

02/22/2024

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 acc. to OSHA HCS

Printing date 02/22/2024

Reviewed on 11/07/2023

1 Identification

- **Product identifier**
- **Trade name:** Assay buffer
- **Article number:** 13801807
- **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
- **Information department:**
Product safety department.
MSDS_Turku@revvity.com
- **Emergency telephone number:**
CHEMTREC (within U.S.) 800 424-9300
CHEMTREC (from outside U.S.) +1-703-572-3887

2 Hazard(s) identification

- **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonized System (GHS).
- **Label elements**
- **GHS label elements**
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**

HEALTH	0	Health = 0
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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Trade name: Assay buffer

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3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of the 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	<0.1%
9005-66-7	Tween 40	<0.1%

4 First-aid measures

- **Description of 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

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **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.
- **Protective Action Criteria for Chemicals**

- **PAC-1:**

77-86-1	trometamol	18 mg/m ³
26628-22-8	sodium azide	0.026 mg/m ³
67-43-6	N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)	3.5 mg/m ³

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· PAC-2:		
77-86-1	trometamol	190 mg/m ³
26628-22-8	sodium azide	0.29 mg/m ³
67-43-6	N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)	39 mg/m ³
· PAC-3:		
77-86-1	trometamol	1,200 mg/m ³
26628-22-8	sodium azide	5.3 mg/m ³
67-43-6	N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)	230 mg/m ³

7 Handling and storage

- **Handling:**
- **Precautions for safe handling** No special measures required.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **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/personal protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters**
- **Components 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 that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
- **Breathing equipment:** 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.

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Trade name: Assay buffer

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9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form:	Solution
Color:	Red
Odor:	Sulphurous
Odor threshold:	Not determined.

· **pH-value at 20 °C (68 °F):** 7.75

· **Change in condition**

Melting point/Melting range:	0 °C (32 °F)
Boiling point/Boiling range:	100 °C (212 °F)

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Not applicable.

· **Decomposition temperature:** Not determined.

· **Ignition temperature:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.

· **Vapor pressure at 20 °C (68 °F):** 23 hPa (17.3 mm Hg)

· **Density at 20 °C (68 °F):** 1.01 g/cm³ (8.43 lbs/gal)

· **Relative density** Not determined.

· **Vapor 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 (68 °F):	0.952 mPas
Kinematic:	Not determined.

· **Solvent content:**

Water:	97.5 %
VOC content:	0.00 %

Solids content: 0.0 %

· **Other information** No further relevant information available.

10 Stability and reactivity

· **Reactivity** No further relevant information available.

· **Chemical stability**

· **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.

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Trade name: Assay buffer

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11 Toxicological information

- **Information on toxicological effects**

- **Acute toxicity:**

- **Primary irritant effect:**

- **on the skin:** No irritant effect.

- **on the eye:** No irritating effect.

- **Sensitization:** No sensitizing effects known.

- **Additional toxicological information:**

The product is not subject to classification according to internally approved calculation methods for preparations:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

915-67-3	trisodium 3-hydroxy-4-(4'-sulphonatonaphthylazo)naphthalene-2,7-disulphonate	3
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- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**

- **Aquatic toxicity:** No further relevant information available.

- **Persistence and degradability:** No further relevant information available.

- **Behavior 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 packagings:**

- **Recommendation:** Hand over to hazardous waste disposers.

- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

- **UN-Number**

- **DOT, ADR, ADN, IMDG, IATA** Void

- **UN proper shipping name**

- **DOT, ADR, ADN, IMDG, IATA** Void

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- | | |
|--|-----------------|
| · Transport hazard class(es) | |
| · DOT, ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT, ADR, IMDG, IATA | Void |
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 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**
No further relevant information available.
- **Sara**

· **Section 355 (extremely hazardous substances):**

26628-22-8	sodium azide
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· **Section 313 (Specific toxic chemical listings):**

26628-22-8	sodium azide
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· **TSCA (Toxic Substances Control Act):**

7732-18-5	water	ACTIVE
7647-14-5	sodium chloride	ACTIVE
77-86-1	trometamol	ACTIVE
9048-46-8	Albumins, bovine serum	ACTIVE
26628-22-8	sodium azide	ACTIVE
9005-66-7	Tween 40	ACTIVE
915-67-3	trisodium 3-hydroxy-4-(4'-sulphonatonaphthylazo)naphthalene-2,7-disulphonate	ACTIVE
67-43-6	N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)	ACTIVE

· **Hazardous Air Pollutants**

None of the ingredients is listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

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· TLV (Threshold Limit Value)		
26628-22-8	sodium azide	A4

· NIOSH-Ca (National Institute for Occupational Safety and Health)		
None of the ingredients is listed.		

- **GHS label elements** Void

- **Hazard pictograms** Void

- **Signal word** Void

- **Hazard statements** Void

- **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.

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

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

- **Date of preparation / last revision** 02/22/2024

- **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

DOT: US Department of Transportation

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

VOC: Volatile Organic Compounds (USA, EU)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

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

US

Safety Data Sheet acc. to OSHA HCS

Printing date 02/22/2024

Reviewed on 11/07/2023

1 Identification

- **Product identifier**
- **Trade name:** Biotinidase Substrate Reagent
- **Article number:** 13807473
- **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
- **Information department:**
Product safety department.
MSDS_Turku@revvity.com
- **Emergency telephone number:**
CHEMTREC (within U.S.) 800 424-9300
CHEMTREC (from outside U.S.) +1-703-572-3887

2 Hazard(s) identification

- **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonized System (GHS).
- **Label elements**
- **GHS label elements**
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**



- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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Reviewed on 11/07/2023

Trade name: **Biotinidase Substrate Reagent**

(Contd. of page 1)

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of the 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	<0.1%

4 First-aid measures

- **Description of 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

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **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.
- **Protective Action Criteria for Chemicals**

· PAC-1:

77-86-1	trometamol	18 mg/m ³
26628-22-8	sodium azide	0.026 mg/m ³

· PAC-2:

77-86-1	trometamol	190 mg/m ³
26628-22-8	sodium azide	0.29 mg/m ³

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Trade name: **Biotinidase Substrate Reagent**

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· PAC-3:		
77-86-1	trometamol	1,200 mg/m ³
26628-22-8	sodium azide	5.3 mg/m ³

7 Handling and storage

- **Handling:**
- **Precautions for safe handling** No special measures required.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **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/personal protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters**
- **Components 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 that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
- **Breathing equipment:** 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

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**
- Form: Fluid
- Color: According to product specification

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Trade name: **Biotinidase Substrate Reagent**

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· Odor:	Characteristic
· Odor threshold:	Not determined.
· pH-value at 20 °C (68 °F):	7.75
· Change in condition	
Melting point/Melting range:	0 °C (32 °F)
Boiling point/Boiling range:	Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Not applicable.
· Decomposition temperature:	Not determined.
· Ignition temperature:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure at 20 °C (68 °F):	23 hPa (17.3 mm Hg)
· Density at 20 °C (68 °F):	1.01 g/cm ³ (8.43 lbs/gal)
· Relative density	Not determined.
· Vapor 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 (68 °F):	0.952 mPas
Kinematic:	Not determined.
· Solvent content:	
Water:	98.0 %
VOC content:	0.00 %
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **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:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.

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Trade name: **Biotinidase Substrate Reagent**

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- **Additional toxicological information:**

The product is not subject to classification according to internally approved calculation methods for preparations:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**

- **Aquatic toxicity:** No further relevant information available.

- **Persistence and degradability** No further relevant information available.

- **Behavior 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 packagings:**

- **Recommendation:** Hand over to hazardous waste disposers.

- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

- **UN-Number**

- **DOT, ADR, ADN, IMDG, IATA** Void

- **UN proper shipping name**

- **DOT, ADR, ADN, IMDG, IATA** Void

- **Transport hazard class(es)**

- **DOT, ADR, ADN, IMDG, IATA**

- **Class** Void

- **Packing group**

- **DOT, ADR, IMDG, IATA** Void

- **Environmental hazards:**

- **Marine pollutant:** No

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Trade name: **Biotinidase Substrate Reagent**

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· Special precautions for user	Not applicable.
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· Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.
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· UN "Model Regulation":	Void
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15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture
No further relevant information available.

· Sara

· Section 355 (extremely hazardous substances):

26628-22-8	sodium azide
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· Section 313 (Specific toxic chemical listings):

26628-22-8	sodium azide
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· TSCA (Toxic Substances Control Act):

7732-18-5	water		ACTIVE
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7647-14-5	sodium chloride		ACTIVE
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77-86-1	trometamol		ACTIVE
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9048-46-8	Albumins, bovine serum		ACTIVE
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26628-22-8	sodium azide		ACTIVE
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· Hazardous Air Pollutants

None of the ingredients is listed.

· Proposition 65

· Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Carcinogenic categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

· TLV (Threshold Limit Value)

26628-22-8	sodium azide		A4
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· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

· GHS label elements Void

· Hazard pictograms Void

· Signal word Void

· Hazard statements Void

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

-US

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Trade name: Biotinidase Substrate Reagent

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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.

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

· **Contact:** MSDS_Turku@revvity.com

· **Date of preparation / last revision** 02/22/2024

· **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

DOT: US Department of Transportation

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

VOC: Volatile Organic Compounds (USA, EU)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

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

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Safety Data Sheet acc. to OSHA HCS

Printing date 02/22/2024

Reviewed on 11/07/2023

1 Identification

- **Product identifier**
- **Trade name:** Biotinidase SA Reagent
- **Article number:** 13807474
- **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
- **Information department:**
Product safety department.
MSDS_Turku@revvity.com
- **Emergency telephone number:**
CHEMTREC (within U.S.) 800 424-9300
CHEMTREC (from outside U.S.) +1-703-572-3887

2 Hazard(s) identification

- **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonized System (GHS).
- **Label elements**
- **GHS label elements**
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**



- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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Trade name: **Biotinidase SA Reagent**

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3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of the 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	<0.1%
9005-66-7	Tween 40	<0.1%

4 First-aid measures

- **Description of 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

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **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.
- **Protective Action Criteria for Chemicals**

- **PAC-1:**

77-86-1	trometamol	18 mg/m ³
26628-22-8	sodium azide	0.026 mg/m ³
67-43-6	N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)	3.5 mg/m ³

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· PAC-2:		
77-86-1	trometamol	190 mg/m ³
26628-22-8	sodium azide	0.29 mg/m ³
67-43-6	N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)	39 mg/m ³
· PAC-3:		
77-86-1	trometamol	1,200 mg/m ³
26628-22-8	sodium azide	5.3 mg/m ³
67-43-6	N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)	230 mg/m ³

7 Handling and storage

- **Handling:**
- **Precautions for safe handling** No special measures required.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **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/personal protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters**
- **Components 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 that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
- **Breathing equipment:** 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.

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Trade name: *Biotinidase SA Reagent*

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9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· Form:	Fluid
· Color:	Red
· Odor:	Sulphurous
· Odor threshold:	Not determined.

· **pH-value at 20 °C (68 °F):** 7.75

· **Change in condition**

· Melting point/Melting range:	0 °C (32 °F)
· Boiling point/Boiling range:	100 °C (212 °F)

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Not applicable.

· **Decomposition temperature:** Not determined.

· **Ignition temperature:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

· Lower:	Not determined.
· Upper:	Not determined.

· **Vapor pressure at 20 °C (68 °F):** 23 hPa (17.3 mm Hg)

· **Density at 20 °C (68 °F):** 1.01 g/cm³ (8.43 lbs/gal)

· **Relative density** Not determined.

· **Vapor 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 (68 °F):	0.952 mPas
· Kinematic:	Not determined.

· **Solvent content:**

· Water:	97.5 %
· VOC content:	0.00 %

· **Solids content:** 0.0 %

· **Other information** No further relevant information available.

10 Stability and reactivity

· **Reactivity** No further relevant information available.

· **Chemical stability**

· **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.

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11 Toxicological information

- **Information on toxicological effects**

- **Acute toxicity:**

- **Primary irritant effect:**

- **on the skin:** No irritant effect.

- **on the eye:** No irritating effect.

- **Sensitization:** No sensitizing effects known.

- **Additional toxicological information:**

The product is not subject to classification according to internally approved calculation methods for preparations:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

915-67-3	trisodium 3-hydroxy-4-(4'-sulphonatonaphthylazo)naphthalene-2,7-disulphonate	3
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- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**

- **Aquatic toxicity:** No further relevant information available.

- **Persistence and degradability** No further relevant information available.

- **Behavior 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 packagings:**

- **Recommendation:** Hand over to hazardous waste disposers.

- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

- **UN-Number**

- **DOT, ADR, ADN, IMDG, IATA** Void

- **UN proper shipping name**

- **DOT, ADR, ADN, IMDG, IATA** Void

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Trade name: **Biotinidase SA Reagent**

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- | | |
|--|-----------------|
| · Transport hazard class(es) | |
| · DOT, ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT, ADR, IMDG, IATA | Void |
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 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**
No further relevant information available.
- Sara**

· Section 355 (extremely hazardous substances):

26628-22-8	sodium azide
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· Section 313 (Specific toxic chemical listings):

26628-22-8	sodium azide
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· TSCA (Toxic Substances Control Act):

7732-18-5	water	ACTIVE
7647-14-5	sodium chloride	ACTIVE
77-86-1	trometamol	ACTIVE
9048-46-8	Albumins, bovine serum	ACTIVE
26628-22-8	sodium azide	ACTIVE
9005-66-7	Tween 40	ACTIVE
915-67-3	trisodium 3-hydroxy-4-(4'-sulphonatonaphthylazo)naphthalene-2,7-disulphonate	ACTIVE
67-43-6	N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)	ACTIVE

· Hazardous Air Pollutants

None of the ingredients is listed.

· Proposition 65

· Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Carcinogenic categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

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Trade name: Biotinidase SA Reagent

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· **TLV (Threshold Limit Value)**

26628-22-8	sodium azide	A4
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· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **GHS label elements** Void

· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **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.

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

· **Contact:** MSDS_Turku@revvity.com

· **Date of preparation / last revision** 02/22/2024

· **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

DOT: US Department of Transportation

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

VOC: Volatile Organic Compounds (USA, EU)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

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