



Safety Data Sheet

According to Regulation (EC) No 1907/2006

Version 05

Revision: 24.09.2018

Useable for:

DER8300 Nephtrines Plasma RIA

Single components with dangerous ingredients:

REF: BA R-0120	<u>^{125}I – Adrenaline - Metanephrine</u>	^{125}I -ADR
REF: BA R-0220	<u>^{125}I – Noradrenaline - Normetanephrine</u>	^{125}I -NAD
REF: BA R-8312	<u>Acylation Concentrate</u>	ACYL-CONC

Not listed single components contain no hazardous substances in concentrations to be declared, a labelling is not required.

1 Identification of the substance / mixture and of the company / undertaking

1.1 Product identifier

Trade name:

¹²⁵I – Adrenaline - Metanephrine

¹²⁵I – Noradrenaline - Normetanephrine

Article number:

BA R-0120

BA R-0220

¹²⁵I-ADR

¹²⁵I-NAD

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

Identified uses:

laboratory reagent / Immunoassay

The product is intended for professional use.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Demeditec Diagnostics GmbH

Lise-Meitner-Str. 2

24145 Kiel, Germany

Phone +49 431 71922 0

Fax +49 431 71922 55

E-mail info@demeditec.de

1.4 Emergency telephone number

+49 431 71922 0

2 Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Not applicable.

According to EC directives or corresponding national laws, the product does not need to be classified or labelled.

2.2 Label elements



REGULATION (EC) No 1272/2008

Hazard pictograms: void

Signal word: void

Hazard statements: void

Precautionary statements: void

2.3 Other hazards

Information concerning particular hazards for human and environment:

Radioactive

material.

No special remarkable hazards. Please observe the information given in this safety data sheet.

3 Composition / information on ingredients

3.1 Substances

Not applicable.

3.2 Mixtures

Hazardous components

¹²⁵Iodine Radionuclide, Activity: < 200 kBq

Additional information:

For the wording of the listed risk phrases refer to section 16.

4 First aid measures

4.1 First aid measures

After inhalation: Call a doctor immediately.

After skin contact: wash off with plenty of water. Remove contaminated clothing.

After eye contact: rinse out with plenty of water with the eyelid held wide open.

Call a doctor if necessary.

After swallowing: Do not induce vomiting; call for medical help immediately.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2 Special hazards arising from the substance or mixture

No further relevant information available.

5.3 Advice for firefighters

Special protective equipment for firefighters

No special equipment required.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective clothing.

6.2 Environmental precautions

No special actions required.

6.3 Methods and materials for containment and cleaning up

6.4 Reference to other sections

Indications about possible material restrictions, see section 7, personal protection, see section 8 and about waste treatment see section 13.

7 Handling and storage

7.1 Precautions for safe handling

Advice on safe handling:

Observe label precautions.

Hygiene measures:

Change contaminated clothing. Wash hands after working with substance.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions:

Store in separated, identified rooms.

7.3 Specific end use(s)

No further relevant information available.

8 Exposure controls / personal protection

8.1 Control parameters

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2 Exposure controls

Engineering measures:

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

See section 7.1.

Individual protection measures:

General protective and hygienic measures:

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Store protective clothing separately. Avoid contact with the eyes and skin.

Respiratory protection:

Not necessary.

Protection of hands:

Protective gloves.

Material of gloves:

Chemical protection gloves are to be selected according to the concentration and quantity of the hazardous substance concentration and quantity in workplace.

The glove material has to be impermeable and resistant to the product / the substance / the preparation.

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374.

Eye protection:

Tightly sealed goggles

Body protection:

lab coat



9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form	liquid
Colour	red
Odour	odourless
Odour Threshold	Not applicable
pH	7.5 at 20 °C
Melting point	No information available
Boiling point/boiling range	No information available
Flash point	No information available
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Lower explosion limit	No information available
Upper explosion limit	No information available
Vapour pressure	No information available
Relative vapour density	No information available
Density	Not determined
Relative density	No information available
Water solubility	Fully miscible
Partition coefficient: n-octanol/water	No information available
Auto-ignition temperature	No information available
Decomposition temperature	No information available
Viscosity, dynamic	No information available
Explosive properties	Not classified as explosive
Oxidizing properties	None

9.2 Other data

No other data available.

10 Stability and reactivity

10.1 Reactivity

See section 10.3.

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature).

10.3 Possibility of hazardous reactions

No dangerous reactions known.

10.4 Conditions to avoid

No further relevant information available.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous decomposition products

No dangerous decomposition products known.

11 Toxicological information

11.1 Information on toxicological effects

Acute toxicity

No information available.

Skin corrosion/irritation

No information available.

Serious eye damage/irritation

No information available.

Respiratory or skin sensitisation

No sensitizing effects known.

Germ cell mutagenicity

No information available.

Carcinogenicity

No information available.

Reproductive toxicity

No information available.

STOT-single exposure

No information available.

STOT-repeated exposure

No information available.

Aspiration hazard

No information available.

11.2 Additional information

On the basis of the morphology of the product, no hazardous properties are to be expected when it is handled and used with appropriate care. Handle in accordance with good industrial hygiene and safety practice.

12 Ecological information

12.1 Toxicity

No further relevant information available.

12.2 Persistence and degradability

No further relevant information available.

12.3 Bioaccumulative potential

No further relevant information available.

12.4 Mobility in soil

No further relevant information available.

12.5 Results of PBT and vPvB assessment

Substance(s) in the mixture do(es) not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII, or a PBT/vPvB assessment was not conducted.

12.6 Other adverse effects

No further relevant information available.

13 Disposal considerations

13.1 Waste treatment methods

Dispose of packaging according to applicable local, state, and federal regulations. Packaging's that may not be cleansed are to be disposed of in the same manner as the product.

14 Transport information

This product is part of a kit. Information in this section refers to the kit as a whole.

14.1 UN No.

No dangerous good in sense of this transport regulation.

14.2 UN Proper shipping name

No dangerous good in sense of this transport regulation.

14.3 Class

No dangerous good in sense of this transport regulation.

14.4 Packing group

No dangerous good in sense of this transport regulation.

14.5 Environmental hazards

No.

14.6 Special precautions for user

No.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not relevant.

15 Regulatory information

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

GHS label elements: void

Hazard pictograms: void

Signal word: void

Hazard statements: void

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Radioactive material

Department issuing SDS:

Safety Representative

Contact:

Demeditec Diagnostics GmbH

1 Identification of the substance / mixture and of the company / undertaking

1.1 Product identifier

Trade name: **Acylation Concentrate** ACYL-CONC

Article number: **BA R-8312**

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

Identified uses:

laboratory reagent / Immunoassay
The product is intended for professional use.

1.3 Details of the supplier of the safety data sheet

Manufacturer / Supplier:

Demeditec Diagnostics GmbH
Lise-Meitner-Str. 2
24145 Kiel, Germany
Phone +49 431 71922 0
Fax +49 431 71922 55
E-mail info@demeditec.de

1.4 Emergency telephone number

+49 431 71922 0

2 Hazards identification

2.1 Classification of the substance or mixture

REGULATION (EC) No 1272/2008

Acute toxicity, Category 4, Oral, H302
Skin corrosive, Category 1B, H314
Respiratory sensitisation, Category 1, H334
Skin sensitisation, Category 1, H317
Specific target organ toxicity – single exposure, Category 3, Respiratory system, H335

2.2 Label elements

REGULATION (EC) No 1272/2008

Hazard pictograms:



Signal word:

Danger

Hazard statements:

H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.

Precautionary statements:

P280	Wear protective gloves/ protective clothing.
P301 + P330 + P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P302 + P352	IF ON SKIN: Wash with plenty of water and soap.
P304 + P340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P310	IF exposed or concerned: immediately call a POISON CENTER or doctor / physician.

2.3 Other hazards

None known.

3 Composition / information on ingredients

3.1 Substances

Not applicable.

3.2 Mixtures

Composition / information on ingredients

CAS: 108-30-5 Succinic anhydride ≥ 20 % - < 30 %

H302; H314; H334; H317; H335

Additional information

For the full text of the H-Statements mentioned in this section, see section 16.

4 First aid measures

4.1 First aid measures

After inhalation: fresh air, consult doctor in case of complaints.

After skin contact: wash off with plenty of water. Remove contaminated clothing.

After eye contact: rinse out with plenty of water with the eyelid held wide open. Call in ophthalmologist if necessary.

After swallowing: drink water (two glasses at most), avoid vomiting. Consult doctor if feeling unwell.

4.2 Most important symptoms and effects, both acute and delayed

Gastrointestinal disturbance, nausea, impairment of vision irritation and corrosion, allergic reactions, cough, shortness of breath.

4.3 Indication of any immediate medical attention and special treatment needed

No information available.

5 Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Water, Foam, Carbon dioxide (CO₂), Dry powder

Unsuitable extinguishing media:

For this substance / mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture

Combustible.

Vapors are heavier than air and may spread along floors. Development of hazardous combustion gases or vapors possible in the event of fire.

5.3 Advice for firefighters

Special protective equipment for firefighters:

In the event of fire, wear self-contained breathing apparatus.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Do not breathe vapours, aerosols. Evacuate the danger area, observe emergency procedures, consult an expert.

Advice for emergency responders: Protective equipment see section 8.

6.2 Environmental precautions

Do not empty into drains.

6.3 Methods and materials for containment and cleaning up

Observe possible material restrictions! Take up with liquid-absorbent and neutralising material. Dispose of properly. Clean up affected area.

6.4 Reference to other sections

Indications about possible material restrictions see sections 7 and 10 and about waste treatment see section 13.

7 Handling and storage

7.1 Precautions for safe handling

Advice on safe handling:

Observe label precautions.

Hygiene measures:

Change contaminated clothing. Wash hands after working with substance.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions:

Tightly closed and dry.

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

8 Exposure controls / personal protection

8.1 Control parameters

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2 Exposure controls

Engineering measures:

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

See section 7.1.

Individual protection measures:

General protective and hygienic measures:

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Store protective clothing separately. Avoid contact with the eyes and skin.

Respiratory protection:

In case of good room ventilation, not necessary.

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Protection of hands:

Protective gloves.

Material of gloves:

Chemical protection gloves are to be selected according to the concentration and quantity of the hazardous substance concentration and quantity in workplace.

The glove material has to be impermeable and resistant to the product / the substance / the preparation.

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374.

Eye protection:

Tightly sealed goggles



Body protection:

lab coat

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form	liquid
Colour	No information available
Odour	stinging
Odour Threshold	Not applicable
pH	No information available
Melting point	No information available
Boiling point/boiling range	No information available
Flash point	No information available
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Lower explosion limit	No information available
Upper explosion limit	No information available
Vapour pressure	No information available
Relative vapour density	No information available
Density	No information available
Relative density	No information available
Water solubility	at 20 °C soluble
Partition coefficient: n-octanol/water	No information available
Auto-ignition temperature	No information available
Decomposition temperature	No information available
Viscosity, dynamic	No information available
Explosive properties	Not classified as explosive
Oxidizing properties	none

9.2 Other data

No other data available.

10 Stability and reactivity

10.1 Reactivity

Forms explosive mixtures with air on intense heating.

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature).

10.3 Possibility of hazardous reactions

Violent reactions possible with: bases, peroxide compounds, amines, alcohols, strong oxidizing agents, acids.

10.4 Conditions to avoid

Strong heating.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous decomposition products

No dangerous decomposition products known.

11 Toxicological information

11.1 Information on toxicological effects

Acute toxicity

LD50 oral rat 1.795 mg/kg

LD50 dermal rat >2.000 mg/kg

Skin corrosion/irritation

corrosive

Serious eye damage/irritation

Causes serious eye damage. Risk of blindness!

Respiratory or skin sensitisation

May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Germ cell mutagenicity

No information available.

Carcinogenicity

No information available.

Reproductive toxicity

No information available.

STOT-single exposure

May cause respiratory irritation.

STOT-repeated exposure

No information available.

Aspiration hazard

No information available.

11.2 Additional information

After absorption: gastrointestinal disturbance, nausea, impairment of vision.

On the basis of the morphology of the product, no hazardous properties are to be expected when it is handled and used with appropriate care.

Handle in accordance with good industrial hygiene and safety practice.

12 Ecological information

12.1 Toxicity

LC50 Danio rerio (zebra fish): > 100 mg/l; 96 h

EC50 Daphnia magna (Water flea): > 100 mg/l; 48 h

ErC50 Pseudokirchnerella subcapitata (green algae): > 100 mg/l; 72 h

EC50 activated sludge: > 300 mg/l; 3 h

12.2 Persistence and degradability

Easily biodegradable.

12.3 Bioaccumulative potential

No further relevant information available.

12.4 Mobility in soil

No further relevant information available.

12.5 Results of PBT and vPvB assessment

Substance(s) in the mixture do(es) not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII, or a PBT/vPvB assessment was not conducted.

12.6 Other adverse effects

No further relevant information available.

13 Disposal considerations

13.1 Waste treatment methods

Dispose of packaging according to applicable local, state, and federal regulations.
Packaging's that may not be cleansed are to be disposed of in the same manner as the product.

14 Transport information

This product is part of a kit. Information in this section refers to the kit as a whole.

14.1 UN No.

No dangerous good in sense of this transport regulation.

14.2 UN Proper shipping name

No dangerous good in sense of this transport regulation.

14.3 Class

No dangerous good in sense of this transport regulation.

14.4 Packing group

No dangerous good in sense of this transport regulation.

14.5 Environmental hazards

No.

14.6 Special precautions for user

No.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not relevant.

15 Regulatory information

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

EU regulations

Major Accident Hazard: SEVESO III

Not applicable

Employment restrictions:

Observe employment restrictions in accordance with the youth employment protection regulations (94/33/EC).

Substances of very high concern (SVHC):

This product does not contain substances of very high concern according to Regulation (EC) No 1907/2006 (REACH).

National legislation

Water hazard class:

WGK 1 (slightly water hazardous)

Storage class:

8B

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Relevant phrases:

- | | |
|------|--|
| H302 | Harmful if swallowed. |
| H314 | Causes severe skin burns and eye damage. |
| H317 | May cause an allergic skin reaction. |
| H334 | May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| H335 | May cause respiratory irritation. |

Department issuing SDS:

Safety Representative

Contact:

Demeditec Diagnostics GmbH