

SAFETY DATA SHEET

Product name:	Radiometer SDS M3 073	Page:	1/13
Supersedes date:	2022-08-15	Revision:	2022-08-17
Product No.:		SDS-ID:	EU-EN/5.3

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name: Radiometer SDS M3 073

Product name: 942-065 D7066 MEMBRANE BOX for Glucose Electrode
942-066 D7077 MEMBRANE BOX for Lactate Electrode
944-061 Dispenser with inner liquide S974

Container size: (Membrane box)

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

Application: Chemicals for Radiometer Equipment.

1.3. Details of the supplier of the safety data sheet

Manufacturer: Radiometer Medical ApS
Åkandevvej 21
2700 Brønshøj
Denmark
Tel: +45 3827 3827
www.radiometer.com

Responsible for safety data sheet authoring: environment@radiometer.dk

1.4. Emergency telephone number

Emergency telephone: Poison Control Centers may be available in specific member countries.

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SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

CLP: The product is classified: Repr. 1B;H360D

References: The full text for all hazard statements is displayed in section 16.

2.2. Label elements



Signal word Danger

Contains: Imidazole

H360D May damage the unborn child.

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

P308 + P313 IF exposed or concerned: Get medical advice/attention.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local regulations.

Contains 5-chloro-2-methyl-4-isothiazolin-3-one, mixed (3:1) with 2-methyl-2H-isothiazol-3-one. May produce an allergic reaction.

Restricted to professional users.

2.3. Other hazards

PBT/vPvB: This product does not contain any PBT or vPvB substances.

Other: Endocrine Disruptor Information: Contains Octylphenolethoxylate.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

The product contains: water, salts/additives and preservative.

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CLP:

<u>%:</u>	<u>CAS-No.:</u>	<u>EC No.:</u>	<u>REACH Reg. No:</u>	<u>Chemical name:</u>	<u>Hazard classification:</u>	<u>Notes:</u>
0,1 - < 1	288-32-4	206-019-2	-	Imidazole	Acute Tox. 4;H302 Skin Corr. 1B;H314 Repr. 1B;H360D	
< 0,01	9036-19-5	618-541-1	-	Octylphenoethoxylate	Acute Tox. 4;H302 Skin Irrit. 2;H315 Eye Dam. 1;H318 Aquatic Acute 1;H400 Aquatic Chronic 1;H410	SVHC
0,00015 - < 0,0015	55965-84-9	611-341-5	-	5-chloro-2-methyl-4-isothiazolin-3-one, mixed (3:1) with 2-methyl-2H-isothiazol-3-one	Acute Tox. 2;H330 Acute Tox. 2;H310 Acute Tox. 3;H301 Skin Corr. 1C;H314 Eye Dam. 1;H318 Skin Sens. 1A;H317 Aquatic Acute 1;H400 Aquatic Chronic 1;H410 EUH071	

Notes:

SVHC = Substance of Very High Concern.

SCL (CAS 9036-19-5):
M(ac): 10
M(chr): 10

SCL (CAS 55965-84-9):
Skin Corr. 1C;H314: C ≥ 0,6%
Skin Irrit. 2;H315: 0,06% ≤ C <0,6%
Eye Dam. 1;H318: C ≥ 0,6%
Eye Irrit. 2;H319: 0,06% ≤ C <0,6%
Skin Sens. 1A;H317: C ≥ 0,0015%
M (ac): 100
M (chr): 100

References: The full text for all hazard statements is displayed in section 16.

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SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation: Move into fresh air and keep at rest.

Skin contact: Remove contaminated clothes and rinse skin thoroughly with water. In case of eczema or other skin disorders: Seek medical attention and bring along these instructions.

Eye contact: Immediately flush with plenty of water for at least 15 minutes. Remove any contact lenses and open eyelids widely. If irritation persists: Seek medical attention and bring along these instructions.

Ingestion: Immediately rinse mouth and drink 1-2 glasses of water. Keep person under observation. If uncomfortable: Transportation to hospital. Bring along these instructions.

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

Symptoms/effects: See section 11 for more detailed information on health effects and symptoms.

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

Medical attention/treatments: Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Extinguishing media: Use fire-extinguishing media appropriate for surrounding materials.

5.2. Special hazards arising from the substance or mixture

Specific hazards: No specific precautions.

5.3. Advice for firefighters

Protective equipment for fire-fighters: Selection of respiratory protection for fire fighting: follow the general fire precautions indicated in the workplace.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Avoid any exposure. Follow precautions for safe handling described in this safety data sheet.

6.2. Environmental precautions

Environmental precautions: Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up: Absorb spillage with suitable absorbing material. Collect spillage in metal/plastic container with tight-fitting lid, with indication of the contents.

6.4. Reference to other sections

References: For personal protection, see section 8.
For waste disposal, see section 13.

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SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Safe handling advice: Observe good laboratory/industrial hygiene practices. Avoid any exposure.

Technical measures: Do not eat, drink or smoke when using the product. Do not store tobacco, food or beverage in work rooms or areas where the product is used. Use work methods which minimise spreading of vapours, dust, smoke, aerosols, splashes etc. to the extent technically possible.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: See storage temperature on the product label.

7.3. Specific end use(s)

Specific use(s): Not relevant.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

No occupational exposure limit assigned.

8.2. Exposure controls

Engineering measures: Provide adequate ventilation.

Personal protection: Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

Respiratory equipment: No special precautions.

Hand protection: Wear protective gloves. Nitrile gloves are recommended. Thickness: 0,11 mm. Breakthrough time: > 480 min. The most suitable glove must be chosen in collaboration with the supplier of gloves, who can inform about the breakthrough time of the glove material.

Eye protection: Risk of splashes: Wear goggles/face shield.

Skin protection: Wear apron or protective clothing.

Hygiene measures: Wash hands after handling. When using do not eat, drink or smoke. Wash contaminated clothing before reuse. Personal protection must be kept separate from other clothes.

Environmental Exposure Controls: Not available.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

<u>Physical state:</u>	Liquid.
<u>Odour:</u>	Odourless.
<u>Odour threshold:</u>	Not available.
<u>pH:</u>	approx. 7
<u>Melting point / freezing point:</u>	Not available.
<u>Boiling point:</u>	> 100°C
<u>Flash point:</u>	Not available.
<u>Evaporation rate:</u>	Not available.
<u>Explosion limits:</u>	Not available.
<u>Vapour pressure:</u>	Not available.
<u>Vapour density:</u>	Not available.
<u>Relative density:</u>	approx. 1,0-1,1
<u>Solubility:</u>	Completely soluble in water.
<u>Partition coefficient (n-octanol/water):</u>	Not available.
<u>Auto-ignition temperature (°C):</u>	Not available.
<u>Decomposition temperature (°C):</u>	Not available.
<u>Viscosity:</u>	Not available.
<u>Explosive properties:</u>	Not relevant.
<u>Oxidising properties:</u>	Not available.

9.2. Other information

<u>Other data:</u>	Not relevant.
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SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity: Not known.

10.2. Chemical stability

Stability: Stable under the prescribed storage conditions.

10.3. Possibility of hazardous reactions

Hazardous Reactions: None known.

10.4. Conditions to avoid

Conditions/materials to avoid: None specific.

10.5. Incompatible materials

Incompatible materials: Strong oxidizing substances. Strong alkalis.

10.6. Hazardous decomposition products

Hazardous decomposition products: None in particular.

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SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute Toxicity (Oral): Based on available data, the classification criteria are not met.

Acute Toxicity (Dermal): Based on available data, the classification criteria are not met.

Acute Toxicity (Inhalation): Based on available data, the classification criteria are not met.

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: May damage the unborn child.

STOT - Single exposure: Based on available data, the classification criteria are not met.

STOT - Repeated exposure: Based on available data, the classification criteria are not met.

Aspiration hazard: Based on available data, the classification criteria are not met.

Inhalation: Not relevant at normal room temperatures.

Skin contact: Prolonged or repeated contact may cause irritation. The product contains a small amount of sensitising substance which may provoke an allergic reaction among sensitive individuals.

Eye contact: May cause temporary eye irritation.

Ingestion: Low acute toxicity. May irritate and cause malaise.

11.2. Information on other hazards

Endocrine disrupting properties: The product contains no substances identified as having endocrine disrupting properties in humans.

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SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity: The product contains a small amount of a substance which is very toxic to aquatic organisms.
5-chloro-2-methyl-4-isothiazolin-3-one, mixed (3:1) with 2-methyl-2H-isothiazol-3-one:
M-factor (acute): 1
M-factor (chronic): 1
Octylphenoethoxylate:
M-factor (acute): 10
M-factor (chronic): 10

12.2. Persistence and degradability

Degradability: The product is expected to be biodegradable.

12.3. Bioaccumulative potential

Bioaccumulative potential: Will not bio-accumulate.

12.4. Mobility in soil

Mobility: No data available.

12.5. Results of PBT and vPvB assessment

PBT/vPvB: Not relevant.

12.6. Endocrine disrupting properties

Endocrine disrupting properties: Contains Octylphenoethoxylate. The substance degrades to 4-tert-octylphenol [4-tert-OP] in wastewater treatment plants and sediments and soils. 4-tert-OP is considered to be endocrine active in aquatic organisms through an estrogen mediated mode of action.

12.7. Other adverse effects

Other adverse effects: None known.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste and residues in accordance with local authority requirements. Waste is classified as hazardous waste.

Waste from residues: EWC-code: 16 05 06

Contaminated packaging: Dispose of contaminated packings as residue.

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SECTION 14: TRANSPORT INFORMATION

The product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/AND/RID).

14.1. UN number

UN-No: -

14.2. UN proper shipping name

Proper Shipping Name: -

14.3. Transport hazard class(es)

Class: -

14.4. Packing group

PG: -

14.5. Environmental hazards

Marine pollutant: -

Environmentally Hazardous substance: -

14.6. Special precautions for user

Special precautions: None known.

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

Transport in bulk: This product is not intended for transport in bulk.

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SECTION 15: REGULATORY INFORMATION

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

Special provisions: Pregnant or breastfeeding women must not handle this product.

As a general rule, persons under 18 years of age are not allowed to work with this product. Users must be carefully instructed in the proper work procedure, the dangerous properties of the product and the necessary safety instructions.

National regulation: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, with amendments.

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 with amendments.

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work, with amendments.

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC).

Commission Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, with amendments.

Commission Directive 91/322/EEC of 29 May 1991 on establishing indicative limit values by implementing Council Directive 80/1107/EEC on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work, with amendments.

Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, with amendments.

Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work, with amendments.

Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work, with amendments.

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, with amendments.

2014/955/EC: Commission Decision of 18 December 2014 amending Decision 2000/532/EC as regards the list of wastes.

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15.2. Chemical Safety Assessment

CSA status: No chemical safety assessment has been carried out.

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SECTION 16: OTHER INFORMATION

For restrictions on use see section 15.

The following sections contain revisions or new statements: 1.

This SDS refers to the following internal drawings:

942-065: MFG-011125 rev 3

942-066: MFG-011124 rev 2

944-061: MFG-008742 rev1

Abbreviations and acronyms used in the safety data sheet: CSA = Chemical Safety Assessment.
M(ac) = M-factor acute toxicity.
M(chr) = M-factor chronic toxicity.
PBT = Persistent, Bioaccumulative and Toxic.
vPvB = very Persistent and very Bioaccumulative.
SCL = Specific Concentration Limit.
STOT = Specific Target Organ Toxicity.
SVHC = Substance of Very High Concern.

Additional information: Classification according to Regulation (EC) No. 1272/2008: Calculation method.

Wording of H-statements:

EUH071	Corrosive to the respiratory tract.
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H331	Toxic if inhaled.
H360D	May damage the unborn child.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

The information on this data sheet represents our current data and is reliable provided that the product is used under the prescribed conditions and in accordance with the application specified on the packaging and/or in the technical guidance literature. Any other use of the product which involves using the product in combination with any other product or any other process is the responsibility of the user.