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 2011-04-15
 Revision:
 2013-03-21

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

Product identifier

Name: Radiometer SDS M2 005

Product name: Product specification see section 16.

<u>Container size:</u> Various

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

Application: Chemicals for Radiometer Equipment.

Details of the supplier of the safety data sheet

Supplier: Radiometer America Inc.

810 Sharon Drive

Westlake OH, 44145, USA

Tel:440-871-8900 www.radiometer.com

Manufacturer Radiometer Medical ApS

Åkandevej 21

DK-2700 Brønshøj, DENMARK

Tel: +45 3827 2853 Tel: +45 3827 2828 www.radiometer.com

Responsible for material envir

safety data sheet authoring:

environment@radiometer.dk

Emergency telephone number

Emergency telephone: 911

(National Capital Poison Center: 1-800-222-1222)

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SECTION 2: HAZARDS IDENTIFICATION

Classification of the substance or mixture

This product is covered by the OSHA Hazard Communication Rule 29, CFR 1910.1200

Physical and Chemical

Not relevant.

Hazards:

<u>Human health:</u> The hazardous properties of the product are considered limited. However, the

product contains a small amount of sensitizing substance which may provoke an

allergic reaction among sensitive individuals.

Environment: The hazardous properties of the product in the environment are considered to be

limited.

Label elements

Based on information from the manufacturer regarding the chemical composition,

the product is not liable to classification and labeling.

EC Label:

Safety data sheet available on request.

Other hazards

PBT/vPvB: Not relevant.

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Mixtures

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

67/548/EEC:

<u>%:</u>	CAS-No.:	EC No.:	REACH Reg. No:	Chemical name:	Hazard classification:	Notes:
0.5-3 *)	7365-45-9	230-907-9	-	4-(2-Hydroxyethyl)piperazin-1 -ylethanesulphonic acid	Xi;R36/37/38	
0.5-3 *)	75277-39-3	278-169-7	-	Sodium 4-(2 -hydroxyethyl)piperazin-1 -ylethanesulphonate	-	
<0.1	2682-20-4	220-239-6	-	2-Methyl-2H-isothiazol-3-one	T;R24/25 C;R34 Xi;R37 R43 N;R50	
GHS:						
<u>%:</u>	CAS-No.:	EC No.:	REACH Reg. No:	Chemical name:	Hazard classification:	Notes:
0.5-3 *)	7365-45-9	230-907-9	-	4-(2-Hydroxyethyl)piperazin-1 -ylethanesulphonic acid	Eye Irrit. 2;H319 Skin Irrit. 2;H315 STOT SE 3;H335	
0.5-3 *)	75277-39-3	278-169-7	-	Sodium 4-(2 -hydroxyethyl)piperazin-1 -ylethanesulphonate	-	
<0.1	2682-20-4	220-239-6	-	2-Methyl-2H-isothiazol-3-one	Acute Tox. 3;H301 Acute Tox. 3;H311 Skin Corr. 1B;H314	

Notes: *) Buffer

References: The full text for all R-phrases and hazard statements are displayed in section 16.

Skin Sens. 1;H317 STOT SE 3;H335 Aquatic Acute 1;H400

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SECTION 4: FIRST AID MEASURES

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 these

instructions.

Eye contact: Immediately flush with plenty of water for up to 15 minutes. Remove any contact

lenses and open eyelids widely. If irritation persists: Seek medical attention and

bring these instructions.

Immediately rinse mouth and drink plenty of water. Keep person under

observation. If person becomes uncomfortable seek hospital and bring these

instructions.

Most important symptoms and effects, both acute and delayed

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

Indication of any immediate medical attention and special treatment needed

Medical attention/treatments: Not known.

SECTION 5: FIREFIGHTING MEASURES

Extinguishing media

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

Special hazards arising from the substance or mixture

<u>Specific hazards:</u> No specific precautions.

Advice for firefighters

<u>Protective equipment for</u> Selection of respiratory protection for fire fighting: follow the general fire

<u>fire-fighters:</u> precautions indicated in the workplace.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

<u>Personal precautions:</u> Avoid contact with skin and eyes.

Environmental precautions

<u>Environmental</u> Avoid discharge into drains, water courses or onto the ground.

precautions:

Methods and material for containment and cleaning up

<u>Spill Cleanup Methods:</u> Flush away small spillages with plenty of water.

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

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.

Conditions for safe storage, including any incompatibilities

<u>Storage conditions:</u> See storage temperature on the product label.

Specific end use(s)

Specific use(s): Not relevant.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

No occupational exposure limit assigned.

Exposure controls

Engineering measures: Provide adequate ventilation. Avoid forming spray/aerosol mists.

<u>Personal protection:</u> Protective gloves and goggles are recommended.

Hygiene measures: Wash hands after contact.

Environmental Exposure

Controls:

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance: Liquid.

Odor: Odorless.

pH: 6.8 - 7.8

Boiling point: approx. 212°F / 100°C

Relative density: approx. 1.0

Solubility: Completely soluble in water.

Other information

Other data: Not relevant.

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SECTION 10: STABILITY AND REACTIVITY

Reactivity

Reactivity: Not known.

Chemical stability

Stability: Stable under the prescribed storage conditions.

Possibility of hazardous reactions

Hazardous Reactions: None known.

Conditions to avoid

Conditions/materials to avoid: None specific.

Incompatible materials

Incompatible materials: Not known.

Hazardous decomposition products

<u>Hazardous decomposition</u> No

products:

None in particular.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on toxicological effects

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

<u>Inhalation:</u> Inhalation of aerosols: May irritate the respiratory system.

Skin contact: Prolonged or repeated contact may cause irritation.

<u>Eye contact:</u> Direct contact may irritate.

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

pain and vomiting.

<u>Specific effects:</u> The product contains very small amounts of Isothiazolone which may provoke an

allergic reaction among sensitive individuals.

Contains: HEPES (4-(2-Hydroxyethyl)piperazin-1-ylethanesulphonic acid). This

substance is listed on the Danish EPA list of advisory classifications as:

May cause sensitisation by skin contact.

This product contains no ingredient listed on the NTP, IARC or California

Proposition 65 carcinogen lists.

<u>Additional information:</u> This product contains no substances evaluated as:

Carcinogen/Mutagen/Reprotoxic (CMR)

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SECTION 12: ECOLOGICAL INFORMATION

Toxicity

<u>Ecotoxicity:</u> The ecotoxicity of the product is considered to be limited.

Persistence and degradability

<u>Degradability:</u> The product is expected to be biodegradable.

Bioaccumulative potential

Bioaccumulative potential: Will not bio-accumulate.

Mobility in soil

Mobility: No data available.

Results of PBT and vPvB assessment

PBT/vPvB: Not relevant.

Other adverse effects

Other adverse effects: None known.

SECTION 13: DISPOSAL CONSIDERATIONS

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.

<u>Contaminated packaging:</u> 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, DOT).

UN number

<u>UN-No:</u>

UN proper shipping name

Proper Shipping Name: -

Transport hazard class(es)

<u>Class:</u> -

Packing group

PG: -

Environmental hazards

Marine pollutant: -

Environmentally Hazardous

substance:

Special precautions for user

Special precautions: None known.

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

<u>Transport in bulk:</u> Not relevant.

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SECTION 15: REGULATORY INFORMATION

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

When product is in use it will contain human blood. Follow the requirements in the Bloodborne Pathogens Standard (CFR 29 1910.1030)

Special provisions: TSCA: Listed.

SARA Section 302: Not listed. SARA Section 313: Not listed.

SARA (311/312) Hazard categories:

Acute Health: Yes.

This product contains no ingredient listed on the NTP, IARC or California

Proposition 65 carcinogen lists.

NFPA Rating: Health:1 Fire:0 Reactivity:0 Other:-

<u>National regulation:</u> The following lists and legislation have been checked:

The Code of Federal Regulation, Title 29, part 1910. Occupational Safety and

Health Standards, Hazard Communication, with amendments.

The Code of Federal Regulation, Title 40, part 261.33. Identification and listning

of hazardous waste.

The Code of Federal Regulation. Title 40, part 355.50. Emergency Planning and

Notification.

The Code of Federal Regulation. Title 40, part 302.4. Designation, Reportable

Quantities, and Notification.

The Code of Federal Regulation. Title 40, part 68.130. Chemical Accident

Prevention Provisions.

The Code of Federal Regulation. Title 40, part 372.65. Toxic Chemical Release

Reporting: Community Right to Know.

Threshold Limit Values (2012), ACGIH, by the American Conference on

Governmental Industrial Hygienists.

The Code of Federal Regulation, Title 29, part 1910. Occupational Safety and

Health Standards, Air contaminants (OSHA), with amendments.

U.S. Department of health and human services: 2011 - Report on Carcinogens -

12th Edition.

International Agency for Research on Cancer (IARC): IARC Monographs on the

Evaluation of Carcinogenic Risks to Humans. Lyon: IARC, World Health

Organization.

State of California. Environmental Protection Agency. California Proposition 65,

with amendments.

Chemical Safety Assessment

<u>CSA status:</u> Not relevant.

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: 1, 3, 7, 8, 16.

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Product specification:

943-961 S5530 MULTICHECK, level 1 943-962 S5540 MULTICHECK, level 2

943-963 S5550 MULTICHECK, level 3

944-045 S7230 QUALICHECK 2+, Level 1

944-046 S7240 QUALICHECK 2+, Level 2

944-047 S7250 QUALICHECK 2+, Level 3

944-048 S7260 QUALICHECK 2+, Level 4

944-049 S7330 QUALICHECK 3+, Level 1

944-050 S7340 QUALICHECK 3+, Level 2

944-051 S7350 QUALICHECK 3+, Level 3

944-017 S7730 QUALICHECK 5+, Level 1

944-018 S7740 QUALICHECK 5+, Level 2

944-019 S7750 QUALICHECK 5+, Level 3

944-151 Range+ QUALICHECK level 1, box of

944-152 Range+ QUALICHECK level 2, box of

944-153 Range+ QUALICHECK level 3, box of

943-831 S1585 Calibration Solution 1

943-832 S1595 Calibration Solution 2

944-015 S1583 Calibration Solution 1

944-021 S7770 tHb calibration Solution

944-024 S1720 Calibration Solution 1

944-030 S1584 Calibration Solution 1

944-064 S1720 Calibration Solution 1

944-127 S1820 Calibration Solution 1

944-127 STOZO Calibration Solution 1

944-128 S1820 Calibration Solution 1

944-074 S7735 AUTOCHECK 5+, Level 1

944-075 S7745 AUTOCHECK 5+, Level 2

944-076 S7755 AUTOCHECK 5+, Level 3

944-082 S7335 AUTOCHECK 3+, Level 1

944-083 S7345 AUTOCHECK 3+, Level 2 944-084 S7355 AUTOCHECK 3+, Level 3

244 004 07005 AUTOOUEOK 0., Lovel 0

944-094 S7835 AUTOCHECK 6+, Level 1

944-095 S7845 AUTOCHECK 6+, Level 2

944-096 S7855 AUTOCHECK 6+, Level 3

944-162 Demovæske til Safe PICO 944-293 S1720 Cal 1 solution for ABL7XX/8XX

This SDS refers to the following internal drawings:

943-961: A4-25815 rev 30

943-962: A4-25816 rev 30

943-963: A4-25817 rev 30

944-045: A4-28793 rev 15

944-046: A4-28794 rev 14

944-047: A4-28795 rev 14

944-048: A4-28796 rev 16

944-049: A4-29550 rev 18

944-050: A4-29551 rev 16

944-051: A4-29552 rev 18

944-017: A4-30970 rev 5

944-018: A4-30971 rev 4

944-019: A4-30972 rev 3

944-151: A4-34452 rev 10

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944-152: A4-34453 rev 10 944-153: A4-34454 rev 10 943-831: A4-23726 rev 15 943-832: A4-23727 rev 14 944-015: A4-27391 rev 9 944-021: A4-28303 rev 18 944-024: A4-37072 rev 2 944-030: A4-27070 rev 13 944-064: A4-37072 rev 2 944-127: A4-37072 rev 2 944-128: A4-37072 rev 2 944-074: A4-30970 rev 5 944-075: A4-30971 rev 4 944-076: A4-30972 rev 3 944-082: A4-30970 rev 5 944-083: A4-30971 rev 4 944-084: A4-30972 rev 3 944-094: A4-32179 rev 11 944-095: A4-32180 rev 9 944-096: A4-32181 rev 8 944-162: A4-34890 944-293: A4-37072 rev 2

Wording of H-statements:

R24/25 Toxic in contact with skin and if swallowed.

R34 Causes burns.

R36/37/38 Irritating to eyes, respiratory system and skin.

R37 Irritating to respiratory system.

R43 May cause sensitisation by skin contact.

R50 Very toxic to aquatic organisms.

H301 Toxic 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.

H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

H400 Very toxic to aquatic life.

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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, Agern Allé 5, DK-2970 Hørsholm, Denmark. www.dhigroup.com.