22.02.2024	Kit components
Product code	Description

3308-0010	GSP Neonatal Phenylalanine kit
I and the second	3308-0010, 3308-001B, 3308-0010Z, 3308-001BZ

Components:

13807549	Neonatal Extraction Solution
13807547	Neonatal Phenylalanine Enzyme Reagent
13807546	Neonatal Phenylalanine Assay Buffer
13807548	Neonatal Phenylalanine Substrate Reagent



Revision: 07.11.2023



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

Printing date 22.02.2024

Version number 7 (replaces version 6)

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

- · 1.1 Product identifier GSP Neonatal Total Galactose kit
- · Trade name: Neonatal Extraction Solution
- · Article number: 13807549
- · 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

Laboratory chemicals In vitro diagnostics

- · 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



GHS02 flammable

Flam. Liq. 2 H225 Highly flammable liquid and vapour.



GHS05 corrosive

Eye Dam. 1 H318 Causes serious eye damage.



Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.



STOT SE 3

H336 May cause drowsiness or dizziness.

(Contd. on page 2)

Version number 7 (replaces version 6) Printing date 22.02.2024 Revision: 07.11.2023

Trade name: Neonatal Extraction Solution

(Contd. of page 1)

· 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









GHS05

· Signal word Danger

· Hazard-determining components of labelling:

Zinc sulfate heptahydrate propan-2-ol

· Hazard statements

H225 Highly flammable liquid and vapour.

H318 Causes serious eye damage.

H336 May cause drowsiness or dizziness.

H411 Toxic to aquatic life with long lasting effects.

· Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No

smoking.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with

water [or shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor.

P405 Store locked up.

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.

· Dangerous components:		
CAS: 67-63-0	propan-2-ol	25-50%
EINECS: 200-661-7	🚱 Flam. Liq. 2, H225; <equation-block> Eye Irrit. 2, H319; STOT SE 3, H336</equation-block>	
Index number: 603-117-00-0	• • • • • • • • • • • • • • • • • • • •	
CAS: 7446-20-0	Zinc sulfate heptahydrate	≥3-<5%
EC number: 616-097-3	📀 Eye Dam. 1, H318; 🕸 Aquatic Chronic 1, H410; 아 Acute Tox.	
Index number: 030-006-00-9	4, H302	
· Other ingredients		
0.10 ==0.0 10 =		-00 /

Other ingrements		
CAS: 7732-18-5	water	50-75%
EINECS: 231-791-2		

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

Printing date 22.02.2024 Version number 7 (replaces version 6) Revision: 07.11.2023

Trade name: Neonatal Extraction Solution

(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; consult doctor in case of complaints.
- · After skin contact: Immediately rinse with water.
- · After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- · 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:

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- 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

Wear protective equipment. Keep unprotected persons away.

· 6.2 Environmental precautions:

Prevent seepage into sewage system, workpits and cellars.

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).

Use neutralising agent.

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:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles: Store in a cool location.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:

Keep container tightly sealed.

Store in cool, dry conditions in well sealed receptacles.

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Printing date 22.02.2024 Version number 7 (replaces version 6) Revision: 07.11.2023

Trade name: Neonatal Extraction Solution

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

(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:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes.

Avoid contact with the eyes and skin.

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.

Fluid

Clear

· Eye/face protection



Tightly sealed goggles

SECTION 9: Physical and chemical properties

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

· Physical state · Colour: · Odour:

• Odour: Sulfurous
• Odour threshold: Not determined.

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Printing date 22.02.2024 Version number 7 (replaces version 6) Revision: 07.11.2023

Trade name: Neonatal Extraction Solution

	(Contd. of page
Melting point/freezing point:	Undetermined.
Boiling point or initial boiling point and boiling	
range	82 °C
Flammability	Highly flammable.
Lower and upper explosion limit	
Lower:	2 Vol %
Upper:	12 Vol %
Flash point:	13 °C
Auto-ignition temperature:	425 °C
Decomposition temperature:	Not determined.
pH at 20 °C	4.5
Viscosity:	,,,
Kinematic viscosity	Not determined.
Dynamic:	Not determined.
Solubility	ivoi uciei mineu.
water:	Fully miscible.
	Not determined.
Partition coefficient n-octanol/water (log value) Vapour pressure at 20°C:	Not determined. 43 hPa
v apour pressure at 20 °C: Density and/or relative density	45 n1 u
	0.06 / 3
Density at 20 °C:	0.96 g/cm ³
Relative density	Not determined.
Vapour density	Not determined.
9.2 Other information	
Appearance:	
Form:	Solution
Important information on protection of health an environment, and on safety.	d
environment, and on sajety. Ignition temperature:	Product is not selfigniting.
Explosive properties:	Product is not explosive. However, formation
Calmanda and and	explosive air/vapour mixtures are possible.
Solvent content:	22.0.0/
Organic solvents:	32.8 %
Water:	64.3 %
Solids content:	0.0 %
Change in condition	
Evaporation rate	Not determined.
Information with regard to physical hazard classe	S
Explosives	Void
Flammable gases	Void
Aerosols	Void
Oxidising gases	Void
Gases under pressure	Void
Flammable liquids	Highly flammable liquid and vapour.
Flammable solids	Void
Self-reactive substances and mixtures	Void
Sey-reactive substances and mixtures Pyrophoric liquids	Void
· ·	voia Void
Pyrophoric solids	
Self-heating substances and mixtures	Void
Substances and mixtures, which emit flammable	77 - 1
	Void
gases in contact with water Oxidising liquids	Void
Oxidising liquids Oxidising solids	Void
Oxidising liquids	

(Contd. on page 6)

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Trade name: Neonatal Extraction Solution

(Contd. of page 5)

· Desensitised explosives

Void

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 hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:

67-63-0	propan-2-ol
---------	-------------

Oral	LD50	5,045 mg/kg (rat)
	LD50	5,045 mg/kg (rat) 12,800 mg/kg (rabbit)
Inhalative	LC50/4 h	30 mg/l (rat)

- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Causes serious eye damage.
- · 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 May cause drowsiness or dizziness.
- · 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
- · Remark: Toxic for fish
- · 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. Must not reach sewage water or drainage ditch undiluted or unneutralised.

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Trade name: Neonatal Extraction Solution

(Contd. of page 6)

Danger to drinking water if even small quantities leak into the ground. Also poisonous for fish and plankton in water bodies.

Toxic for 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.

· 14.1 UN number or ID number · ADR, IMDG, IATA	UN1993
· 14.2 UN proper shipping name · ADR	1993 FLAMMABLE LIQUID, N.O.S. (ISOPROPANO (ISOPROPYL ALCOHOL)), ENVIRONMENTALI HAZARDOUS
· IMDG · IATA	FLAMMABLE LIQUID, N.O.S. (ISOPROPANO (ISOPROPYL ALCOHOL), Zinc sulfate heptahydrat MARINE POLLUTANT FLAMMABLE LIQUID, N.O.S. (ISOPROPANO (ISOPROPYL ALCOHOL) solution)
· 14.3 Transport hazard class(es)	(1301 KOI 1L ALCOHOL) solution)
· ADR, IMDG	
· Class · Label	3 Flammable liquids. 3
· IATA	
Class	3 Flammable liquids.
· Label	3
· 14.4 Packing group · ADR, IMDG, IATA	II
14.5 Environmental hazards:	Product contains environmentally hazardous substance Zinc sulfate heptahydrate
· Marine pollutant:	Not applicable Symbol (fish and tree)
· Special marking (ADR):	Symbol (fish and tree)
· 14.6 Special precautions for user · Hazard identification number (Kemler code): · EMS Number:	Warning: Flammable liquids. 33 F-E,S-E

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Trade name: Neonatal Extraction Solution

	(Contd. of page
Stowage Category	B
14.7 Maritime transport in bulk accord	ding to IMO
instruments	Not applicable.
Transport/Additional information:	
ADR	
Limited quantities (LQ)	IL
Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
Transport category	2
Tunnel restriction code	D/E
<i>IMDG</i>	
Limited quantities (LQ)	IL
Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
UN "Model Regulation":	UN 1993 FLAMMABLE LIQUID, N.O.S
<u> </u>	(ISOPROPANOL (ISOPROPYL ALCOHOL)), 3, 1
	ENVIRONMENTALLY HAZARDOUS

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.
- · Seveso category

E2 Hazardous to the Aquatic Environment

P5c FLAMMABLE LIQUIDS

- · Qualifying quantity (tonnes) for the application of lower-tier requirements 200 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 500 t
- 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.

- E

Printing date 22.02.2024

Version number 7 (replaces version 6)

Trade name: Neonatal Extraction Solution

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Revision: 07.11.2023

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

H225 Highly flammable liquid and vapour.

H302 Harmful if swallowed.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

H410 Very toxic to aquatic life with long lasting effects.

· Department issuing SDS: Product safety department.

· Contact: MSDS_Turku@revvity.com

Date of previous version: 21.09.2023

· Version number of previous version: 6

· Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids – Category 2

Acute Tox. 4: Acute toxicity – Category 4

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

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

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard - Category 2

· * Data compared to the previous version altered.

EU



Revision: 07.11.2023



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

Printing date 22.02.2024

Version number 4 (replaces version 3)

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

- · 1.1 Product identifier
- · Trade name: Neonatal Phenylalanine Enzyme Reagent
- · Article number: 13807547
- · 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
- · 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.
- · Dangerous components: Void

(Contd. on page 2)

Printing date 22.02.2024 Version number 4 (replaces version 3) Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Enzyme Reagent

(Contd. of page 1)

		(Conta. or page 1)
· Other ingredients		
CAS: 9048-46-8 EINECS: 232-936-2	Albumins, bovine serum	85-90%
CAS: 9001-18-7	Dehydrogenase, lipoamide	5-10%
EINECS: 232-587-6		
CAS: 10049-21-5	phosphoric acid, monosodium salt, monohydrate	2.5-5%
CAS: 62758-13-8 CAS: 69403-12-9	7-sodiooxy-3H-phenoxazin-3-one 10-oxide L-Phenylalanine Dehydrogenase	1-2.5% <1%
	ion: For the wording of the listed hazard phrases refer to section 16.	~170

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.
- \cdot 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

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
- · 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.

EU

Printing date 22.02.2024 Version number 4 (replaces version 3) Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Enzyme Reagent

(Contd. of page 2)

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:

The usual precautionary measures are to be adhered to when handling chemicals.

- · 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
Colour:
Odour:
Odour threshold:
Melting point/freezing point:

Solid
Blue
Sulfurous
Not determined.
Undetermined.

· Boiling point or initial boiling point and boiling

range Undetermined.
Flammability Not determined.

· Lower and upper explosion limit

Lower and apper explosion limit

Lower:

Not determined.

Vipper:

Not applicable.

Not applicable.

Not determined.

Not applicable.

Not applicable.

· Viscosity:

Kinematic viscosityDynamic:Not applicable.Not applicable.

·Solubility

water: Soluble.

· Partition coefficient n-octanol/water (log value) Not determined.

· Vapour pressure at 20 °C: 23 hPa

· Density and/or relative density

· **Density:** Not determined.

(Contd. on page 4)

(Contd. of page 3)

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

Printing date 22.02.2024 Version number 4 (replaces version 3) Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Enzyme Reagent

· Relative density Not determined. · Vapour density *Not applicable.* · Particle characteristics See section 3. · 9.2 Other information · Appearance: · Form: Solid · Important information on protection of health and environment, and on safety. · Ignition temperature: Product is not selfigniting. · Explosive properties: Product does not present an explosion hazard. · Solvent content: · Solids content: 3.8 % · Change in condition · Evaporation rate Not applicable. · Information with regard to physical hazard classes · Explosives Void Void · Flammable gases

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 Void · Oxidising liquids Void · Oxidising solids Void · Organic peroxides Void · Corrosive to metals

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.

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.

(Contd. on page 5)

Printing date 22.02.2024 Version number 4 (replaces version 3) Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Enzyme Reagent

(Contd. of page 4)

- · 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: Not hazardous for water.

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 or ID 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, IMDĞ, İATA	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.	

(Contd. on page 6)

Printing date 22.02.2024 Version number 4 (replaces version 3) Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Enzyme Reagent

(Contd. of page 5)

· 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.

- · Department issuing SDS: Product safety department.
- · Contact: MSDS_Turku@revvity.com
- · Date of previous version: 23.05.2022
- · Version number of previous version: 3
- · 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

· * Data compared to the previous version altered.

DI 1



Revision: 07.11.2023



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

Printing date 22.02.2024

Version number 6 (replaces version 5)

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

- · 1.1 Product identifier
- · Trade name: Neonatal Phenylalanine Assay Buffer
- · Article number: 13807546
- · 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
- · 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.
- · Dangerous components: Void

(Contd. on page 2)

Printing date 22.02.2024 Version number 6 (replaces version 5) Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Assay Buffer

		(Contd. of page 1)
· Other ingredients		
CAS: 7732-18-5 EINECS: 231-791-2	water	95-100%
CAS: 56-40-6 EINECS: 200-272-2	glycine	2.5-5%
CAS: 26628-22-8 EINECS: 247-852-1 Index number: 011-004-00-7	sodium azide Acute Tox. 2, H300; Acute Tox. 1, H310; Aquatic Acute 1, H400; Aquatic Chronic 1, H410, EUH032	≥0.025-<0.1%

[·] 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

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
- 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.

EU

Printing date 22.02.2024 Version number 6 (replaces version 5) Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Assay Buffer

(Contd. of page 2)

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:

The usual precautionary measures are to be adhered to when handling chemicals.

- · 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 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
Colourless
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 9.6

· Viscosity:

Kinematic viscosity
 Dynamic at 20 °C:
 Not determined.
 0.952 mPas

·Solubility

• water: Fully miscible. • Partition coefficient n-octanol/water (log value) Not determined.

· Vapour pressure at 20 °C: 23 hPa

· Density and/or relative density

• **Density at 20 °C:** 1.02 g/cm³

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Printing date 22.02.2024 Version number 6 (replaces version 5) Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Assay Buffer

	(Contd. of page
Relative density	Not determined.
Vapour density	Not determined.
9.2 Other information	
Appearance:	
Form:	Fluid
Important information on protection of heal	th and
environment, and on safety.	
Ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion hazard.
Solvent content:	1
Water:	96.3 %
VOC (EC)	0.00 %
Solids content:	0.0 %
Molecular weight	18.02 g/mol
Change in condition	
Evaporation rate	Not determined.
Information with regard to physical hazard o	classes
Explosives	Void
Flammable gases	Void
Aerosols	Void
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 flamm	able
gases in contact with water	Void
Oxidising liquids	Void
Oxidising solids	Void
Organic peroxides	Void
Corrosive to metals	Void
Desensitised explosives	Void

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 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.

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Printing date 22.02.2024 Version number 6 (replaces version 5) Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Assay Buffer

(Contd. of page 4)

- · 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: Not hazardous for water.

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 or ID number		
ADR, IMDG, IATA	Void	
· 14.2 UN proper shipping name		
ADR, 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.	

(Contd. on page 6)

Printing date 22.02.2024 Version number 6 (replaces version 5) Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Assay Buffer

(Contd. of page 5)

· 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

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.

EUH032 Contact with acids liberates very toxic gas.

- · Department issuing SDS: Product safety department.
- · Contact: MSDS Turku@revvity.com
- · Date of previous version: 23.05.2022
- · Version number of previous version: 5
- · 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)

VOC: Volatile Organic Compounds (USA, EU)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

· * Data compared to the previous version altered.



Revision: 07.11.2023



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

Printing date 22.02.2024

Version number 5 (replaces version 4)

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

- · 1.1 Product identifier
- · Trade name: Neonatal Phenylalanine Substrate Reagent
- · *Article number:* 13807548
- · 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
- · 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.
- · Dangerous components: Void

(Contd. on page 2)

Printing date 22.02.2024 Version number 5 (replaces version 4) Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Substrate Reagent

(Contd. of page 1)

	(F8)
· Other ingredients		
CAS: 53-84-9 EINECS: 200-184-4	nadide	90-95%
CAS: 9048-46-8 EINECS: 232-936-2	Albumins, bovine serum	5-10%
CAS: 10049-21-5	phosphoric acid, monosodium salt, monohydrate	1-2.5%

[·] 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: 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 measures required.
- · 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.

EU

Printing date 22.02.2024 Version number 5 (replaces version 4) Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Substrate Reagent

(Contd. of page 2)

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:

The usual precautionary measures are to be adhered to when handling chemicals.

- · 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
Colour:
Odour:
Odour threshold:
Melting point/freezing point:

Solid
White
Sulfurous
Not determined.
Undetermined.

· Boiling point or initial boiling point and boiling

range Undetermined.

Flammability Not determined.

· Lower and upper explosion limit

Lower and upper explosion limit

Lower:

Not determined.

Vipper:
Not applicable.

Not applicable.

Not determined.

Not applicable.

Not applicable.

Not applicable.

· Viscosity:

Kinematic viscosityDynamic:Not applicable.Not applicable.

·Solubility

water: Soluble.

· Partition coefficient n-octanol/water (log value) Not determined. · Vapour pressure: Not applicable.

· Density and/or relative density

· **Density:** Not determined.

(Contd. on page 4)

Printing date 22.02.2024 Version number 5 (replaces version 4) Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Substrate Reagent

	(Conta. of page 3)
Not determined.	

Not applicable.

· Particle characteristics

See section 3.

· Relative density · Vapour density

· 9.2 Other information

· Appearance:

· Form: Solid · Important information on protection of health and

environment, and on safety.

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

• Explosive properties: Product does not present an explosion hazard.

· Solvent content:

· Solids content: 100.0 %

· Change in condition

· Evaporation rate Not applicable.

Information with regard to physical hazard c	lasses
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· 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 flamme	able
gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	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.

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.

(Contd. on page 5)

Printing date 22.02.2024 Version number 5 (replaces version 4) Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Substrate Reagent

(Contd. of page 4)

- · 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 1 (German Regulation) (Self-assessment): slightly hazardous for water

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 or ID 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 Maritime transport in bulk according		
instruments	Not applicable.	

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Trade name: Neonatal Phenylalanine Substrate Reagent

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· 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.

- · Department issuing SDS: Product safety department.
- · Contact: MSDS Turku@revvity.com
- · Date of previous version: 23.05.2022
- · Version number of previous version: 4
- · 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

· * Data compared to the previous version altered.

EU