(s) not meeting the PBT criteria of REACH regulation, in accordance with Annex XIII	didecyldimethylammonium chloride (7173-51-5)
Substance(s) not meeting the vPvB criteria of REACH regulation, in accordance with Annex XIII	didecyldimethylammonium chloride (7173-51-5)

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional waste regulation	: Disposal must be done according to official regulations.
Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.
Sewage disposal recommendations	: Disposal must be done according to official regulations.
Product/Packaging disposal recommendations	: Empty container completely. Keep label(s) on container. Disposal must be done according to official regulations. Avoid release to the environment. Prevent entry into storm water systems or watercourses. Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.
Additional information	: Do not re-use empty containers.

SECTION 14: Transport information









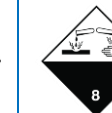

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
UN 1903	UN 1903	UN 1903	UN 1903	UN 1903
14.2. UN proper shipping name				
DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (didecyldimethylammonium chloride ; methanesulphonic acid)	DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (didecyldimethylammonium chloride ; methanesulphonic acid)	Disinfectant, liquid, corrosive, n.o.s. (didecyldimethylammonium chloride ; methanesulphonic acid)	DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (didecyldimethylammonium chloride ; methanesulphonic acid)	DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (didecyldimethylammonium chloride ; methanesulphonic acid)
Transport document description				
UN 1903 DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (didecyldimethylammonium chloride ; methanesulphonic acid), 8, II, (E), ENVIRONMENTALLY HAZARDOUS	UN 1903 DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (didecyldimethylammonium chloride ; methanesulphonic acid), 8, II, MARINE POLLUTANT/ENVIRONMENTALLY HAZARDOUS	UN 1903 Disinfectant, liquid, corrosive, n.o.s. (didecyldimethylammonium chloride ; methanesulphonic acid), 8, II, ENVIRONMENTALLY HAZARDOUS	UN 1903 DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (didecyldimethylammonium chloride ; methanesulphonic acid), 8, II, ENVIRONMENTALLY HAZARDOUS	UN 1903 DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (didecyldimethylammonium chloride ; methanesulphonic acid), 8, II, ENVIRONMENTALLY HAZARDOUS
14.3. Transport hazard class(es)				
8	8	8	8	8

exeol sept first

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

ADR	IMDG	IATA	ADN	RID
 	 	 	 	 
14.4. Packing group				
II	II	II	II	II
14.5. Environmental hazards				
Dangerous for the environment: Yes	Dangerous for the environment: Yes Marine pollutant: Yes EmS-No. (Fire): F-A EmS-No. (Spillage): S-B	Dangerous for the environment: Yes	Dangerous for the environment: Yes	Dangerous for the environment: Yes
No supplementary information available				

14.6. Special precautions for user

Overland transport

Classification code (ADR)	: C9
Special provisions (ADR)	: 274
Limited quantities (ADR)	: 1I
Excepted quantities (ADR)	: E2
Packing instructions (ADR)	: P001, IBC02
Mixed packing provisions (ADR)	: MP15
Tank code (ADR)	: L4BN
Vehicle for tank carriage	: AT
Transport category (ADR)	: 2
Hazard identification number (Kemler No.)	: 80
Orange plates	:



Tunnel restriction code (ADR)	: E
EAC code	: 2X

Transport by sea

Special provisions (IMDG)	: 274
Limited quantities (IMDG)	: 1 L
Excepted quantities (IMDG)	: E2
Packing instructions (IMDG)	: P001
IBC packing instructions (IMDG)	: IBC02
Stowage category (IMDG)	: B
Properties and observations (IMDG)	: A wide variety of corrosive liquids. Causes burns to skin, eyes and mucous membranes.

Air transport

PCA Excepted quantities (IATA)	: E2
PCA Limited quantities (IATA)	: Y840
PCA limited quantity max net quantity (IATA)	: 0.5L
PCA packing instructions (IATA)	: 851
PCA max net quantity (IATA)	: 1L
CAO packing instructions (IATA)	: 855
CAO max net quantity (IATA)	: 30L
Special provisions (IATA)	: A3, A803
ERG code (IATA)	: 8L

Inland waterway transport

Classification code (ADN)	: C9
Special provisions (ADN)	: 274

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Safety Data Sheet

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Limited quantities (ADN) : 1 L
Excepted quantities (ADN) : E2
Equipment required (ADN) : PP, EP
Number of blue cones/lights (ADN) : 0

Rail transport

Classification code (RID) : C9
Special provisions (RID) : 274
Limited quantities (RID) : 1L
Excepted quantities (RID) : E2
Packing instructions (RID) : P001, IBC02
Mixed packing provisions (RID) : MP15
Tank codes for RID tanks (RID) : L4BN
Transport category (RID) : 2
Colis express (express parcels) (RID) : CE6
Hazard identification number (RID) : 80

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals):
Didecyldimethylammonium chloride (7173-51-5)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Dual-Use Regulation (428/2009)

Contains no substance subject to the COUNCIL REGULATION (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items.

VOC Directive

VOC content : 3.92 % (EU Directive 2010/75)

Detergent Regulation (648/2004)

Labelling of contents	
Component	%
cationic surfactants, non-ionic surfactants	≥5-<15%
perfumes	

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

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Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number

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Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Abbreviations and acronyms:

N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disruptor

Other information

: Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations. The mixture must not be used for other uses than those specified in section 1 without having first obtained written handling instructions. It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

Full text of H- and EUH-statements:

Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 2	Flammable liquids, Category 2
H225	Highly flammable liquid and vapour.
H290	May be corrosive to metals.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H372	Causes damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
Met. Corr. 1	Corrosive to metals, Category 1
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
STOT RE 1	Specific target organ toxicity – Repeated exposure, Category 1
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Narcosis

exeol sept first

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

The classification complies with : ATP 12

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

exeol sept first

Neutral pH disinfectant detergent

► Solution to be diluted for cleaning and disinfection by immersion of invasive and non-invasive reusable medical devices before sterilisation or final disinfection.

- **Active in 10 min. at a dilution rate of 0.4% (bactericidal, yeasticidal and virucidal against enveloped viruses).**

- **Proven detergent performance on biofilm according to NF EN ISO 15883-5: 2021**

- **Combination of easily biodegradable complexing agents for metal and alkaline earth ions: increased detergency for hard water.**

- **Neutral pH.**



INSTRUMENTS ENDOSCOPY

PRODUCT

ACTIVE AT
0.4%

ACTIVE IN
10 MIN.

NEUTRAL
PH

GOOD PRACTICES



Direction for use

- **20mL dose:**

Tear open the dose using the pre-cut slot. Pour a 20mL dose into 5L of water at room temperature: 0.4% (4mL/L).

- **1L dosing bottle:**

Remove the cap and press the sides of the bottle to obtain the desired dose. Dilute the dose obtained with water at room temperature: 0.4% (4mL/L). Close the bottle after use.

- **5L container:**

When using for the first time, remove the tamper-proof ring before unscrewing the cap. Attach the 20mL pump to the container and prime it. Do not use the dose obtained before the pump is fully primed. Using the dosing pump, dilute the concentrate with water at room temperature: 0.4% (4mL/L).

The diluted and unused solution can be stored in a covered soaking tank for 72h.

Use:

1. Open and disassemble the medical devices and place them in the solution, ensuring that they are completely immersed. Clean, brush, swab and irrigate the channels as necessary.

2. Contact time: 10 min. Observe the recommended contact time.

3. Remove the medical devices, rinse thoroughly with water.

Used solution must be changed after each use.

exeol sept first can be used in ultrasonic soaking tank.

Commercial presentations

- Box 250 x 20mL: EXS0045
- Box 6 x 1L dosing bottle 20mL: EXS0043
- Box 4 x 5L + 1 x 20mL pump: EXS0088



Product file available on
www.exeol.fr

MD class IIa

CE marking obtained in 2023



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Neutral pH disinfectant detergent

Microbiological properties

Dirty conditions, 0.4%, 10 min., 20°C :

	TESTS	MICRO-ORGANISMS	CONCENTRATION	CONTACT TIME
Bactericidal	EN 13727	<i>Pseudomonas aeruginosa</i> , <i>Staphylococcus aureus</i> , <i>Enterococcus hirae</i> , <i>Escherichia coli</i>	0.4%	10 min.
	EN 14561	<i>Pseudomonas aeruginosa</i> , <i>Staphylococcus aureus</i> , <i>Enterococcus hirae</i>		
Yeasticidal	EN 13624 EN 14562	<i>Candida albicans</i> Additional strain: <i>Candida auris</i>	0.4%	5 min.
Virucidal against enveloped viruses ¹	EN 14476 EN 17111	Vaccinia virus ¹ Elstree strain	0.4%	10 min.

¹ Vaccinia virus is the representative virus of the enveloped viruses presented in Annex A of standards EN 14476+A2 and EN 16777 and in Annex B of standard EN 17111, such as for example: Hepatitis B virus (HBV); Hepatitis C virus (HCV); Human Immunodeficiency Virus (HIV); Herpesviridae (Herpes virus); Coronavirus; Influenza, rabies, rubella, measles viruses; ...

Composition	Characteristics	Precautions
Didecyldimethylammonium chloride, non-ionic surfactant, sequestering agent, dye, fragrance and excipients.	<ul style="list-style-type: none">pure pH: 7.1 - 8.1pH at 0.4%: 6 - 7Fragrance*: LemonColour: Blue	Always read the label and product information before use. UFI: 6SF9-70M0-T00R-S6F7

*Synthetic fragrance



PROFESSIONAL USE ONLY

MADE IN FRANCE

 Sodel
190 rue René Barthélemy
14100 Lisieux, France.
TEL: +33 (0)2 31 31 10 50
www.exeol.fr


A SODEL DIVISION

exeol sept first

Neutral pH disinfectant detergent

► Solution to be diluted for cleaning and disinfection by immersion of invasive and non-invasive reusable medical devices before sterilisation or final disinfection.

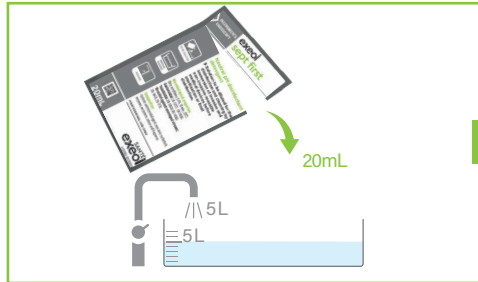


INSTRUMENT
ENDOSCOPY

Before use, check the expiry date on the label.

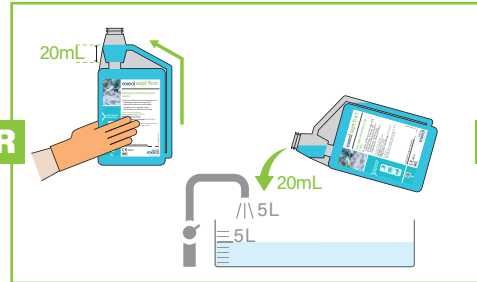


20mL dose



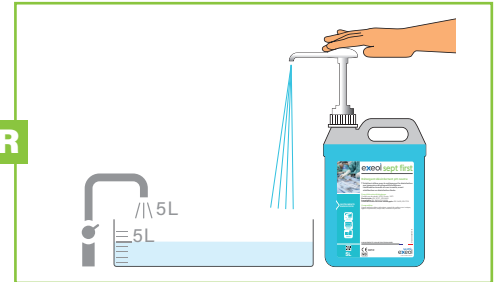
1 Tear open the dose using the pre-cut slot. Pour a 20 mL dose into 5L of water at room temperature: 0.4% (4mL/L).

1L dosing bottle



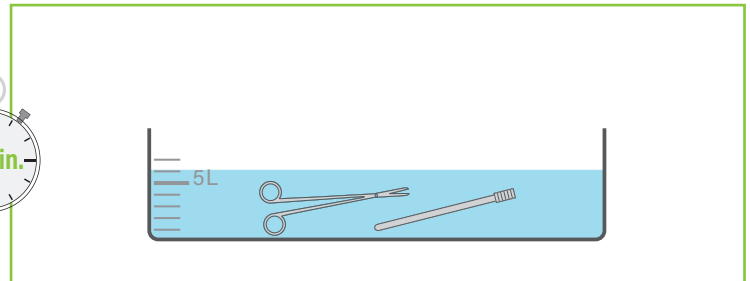
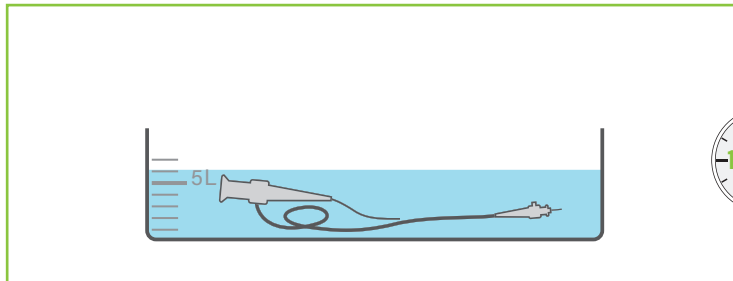
1 Remove the cap and press the sides of the bottle to obtain the desired dose. Dilute the dose obtained with water at room temperature: 0.4% (4mL/L). Close the bottle after use.

5L container



1 When using for the first time, remove the tamper-proof ring before unscrewing the cap. Attach the 20mL pump to the container and prime it. Do not use the dose obtained before the pump is fully primed. Using the dosing pump, dilute the concentrate with water at room temperature: 0.4% (4mL/L).

The diluted and unused solution can be stored in a covered soaking tank for 72h.



2 Open and disassemble the medical devices and place them in the solution, ensuring that they are completely immersed. Clean, brush, swab and irrigate the channels as necessary. Contact time: 10 min. Observe the recommended contact time.



3 Remove the medical devices, rinse thoroughly with water.

Used solution must be changed after each use.
exeol sept first can be used in ultrasonic soaking tank.

Always read the label and product information before use. PPE:



PROFESSIONAL USE ONLY

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Product file available on
www.exeol.fr

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TEL: +33 (0)2 31 31 10 50
www.exeol.fr

CE marking obtained in 2023
MD class IIa

CE 0459

MD



REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.3. Certificatul CE	Certificat EU QMS 39301 rev. 0
I.2. Declarația de conformitate CE	Declaratie de conformitate 06
I.2. Declarația de conformitate CE	Declaratie de conformitate 05
I.2. Declarația de conformitate CE	Declaratie de conformitate 02
I.2. Declarația de conformitate CE	Declaratie de conformitate 07
I.2. Declarația de conformitate CE	Declaratie de conformitate 03
I.2. Declarația de conformitate CE	Declaratie de conformitate 01
I.2. Declarația de conformitate CE	Declaratie de conformitate 04

DM000759214	AGENT DEZINFECTANT PENTRU DISPOZITIVE MEDICALE	EXEOL SEPT E2	DOSING BOTTLE OF 1L X 20ML	EXS0046	Franta	SODEL	ERICON S.R.L.	Rg04-000348	02-12-2024	
DM000759215	AGENT DEZINFECTANT PENTRU DISPOZITIVE MEDICALE	EXEOL SEPT E2	DOSE OF 20ML	EXS0048	Franta	SODEL	ERICON S.R.L.	Rg04-000348	02-12-2024	
DM000759213	AGENT DEZINFECTANT PENTRU DISPOZITIVE MEDICALE	EXEOL SEPT E2	CONTAINER OF 5L	EXS0087	Franta	SODEL	ERICON S.R.L.	Rg04-000348	02-12-2024	
DM000759207	AGENT DEZINFECTANT PENTRU DISPOZITIVE MEDICALE	EXEOL SEPT FIRST	DOSING BOTTLE OF 1L X 20ML	EXS0043	Franta	SODEL	ERICON S.R.L.	Rg04-000348	02-12-2024	
DM000759206	AGENT DEZINFECTANT PENTRU DISPOZITIVE MEDICALE	EXEOL SEPT FIRST	CONTAINER OF 5L	EXS0088	Franta	SODEL	ERICON S.R.L.	Rg04-000348	02-12-2024	
DM000759208	AGENT DEZINFECTANT PENTRU DISPOZITIVE MEDICALE	EXEOL SEPT FIRST	DOSE OF 20ML	EXS0045	Franta	SODEL	ERICON S.R.L.	Rg04-000348	02-12-2024	

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