

Hemodialysis Acid Concentrate

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

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

1.1. Product identifier

Product name : Hemodialysis Acid Concentrate
 Product code : SB – 1000 Series – RENASOL™ Acid Concentrate
 SB – 100 Series – CENTRISOL™ Acid Concentrate
 SB – 300 Series – CENTRISOL™ Acid Concentrate

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 : Concentrate formulation to be used in conjunction with bicarbonate in a compatible artificial kidney (hemodialysis) machine.

1.2.2. Uses advised against

No additional information available.

1.3. Details of the supplier of the safety data sheet

Medivators Inc.
 14605 28th Avenue North
 Minneapolis, MN 55447 - USA
 T 1-800-328-3340

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]

Not classified.

2.2. Label elements

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

EUH-statements : EUH210 - Safety data sheet available on request.
 Unknown acute toxicity (CLP) - SDS : Not applicable.
 Unknown hazards to the aquatic environment (CLP) : Contains 7% of components with unknown hazards to the aquatic environment.

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]
Acetic acid	(CAS No) 64-19-7 (EC no) 200-580-7 (EC index no) 607-002-00-6	0.5 - 1.5	Flam. Liq. 3, H226 Skin Corr. 1A, H314

Specific concentration limits:

Name	Product identifier	Specific concentration limits
Acetic acid	(CAS No) 64-19-7 (EC no) 200-580-7 (EC index no) 607-002-00-6	(10 =< C < 25) Eye Irrit. 2, H319 (10 =< C < 25) Skin Irrit. 2, H315 (25 =< C < 90) Skin Corr. 1B, H314 (C >= 90) Skin Corr. 1A, H314

Full text of H-statements: see section 16

Hemodialysis Acid Concentrate

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures after inhalation : If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical advice/attention if you feel unwell.
- 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. Call a physician if irritation develops and persists.
- First-aid measures after eye contact : In case of contact, immediately flush eyes with plenty of water. Remove contact lenses, if worn. If irritation persists, get medical attention.
- First-aid measures after ingestion : If swallowed, do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell.

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

- Symptoms/injuries after inhalation : May cause respiratory tract irritation. Symptoms include sneezing, sore throat or runny nose.
- Symptoms/injuries after skin contact : May cause skin irritation. Symptoms may include redness, drying, defatting and cracking of the skin.
- Symptoms/injuries after eye contact : May cause eye irritation. Symptoms may include discomfort or pain, excess blinking and tear production, with possible redness and swelling.
- Symptoms/injuries after ingestion : Swallowing may cause burns of mouth, throat, and stomach. May cause stomach distress, nausea or vomiting.

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 : Treat for surrounding material.
- Unsuitable extinguishing media : None known.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : Does not support 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).

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.

6.2. Environmental precautions

Keep out of drains, sewers, ditches, and waterways. Minimize use of water to prevent environmental contamination.

6.3. Methods and material for containment and cleaning up

- For containment : Contain and/or absorb spill with inert material (e.g. sand, vermiculite), then place in a suitable container. Do not flush to sewer or allow to enter waterways. Use appropriate Personal Protective Equipment (PPE).
- Methods for cleaning up : Scoop up material and place in a disposal container.

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

- Precautions for safe handling : Avoid contact with skin and eyes. Avoid breathing vapour or mist. Do not swallow. Handle and open container with care. When using do not eat, drink or smoke.
- Hygiene measures : Launder contaminated clothing before reuse. Wash hands before eating, drinking, or smoking.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Keep out of the reach of children. Keep container tightly closed.

7.3. Specific end use(s)

Not available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Acetic acid (64-19-7)		
EU	IOELV TWA (mg/m ³)	25 mg/m ³
EU	IOELV TWA (ppm)	10 ppm

Hemodialysis Acid Concentrate

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

8.2. Exposure controls

Appropriate engineering controls	: Use ventilation adequate to keep exposures (airborne levels of dust, fume, vapour, etc.) below recommended exposure limits.
Hand protection	: Wear suitable gloves.
Eye protection	: Safety glasses or goggles are recommended when using product.
Skin and body protection	: Wear suitable protective clothing.
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	: Vinegar
Odour threshold	: No data available
pH	: 2 - 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	: > 93 °C (> 199.4 °F)
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	: 1.2
Solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reaction known under conditions of normal use.

10.2. Chemical stability

Stable under normal storage conditions.

10.3. Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use.

10.4. Conditions to avoid

No conditions to avoid known under normal use.

10.5. Incompatible materials

Bases and corrosive to metals.

10.6. Hazardous decomposition products

Will not occur.

Hemodialysis Acid Concentrate

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified.

Hemodialysis Acid Concentrate	
LD50 oral rat	> 2000 mg/kg
LD50 dermal rabbit	> 2000 mg/kg
LC50 inhalation rat	> 20 mg/l/4h

Acetic acid (64-19-7)	
LD50 oral rat	3310 mg/kg
LD50 dermal rabbit	1060 mg/kg
LC50 inhalation rat	11.4 mg/l/4h

Skin corrosion/irritation : Based on available data, the classification criteria are not met.
Serious eye damage/irritation : Based on available data, the classification criteria are not met.
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.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : May cause long-term adverse effects in the aquatic environment.

Acetic acid (64-19-7)	
LC50 fish 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])

12.2. Persistence and degradability

Hemodialysis Acid Concentrate	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

Hemodialysis Acid Concentrate	
Bioaccumulative potential	Not established.

Acetic acid (64-19-7)	
Partition coefficient: n-octanol/water	-0.31 (at 20 °C)

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

Not regulated for transport.

14.2. UN proper shipping name

Not applicable.

Hemodialysis Acid Concentrate

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

14.3. Transport hazard class(es)

Danger labels (ADR) : Not applicable.

14.4. Packing group

Not applicable.

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

Not applicable.

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 REACH 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.

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-statements:

Flam. Liq. 3	Flammable liquids, Category 3
Skin Corr. 1A	Skin corrosion/irritation, Category 1A
H226	Flammable liquid and vapour
H314	Causes severe skin burns and eye damage

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