

Kit components

Product code	Description
3311-0010	GSP Neonatal Creatine Kinase-MM kit 3311-0010, 3311-001U

Components:

13808302	Anti-CK-MM Eu-tracer
13808303	CK-MM Assay Buffer

Safety Data Sheet according to WHS Regulations

Printing date 22.02.2024

Version number 3

Revision: 08.11.2023

1 Identification

- **Product identifier**
- **Trade name:** Anti-CK-MM Eu-tracer
- **Article number:** 13808302
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Product category** PC21 Laboratory chemicals
- **Application of the substance / the mixture**
In vitro diagnostics
Laboratory chemicals
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Revvity Inc.
Wallac Oy
P.O. Box 10
FI-20101 Turku
Finland
+358 2 2678 111
- **Further information obtainable from:**
Product safety department.
MSDS_Turku@revvity.com
- **Emergency telephone number:**
CHEMTREC (whithin U.S.) 800 424-9300
CHEMTREC (from outside U.S.) +1-703-572-3887
- **Information on domestic manufacturers**
Sponsor in Australia:
Revvity Pty. Ltd.
Building C Tenancy A, Level 2
211 Wellington Road
Mulgrave VIC 3170

1800 033 391

2 Hazard(s) Identification

- **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonised System (GHS).

- **Label elements**
- **GHS label elements** The product is labelled according to the IVD regulation
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

AU

(Contd. on page 2)

Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 3

Revision: 08.11.2023


Trade name: *Anti-CK-MM Eu-tracer*

(Contd. of page 1)

3 Composition and Information on Ingredients

- **Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.
- **Dangerous components:** Void

- **Other ingredients**

7732-18-5	water	95-100%
7647-14-5	sodium chloride	<1%
77-86-1	trometamol	<1%
90604-29-8	Albumins, blood plasma, Cohn fraction V	<0.25%
26628-22-8	sodium azide	≥0.025-<0.1%
	 Acute Tox. 1, H300; Acute Tox. 1, H310	

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire Fighting Measures

- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Protective equipment:** No special measures required.

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Dilute with plenty of water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and Storage

- **Handling:**
- **Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.

(Contd. on page 3)

Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 3

Revision: 08.11.2023

Trade name: *Anti-CK-MM Eu-tracer*

(Contd. of page 2)

· **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see section 7.
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Goggles recommended during refilling

9 Physical and Chemical Properties

- **General Information**
- **Appearance:**
- **Form:** Fluid
- **Colour:** Colourless
- **Odour:** Odourless
- **Odour threshold:** Not determined.
- **pH-value at 20 °C:** 7.75
- **Change in condition**
- **Melting point/freezing point:** 0 °C
- **Initial boiling point and boiling range:** 100 °C
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not applicable.
- **Decomposition temperature:** Not determined.
- **Ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Explosion limits:**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Vapour pressure at 20 °C:** 23 hPa
- **Density at 20 °C:** 1.01 g/cm³
- **Relative density** Not determined.
- **Vapour density** Not determined.
- **Evaporation rate** Not determined.
- **Solubility in / Miscibility with**
- **water:** Fully miscible.

(Contd. on page 4)

Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 3

Revision: 08.11.2023

Trade name: *Anti-CK-MM Eu-tracer*

(Contd. of page 3)

- **Partition coefficient: n-octanol/water:** *Not determined.*
- **Viscosity:**
- **Dynamic at 20 °C:** *0.952 mPas*
- **Kinematic:** *Not determined.*
- **Solvent content:**
- **Water:** *98.0 %*
- **Solids content:** *0.9 %*
- **Other information** *No further relevant information available.*

10 Stability and Reactivity

- **Reactivity** *No further relevant information available.*
- **Thermal decomposition / conditions to be avoided:** *No decomposition if used according to specifications.*
- **Possibility of hazardous reactions** *No dangerous reactions known.*
- **Conditions to avoid** *No further relevant information available.*
- **Incompatible materials:** *No further relevant information available.*
- **Hazardous decomposition products:** *No dangerous decomposition products known.*

11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity** *Based on available data, the classification criteria are not met.*
- **Skin corrosion/irritation** *Based on available data, the classification criteria are not met.*
- **Serious eye damage/irritation** *Based on available data, the classification criteria are not met.*
- **Respiratory or skin sensitisation** *Based on available data, the classification criteria are not met.*
- **Germ cell mutagenicity** *Based on available data, the classification criteria are not met.*
- **Carcinogenicity** *Based on available data, the classification criteria are not met.*
- **Reproductive toxicity** *Based on available data, the classification criteria are not met.*
- **STOT-single exposure** *Based on available data, the classification criteria are not met.*
- **STOT-repeated exposure** *Based on available data, the classification criteria are not met.*
- **Aspiration hazard** *Based on available data, the classification criteria are not met.*

12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** *No further relevant information available.*
- **Persistence and degradability** *No further relevant information available.*
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** *No further relevant information available.*
- **Mobility in soil** *No further relevant information available.*
- **Additional ecological information:**
- **General notes:** *Not hazardous for water.*
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*
- **Other adverse effects** *No further relevant information available.*

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation** *Smaller quantities can be disposed of with household waste.*

(Contd. on page 5)

AU

Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 3

Revision: 08.11.2023

Trade name: *Anti-CK-MM Eu-tracer*

(Contd. of page 4)

- **Uncleaned packaging:**
- **Recommendation:** Hand over to hazardous waste disposers.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

· UN-Number · ADG, IMDG, IATA	Void
· UN proper shipping name · ADG, IMDG, IATA	Void
· Transport hazard class(es) · ADG, ADN, IMDG, IATA · Class	Void
· Packing group · ADG, IMDG, IATA	Void
· Environmental hazards:	Not applicable.
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	Void

15 Regulatory information

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

· Australian Inventory of Industrial Chemicals		
7732-18-5	water	
7647-14-5	sodium chloride	
77-86-1	trometamol	
26628-22-8	sodium azide	
· Standard for the Uniform Scheduling of Medicines and Poisons		
77-86-1	trometamol	S4
· Australia: Priority Existing Chemicals		
None of the ingredients is listed.		

- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been 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**
H300 Fatal if swallowed.

(Contd. on page 6)

Safety Data Sheet
according to WHS Regulations

Printing date 22.02.2024

Version number 3

Revision: 08.11.2023

Trade name: Anti-CK-MM Eu-tracer

(Contd. of page 5)

H310 Fatal in contact with skin.

- **Department issuing SDS:** Product safety department.
- **Contact:** MSDS_Turku@revvity.com

- **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

- *** Data compared to the previous version altered.**

AU

Safety Data Sheet according to WHS Regulations

Printing date 22.02.2024

Version number 4

Revision: 08.11.2023

1 Identification

- **Product identifier**
- **Trade name:** CK-MM Assay Buffer
- **Article number:** 13808303
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Product category** PC21 Laboratory chemicals
- **Application of the substance / the mixture**
Laboratory chemicals
In vitro diagnostics
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Revvity Inc.
Wallac Oy
P.O. Box 10
FI-20101 Turku
Finland
+358 2 2678 111
- **Further information obtainable from:**
Product safety department.
MSDS_Turku@revvity.com
- **Emergency telephone number:**
CHEMTREC (whithin U.S.) 800 424-9300
CHEMTREC (from outside U.S.) +1-703-572-3887
- **Information on domestic manufacturers**
Sponsor in Australia:
Revvity Pty. Ltd.
Building C Tenancy A, Level 2
211 Wellington Road
Mulgrave VIC 3170

1800 033 391

2 Hazard(s) Identification

- **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonised System (GHS).

- **Label elements**
- **GHS label elements** The product is labelled according to the IVD regulation
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

AU

(Contd. on page 2)

Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 4

Revision: 08.11.2023


Trade name: CK-MM Assay Buffer

(Contd. of page 1)

3 Composition and Information on Ingredients

- **Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.
- **Dangerous components: Void**

- **Other ingredients**

7732-18-5	water		95-100%
77-86-1	trometamol		1-2.5%
25322-68-3	Polyethylene glycol		1-2.5%
7647-14-5	sodium chloride		<1%
9048-46-8	Albumins, bovine serum		<1%
9007-83-4	Globulins		<0.1%
26628-22-8	sodium azide	 Acute Tox. 1, H300; Acute Tox. 1, H310	≥0.025-<0.1%
9005-64-5	Polysorbate 20		<0.1%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire Fighting Measures

- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Protective equipment:** No special measures required.

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Dilute with plenty of water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and Storage

- **Handling:**
- **Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.

(Contd. on page 3)

-AU

Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 4

Revision: 08.11.2023

Trade name: CK-MM Assay Buffer

(Contd. of page 2)

- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see section 7.
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Goggles recommended during refilling

9 Physical and Chemical Properties

- **General Information**
- **Appearance:**
- **Form:** Fluid
- **Colour:** Red
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **pH-value at 20 °C:** 7.75
- **Change in condition**
- **Melting point/freezing point:** 0 °C
- **Initial boiling point and boiling range:** 100 °C
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not applicable.
- **Decomposition temperature:** Not determined.
- **Ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Explosion limits:**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Vapour pressure at 20 °C:** 23 hPa
- **Density at 20 °C:** 1.01 g/cm³
- **Relative density** Not determined.

(Contd. on page 4)

-AU

Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 4

Revision: 08.11.2023

Trade name: CK-MM Assay Buffer

(Contd. of page 3)

· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with water:	Fully miscible.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
· Dynamic at 20 °C:	0.952 mPas
· Kinematic:	Not determined.
· Solvent content:	
· Water:	96.2 %
· Solids content:	1.5 %
· Other information	No further relevant information available.

10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Not hazardous for water.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

AU
(Contd. on page 5)

Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 4

Revision: 08.11.2023

Trade name: CK-MM Assay Buffer

(Contd. of page 4)

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Hand over to hazardous waste disposers.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

- | | |
|---|-----------------|
| · UN-Number | Void |
| · ADG, ADN, IMDG, IATA | Void |
| · UN proper shipping name | Void |
| · ADG, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · ADG, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · ADG, IMDG, IATA | Void |
| · Environmental hazards: | |
| · Marine pollutant: | Not applicable |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Void |

15 Regulatory information

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

· Australian Inventory of Industrial Chemicals

7732-18-5	water
77-86-1	trometamol
25322-68-3	Polyethylene glycol
7647-14-5	sodium chloride
9048-46-8	Albumins, bovine serum
26628-22-8	sodium azide
9005-64-5	Polysorbate 20
915-67-3	trisodium 3-hydroxy-4-(4'-sulphonatonaphthylazo)naphthalene-2,7-disulphonate
67-43-6	N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)

· Standard for the Uniform Scheduling of Medicines and Poisons

77-86-1	trometamol	S4
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· Australia: Priority Existing Chemicals

None of the ingredients is listed.

- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void

(Contd. on page 6)

Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 4

Revision: 08.11.2023

Trade name: CK-MM Assay Buffer

(Contd. of page 5)

- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been 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**

H300 Fatal if swallowed.

H310 Fatal in contact with skin.

- **Department issuing SDS:** Product safety department.

- **Contact:** MSDS_Turku@revvity.com

- **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

- *** Data compared to the previous version altered.**

-AU-