22.02.2024	Kit components	
Product code	Description	
2207 0010	CCD Noonatal Distinidase kit	

3307-0010	GSP Neonatal Biotinidase kit
	3307-0010

### Components:

13801807	Assay buffer
13807473	Biotinidase Substrate Reagent
13807474	Biotinidase SA Reagent





Printing date 22.02.2024 Version number 4 Revision: 07.11.2023

#### SECTION 1: Identification of the substance/mixture and of the company/undertaking

· 1.1 Product identifier

· Trade name: Assay buffer · Article number: 13801807

- · 1.2 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

- 1.3 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

· 1.4 Emergency telephone number:

CHEMTREC (whithin U.S.) 800 424-9300

CHEMTREC (from outside U.S.) +1-703-572-3887

#### SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

The product is not classified, according to the GB CLP regulation.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008 and 98/79

The product is labelled according to the IVD regulation

- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

#### SECTION 3: Composition/information on ingredients

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

(Contd. on page 2)

Printing date 22.02.2024 Version number 4 Revision: 07.11.2023

Trade name: Assay buffer

		(Contd. of page 1)
· Other ingredients		
CAS: 7732-18-5 EINECS: 231-791-2	water	95-100%
CAS: 7647-14-5 EINECS: 231-598-3	sodium chloride	<1%
CAS: 77-86-1 EINECS: 201-064-4	trometamol	<1%
CAS: 9048-46-8 EINECS: 232-936-2	Albumins, bovine serum	<1%
CAS: 9007-83-4	Globulins	<0.1%
CAS: 26628-22-8 EINECS: 247-852-1	sodium azide  Acute Tox. 2, H300; Acute Tox. 1, H310; Aquatic Acute 1, H400; Aquatic Chronic 1, H410	≥0.025-<0.1%
CAS: 9005-66-7	Tween 40	<0.1%

<sup>·</sup> Additional information: For the wording of the listed hazard phrases refer to section 16.

#### SECTION 4: First aid measures

- · 4.1 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.
- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- · 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

#### **SECTION 5: Firefighting measures**

- · 5.1 Extinguishing media
- · Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: No special measures required.

#### SECTION 6: Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- 6.2 Environmental precautions: Dilute with plenty of water.
- · 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

· 6.4 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.

#### SECTION 7: Handling and storage

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

(Contd. on page 3)

Printing date 22.02.2024 Version number 4 Revision: 07.11.2023

Trade name: Assay buffer

(Contd. of page 2)

- · 7.2 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.
- · 7.3 Specific end use(s) No further relevant information available.

### SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- · 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.
- · 8.2 Exposure controls
- · 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

· Flash point:

· Flammability (solid, gas):

· Decomposition temperature:

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.

Not applicable.

Not applicable.

Not determined.

· Eye protection: Goggles recommended during refilling

#### **SECTION 9: Physical and chemical properties**

· 9.1 Information on basic 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

(Contd. on page 4)

Printing date 22.02.2024 Version number 4 Revision: 07.11.2023

Trade name: Assay buffer

		(Contd. of page 3
· 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:	$1.01 \text{ g/cm}^3$	
· Relative density	Not determined.	
· 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:	97.5 %	
Solids content:	0.0 %	
· 9.2 Other information	No further relevant information available.	

### SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions No dangerous reactions known.
- · 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: No dangerous decomposition products known.

#### SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.
- · Primary irritant effect:
- · 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.
- · Additional toxicological information:
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · 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.

Printing date 22.02.2024 Version number 4 Revision: 07.11.2023

Trade name: Assay buffer

(Contd. of page 4)

### SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes: Not hazardous for water.
- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

#### **SECTION 13: Disposal considerations**

- · 13.1 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.

14.1 UN-Number ADR, ADN, IMDG, IATA	Void	
ADN, ADN, IMDU, IATA	roiu	
14.2 UN proper shipping name		
ADR, ADN, IMDG, IATA	Void	
14.3 Transport hazard class(es)		
ADR, ADN, IMDG, IATA		
Class	Void	
14.4 Packing group		
ADR, IMDG, IATA	Void	
14.5 Environmental hazards:		
Marine pollutant:	Not applicable	
14.6 Special precautions for user	Not applicable.	
14.7 Transport in bulk according to Ann	ex II of	
Marpol and the IBC Code	Not applicable.	
UN "Model Regulation":	Void	

#### SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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Printing date 22.02.2024 Version number 4 Revision: 07.11.2023

Trade name: Assay buffer

(Contd. of page 5)

### SECTION 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.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

- · 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

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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

- GI





Printing date 22.02.2024 Version number 4 Revision: 07.11.2023

#### SECTION 1: Identification of the substance/mixture and of the company/undertaking

- · 1.1 Product identifier
- · Trade name: Biotinidase Substrate Reagent
- · Article number: 13807473
- · 1.2 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

- 1.3 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

· 1.4 Emergency telephone number:

CHEMTREC (whithin U.S.) 800 424-9300

CHEMTREC (from outside U.S.) +1-703-572-3887

#### SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

The product is not classified, according to the GB CLP regulation.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008 and 98/79

The product is labelled according to the IVD regulation

- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

#### SECTION 3: Composition/information on ingredients

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

(Contd. on page 2)

Version number 4 Revision: 07.11.2023 Printing date 22.02.2024

Trade name: Biotinidase Substrate Reagent

(Contd. of page 1)	
95-100%	
<1%	

· Other ingredients		
CAS: 7732-18-5 EINECS: 231-791-2	water	95-100%
CAS: 7647-14-5 EINECS: 231-598-3	sodium chloride	<1%
CAS: 77-86-1 EINECS: 201-064-4	trometamol	<1%
CAS: 9048-46-8 EINECS: 232-936-2	Albumins, bovine serum	<0.1%
EINECS: 247-852-1	sodium azide Acute Tox. 2, H300; Acute Tox. 1, H310; 🚯 Aquatic Acute 1, H400; Aquatic Chronic 1, H410	≥0.025-<0.1%

<sup>·</sup> Additional information: For the wording of the listed hazard phrases refer to section 16.

#### **SECTION 4: First aid measures**

- 4.1 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.
- · 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- · 4.3 Indication of any immediate medical attention and special treatment needed No further relevant information available.

### **SECTION 5: Firefighting measures**

- · 5.1 Extinguishing media
- · Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: No special measures required.

#### SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- **6.2 Environmental precautions:** Dilute with plenty of water.
- · 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

· 6.4 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.

#### SECTION 7: Handling and storage

- · 7.1 Precautions for safe handling No special measures required.
- · Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- Requirements to be met by storerooms and receptacles: No special requirements.

(Contd. on page 3)

Printing date 22.02.2024 Version number 4 Revision: 07.11.2023

Trade name: Biotinidase Substrate Reagent

(Contd. of page 2)

- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: None.
- · 7.3 Specific end use(s) No further relevant information available.

#### SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- · 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.
- · 8.2 Exposure controls
- · 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

9.1 Information on basic physical and ch General Information	F	
Appearance:	El . I	
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.	

(Contd. on page 4)

Printing date 22.02.2024 Version number 4 Revision: 07.11.2023

Trade name: Biotinidase Substrate Reagent

		(Contd. of page
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.	
Partition coefficient: n-octanol/water:	Not determined.	
Viscosity:		
Dynamic at 20 °C:	0.952 mPas	
Kinematic:	Not determined.	
Solvent content:		
Water:	98.0 %	
9.2 Other information	No further relevant information available.	

#### SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions No dangerous reactions known.
- · 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: No dangerous decomposition products known.

#### SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.
- Primary irritant effect:
- · 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.
- · Additional toxicological information:
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · 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.

#### SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.

(Contd. on page 5)

Printing date 22.02.2024 Version number 4 Revision: 07.11.2023

Trade name: Biotinidase Substrate Reagent

(Contd. of page 4)

- · 12.4 Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes: Not hazardous for water.
- · 12.5 Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

#### **SECTION 13: Disposal considerations**

- · 13.1 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.

14.1 UN-Number		
ADR, ADN, IMDG, IATA	Void	
14.2 UN proper shipping name		
ADR, ADN, IMDG, IATA	Void	
14.3 Transport hazard class(es)		
ADR, ADN, IMDG, IATA		
Class	Void	
14.4 Packing group		
ADR, IMDG, IATA	Void	
14.5 Environmental hazards:		
Marine pollutant:	Not applicable	
14.6 Special precautions for user	Not applicable.	
14.7 Transport in bulk according to Anne	ex II of	
Marpol and the IBC Code	Not applicable.	

#### **SECTION 15: Regulatory information**

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

#### SECTION 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.

H400 Very toxic to aquatic life.

(Contd. on page 6)

(Contd. of page 5)

# Safety data sheet according to 1907/2006/EC, Article 31

Printing date 22.02.2024 Version number 4 Revision: 07.11.2023

Trade name: Biotinidase Substrate Reagent

H410 Very toxic to aquatic life with long lasting effects.

· 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

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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





Printing date 22.02.2024 Version number 4 Revision: 07.11.2023

#### SECTION 1: Identification of the substance/mixture and of the company/undertaking

· 1.1 Product identifier

· Trade name: Biotinidase SA Reagent

· Article number: 13807474

· 1.2 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

1.3 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

· 1.4 Emergency telephone number:

CHEMTREC (whithin U.S.) 800 424-9300

CHEMTREC (from outside U.S.) +1-703-572-3887

### SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

The product is not classified, according to the GB CLP regulation.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008 and 98/79

The product is labelled according to the IVD regulation

- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

#### SECTION 3: Composition/information on ingredients

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

(Contd. on page 2)

Printing date 22.02.2024 Version number 4 Revision: 07.11.2023

Trade name: Biotinidase SA Reagent

		(Contd. of page 1)
· Other ingredients		
CAS: 7732-18-5 EINECS: 231-791-2	water	95-100%
CAS: 7647-14-5 EINECS: 231-598-3	sodium chloride	<1%
CAS: 77-86-1 EINECS: 201-064-4	trometamol	<1%
CAS: 9048-46-8 EINECS: 232-936-2	Albumins, bovine serum	<1%
CAS: 9007-83-4	Globulins	<0.1%
CAS: 26628-22-8 EINECS: 247-852-1	sodium azide  Acute Tox. 2, H300; Acute Tox. 1, H310; Aquatic Acute 1, H400; Aquatic Chronic 1, H410	≥0.025-<0.1%
CAS: 9005-66-7	Tween 40	<0.1%

<sup>·</sup> Additional information: For the wording of the listed hazard phrases refer to section 16.

#### SECTION 4: First aid measures

- · 4.1 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.
- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- · 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

#### **SECTION 5: Firefighting measures**

- · 5.1 Extinguishing media
- · Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: No special measures required.

#### SECTION 6: Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- 6.2 Environmental precautions: Dilute with plenty of water.
- · 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

· 6.4 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.

#### SECTION 7: Handling and storage

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

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- · 7.2 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.
- · 7.3 Specific end use(s) No further relevant information available.

### SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- · 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.
- · 8.2 Exposure controls
- · 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

#### SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and	obamical proparties
General Information	chemical properties
· 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 ℃
Initial boiling point and boiling rang	ge: 100 °C
· Flash point:	Not applicable.
· Flammability (solid, gas):	Not applicable.
· Decomposition temperature:	Not determined.

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· 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.
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 %
· 9.2 Other information	No further relevant information available.

### SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions No dangerous reactions known.
- · 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: No dangerous decomposition products known.

#### SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.
- · Primary irritant effect:
- · 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.
- · Additional toxicological information:
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · 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.

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### SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes: Not hazardous for water.
- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

#### **SECTION 13: Disposal considerations**

- · 13.1 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.

14.1 UN-Number ADR, ADN, IMDG, IATA	Void	
ADN, ADN, IMDU, IATA	roiu	
14.2 UN proper shipping name		
ADR, ADN, IMDG, IATA	Void	
14.3 Transport hazard class(es)		
ADR, ADN, IMDG, IATA		
Class	Void	
14.4 Packing group		
ADR, IMDG, IATA	Void	
14.5 Environmental hazards:		
Marine pollutant:	Not applicable	
14.6 Special precautions for user	Not applicable.	
14.7 Transport in bulk according to Ann	ex II of	
Marpol and the IBC Code	Not applicable.	
UN "Model Regulation":	Void	

#### SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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### SECTION 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.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

- · 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

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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

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