

Kit components

Product code	Description
3307-0010	GSP Neonatal Biotinidase kit 3307-0010

Components:

13801807	Assay buffer
13807473	Biotinidase Substrate Reagent
13807474	Biotinidase SA Reagent

Safety Data Sheet according to WHS Regulations

Printing date 22.02.2024

Version number 4

Revision: 07.11.2023

1 Identification

- **Product identifier**
- **Trade name:** *Assay buffer*
- **Article number:** 13801807
- **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.*

Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 4

Revision: 07.11.2023


Trade name: 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%
7647-14-5	sodium chloride		<1%
77-86-1	trometamol		<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%
9005-66-7	Tween 40		<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.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.

(Contd. on page 3)

Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 4

Revision: 07.11.2023

Trade name: Assay buffer

(Contd. of page 2)

- **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:** Solution
- **Colour:** Red
- **Odour:** Sulfurous
- **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.

(Contd. on page 4)

Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 4

Revision: 07.11.2023

Trade name: Assay buffer

(Contd. of page 3)

- | | |
|--|-----------------|
| · 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: | 97.5 % |
| · Solids content: | 0.0 % |
| · 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)

Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 4

Revision: 07.11.2023

Trade name: Assay buffer

(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 | Void |
| · ADG, ADN, IMDG, IATA | Void |
| · UN proper shipping name | Void |
| · ADG, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | Void |
| · ADG, ADN, IMDG, IATA | Void |
| · Class | Void |
| · Packing group | Void |
| · 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
7647-14-5	sodium chloride
77-86-1	trometamol
9048-46-8	Albumins, bovine serum
26628-22-8	sodium azide
9005-66-7	Tween 40
915-67-3	trisodium 3-hydroxy-4-(4'-sulphonatonaphthylazo)naphthalene-2,7-disulphonate
67-43-6	N-carboxymethyliminobis(ethylenitrilo)tetra(acetic acid)

- **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.

AU

(Contd. on page 6)

Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 4

Revision: 07.11.2023

Trade name: Assay buffer

(Contd. of page 5)

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

AU

Safety Data Sheet according to WHS Regulations

Printing date 22.02.2024

Version number 4

Revision: 07.11.2023

1 Identification

- **Product identifier**
- **Trade name:** Biotinidase Substrate Reagent
- **Article number:** 13807473
- **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 4

Revision: 07.11.2023


Trade name: **Biotinidase Substrate Reagent**

(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%
9048-46-8	Albumins, bovine serum		<0.1%
26628-22-8	sodium azide	 Acute Tox. 1, H300; Acute Tox. 1, H310	≥0.025-<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.
- **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 4

Revision: 07.11.2023

Trade name: **Biotinidase Substrate Reagent**

(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:** According to product specification
- **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:** Undetermined.
- **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 4

Revision: 07.11.2023

Trade name: Biotinidase Substrate Reagent

(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 % |
| · 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.
- **Uncleaned packaging:**
- **Recommendation:** Hand over to hazardous waste disposers.

(Contd. on page 5)

Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 4

Revision: 07.11.2023

Trade name: **Biotinidase Substrate Reagent**

(Contd. of page 4)

· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

· UN-Number · ADG, ADN, IMDG, IATA	Void
· UN proper shipping name · 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
7647-14-5	sodium chloride
77-86-1	trometamol
9048-46-8	Albumins, bovine serum
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 4

Revision: 07.11.2023

Trade name: Biotinidase Substrate Reagent

(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

-AU-

Safety Data Sheet according to WHS Regulations

Printing date 22.02.2024

Version number 4

Revision: 07.11.2023

1 Identification

- **Product identifier**
- **Trade name:** Biotinidase SA Reagent
- **Article number:** 13807474
- **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.

Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 4


Revision: 07.11.2023

Trade name: **Biotinidase SA Reagent**

(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%
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%
9005-66-7	Tween 40		<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.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.

(Contd. on page 3)

Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 4

Revision: 07.11.2023

Trade name: *Biotinidase SA Reagent*

(Contd. of page 2)

- **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:** *Sulfurous*
- **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.*

(Contd. on page 4)

Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 4

Revision: 07.11.2023

Trade name: **Biotinidase SA Reagent**

(Contd. of page 3)

- | | |
|--|-----------------|
| · 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: | 97.5 % |
| · Solids content: | 0.0 % |
| · 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)

Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 4

Revision: 07.11.2023

Trade name: *Biotinidase SA Reagent*

(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 | Void |
| · ADG, ADN, IMDG, IATA | Void |
| · UN proper shipping name | Void |
| · ADG, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | Void |
| · ADG, ADN, IMDG, IATA | Void |
| · Class | Void |
| · Packing group | Void |
| · 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
7647-14-5	sodium chloride
77-86-1	trometamol
9048-46-8	Albumins, bovine serum
26628-22-8	sodium azide
9005-66-7	Tween 40
915-67-3	trisodium 3-hydroxy-4-(4'-sulphonatonaphthylazo)naphthalene-2,7-disulphonate
67-43-6	N-carboxymethyliminobis(ethylenitrilo)tetra(acetic acid)

· 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.

AU

(Contd. on page 6)

Safety Data Sheet

according to WHS Regulations

Printing date 22.02.2024

Version number 4

Revision: 07.11.2023

Trade name: Biotinidase SA Reagent

(Contd. of page 5)

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

AU