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

1.1. Product identifier

Product name: Radiometer SDS M3 037

<u>Product name:</u> ABL900 Solution Pack -including:

944-327 ABL900 Solution Pack XL

944-328 ABL900 Solution Pack XL Rilibäk 944-329 ABL900 Solution Pack Rilibäk

944-391 ABL900 Solution Pack

ABL90 FLEX Solution Pack -including: 944-157 ABL90 FLEX Solution pack 944-197 Solution Pack SP90 (RDEU)

944-326 HELIO Cal2

944-369 ABL90 FLEX Solution Pack SP90 Ki

944-370 ABL90 FLEX Solution Pack SP90 Ki (RDEU)

944-457 SOLUTION PACK High Volume

944-497 SOLUTION PACK High Volume RDEU

944-550 Solution Pack for BC

<u>Container size:</u> Cassette containing bags.

Bag 1: Gas.: 150 ml (760 mmHg / 25°C)

Bags 2-7: Liquid.: 2 x 200 ml, 4 x 100 ml

Bags 2-7: Liquid.: 1 x 270 ml, 1 x 280 ml, 4 x 100 ml

Bag 8-9: Waste container

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

<u>Application:</u> Chemicals for Radiometer Equipment.

1.3. Details of the supplier of the safety data sheet

Supplier: Radiometer Ltd.

Manor Court

Manor Royal, Crawley

Crawly, West Sussex RH10 9FY

Tel: +44 (0) 1293 517599 www.radiometer.co.uk

Manufacturer: Radiometer Medical ApS

Åkandevej 21 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: NHS: 111

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SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

CLP: Bag 1: The product is classified: Ox. Gas 1;H270

Bags 2-7: The product is classified: Skin Sens. 1A;H317

References: The full text for all hazard statements is displayed in section 16.

2.2. Label elements

Bag 1:



Signal word Danger

H270 May cause or intensify fire; oxidiser.

P220 Keep away from clothing and other combustible materials.

Bags 2-7:



Signal word Warning

Contains: 2-Methyl-2H-isothiazol-3-one

H317 May cause an allergic skin reaction.

P280 Wear protective gloves, eye and face protection.

P302 + P352 IF ON SKIN: Wash with plenty of water.

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

2.3. Other hazards

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

Other: Bag 1: In high concentrations: May be harmful if inhaled.

Bags 2-7: Causes mild skin irritation. The product contains a small amount of a

substance which is very toxic to aquatic organisms.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

Bag 1: The product contains: Gas.

Bags 2-7: The product contains: water, salts, additives and preservative.

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Bag 1:

CLP:

<u>%:</u>	CAS-No.:	EC No.:	REACH Reg. No:	Chemical name:	Hazard classification:	Notes:
50-55	7727-37-9	231-783-9	-	Nitrogen	Press. Gas, Compressed;H280	
40-45	7782-44-7	231-956-9	-	Oxygen	Ox. Gas 1;H270 Press. Gas	U
3-7	124-38-9	204-696-9	-	Carbon dioxide	Press. Gas, Compressed;H280	#

Bags 2-7:

CLP:

<u>%:</u>	CAS-No.:	EC No.:	REACH Reg. No:	Chemical name:	Hazard classification:	Notes:
0,5 - < 10	1132-61-2	214-478-5	-	4-Morpholinopropane- sulphonic acid	Skin Irrit. 2;H315 Eye Irrit. 2;H319 STOT SE 3;H335	
0,0015 - < 0,025	2682-20-4	220-239-6	-	2-Methyl-2H-isothiazol-3-one	Acute Tox. 2;H330 Acute Tox. 3;H311 Acute Tox. 3;H301 Skin Corr. 1B;H314 Eye Dam. 1;H318 Skin Sens. 1A;H317 Aquatic Acute 1;H400 Aquatic Chronic 1;H410 EUH071	

Notes: #: The substance has been assigned an exposure limit.

References: The full text for all hazard statements is displayed in section 16.

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SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

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

<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 at least 15 minutes. Remove any

contact lenses and open eyelids widely. If irritation persists: Seek medical

attention and bring along these instructions.

Immediately rinse mouth and drink 1-2 glasses of water. Keep person under

observation. If uncomfortable: Transportation to hospital. Bring along these

instructions.

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.

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: Bag 1: May cause or intensify fire; oxidiser. Considering the size of the

packaging, the risk is regarded as minimal.

5.3. Advice for firefighters

Protective equipment for fire- Selection of respiratory protection for fire fighting: follow the general fire

<u>fighters:</u> 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.

In case of breakage of the packaging: 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: 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.

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SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

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

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

Damaged units: 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:

<u>Storage conditions:</u> 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

Bag 1:

Occupational exposure limits:

CAS-No.: Chemical name: Exposure limits: Type: Notes: References: 124-38-9 **TWA** Carbon dioxide 5000 ppm 9150 mg/m3 EH40 STEL 15000 ppm 27400 mg/m3 15min

Notes: EH40: EH40/2005.

8.2. Exposure controls

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

Bag 1: Observe occupational exposure limits and minimise the risk of

inhalation.

NOTE: Due to the small packaging the risk of inhalation is minimal.

<u>Personal protection:</u> Contact with the product is not likely when used according to directions.

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 special precautions. Due to the small packaging the risk of inhalation is

minimal.

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

are recommended. Thickness: ≥ 0,12 mm. Breakthrough time: > 480 min.

Other types of gloves can be recommended by the glove supplier.

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

<u>Hygiene measures:</u> 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

<u>Physical state:</u> Bag 1: Cassette containing bags.

(Gas.)

Bags 2-7: Cassette containing bags.

(Liquid.)

Odour: Bag 1: Pungent.

Bags 2-7: Odourless.

pH: Bag 1: Not available.

Bags 2-7: 6,8-7,5

Boiling point: Bag 1: Not available.

Bags 2-7: approx. 100°C

Flash point: Not available.

Explosive limits Not available.

Vapour pressure: Not available.

Vapour density: Not available.

Relative density: Not available.

Solubility: Bag 1: Slightly soluble in water.

Bags 2-7: Completely soluble in water.

Explosive properties: Not available.

9.2. Other information

Other data: Not relevant.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity: Not known.

10.2. Chemical 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: Bag 1: Keep away from heat, sparks and open flame.

10.5. Incompatible materials

Incompatible materials: None known.

10.6. Hazardous decomposition products

<u>Hazardous decomposition</u> None in particular.

products:

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SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute Toxicity (Oral): Bag 1: Based on available data, the classification criteria are not met.

Bags 2-7: Based on available data, the classification criteria are not met.

Acute Toxicity (Dermal): Bag 1: Based on available data, the classification criteria are not met.

Bags 2-7: Based on available data, the classification criteria are not met.

Bag 1: Based on available data, the classification criteria are not met. Acute Toxicity (Inhalation):

Bags 2-7: Based on available data, the classification criteria are not met.

Skin Corrosion/Irritation: Bag 1: Based on available data, the classification criteria are not met.

Bags 2-7: Based on available data, the classification criteria are not met.

Serious eye damage/irritation: Bag 1: Based on available data, the classification criteria are not met.

Bags 2-7: Based on available data, the classification criteria are not met.

Bag 1: Based on available data, the classification criteria are not met. Respiratory or skin

sensitisation:

Bags 2-7: May cause an allergic skin reaction.

Bag 1: Based on available data, the classification criteria are not met. Germ cell mutagenicity:

Bags 2-7: Based on available data, the classification criteria are not met.

Carcinogenicity: Bag 1: Based on available data, the classification criteria are not met.

Bags 2-7: Based on available data, the classification criteria are not met.

Reproductive Toxicity: Bag 1: Based on available data, the classification criteria are not met.

Bags 2-7: Based on available data, the classification criteria are not met.

Bag 1: Based on available data, the classification criteria are not met. STOT - Single exposure:

Bags 2-7: Based on available data, the classification criteria are not met.

STOT - Repeated exposure: Bag 1: Based on available data, the classification criteria are not met.

Bags 2-7: Based on available data, the classification criteria are not met.

Aspiration hazard: Bag 1: Based on available data, the classification criteria are not met.

Bags 2-7: Based on available data, the classification criteria are not met.

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

> Bag 1: In high concentrations: May be harmful if inhaled. Bags 2-7: Aerosols may irritate the respiratory system.

Skin contact: Bag 1: -

Bags 2-7: Not relevant during normal use. In case of breakage of the packaging:

Liquid may irritate the skin. Risk of sensitisation or allergic reactions among

sensitive individuals.

Eye contact: Bag 1: -

Bags 2-7: Not relevant during normal use. In case of breakage of the packaging:

Direct contact may irritate.

Bag 1: -Ingestion:

Bags 2-7: Not relevant during normal use. In case of breakage of the packaging:

May irritate and cause malaise.

11.2. Information on other hazards

Endocrine disrupting The product does not contain any substance identified as having endocrine

properties: disrupting properties.

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SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity: Bags 2-7: The product contains a small amount of a substance which is very toxic

to aquatic organisms.

2-Methyl-2H-isothiazol-3-one:

M-factor (acute): 10 M-factor (chronic): 1

12.2. Persistence and degradability

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

12.3. Bioaccumulative potential

Bioaccumulative potential: No data available on bioaccumulation.

12.4. Mobility in soil

Mobility: No data available.

12.5. Results of PBT and vPvB assessment

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

12.6. Endocrine disrupting properties

Endocrine disrupting

The product does not contain any substance identified as having endocrine

<u>properties:</u> disrupting properties.

12.7. 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.

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

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

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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/AND/RID).

14.1. UN number

<u>UN-No:</u>

14.2. UN proper shipping name

Proper Shipping Name:

14.3. Transport hazard class(es)

<u>Class:</u> -

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> This product is not intended for transport in bulk.

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SECTION 15: REGULATORY INFORMATION

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

Special provisions: Bags 2-7: As a general rule, persons under 18 years of age are not allowed to

work with this product. Users must be carefully instructed in the proper work procedure, the dangerous properties of the product and the necessary safety

instructions.

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.

The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019 No.

720), as amended.

The Control of Substances Hazardous to Health Regulations 2002 (S.I 2002 No.

2677) with amendments.

European Union (Withdrawal) Act 2018, as amended.

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

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

The Management of Health and Safety at Work Regulations 1999 (SI 1999 No.

3242), with amendments.

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

15.2. Chemical Safety Assessment

<u>CSA status:</u> No chemical safety assessment has been carried out.

SECTION 16: OTHER INFORMATION

The user must be instructed in the proper work procedure and be familiar with the contents of these instructions.

For restrictions on use see section 15.

The following sections contain revisions or new statements: 1.

This SDS refers to the following internal drawings:

Bag 1 (Gas.):

Gas: MFG-008874 rev 4

Bags 2-7 (Liquid.):

Cal1: MFG-008869 rev 3

Cal2: MFG-008875 rev 3 Cal3: MFG-008876 rev 4

QC1: MFG-008871 rev 6 QC2: MFG-008872 rev 6

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QC3: MFG-008873 rev 7 944-326: MFG-012418 rev 3

used in the safety data sheet: M(ac) = M-factor acute toxicity.

M(chr) = M-factor chronic toxicity.

PBT = Persistent, Bioaccumulative and Toxic.

SCL = Specific Concentration Limit. STOT = Specific Target Organ Toxicity.

vPvB = very Persistent and very Bioaccumulative.

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

> Health Hazards: Calculation method. Physical Hazards: Expert judgement.

Wording of H-statements:

EUH071 Corrosive to the respiratory tract.

H270 May cause or intensify fire; oxidiser.

H280 Contains gas under pressure; may explode if heated.

H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage. H319 Causes serious eye irritation.

H330 Fatal if inhaled.

H335 May cause respiratory irritation.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

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.