

# RENALIN<sup>®</sup> 100 Cold Sterilant

## Safety Data Sheet

according to Regulation (EC) No. 453/2010

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

#### 1.1. Product identifier

Product name : RENALIN<sup>®</sup>/ RENALIN PA<sup>®</sup>/ RENALIN<sup>®</sup> 100 Cold Sterilant  
Product code : 78397-638,78397-639,78397-970,78398-060,78397-521,78397-741,78397-872

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

##### 1.2.1. Relevant identified uses

Main use category : Professional use  
Use of the substance/mixture : Reprocessing of hemodialysis dialyzers

##### 1.2.2. Uses advised against

No additional information available.

#### 1.3. Details of the supplier of the safety data sheet

MEDIVATORS BV  
Sourethweg 11  
6422PC Heerlen - Netherlands  
T (31) 45 5 471 471; 0800 894575 (UK)  
[csnl@medivators.com](mailto:csnl@medivators.com)

#### 1.4. Emergency telephone number

Emergency number : CHEMTREC International +1 (703) 527-3887 24 hr

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

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

Ox. Liq. 1 H271  
Org. Perox. G -  
Met. Corr. 1 H290  
Skin Corr. 1A H314  
Eye Dam. 1 H318

Acute Tox. 4 (Inhalation) H332

STOT SE 3 H335  
H336

Full text of H-phrases: see section 16

##### Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

O; R7  
Xn; R22  
C; R34  
Xi; R41

Full text of R-phrases: see section 16

##### Adverse physicochemical, human health and environmental effects

No additional information available.

#### 2.2. Label elements

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

Hazard pictograms (CLP) :



Signal word (CLP) :

Danger

Hazard statements (CLP) :

H271 - May cause fire or explosion; strong oxidiser.  
H290 - May be corrosive to metals.  
H314 - Causes severe skin burns and eye damage.  
H332- Harmful if inhaled.  
H335- May cause respiratory irritation.  
H336- May cause drowsiness and dizziness.  
Precautionary statements (CLP) : P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

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P221 - Take any precaution to avoid mixing with combustibles (metals, oxidizing materials, alkalis, caustics, chlorine, formaldehyde, salts, flammable organics).  
P260 - Do not breathe dust/fume/gas/mist/vapours/spray.  
P280 - Wear protective gloves/protective clothing/eye protection/face protection.  
P303+P361+P353+P310 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER/doctor.  
P304+P340+ P311 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor.  
P305+P351+P338+ P310 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.  
P371 + P380 + P375 - In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion.  
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed.

### 2.3. Other hazards

No additional information available.

## SECTION 3: Composition/information on ingredients

### 3.1. Substance

Not applicable.

### 3.2. Mixture

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Hydrogen peroxide	(CAS No) 7722-84-1 (EC no) 231-765-0 (EC index no) 008-003-00-9	10 - 30	Ox. Liq. 1, H271 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation), H332 Skin Corr. 1A, H314 (C >= 70)
Acetic acid	(CAS No) 64-19-7 (EC no) 200-580-7 (EC index no) 607-002-00-6	5 - 10	Flam. Liq. 3, H226 Acute Tox. 4 (Dermal), H312 Skin Corr. 1A, H314 (C >= 90)
Peroxyacetic acid	(CAS No) 79-21-0 (EC no) 201-186-8 (EC index no) 607-094-00-8	3 - 7	Flam. Liq. 3, H226 Org. Perox. D, H242 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation), H332 Skin Corr. 1A, H314 STOT SE 3, H335 Aquatic Acute 1, H400
Stabilizer	Proprietary	0.5 – 1.5	Eye Dam. 1, H318 Met. Corr. 1, H290

Name	Product identifier	%	Classification according to Directive 67/548/EEC
Hydrogen peroxide	(CAS No) 7722-84-1 (EC no) 231-765-0 (EC index no) 008-003-00-9	10 - 30	O; R8 Xn; R20 (C >= 50) Xn; R22 C; R35 (C >= 70) R5
Acetic acid	(CAS No) 64-19-7 (EC no) 200-580-7 (EC index no) 607-002-00-6	5 - 10	R10 Xn; R21 C; R35 (C >= 90)
Peroxyacetic acid	(CAS No) 79-21-0 (EC no) 201-186-8 (EC index no) 607-094-00-8	3 - 7	R10 O; R7 Xn; R20/21/22 C; R35 N; R50
Stabilizer	Proprietary	0.5 – 1.5	Xi; R41

Full text of R- and H-phrases: see section 16

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

- First-aid measures after inhalation : If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get immediate medical advice/attention.
- First-aid measures after skin contact : In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Get immediate medical advice/attention.
- First-aid measures after eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lenses, if worn. Get immediate medical advice/attention.
- First-aid measures after ingestion : Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.

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

- Symptoms/injuries after inhalation : Harmful if inhaled. May cause respiratory irritation. May cause dizziness or drowsiness.
- Symptoms/injuries after skin contact : Causes severe skin burns. Symptoms may include redness, pain, blisters.
- Symptoms/injuries after eye contact : Causes serious eye damage. Symptoms may include discomfort or pain, excess blinking and tear production, with marked redness and swelling of the conjunctiva. May cause burns.
- Symptoms/injuries after ingestion : May be harmful if swallowed. May cause stomach distress, nausea or vomiting. May cause burns to the linings of the mouth, throat, and gastrointestinal tract.

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

Symptoms may not appear immediately. In case of accident or if you feel unwell, seek medical advice immediately (show the label or SDS where possible).

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

- Suitable extinguishing media : Water spray, dry chemical, foam, carbon dioxide.
- Unsuitable extinguishing media : Do not use water jet.

### 5.2. Special hazards arising from the substance or mixture

- Fire hazard : Products of combustion may include, and are not limited to: oxides of carbon, oxygen. Danger of developing toxic pyrolyse products.
- Explosion hazard : Heat may build pressure, rupturing closed containers, spreading fire and increasing risk of burns and injuries. This material increases the risk of fire and may aid combustion.

### 5.3. Advice for firefighters

- Protection during firefighting : Keep upwind of fire. Wear full fire fighting turn-out gear (full Bunker gear) and respiratory protection (SCBA). Use water spray to cool exposed surfaces.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Use personal protection recommended in Section 8. Isolate the hazard area and deny entry to unnecessary and unprotected personnel. Remove ignition sources.

### 6.2. Environmental precautions

Relevant water authorities should be notified of any large spillage to water course or drain.

### 6.3. Methods and material for containment and cleaning up

- For containment : In case of accidental spillage, contain the spill and neutralize it with sodium bicarbonate or sodium carbonate. Use appropriate personal protection equipment (PPE).
- Methods for cleaning up : Scoop up material and place in a disposal container. Absorb spillage to prevent material damage. Provide ventilation. Do not reuse the liquid material.

### 6.4. Reference to other sections

See section 8 for further information on protective clothing and equipment and section 13 for advice on waste disposal.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

- Additional hazards when processed : May be corrosive to metals.
- Precautions for safe handling : Keep away from sources of ignition. Do not get in eyes, on skin, or on clothing. Do not breathe dust/fume/gas/mist/vapors/spray. Do not swallow. Handle and open container with care. Use only outdoors or in a well-ventilated area. When using do not eat, drink or smoke. Never return unused material to original container.
- Hygiene measures : Launder contaminated clothing before reuse. Wash hands before eating, drinking, or smoking.

### 7.2. Conditions for safe storage, including any incompatibilities

- Technical measures : Proper grounding procedures to avoid static electricity should be followed.
- Storage conditions : Keep out of the reach of children. Keep container tightly closed. Keep only in the original container in a cool, well-ventilated place. Store away from other materials. Floor needs a protective coating against acid. Store at temperatures not exceeding 23.9 °C (75 °F). Protect from sunlight. Store locked up.

### 7.3. Specific end use(s)

Not available.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Hydrogen peroxide (7722-84-1)		
United Kingdom	WEL TWA (mg/m³)	1.4 mg/m³
United Kingdom	WEL TWA (ppm)	1 ppm
United Kingdom	WEL STEL (mg/m³)	2.8 mg/m³

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Hydrogen peroxide (7722-84-1)		
United Kingdom	WEL STEL (ppm)	2 ppm
Acetic acid (64-19-7)		
EU	IOELV TWA (mg/m³)	25 mg/m³
EU	IOELV TWA (ppm)	10 ppm

### 8.2. Exposure controls

Appropriate engineering controls	: Use ventilation adequate to keep exposures (airborne levels of dust, fume, vapor, etc.) below recommended exposure limits. Ensure that eyewash stations and safety showers are close to the workstation location.
Hand protection	: Wear chemically resistant protective gloves.
Eye protection	: Wear approved eye protection (properly fitted dust- or splash-proof chemical safety goggles) and face protection (face shield).
Skin and body protection	: Wear suitable protective clothing. Wear solvent resistant apron and boots for spills.
Respiratory protection	: In case of insufficient ventilation, wear suitable respiratory equipment. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.
Environmental exposure controls	: Maintain levels below Community environmental protection thresholds.
Other information	: Do not eat, smoke or drink where material is handled, processed or stored. Wash hands carefully before eating or smoking. Handle according to established industrial hygiene and safety practices.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Clear
Colour	: Colourless
Odour	: Acidic
Odour threshold	: No data available
pH	: 0.8 +/- 3
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Not flammable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: 1.09 - 1.14
Solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: Strong oxidiser
Explosive limits	: No data available
SADT	: >60°C

### 9.2. Other information

No additional information available.

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

May cause or contribute to the combustion of other material generally by yielding oxygen. May be corrosive to metals.

### 10.2. Chemical stability

Stable under normal storage conditions. Decomposes slowly to release oxygen.

### 10.3. Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use.

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### 10.4. Conditions to avoid

Heat. Sources of ignition. Incompatible materials.

### 10.5. Incompatible materials

Metals. Oxidizing materials. Alkalis. Caustics. Chlorine. Formaldehyde. Salts. Flammable organics.

### 10.6. Hazardous decomposition products

May include, and are not limited to: oxides of carbon, oxygen. Do not mix with chlorinated products as this could liberate toxic corrosive chlorine gas.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Harmful if inhaled.

RENALIN 100 Cold Sterilant	
LD50 oral rat	> 2000 mg/kg
LD50 dermal rabbit	> 2000 mg/kg
LC50 inhalation rat	>2.0 but ≤10.0 mg/l (Calculated using ATE values)
Hydrogen peroxide (7722-84-1)	
LD50 oral rat	801 mg/kg
LD50 dermal rat	4060 mg/kg
LD50 dermal rabbit	2000 mg/kg
LC50 inhalation rat	2 g/m <sup>3</sup> /4 h
Acetic acid (64-19-7)	
LD50 oral rat	3310 mg/kg
LD50 dermal rabbit	1060 mg/kg
Peroxyacetic acid (79-21-0)	
LD50 oral rat	1540 mg/kg
LD50 dermal rabbit	1410 µl/kg
LC50 inhalation mouse	0.524 mg/l/4h
Stabilizer (Proprietary)	
LD50 oral rat	2400 mg/kg
LD50 dermal rabbit	> 7940 mg/kg

Skin corrosion/irritation	: Causes severe skin burns.
Serious eye damage/irritation	: Causes serious eye damage.
Respiratory or skin sensitisation	: Based on available data, the classification criteria are not met.
Germ cell mutagenicity	: Based on available data, the classification criteria are not met.
Carcinogenicity	: Based on available data, the classification criteria are not met.
Reproductive toxicity	: Based on available data, the classification criteria are not met.
Specific target organ toxicity (single exposure)	: Based on available data, the classification criteria are not met.
Specific target organ toxicity (repeated exposure)	: Based on available data, the classification criteria are not met.
Aspiration hazard	: Based on available data, the classification criteria are not met.
Other information	: May cause respiratory irritation, dizziness, or drowsiness.

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general : Not considered to be harmful to aquatic life.

Hydrogen peroxide (7722-84-1)	
LC50 fishes 1	16.4 mg/l (96 h - Pimephales promelas)
EC50 Daphnia 1	18 - 32 mg/l 48 h - Daphnia magna [Static]
LC50 fish 2	18 - 56 mg/l (96 h - Lepomis macrochirus [static])
Acetic acid (64-19-7)	
LC50 fishes 1	79 mg/l (96 h - Pimephales promelas [static])
EC50 Daphnia 1	65 mg/l (48 h - Daphnia magna [Static])
LC50 fish 2	75 mg/l (96 h - Lepomis macrochirus [static])
Stabilizer (Proprietary)	
LC50 fishes 1	868 mg/l (96 h - Lepomis macrochirus [static])
EC50 Daphnia 1	527 mg/l (48 h - Daphnia magna)
LC50 fish 2	360 mg/l (96 h - Oncorhynchus mykiss [static])
NOEC (acute)	1000 mg/kg (14 Days - Eisenia foetida [soil dry weight])

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### 12.2. Persistence and degradability

No additional information available.

### 12.3. Bioaccumulative potential

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Bioaccumulative potential	Not established.
Hydrogen peroxide (7722-84-1)	
BCF fish 1	(no bioaccumulation)
Acetic acid (64-19-7)	
Log Pow	-0.31 (at 20 °C)
Peroxyacetic acid (79-21-0)	
BCF fish 1	(not bioaccumulative, rapid degradation)
Stabilizer (Proprietary)	
BCF fish 1	< 50
Log Pow	3.49

### 12.4. Mobility in soil

No additional information available.

### 12.5. Results of PBT and vPvB assessment

No additional information available.

### 12.6. Other adverse effects

No additional information available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste disposal recommendations : This material must be disposed of in accordance with all local, state, provincial, and federal regulations. The generation of waste should be avoided or minimized wherever possible.

## SECTION 14: Transport information

In accordance with ADR.

### 14.1. UN number

UN-No. (ADR) : 3149

### 14.2. UN proper shipping name

Proper Shipping Name (ADR) : HYDROGEN PEROXIDE AND PEROXYACETIC ACID MIXTURE, STABILIZED

### 14.3. Transport hazard class(es)

Class (ADR) : 5.1 (8)

Danger labels (ADR) :



### 14.4. Packing group

Packing group (ADR) : II

### 14.5. Environmental hazards

Dangerous for the environment : No.

Marine pollutant : No.

Other information : No supplementary information available.

### 14.6. Special precautions for user

Special transport precautions : Do not handle until all safety precautions have been read and understood.

### 14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No additional information.

## SECTION 15: Regulatory information

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

#### 15.1.1. EU-Regulations

Contains no substances with Annex XVII restrictions.

Contains no REACH candidate substance.

Contains no REACH Annex XIV substances.

#### 15.1.2. National regulations

No additional information available.

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### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

### SECTION 16: Other information

Indication of changes:

None.

Data sources

: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information

: None.

Full text of R-, H- and EUH-phrases:

Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Inhalation)	Acute toxicity (inhal.), Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Flam. Liq. 3	Flammable liquids, Category 3
Met. Corr. 1	Corrosive to metals, Category 1
Org. Perox. G	Organic Peroxides, Type G
Ox. Liq. 1	Oxidising Liquids, Category 1
Skin Corr. 1A	Skin corrosion/irritation, Category 1A
STOT SE 3	Specific target organ toxicity - Single exposure, Category 3
H226	Flammable liquid and vapour
H271	May cause fire or explosion; strong oxidiser
H290	May be corrosive to metals
H302	Harmful if swallowed
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H332	Harmful if inhaled
H335	May cause respiratory irritation
H336	May cause drowsiness or dizziness
H400	Very toxic to aquatic life
R10	Flammable
R20/21/22	Harmful by inhalation, in contact with skin and if swallowed
R20/22	Harmful by inhalation and if swallowed
R21	Harmful in contact with skin
R22	Harmful if swallowed
R34	Causes burns
R35	Causes severe burns
R41	Risk of serious damage to eyes
R5	Heating may cause an explosion
R50	Very toxic to aquatic organisms
R7	May cause fire
R8	Contact with combustible material may cause fire
C	Corrosive
N	Dangerous for the environment
O	Oxidising
Xi	Irritant
Xn	Harmful

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Ox. Liq. 1	H271	Expert judgment
Org. Perox. G	-	Expert judgment
Met. Corr. 1	H290	Expert judgment
Acute Tox. 4 (Inhalation)	H332	Calculation method
Skin Corr. 1A	H314	On basis of test data/Concentration limits
Eye Dam. 1	H318	Concentration limits

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