

RAPICIDE[®] High-Level Disinfectant and 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 : RAPICIDE High-Level Disinfectant and Sterilant

Product code : ML02-0059

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 : Glutaraldehyde High-Level Disinfectant and Sterilant.

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) - F (31) 45 5 429 695
bv-cs@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]

Acute Tox. 3 (Inhalation) H331

Skin Irrit. 2 H315

Eye Dam. 1 H318

Resp. Sens. 1 H334

Skin Sens. 1 H317

STOT SE 3 H335

Full text of H-phrases: see section 16

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

Xn; R20/22

Xi; R37/38

Xi; R41

R42

R43

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) :



GHS05

GHS06

GHS08

Signal word (CLP) : Danger

Hazard statements (CLP) : H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H331 - Toxic if inhaled.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335 - May cause respiratory irritation.

Precautionary statements (CLP) : P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.

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P302+P352+P333+P313 - IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention.
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.
P403+P233 - Store in a well-ventilated place. Keep container tightly closed.
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations.

Unknown hazards to the aquatic environment (CLP) : Contains 3 % 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]
Glutaraldehyde	(CAS No) 111-30-8 (EC no) 203-856-5 (EC index no) 605-022-00-X	1 - 5	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Inhalation), H331 Skin Corr. 1B, H314 Resp. Sens. 1, H334 Skin Sens. 1, H317 STOT SE 3, H335 Aquatic Acute 1, H400
Sodium nitrite	(CAS No) 7632-00-0 (EC no) 231-555-9 (EC index no) 007-010-00-4	0.1 - 1	Ox. Sol. 3, H272 Acute Tox. 3 (Oral), H301 Eye Irrit. 2, H319 Aquatic Acute 1, H400

Name	Product identifier	Specific concentration limits
Glutaraldehyde	(CAS No) 111-30-8 (EC no) 203-856-5 (EC index no) 605-022-00-X	(C >= 0.5) STOT SE 3, H335 (C >= 0.5) Skin Sens. 1, H317 (0.5 <= C < 10) Skin Irrit. 2, H315 (0.5 <= C < 2) Eye Irrit. 2, H319 (2 <= C < 10) Eye Dam. 1, H318 (C >= 10) Skin Corr. 1B, H314

Name	Product identifier	%	Classification according to Directive 67/548/EEC
Glutaraldehyde	(CAS No) 111-30-8 (EC no) 203-856-5 (EC index no) 605-022-00-X	1 - 5	T; R23/25 C; R34 R42 R43 Xi; R37 N; R50
Sodium nitrite	(CAS No) 7632-00-0 (EC no) 231-555-9 (EC index no) 007-010-00-4	0.1 - 1	T; R25 Xi; R36 N; R50 O; R8

Name	Product identifier	Specific concentration limits
Glutaraldehyde	(CAS No) 111-30-8 (EC no) 203-856-5 (EC index no) 605-022-00-X	(0.5 <= C < 2) Xi;R36/37/38 (C >= 0.5) R43 (2 <= C < 50) Xn;R22 (2 <= C < 25) Xn;R20 (2 <= C < 10) Xi;R37/38-R41 (C >= 10) C;R34 (C >= 25) T;R23 (C >= 50) T;R25
Sodium nitrite	(CAS No) 7632-00-0 (EC no) 231-555-9 (EC index no) 007-010-00-4	(1 <= C < 5) Xn;R22 (C >= 5) T;R25

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. Call a physician if irritation develops and persists.

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- 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 medical attention immediately.
- 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 : Toxic if inhaled. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause respiratory tract irritation.
- Symptoms/injuries after skin contact : Causes skin irritation. Symptoms may include redness, edema, drying, defatting and cracking of the skin. May cause sensitisation by skin contact.
- 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.
- Symptoms/injuries after ingestion : May be harmful if swallowed. 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 : Products of combustion may include, and are not limited to: oxides of carbon.

5.3. Advice for firefighters

- Protection during firefighting : Keep upwind of fire. Wear full firefighting 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

No additional information available.

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. Provide ventilation.

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 dust/fume/gas/mist/vapours/spray. Do not swallow. Handle and open container with care. When using do not eat, drink or smoke. Use only outdoors or in a well-ventilated area.
- 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 and in a well-ventilated place.

7.3. Specific end use(s)

Not available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Glutaraldehyde (111-30-8)		
United Kingdom	WEL TWA (mg/m ³)	0.2 mg/m ³
United Kingdom	WEL TWA (ppm)	0.05 ppm
United Kingdom	WEL STEL (mg/m ³)	0.2 mg/m ³
United Kingdom	WEL STEL (ppm)	0.05 ppm

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8.2. Exposure controls

Appropriate engineering controls	: Use ventilation adequate to keep exposures (airborne levels of dust, fume, vapor, etc.) below recommended exposure limits.
Hand protection	: Wear chemically resistant protective gloves.
Eye protection	: Wear eye protection.
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	: Pale yellow.
Odour	: Mild but distinctive.
Odour threshold	: No data available.
pH	: 6.3 - 6.4
Relative evaporation rate (butylacetate=1)	: No data available.
Melting point	: No data available.
Freezing point	: No data available.
Boiling point	: >100 °C (212 °F)
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	: 1.013
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

Heat.

10.5. Incompatible materials

Strong oxidizing agents, strong acids, strong bases.

10.6. Hazardous decomposition products

May include, and are not limited to: oxides of carbon.

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Inhalation: Toxic if inhaled.

RAPICIDE High-Level Disinfectant and Sterilant	
LD50 oral rat	> 2000 mg/kg
LD50 dermal rabbit	> 2000 mg/kg
LC50 inhalation rat	>2.0 but ≤10.0 mg/l/4h

Glutaraldehyde (111-30-8)	
LD50 oral rat	134 mg/kg
LD50 dermal rabbit	> 2000 mg/kg
LC50 inhalation rat	0.224 mg/l/4h

Sodium nitrite (7632-00-0)	
LD50 oral rat	180 mg/kg
LC50 inhalation rat	5.5 mg/l/4h

Skin corrosion/irritation : Causes skin irritation.
Serious eye damage/irritation : Causes serious eye damage.
Respiratory or skin sensitisation : May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.
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) : May cause respiratory irritation.
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.

Glutaraldehyde (111-30-8)	
LC50 fishes 1	7.8 - 22 mg/l (96 h <i>Lepomis macrochirus</i> [static])
EC50 Daphnia 1	14 mg/l (48 h <i>Daphnia magna</i>)
LC50 fish 2	2.6 - 4.8 mg/l (96 h <i>Oncorhynchus mykiss</i> [flow-through])
EC50 Daphnia 2	0.56 - 1.0 mg/l (48 h <i>Daphnia magna</i> [Static])

Sodium nitrite (7632-00-0)	
LC50 fishes 1	0.19 mg/l (96 h <i>Oncorhynchus mykiss</i> [flow-through])
LC50 fish 2	0.092 - 0.13 mg/l (96 h <i>Oncorhynchus mykiss</i> [flow-through])

12.2. Persistence and degradability

RAPICIDE High-Level Disinfectant and Sterilant	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

RAPICIDE High-Level Disinfectant and Sterilant	
Bioaccumulative potential	Not established.

Glutaraldehyde (111-30-8)	
Partition coefficient: n-octanol/water	0.22 (at 25 °C)

Sodium nitrite (7632-00-0)	
Partition coefficient: n-octanol/water	-3.7 (at 25 °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.

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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.

14.3. Transport hazard class(es)

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 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.

Other information : None.

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

Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Ox. Sol. 3	Oxidising Solids, Category 3
Resp. Sens. 1	Sensitisation — Respiratory, category 1
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Sensitisation — Skin, category 1
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H272	May intensify fire; oxidiser
H301	Toxic if swallowed
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	May cause an allergic skin reaction

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H318	Causes serious eye damage
H319	Causes serious eye irritation
H331	Toxic if inhaled
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life
R20/22	Harmful by inhalation and if swallowed
R23/25	Toxic by inhalation and if swallowed
R25	Toxic if swallowed
R34	Causes burns
R36	Irritating to eyes
R37/38	Irritating to respiratory system and skin
R41	Risk of serious damage to eyes
R42	May cause sensitization by inhalation
R43	May cause sensitisation by skin contact
R50	Very toxic to aquatic organisms
R8	Contact with combustible material may cause fire
C	Corrosive
N	Dangerous for the environment
O	Oxidising
T	Toxic
Xi	Irritant
Xn	Harmful

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

Acute Tox. 3 (Inhalation)	H331	Calculation method
Skin Irrit. 2	H315	Concentration limits
Eye Dam. 1	H318	Concentration limits
Resp. Sens. 1	H334	Concentration limits
Skin Sens. 1	H317	Concentration limits
STOT SE 3	H335	Concentration limits

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