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

1.1. Product identifier

Product name: Radiometer MSDS M1 039

Product name: 944-231 AQT90 FLEX LQC Multi-CHECK level 1 (MC1)

944-232 AQT90 FLEX LQC Multi-CHECK level 2 (MC2) 944-233 AQT90 FLEX LQC Multi-CHECK level 3 (MC3)

Container size: ÎÍ €Á Š

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

Application: Quality Control Solution for in vitro diagnostic use.

1.3. Details of the supplier of the safety data sheet

Supplier: Radiometer Ltd.

Manor Court

Manor Royal, Crawley

Crawly, West Sussex RH10 9FY

www.radiometer.co.uk Radiometer Medical ApS

Åkandevej 21

DK-2700 Brønshøj, DENMARK

Tel:+45 38 27 38 27 www.radiometer.com

environment@radiometer.dk

1.4. Emergency telephone number

Emergency telephone: 112

(+44 1293 517599)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

67/548/EEC: The product is not classified.

Due to the design of the product, exposure is likely to be brief and in small

quantities.

Physical and Chemical

Hazards:

Not relevant.

<u>Human health:</u> May be harmful if swallowed. Due to the small packaging the risk of ingestion is

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

infectious.

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

limited.

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.

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

The product contains: Human plasma, water, additives and active ingredients.

67/548/EEC:

<u>%:</u>	CAS-No.:	EC No.:	<u>REACH Reg.</u> <u>No:</u>	Chemical name:	Hazard classification:	Notes:
0,1-1	4432-31-9	224-632-3	-	2-Morpholinoethanesulphonic acid	Xi;R36/37/38	
1-5	57-50-1	200-334-9	-	Sucrose	-	
GHS/CLP:						
<u>%:</u>	CAS-No.:	EC No.:	REACH Reg.	Chemical name:	Hazard classification:	Notes:
			No:			
0,1-1	4432-31-9	224-632-3	No:	2-Morpholinoethanesulphonic acid	Eye Irrit. 2;H319 Skin Irrit. 2;H315 STOT SE 3;H335	

References: The Full Text for all R-Phrases and Hazard Statements are 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.

<u>Inhalation:</u> 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 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: None known.

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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: Due to the small packaging, the risk of inhaling gases formed in a fire is minimal.

5.3. Advice for firefighters

Protective measures in fire: 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

<u>Personal precautions:</u> Follow precautions for safe handling described in this safety data sheet. For

personal protection, see section 8.

6.2. Environmental precautions

Environmental Not relevant considering the small amounts used.

precautions:

6.3. Methods and material for containment and cleaning up

Methods for cleaning up: Collect in containers and seal securely.

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> 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

<u>Storage conditions:</u> Store in tightly closed original container.

Storage temperature: < -18 °C (recommended)

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

Occupational exposure limits:

CAS-No.: Chemical name: As: Exposure limits: Type: Notes: Reference

:

57-50-1 Sucrose - 10 mg/m3 TWA - EH40

- 20 mg/m3 STEL 15min

8.2. Exposure controls

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

<u>Personal protection:</u> Contains biological materials of human origin. Observe routine biosafety

procedures in handling the product and consider all materials as potentially

infectious.

Hand protection: Risk of contact: Synthetic rubber gloves.

Eye protection: Risk of contact: Wear goggles/face shield.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance: Clear, yellowish liquid.

<u>Odour:</u> Mild. <u>pH:</u> 6,0 - 6.4

Boiling point: Not available.

Relative density: Not available.

Solubility: Completely soluble in water.

9.2. Other information

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SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity: Not known.

10.2. Chemical stability

Stability: Stable.

10.3. Possibility of hazardous reactions

<u>Hazardous Reactions:</u> Not known.

10.4. Conditions to avoid

<u>Conditions/</u> Heating.

materials to avoid:

10.5. Incompatible materials

Incompatible materials: Not known.

10.6. Hazardous decomposition products

Hazardous decomposition

products:

None in particular.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. 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.

<u>Skin contact:</u> Prolonged contact may cause redness and irritation.

Eye contact: Splashes may irritate.

<u>Ingestion:</u> May be harmful if swallowed.

<u>Specific effects:</u> Contains biological materials of human origin. Observe routine biosafety

procedures in handling the product and consider all materials as potentially

infectious.

May produce an allergic reaction.

Contains: 2-Morpholinoethanesulphonic acid. This substance is listed on the

Danish EPA list of advisory classifications as: R43 - May cause sensitisation by skin contact.

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SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

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

12.2. Persistence and degradability

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

12.3. Bioaccumulative potential

Bioaccumulative Will not bio-accumulate.

potential:

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 (or18 01 03)

<u>Contaminated packaging:</u> Dispose of contaminated packings as residue.

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14. 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

- 14.2. UN proper shipping name
- 14.3. Transport hazard class(es)
- 14.4. Packing group
- 14.5. Environmental hazards
- 14.6. Special precautions for user

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

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

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

The Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 (S.I 2009 No. 716).

The Control of Substances Hazardous to Health Regulations 2002 (S.I 2002 No. 2677) with amendments.

EH40/2005, Workplace exposure limits 2005, with amendments.

The List of Wastes (England) (Amendment) Regulations 2005. (SI 2005 No. 895).

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.

Classification according to Regulation (EC) No. 1272/2008:

Not classified.

Additional information:

Wording of R-phrases/H-

statements:

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

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

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.