13.02.2024 Kit components		
Product code	Description	
3018-0010	Neonatal Biotinidase kit 3018-0010, 3018-001B	
Components:		
13805677	Biotinidase Substrate Reagent	
13805676	Biotinidase Reconstitution Buffer	



Revision: 13.02.2024



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

Printing date 13.02.2024

Version number 3 (replaces version 2)

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

- · 1.1 Product identifier
- · Trade name: Biotinidase Substrate Reagent
- · Article number: 13805677
- · 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 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
- · Additional information:

Safety data sheet available on request.

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

SECTION 3: Composition/information on ingredients

- · 3.2 Mixtures
- · **Description:** Mixture of substances listed below with nonhazardous additions.

(Contd. on page 2)

Printing date 13.02.2024 Version number 3 (replaces version 2) Revision: 13.02.2024

Trade name: Biotinidase Substrate Reagent

		(Con	ntd. of page 1
· Dangerous compone	ents:		
CAS: 3483-12-3		(R^*,R^*) -1,4-dimercaptobutane-2,3-diol	≥5-<10%
EINECS: 222-468-7		♠ Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319	
CAS: 7664-38-2		phosphoric acid	2.5-5%
EINECS: 231-633-2		♦ Skin Corr. 1B, H314	
Index number: 015-0	011-00-6	Specific concentration limits: Skin Corr. 1B; H314: C≥25 %	
		Skin Irrit. 2; H315: 10 % ≤ C < 25 %	
		Eye Irrit. 2; H319: 10 % ≤ C < 25 %	
· Other ingredients			
CAS: 57-50-1	sucrose, pure		85-90%
EINECS: 200-334-9		•	
CAS: 91853-89-3 Biotinyl		-6-amidoquinoline	<1%
	BAQ		
(3aS,4S,6aR)-Hexahydro-2-oxo-N-6-quinolinyl-1H-thieno- [3,4-d]imidazole-4-pentanamide ◆ Acute Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332; Skin Irrit. H315; Eye Irrit. 2, H319; STOT SE 3, H335			
		midazole-4-pentanamide	
		e Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332; Skin Irrit. 2	,
Additional informati		the wording of the listed hazard phrases refer to section 16.	

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · 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: No special measures required.
- · 6.3 Methods and material for containment and cleaning up: Pick up mechanically.
- · 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 precautions are necessary if used correctly.
- · Information about fire and explosion protection: No special measures required.

(Contd. on page 3)

Printing date 13.02.2024 Version number 3 (replaces version 2) Revision: 13.02.2024

Trade name: Biotinidase Substrate Reagent

(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

· Ingredients with limit values that require monitoring at the workplace:

7664-38-2 phosphoric acid

IOELV Short-term value: 2 mg/m³ Long-term value: 1 mg/m³

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see section 7.
- · Individual protection measures, such as personal protective equipment
- · General protective and hygienic measures: Wash hands before breaks and at the end of work.
- · Respiratory protection: Not required.
- · Hand protection

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/face protection Not required.

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Physical state Solid

• Colour: According to product specification

Odour: Sulfurous
 Odour threshold: Not determined.
 Melting point/freezing point: Undetermined.

· Boiling point or initial boiling point and boiling

range Undetermined.
• Flammability Not determined.

· Lower and upper explosion limit

Lower: Not determined.
Upper: Not determined.
Flash point: Not applicable.
Decomposition temperature: Not determined.
pH Not applicable.

(Contd. on page 4)

Printing date 13.02.2024 Version number 3 (replaces version 2) Revision: 13.02.2024

Trade name: Biotinidase Substrate Reagent

	(Contd. of page
Viscosity:	
Kinematic viscosity	Not applicable.
Dynamic:	Not applicable.
Solubility	
water:	Soluble.
Partition coefficient n-octanol/water (log value)	Not determined.
Vapour pressure:	Not applicable.
Density and/or relative density	11
Density:	Not determined.
Relative density	Not determined.
Vapour density	Not applicable.
Particle characteristics	11
See section 3.	
9.2 Other information	
Appearance:	
Form:	Solid
Important information on protection of health an	
environment, and on safety.	
Ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion hazard.
Solvent content:	1. camer wees not present an empression mazara.
Solids content:	100.0 %
Change in condition	100.070
Evaporation rate	Not applicable.
•	
Information with regard to physical hazard classe	e s Void
Explosives	Void
Flammable gases	voia Void
Aerosols	
Oxidising gases	Void
Gases under pressure	Void
Flammable liquids	Void
Flammable solids Void	
Self-reactive substances and mixtures	Void
Pyrophoric liquids	Void
Pyrophoric solids	Void
Self-heating substances and mixtures	Void
Substances and mixtures, which emit flammable	
gases in contact with water	Void
Oxidising liquids	Void
Oxidising solids	Void
Organic peroxides	Void
Corrosive to metals	Void
B 1/1 1 1 1	17 • 1

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- 10.2 Chemical stability

· Desensitised explosives

· Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

Void

- · 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.

Printing date 13.02.2024 Version number 3 (replaces version 2) Revision: 13.02.2024

Trade name: Biotinidase Substrate Reagent

(Contd. of page 4)

SECTION 11: Toxicological information

- · 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · 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.
- · 11.2 Information on other hazards
- Endocrine disrupting properties

None of the ingredients is listed.

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.
- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- · 12.7 Other adverse effects
- · Additional ecological information:
- · General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

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

SECTION 14: Transport information

- · 14.1 UN number or ID number
- · ADR, ADN, IMDG, IATA Void
- · 14.2 UN proper shipping name
- · ADR, ADN, IMDG, IATA Void

(Contd. on page 6)

Printing date 13.02.2024 Version number 3 (replaces version 2) Revision: 13.02.2024

Trade name: Biotinidase Substrate Reagent

		(Contd. of page :
· 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 Maritime transport in bulk according	g to IMO	
instruments	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.
- · DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment Annex II

None of the ingredients is listed.

- · REGULATION (EU) 2019/1148
- · Annex I RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

· Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

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

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

- · Department issuing SDS: Product safety department.
- · Contact: MSDS Turku@revvity.com
- · Date of previous version: 21.09.2023

(Contd. on page 7)

Printing date 13.02.2024 Version number 3 (replaces version 2) Revision: 13.02.2024

Trade name: Biotinidase Substrate Reagent

(Contd. of page 6)

· Version number of previous version: 2

· 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

Acute Tox. 4: Acute toxicity - Category 4

Skin Corr. 1B: Skin corrosion/irritation - Category 1B

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

* Data compared to the previous version altered.



Revision: 13.02.2024



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

Printing date 13.02.2024

Version number 3 (replaces version 2)

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

- · 1.1 Product identifier
- · Trade name: Biotinidase Reconstitution Buffer
- · Article number: 13805676
- · 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



Skin Sens. 1

H317 May cause an allergic skin reaction.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

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

The product is labelled according to the IVD regulation

The product is classified and labelled according to the CLP regulation.

· Hazard pictograms



- · Signal word Warning
- · Hazard-determining components of labelling: reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)

(Contd. on page 2)

Printing date 13.02.2024 Version number 3 (replaces version 2) Revision: 13.02.2024

Trade name: Biotinidase Reconstitution Buffer

(Contd. of page 1)

· Hazard statements

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

· Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P273 Avoid release to the environment.

P280 Wear protective gloves.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P321 Specific treatment (see on this label).

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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

SECTION 3: Composition/information on ingredients

- · 3.2 Mixtures
- · Description: Mixture of substances listed below with nonhazardous additions.

CAS: 55965-84-9 reaction mass		
Index number: 613-167-00-5 [EC no. 247-50] no. 220-239-6]	of: 5-chloro-2-methyl-4-isothiazolin-3-one 00-7] and 2-methyl-2H-isothiazol-3-one [EC 1 (3:1) 3, H301; Acute Tox. 2, H310; Acute Tox. 2, Corr. 1C, H314; Eye Dam. 1, H318; ute 1, H400 (M=100); Aquatic Chronic 1, 0); \diamondsuit Skin Sens. 1A, H317, EUH071 intration limits: Skin Corr. 1C; H314: $C \ge 0.6$ % Skin Irrit. 2; H315: 0.06 % $\le C < 0.6$ % Eye Dam. 1; H318: $C \ge 0.6$ % Eye Irrit. 2; H319: 0.06 % $\le C < 0.6$ %	≥0.0025-<0.01%

· Other ingredients		
CAS: 7732-18-5 EINECS: 231-791-2	water	95-100%
CAS: 16788-57-1	phosphoric acid, dipotassium salt, trihydrate	1-2.5%
CAS: 7778-77-0 EINECS: 231-913-4	potassium dihydrogenorthophosphate	<1%
CAS: 6381-92-6	EDTA Titriplex III STOT RE 2, H373; Acute Tox. 4, H332; Aquatic Chronic 3, H412	<1%
CAS: 57-50-1 EINECS: 200-334-9	sucrose, pure	<1%
	salt-free proprietary glycol	≥0-<0.1%

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

– EU

Printing date 13.02.2024 Version number 3 (replaces version 2) Revision: 13.02.2024

Trade name: Biotinidase Reconstitution Buffer

(Contd. of page 2)

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · General information: Immediately remove any clothing soiled by the product.
- · After inhalation:

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

- · After skin contact: Immediately wash with water and soap and rinse thoroughly.
- · 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:

Inform respective authorities in case of seepage into water course or sewage system.

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).

Dispose contaminated material as waste according to section 13.

Ensure adequate ventilation.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

- · Information about fire and explosion protection: No special measures required.
- · 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.

ΕI

Printing date 13.02.2024 Version number 3 (replaces version 2) Revision: 13.02.2024

Trade name: Biotinidase Reconstitution Buffer

(Contd. of page 3)

SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- · 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
- · Appropriate engineering controls No further data; see section 7.
- · Individual protection measures, such as personal protective equipment
- · General protective and hygienic measures:

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

· Respiratory protection:

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

· Hand protection



Protective gloves

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/face protection Goggles recommended during refilling

SECTION 9: Physical and chemical properties

- · 9.1 Information on basic physical and chemical properties
- · General Information

Physical state
Colour:
Odour:
Odour threshold:
Fluid
Clear
Sulfurous
Not determined.

• Melting point/freezing point: $0 \, ^{\circ}C$

· Boiling point or initial boiling point and boiling

range Undetermined.
Flammability Not applicable.

· Lower and upper explosion limit

Lower: Not determined.
Upper: Not determined.
Flash point: Not applicable.
Decomposition temperature: Not determined.

• pH at 20 °C 5.5

(Contd. on page 5)

Printing date 13.02.2024 Version number 3 (replaces version 2) Revision: 13.02.2024

Trade name: Biotinidase Reconstitution Buffer

	(Contd. of pag	
Viscosity:		
Kinematic viscosity	Not determined.	
Dynamic at 20 °C:	0.952 mPas	
Solubility		
water:	Fully miscible.	
Partition coefficient n-octanol/water (log valu	ue) Not determined.	
Vapour pressure at 20 °C:	23 hPa	
Density and/or relative density		
Density at 20 °C:	1.02 g/cm^3	
Relative density	Not determined.	
Vapour density	Not determined.	
9.2 Other information		
Appearance:		
Form:	Liquid	
I orm. Important information on protection of healt.	•	
environment, and on safety.		
Ignition temperature:	Product is not selfigniting.	
Explosive properties:	Product does not present an explosion hazard.	
Solvent content:	Trouble woes not present an enpression mazara.	
Water:	96.0 %	
Solids content:	0.0 %	
Molecular weight	18.02 g/mol	
Change in condition	8	
Evaporation rate	Not determined.	
•	I	
Information with regard to physical hazard cl		
Explosives	Void Void	
Flammable gases	Void V-:-1	
Aerosols	Void V-:-1	
Oxidising gases	Void V-:-1	
Gases under pressure	Void	
Flammable liquids	Void Void	
Flammable solids	Void	
Self-reactive substances and mixtures	Void Void	
Pyrophoric liquids	Void Void	
Pyrophoric solids	Void Void	
Self-heating substances and mixtures	Void	
Substances and mixtures, which emit flamma	ible Void	
gases in contact with water	v ota Void	
Oxidising liquids		
Oxidising solids	Void Void	
Organic peroxides	Void	

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability

· Corrosive to metals

· Desensitised explosives

• Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

Void

Void

- · 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.

Printing date 13.02.2024 Version number 3 (replaces version 2) Revision: 13.02.2024

Trade name: Biotinidase Reconstitution Buffer

(Contd. of page 5)

SECTION 11: Toxicological information

- · 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · 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 May cause an allergic skin reaction.
- · 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.
- $\cdot \textbf{STOT-repeated exposure } \textit{Based on available data, the classification criteria are not met.} \\$
- · Aspiration hazard Based on available data, the classification criteria are not met.
- · 11.2 Information on other hazards
- · Endocrine disrupting properties

None of the ingredients is listed.

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.
- · 12.5 Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.
- · 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- · 12.7 Other adverse effects
- · Remark: Harmful to fish
- · Additional ecological information:
- · General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water Harmful to aquatic organisms

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

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

SECTION 14: Transport information

- · 14.1 UN number or ID number
- · ADR, ADN, IMDG, IATA Void
- · 14.2 UN proper shipping name
- · ADR, ADN, IMDG, IATA Void

(Contd. on page 7)

Printing date 13.02.2024 Version number 3 (replaces version 2) Revision: 13.02.2024

Trade name: Biotinidase Reconstitution Buffer

		(Contd. of page 6
· 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 Maritime transport in bulk according	g to IMO	
instruments	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.
- · REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment Annex II

None of the ingredients is listed.

- · REGULATION (EU) 2019/1148
- · Annex I RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

· Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

· Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

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
- H301 Toxic if swallowed.
- H310 Fatal in contact with skin.
- H314 Causes severe skin burns and eye damage.
- H317 May cause an allergic skin reaction.
- H318 Causes serious eye damage.
- H330 Fatal if inhaled.
- H332 Harmful if inhaled.
- H373 May cause damage to organs through prolonged or repeated exposure.
- H400 Very toxic to aquatic life.
- *H410 Very toxic to aquatic life with long lasting effects.*

(Contd. on page 8)

Printing date 13.02.2024

Version number 3 (replaces version 2) Revision: 13.02.2024

Trade name: Biotinidase Reconstitution Buffer

(Contd. of page 7)

Harmful to aquatic life with long lasting effects. H412

EUH071 Corrosive to the respiratory tract.

- · Department issuing SDS: Product safety department.
- · Contact: MSDS Turku@revvity.com Date of previous version: 21.09.2023
- · Version number of previous version: 2
- 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

Acute Tox. 3: Acute toxicity - Category 3

Acute Tox. 2: Acute toxicity - Category 2

Skin Corr. 1C: Skin corrosion/irritation – Category 1C

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Skin Sens. 1: Skin sensitisation - Category 1

Skin Sens. 1A: Skin sensitisation - Category 1A

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard - Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard — Category 1 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard — Category 3

* Data compared to the previous version altered.