

# SAFETY DATA SHEET

RADIOMETER 

Product name: Radiometer SDS M2 047 Page: 1/10  
Supersedes date: 2013-03-01 Revision: 2017-03-30  
Product No.: SDS-ID: EU-EN/3.0

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

### 1.1. Product identifier

Product name: Radiometer SDS M2 047  
Product name: 5601500 Fixation Rings 32 kit for TOSCA Sensor 92 and tc Sensor 54  
5601300 Attachment clip for TOSCA 92 Sensor and tc Sensor 54  
905-873 Fixation Rings N20 kit for tc Sensor 84 and tc Sensor 54  
905-872 Adhesive Rings N20 kit for tc Sensor 84 and tc Sensor 54  
905-872 Adhesive Rings N20 kit  
945-736 tc Sensor 54, pCO2  
607110 Application set  
607120 Application set neonatal  
603210.10 Contact gel (10 x 10 ml)  
603210 Contact gel (1 x 10 ml)  
Container size: 10 ml

### 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  
Åkandevej 21  
DK-2700 Brønshøj, DENMARK  
Tel: +45 3827 2853  
Tel: +45 3827 2828  
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.

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

CLP: The product is not classified.

### 2.2. Label elements

The substance/mixture does not meet the criteria for classification, but the following labelling must be applied:

Contains cis-1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride. May produce an allergic reaction.  
Safety data sheet available on request.

### 2.3. Other hazards

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

Other: Contains a small amount of a substance which may cause harm to the unborn child.

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## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.2. Mixtures

The product contains: water, propylene glycol, additives and preservative.

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>
30-60	57-55-6	200-338-0	-	Propylene glycol	-	
0,1-0,2	51229-78-8	426-020-3	-	cis-1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	Flam. Sol. 2;H228 Acute Tox. 3;H311 Acute Tox. 4;H302 Skin Irrit. 2;H315 Eye Irrit. 2;H319 Skin Sens. 1;H317 Repr. 2;H361d Aquatic Chronic 2;H411	

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

<u>Inhalation:</u>	Move into fresh air and keep at rest.
<u>Skin contact:</u>	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.
<u>Eye contact:</u>	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.
<u>Ingestion:</u>	Immediately rinse mouth and drink plenty of water. Keep person under observation. If person becomes uncomfortable seek hospital and bring 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: In case of fire, toxic gases may be formed.

### 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.

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## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Avoid contact with eyes. Avoid prolonged skin contact.

### 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.

### 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: Observe good laboratory/industrial hygiene practices.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: Store in tightly closed original container. 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. Avoid forming spray mists/aerosols.

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 specific recommendation made, but respiratory protection may still be required under exceptional circumstances when excessive air contamination exists.

Hand protection: Risk of contact: Nitrile gloves are recommended.

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

Appearance: Clear and colourless to slightly yellow viscous solution.

Odour: Not available.

Odour threshold: Not available.

pH: 7,0-8,5 (10% aqueous solution)

Melting point / freezing point: Not available.

Boiling point: Not available.

Flash point: Not available.

Evaporation rate: Not available.

Explosion limits: Not available.

Vapour pressure: Not available.

Vapour density: Not available.

Relative density: 1,035

Solubility: Completely soluble in water.

Partition coefficient (n-octanol/water): Not available.

Auto-ignition temperature (°C): Not available.

Decomposition temperature (°C): Not available.

Viscosity: Not available.

Oxidising properties: Not available.

### 9.2. Other information

Other data: Not available.

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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: Transport max. 14 days.  
Temperatures below: -10°C. Temperatures above: +50°C

### **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

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: 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: Aerosols irritate the respiratory system, and may cause coughing and difficulties in breathing.

Skin contact: Prolonged or repeated contact may cause irritation.

Eye contact: Direct contact may irritate.

Ingestion: No harmful effects expected in amounts likely to be ingested by accident.

Specific effects: The product contains a small amount of sensitising substance which may provoke an allergic reaction among sensitive individuals after repeated contact.

Additional information: Contains a small amount of a substance which may cause harm to the unborn child.

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## SECTION 12: ECOLOGICAL INFORMATION

### **12.1. Toxicity**

Ecotoxicity: The product contains a small amount of a substance which is toxic to aquatic organisms and which may cause long term adverse effects in the aquatic environment.

### **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. 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 from residues: EWC-code: 16 05 09

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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/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: Not relevant.

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## SECTION 15: REGULATORY INFORMATION

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

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.

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.

### 15.2. Chemical Safety Assessment

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

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## 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:

Abbreviations and acronyms used in the safety data sheet: PBT = Persistent, Bioaccumulative and Toxic.  
vPvB = very Persistent and very Bioaccumulative.

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

Wording of H-statements:

H228	Flammable solid.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H361d	Suspected of damaging the unborn child.
H411	Toxic to aquatic life with long lasting effects.

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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.  
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