

 Product name:
 Radiometer SDS M1 038
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 Supersedes date:
 2017-03-24
 Revision:
 2020-04-22

 Product No.:
 SDS-ID:
 EU-EN/4.0

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

#### 1.1. Product identifier

Product name: Radiometer SDS M1 038

Product name: ABL90 FLEX Sensor Cassette - including:

946-005 ABL90 FLEX Sensor cassette 946-008 ABL90 FLEX Sensor cassette 946-009 SC90 900 BG, LYT, MET, OXI + QC 946-010 SC90 100 BG, LYT, MET, OXI + QC 946-013 SC90 600 BG, LYT, MET, OXI + QC 946-040 ABL90 FLEX Demo Sensor cassette 946-056 SC90 900 BG, LYT, MET MOD, OXI + QC

946-059 SC90 300 BG, Lyt, Met, Hb + QC 946-060 SC90 1200 BG, LYT, MET, OXI+QC 946-061 SC90 600 BG, LYT, MET, Hb +QC 946-062 SC90 900 BG, LYT, MET, Hb +QC 946-063 SC90 100 BG, LYT, MET, Hb +QC

946-705 SC90 Ki 300 BG, LYT, MET, UREA, CREA, OXI + QC

946-712 Sensor Cassette SC300 (BEC)

944-384 Kontrolampul SC90

Container size: 2 ml

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

<u>Application:</u> Cassette containing inner liquid electrolyte.

#### 1.3. Details of the supplier of the safety data sheet

Manufacturer: Radiometer Medical ApS

Åkandevej 21

DK-2700 Brønshøj, DENMARK

Tel: +45 3827 3827 www.radiometer.com

Responsible for safety data

environment@radiometer.dk

sheet authoring:

# 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

Under the REACH regulation this product is defined as an article with no intended release of substances. The product is not covered by the EU regulations on classification and labelling of chemical substances and materials.

#### 2.2. Label elements

The product is not covered by the EU regulations on classification and labelling of chemical substances and materials.

#### 2.3. Other hazards

PBT/vPvB: Not relevant.

# **SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

#### 3.2. Mixtures

The product contains: water, salts and additives.

# **SECTION 4: FIRST AID MEASURES**

#### 4.1. Description of first aid measures

Not relevant during normal use. In case of breakage of the packaging:

Inhalation: Not relevant.

Skin contact: Wash skin with soap and water.

Eye contact: Rinse with water.

<u>Ingestion:</u> Rinse mouth and drink plenty of water.

# 4.2. 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.

# 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

<u>Protective equipment for fire-</u> Use protection equipment appropriate for surrounding materials.

fighters:

## **SECTION 6: ACCIDENTAL RELEASE MEASURES**

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

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

#### 6.2. Environmental precautions

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

precautions:

## 6.3. Methods and material for containment and cleaning up

Methods for cleaning up: Absorb spillage with suitable absorbing material. Flush away small spillages with

plenty of 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

<u>Safe handling advice:</u> No special precautions when handling undamaged units.

Damaged units: Observe good chemical hygiene practices. 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

<u>Technical measures for safe</u> No special precautions.

storage:

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.

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#### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1. Control parameters

No occupational exposure limit assigned.

#### 8.2. Exposure controls

<u>Engineering measures:</u> Provide adequate ventilation.

<u>Personal protection:</u> No special precautions when handling undamaged units.

<u>Hand protection:</u> In case of contact with spilled product: Nitrile gloves are recommended.

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

<u>Hygiene measures:</u> Wash hands after contact.

Environmental Exposure Not available.

Controls:

#### **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

## 9.1. Information on basic physical and chemical properties

<u>Appearance:</u> Cassette containing inner liquid electrolyte.

Odour: Odourless. Odour threshold: Not available. 5,35 - 5,55pH: Melting point / freezing point: Not available. **Boiling point:** Not available. Flash point: Not available. **Evaporation rate:** Not available. Not available. **Explosion limits:** Not available. Vapour pressure: Vapour density: Not available. Relative density: 1,08 (22°C)

Solubility: Completely soluble in water.

Partition coefficient (n- Not available.

octanol/water):

<u>Auto-ignition</u> Not available.

temperature (°C):

<u>Decomposition</u> Not available.

temperature (°C):

<u>Viscosity:</u> Not available. <u>Oxidising properties:</u> Not available.

9.2. Other information

Other data: Not relevant.

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#### **SECTION 10: STABILITY AND REACTIVITY**

10.1. Reactivity

Reactivity: Not reactive.

10.2. Chemical stability

Stability: Stable under the prescribed storage conditions.

10.3. Possibility of hazardous reactions

None known. Hazardous Reactions:

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 None under normal conditions.

products:

#### **SECTION 11: TOXICOLOGICAL INFORMATION**

#### 11.1. Information on toxicological effects

Not relevant during normal use. In case of breakage of the packaging:

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

sensitisation:

Respiratory or skin 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: Not relevant at normal room temperatures.

Skin contact: Prolonged or repeated contact may cause irritation.

Eye contact: Direct contact may irritate.

Ingestion: Not likely, due to the form of the product.

Specific effects: None known.

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# **SECTION 12: ECOLOGICAL INFORMATION**

12.1. Toxicity

Ecotoxicity: There are no data on the ecotoxicity of this product.

12.2. Persistence and degradability

<u>Degradability:</u> 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.

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 09 (or 18 01 03)

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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

<u>UN-No:</u>

# 14.2. UN proper shipping name

Proper Shipping Name:

# 14.3. Transport hazard class(es)

Class:

# 14.4. Packing group

<u>PG:</u> -

#### 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

<u>Transport in bulk:</u> 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, 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.

# 15.2. Chemical Safety Assessment

CSA status: Not relevant.

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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: 1, 16.

This SDS refers to the following internal drawings: MFG-009185 rev 13

<u>used in the safety data sheet:</u> PBT = Persistent, Bioaccumulative and Toxic.

vPvB = very Persistent and very Bioaccumulative.

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.