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Product No.:	See Section 16	SDS-ID:	EU-EN/3.1

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

1.1. Product identifier

Name: Radiometer SDS M1 044
Product name: Product specification see section 16.

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

Application: Radiometer Samplers.

1.3. Details of the supplier of the safety data sheet

Manufacturer Radiometer Medical ApS
Åkandevvej 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

The product is not classified.

Physical and Chemical Hazards: Not relevant.

Human health: Not relevant.

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: Filter paper with heparin 60 - 80 IU and salts.
After sterilization the residuals of ethylene oxide in SafePICO samplers are below 2,000 µg/device.

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.
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: None 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: Use protection equipment appropriate for surrounding materials.

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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: Not relevant considering the small amounts used.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up: Collect in marked containers and deliver to approved depot.

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: 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

Technical measures for safe storage: No special precautions.

Storage conditions: Store in a dark place. 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

Personal protection: No special precautions when handling undamaged units.

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

Hygiene measures: Wash hands after handling.

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: White.
Odour: not relevant
Relative density: not available
Solubility: not relevant
Decomposition temperature: not relevant

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 under normal conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

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

Inhalation: Not relevant.
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: The product is not expected to be hazardous to the environment.

12.2. Persistence and degradability

Degradability: There are no data on the degradability of this product.

12.3. Bioaccumulative potential

Bioaccumulative potential: No data available on bioaccumulation.

12.4. Mobility in soil

Mobility: Not relevant, due to the form of the product.

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: 18 01 01

Contaminated packaging: EWC-code: 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

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.

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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, 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.

Directives 67/548/EEC on dangerous substances and 1999/45/EC on dangerous preparations, including 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.

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: 6, 16.

This SDS refers to the following internal drawings:

Internal drawing 941-838: A4-28104 rev. 7

Internal drawing 941-839: A4-28651 rev. 6

Standard Operating Procedure #3005 from Celsus regarding Heparin Sodium - Specifications (10/14/09)

Standard Operating Procedure #3007 from Celsus regarding Heparin Sodium Solution (PU) (10/14/09)

Standard Operating Procedure #3075 from Celsus regarding Heparin Lithium - Specifications (06/01/08)

Radiometer SafePICO Certificate (BKH/20-09-2010)

Product specification:

956-518 PICO70 w/o needle 0.3-1.5mL

956-519* PICO70 w/o needle 0.3-1.5mL

956-522 PICO70 22G × 25 mm 0.3-1.5mL

956-525 PICO70 22G × 32 mm 0.3-1.5mL

956-529 PICO70 23G × 16 mm 0.3-1.5mL

956-533 PICO70 23G × 25 mm 0.3-1.5mL

956-534 PICO70 23G × 32 mm 0.3-1.5mL

956-546* PICO70 23G × 16 mm 0.3-1.5mL

956-547 PICO70 25G × 16 mm 0.3-1.5mL

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956-563* PICO70 22G × 25 mm 0.3-1.5mL
956-608* safePICO70 + (nsd) 22G × 32 mm 0.3-1.5mL
956-609* safePICO70 + (nsd) 23G × 16 mm 0.3-1.5mL
956-624* safePICO70 + (nsd) 23G × 25 mm 0.3-1.5mL
956-634* safePICO70 + (nsd) 23G × 32 mm 0.3-1.5mL
956-610* safePICO w/o needle 0.7-1.5mL
956-611 safePICO Self-fill with TsafeTTIPCAP w/o (nsd) 22G x 32 mm, 0.7-1.5 mL (100 units)
956-612 safePICO 23G × 16 mm 0.7-1.5mL
956-613 safePICO 22G × 25 mm 0.7-1.5mL
956-636 safePICO 23G × 25 mm 0.7-1.5mL
956-637 safePICO 23G × 32 mm 0.7-1.5mL
956-614* safePICO + (nsd) 22G × 32 mm 0.7-1.5mL
956-615* safePICO + (nsd) 23G × 16 mm 0.7-1.5mL
956-616* safePICO + (nsd) 23G × 25 mm 0.7-1.5mL
956-620* safePICO + (nsd) 22G × 25 mm 0.7-1.5mL
956-623 safePICO + (nsd) 25G x 16mm 0.7-1.5mL
956-635* safePICO + (nsd) 23G × 32 mm 0.7-1.5mL
956-552 PICO50 0.5-2 mL
956-622 safePICO aspirator 0.7-1.7mL

* No needle cube

(nsd) = needle shield device

905-661 CLINITUBES D956G-70-35X1
905-663 CLINITUBES D956G-70-100X1
905-664 CLINITUBES D956G-70-125X1
905-666 CLINITUBES D956G-70-210X1942-878 CLINITUBES D957G-70-100x5 with balanced heparin, 100 µL
942-880 CLINITUBES D957G-70-125x5 with balanced heparin, 125 µL
942-882 CLINITUBES D941G-80-140X5
942-884 CLINITUBES D957G-70-210X5
942-885 CLINITUBES D941G-240-55X5 with sodium heparin, 55 µL
942-889 SAFE CLINIT. D941P-NA-240-55X3
942-890 SAFE CLINIT. D941P-240-85X1
942-891 SAFE CLINIT. D941P-NA-240-85X3
942-892 CLINITUBES D957P-70-100x1 with balanced heparin, 100 µL
942-893 CLINITUBES D957P-70-125x1 with balanced heparin, 125 µL
942-894 SAFE CLINIT. VIAL D941P-240-55
942-895 SAFE CLINIT. VIAL D941P-240-85
942-896 SAFE CLINIT. VIAL D957P-70-100
942-897 SAFE CLINIT. VIAL D957P-70-125
942-898 CLINITUBES D957P-70-70x1 with balanced heparin, 70 µL
942-899 SAFE CLINITU. VIAL D957P-70-70
942-869 CLINITUBES D957G-70-35X5
942-873 CLINITUBES D941G-NA-240-55X10
942-875 CLINITUBES D941G-240-85X5
942-876 CLINITUBES D941G-NA-240-85X10
942-878 CLINITUBES D957G-70-100X5
942-880 CLINITUBES D957G-70-125X5
942-882 CLINITUBES D941G-80-140X5
942-884 CLINITUBES D957G-70-210X5

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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, Artensvej 5, DK-2970 Hørsholm, Denmark.
www.dhigroup.com.
