SAFETY DATA SHEET

RADIOMETER

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

1.1. Product identifier

Name: Radiometer SDS M1 043

Product name:
903-006 AQT90 FLEX Reagent pack
942-903 AQT90 FLEX TnI Test kit
942-906 AQT90 FLEX CKMB Test kit
942-909 AQT90 FLEX Myo Test kit
942-915 AQT90 FLEX D-dimer Test kit
942-918 AQT90 FLEX ßhCG Test kit
942-930 AQT90 FLEX NT-proBNP test kit
942-936 AQT90 FLEX CRP Test kit
942-940 AQT90 FLEX TnT Test kit
942-964 PCT Test Kit
942-967 AQT90 FLEX TnT (8-test) Test kit
942-970 PCT (8-test) Test kit
942-973 PCT Test kit PE
944-212 AQT90 FLEX TnI CAL Cartridgge
944-214 AQT90 FLEX Myo CAL Cartridge
944-216 AQT90 FLEX CKMB CAL Cartridge
944-220 AQT90 FLEX D-dimer CAL Cartridge
944-222 AQT90 FLEX ßhCG CAL Cartridge
944-234 AQT90 FLEX LQC D-dimer CHECK level 1 (D-dim1)
944-235 AQT90 FLEX LQC D-dimer CHECK level 2 (D-dim2)
944-236 AQT90 FLEX LQC hCG-CHECK level 1 (hCG1)
944-237 AQT90 FLEX LQC hCG-CHECK level 2 (hCG2)
944-258 AQT90 FLEX NT-proBNP CAL Cartridge
944-267 AQT90 FLEX CRP CAL Cartridge
944-268 AQT90 FLEX TnT CAL Cartridge
944-299 LQC CRP-CHECK level 1
944-300 LQC CRP-CHECK level 2
944-394 PCT CAL Cartridge
944-410 PCT-CHECK Level 1
944-411 PCT-CHECK Level 2
944-500 PCT-CHECK Level 2 PE
944-501 PCT CAL Cartridge PE
944-502 PCT-CHECK Level 1 PE
955-137 POUCH FOR ASSAY BUFFER

Container size: Various

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

Application: Chemicals for Radiometer Equipment.

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

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: Emergency telephone: 112

(Poison Control Centers may be available in specific member countries.)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

67/548/EEC / 1999/45/EC: The product is not classified.

GHS/CLP: The product is not classified.

2.2. Label elements

Based on information from the manufacturer regarding the chemical composition, the product is not liable to classification and labelling.

2.3. Other hazards

PBT/vPvB: Not relevant.

Other: Contains biological materials of human origin. Observe routine biosafety procedures in handling the product and consider all materials as potentially infectious.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

The product contains: water and salts / additives / active ingredients.

Contains biological materials of human origin.

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: Not relevant.

Skin contact: Wash skin with soap and water.

Eye contact: Rinse with water.

Ingestion: Rinse mouth and drink plenty of water.

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: Not known.

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: 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

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

Personal protection: Contains biological materials of human origin. Observe routine biosafety procedures in handling the product and consider all materials as potentially infectious.

Hand protection: In case of contact with spilled product: Wear protective gloves.

Hygiene measures: Wash hands after contact.

Environmental Exposure Controls: Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance: Liquid.

Odour: Odourless.

pH: approx. 7

Boiling point: approx. 100°C

Relative density: approx. 1

Solubility: Completely soluble in water.

9.2. Other information

Other data: Not relevant.

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: Not known.

10.6. Hazardous decomposition products

Hazardous decomposition products: None known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

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

Inhalation: Not relevant at normal room temperatures.

Skin contact: Prolonged or repeated contact may cause irritation.

Eye contact: May cause temporary eye irritation.

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

Specific effects: Contains biological materials of human origin. Observe routine biosafety procedures in handling the product and consider all materials as potentially infectious.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity: The ecotoxicity of the product is considered to be limited.

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. It is the responsibility of the waste producer to classify the waste correctly according to knowledge of patients and legislation.
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 unless proven non-infectious.

Waste from residues: EWC-code: 16 05 09 (or 18 01 03/18 01 04)

Contaminated packaging: Dispose of contaminated packings as residue.

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 73/78 and the IBC Code

Transport in bulk: Not relevant.

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, including 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.
Directives 67/548/EEC on dangerous substances and 1999/45/EC on dangerous preparations, including amendments.
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.
2001/118/EC: Commission Decision of 16 January 2001 amending Decision 2000/532/EC as regards the list of wastes.

15.2. Chemical Safety Assessment

CSA status: 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, 2, 3, 8, 11, 16.

This SDS refers to the following internal drawings:
955-137: A4-35206 rev 15

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

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.

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