

SAFETY DATA SHEET

Product name: Radiometer SDS M3 190 Page: 1/13
Supersedes date: 2022-08-25 Revision: 2022-08-29
Product No.: SDS-ID: EU-EN/6.3

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

1.1. Product identifier

Product name: Radiometer SDS M3 190
Product name: Product specification see section 16.
Container size: Various

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: Skin Sens. 1A;H317

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

2.2. Label elements



Signal word Warning

Contains: 2-Methyl-2H-isothiazol-3-one

H317 May cause an allergic skin reaction.

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

P302 + P352 IF ON SKIN: Wash with plenty of water.

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

2.3. Other hazards

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

Other: The product contains a small amount of a substance which is very toxic to aquatic organisms.

Endocrine Disruptor Information: Contains Octylphenoethoxylate.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

The product contains: Buffer, water, salts and preservative.

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CLP:

<u>%:</u>	<u>CAS-No.:</u>	<u>EC No.:</u>	<u>Chemical name:</u>	<u>Hazard classification:</u>	<u>Notes:</u>
0,0015 - < 0,025	2682-20-4	220-239-6	2-Methyl-2H-isothiazol-3-one	Acute Tox. 2;H330 Acute Tox. 3;H311 Acute Tox. 3;H301 Skin Corr. 1B;H314 Eye Dam. 1;H318 Skin Sens. 1A;H317 Aquatic Acute 1;H400 Aquatic Chronic 1;H410 EUH071	
< 0,01	9036-19-5	618-541-1	Octylphenolethoxylate	Acute Tox. 4;H302 Skin Irrit. 2;H315 Eye Dam. 1;H318 Aquatic Acute 1;H400 Aquatic Chronic 1;H410	SVHC

Notes: SVHC = Substance of Very High Concern.

SCL (CAS 2682-20-4):
Skin Sens. 1A;H317: C ≥ 0,0015 %
M(ac): 10
M(chr): 1

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

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

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Considering the size of the packaging, the risk is regarded as minimal.

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.

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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 contact with skin and eyes.

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. Wash contaminated area with water.

6.4. Reference to other sections

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

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Safe handling advice: Avoid contact with skin and eyes.
When product is in use it will contain human blood. Observe routine biosafety procedures in handling the product and consider all materials as potentially infectious.

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.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

No occupational exposure limit assigned.

8.2. Exposure controls

Engineering measures:

Provide adequate ventilation. Avoid forming spray mists/aerosols.

Personal protection:

Protective gloves and goggles are recommended.
Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

Hand protection:

Wear protective gloves. Nitrile gloves are recommended. Thickness: 0,11 mm.
Breakthrough time: > 480 min. Other types of gloves can be recommended by the glove supplier.

Eye protection:

Risk of splashes: Wear goggles/face shield.

Hygiene measures:

Wash hands after contact.

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>	6,8 - 7,8
<u>Melting point / freezing point:</u>	Not available.
<u>Boiling point:</u>	approx. 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
<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 available.
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SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity: None 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: Not known.

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

Considering the size of the packaging, the risk is regarded as minimal.

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: 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.

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: Inhalation of aerosols: May irritate the respiratory system.

Skin contact: Prolonged or repeated contact may cause irritation. Risk of sensitisation or allergic reactions among sensitive individuals.

Eye contact: Direct contact may irritate.

Ingestion: Not likely, due to the packaging. However, ingestion may cause nausea, stomach pain and vomiting.

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.

2-Methyl-2H-isothiazol-3-one:

M-factor (acute): 10

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.

NOTE: When product is in use it will contain human blood. Observe routine biosafety procedures in handling the product and consider all materials as potentially infectious.

Waste from residues: EWC-code: 16 05 06 (or 18 01 03)

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: 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.

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.

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.

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

15.2. Chemical Safety Assessment

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

SECTION 16: OTHER INFORMATION

The user must be instructed in the proper work procedure and be familiar with the contents of these instructions.

The following sections contain revisions or new statements: 16.

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For restrictions on use see section 15.

Product specification:

941-832 S951 Væske til membranunitkontrol karvæske
943-831 S1585 Calibration Solution 1
944-024 S1720 Calibration Solution 1
944-026 S4970 Rinse Solution
944-057 S4970 Rinse 1 Solution
944-058 S4970 Rinse 1 Solution
944-127 S1820 Calibration Solution 1
944-128 S1820 Calibration Solution 1
944-130 S4980 Rinse Solution
944-131 S4980 Rinse Solution
944-132 S4980 Rinse Solution
944-155 S4987 Rinse Solution II
944-158 S4987 Rinse Solution II
944-159 S4987 Rinse Solution II
944-160 Dispenser med Crea indervæske
944-257 RINSE SOLUTION ABL7XX/8XX
944-293 S1720 Cal 1 solution for ABL7XX/8XX
944-312 Væske til Rinse II Solution
944-353 S2610 Lin Glu, kont. Lac til slutkontrol
944-354 S2630 Rinse til glu/lac slutkontrol
944-355 S2640 PAM/HEPES til glu/lac slutkontrol
944-356 S2650 GOD: Galactose til glu/lac slutkont.
944-357 S2660 LOD: Glycolic acid til glu/lac slutk.
944-358 S2620 Lin Lac, kont. Glu til slutkontrol
948-077 Reference solution: S1585 - raw
948-078 Reference solution: S1595 - raw
991-183 RENSEVÆSKE M. 2mM L-PROLIN

This SDS refers to the following internal drawings:

941-832: MFG-008750 rev 1
943-831: A4-23726 rev 16
944-024: MFG-008968 rev 3
944-026: MFG-009412 rev 1
944-057: MFG-009412 rev 1
944-058: MFG-009412 rev 1
944-127: MFG-008968 rev 3
944-128: MFG-008968 rev 3
944-130: MFG-009412 rev 1
944-131: MFG-009412 rev 1
944-132: MFG-009412 rev 1
944-155: MFG-009364 rev 1
944-158: MFG-009364 rev 1
944-159: MFG-009364 rev 1
944-160: A4-34561 rev 6
944-257: MFG-009412 rev 1
944-293: MFG-008968 rev 3
944-312: MFG-009364 rev 1
944-353: A4-37951 rev 5
944-354: DRW-000239 rev 5
944-355: DRW-000240 rev 6

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944-356: DRW-000241 rev 5
944-357: DRW-000242 rev 4
944-358: MFG-010300 rev 2
948-077: MFG-011257 rev 1
948-078: MFG-011258 rev 2
991-183: A4-35050 rev 4

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.
SCL = Specific Concentration Limit.
SVHC = Substance of Very High Concern.
vPvB = very Persistent and very Bioaccumulative.

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.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
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.

Made by DHI - Environment and Toxicology, Artvej 5, DK-2970 Hørsholm, Denmark.
www.dhigroup.com.
