

Kit components

Product code	Description
3308-0010	GSP Neonatal Phenylalanine kit 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

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

Printing date 22.02.2024

Version number 7

Revision: 07.11.2023

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

- **1.1 Product identifier**
- **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**



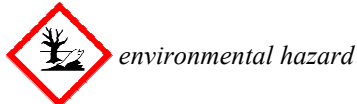
flammable

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



corrosive

Eye Dam. 1 H318 Causes serious eye damage.



environmental hazard

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)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.02.2024

Version number 7

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 GB CLP regulation.

Hazard pictograms

GHS02 GHS05 GHS07 GHS09

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 Chemical characterisation: Mixtures**Description:** Mixture of substances listed below with nonhazardous additions.**Dangerous components:**

CAS: 67-63-0 EINECS: 200-661-7	propan-2-ol Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336	25-50%
CAS: 7446-20-0 EC number: 616-097-3	Zinc sulfate heptahydrate Eye Dam. 1, H318; Aquatic Chronic 1, H410; Acute Tox. 4, H302	≥3-<5%

Other ingredients

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

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

GB

(Contd. on page 3)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.02.2024

Version number 7

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.

(Contd. on page 4)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.02.2024

Version number 7

Revision: 07.11.2023

Trade name: Neonatal Extraction Solution

(Contd. of page 3)

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

SECTION 8: Exposure controls/personal protection

- 8.1 **Control parameters**
- **Additional information about design of technical facilities:** No further data; see section 7.

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

67-63-0 propan-2-ol

WEL	Short-term value: 1250 mg/m ³ , 500 ppm
	Long-term value: 999 mg/m ³ , 400 ppm

· **Additional information:** The lists valid during the making were used as basis.· 8.2 **Exposure controls**· **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.

· **Protection of hands:**

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 protection:**

Tightly sealed goggles

SECTION 9: Physical and chemical properties

· 9.1 **Information on basic physical and chemical properties**· **General Information**· **Appearance:**

Form:	Solution
Colour:	Clear

(Contd. on page 5)

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

Printing date 22.02.2024

Version number 7

Revision: 07.11.2023

Trade name: Neonatal Extraction Solution

(Contd. of page 4)

· Odour:	Sulfurous
· Odour threshold:	Not determined.
· pH-value at 20 °C:	4.5
· Change in condition	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	82 °C
· Flash point:	13 °C
· Flammability (solid, gas):	Highly flammable.
· Auto-ignition temperature:	425 °C
· Decomposition temperature:	Not determined.
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· Explosion limits:	
Lower:	2 Vol %
Upper:	12 Vol %
· Vapour pressure at 20 °C:	43 hPa
· Density at 20 °C:	0.96 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with water:	Fully miscible.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
Organic solvents:	32.8 %
Water:	64.3 %
Solids content:	0.0 %
· 9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

(Contd. on page 6)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.02.2024

Version number 7

Revision: 07.11.2023

Trade name: Neonatal Extraction Solution

(Contd. of page 5)

· **LD/LC50 values relevant for classification:**

67-63-0 propan-2-ol

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

- **Primary irritant effect:**
- **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.
- **Additional toxicological information:**
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure**
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.

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.
- **Ecotoxicological 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.
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
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
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.

GB

(Contd. on page 7)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.02.2024




Version number 7

Revision: 07.11.2023

Trade name: Neonatal Extraction Solution

(Contd. of page 6)

SECTION 14: Transport information

<ul style="list-style-type: none"> · 14.1 UN-Number · ADR, IMDG, IATA 	<p style="margin: 0;">UN1993</p>
<ul style="list-style-type: none"> · 14.2 UN proper shipping name · ADR · IMDG · IATA 	<p style="margin: 0;">1993 FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL (ISOPROPYL ALCOHOL)), ENVIRONMENTALLY HAZARDOUS</p> <p style="margin: 0;">FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL (ISOPROPYL ALCOHOL), Zinc sulfate heptahydrate), MARINE POLLUTANT</p> <p style="margin: 0;">FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL (ISOPROPYL ALCOHOL) solution)</p>
<ul style="list-style-type: none"> · 14.3 Transport hazard class(es) · ADR, IMDG 	<div style="display: flex; align-items: center; gap: 10px;">   </div> <p style="margin: 0;">3 Flammable liquids.</p> <p style="margin: 0;">3</p>
<ul style="list-style-type: none"> · IATA 	<div style="display: flex; align-items: center; gap: 10px;">  </div> <p style="margin: 0;">3 Flammable liquids.</p> <p style="margin: 0;">3</p>
<ul style="list-style-type: none"> · 14.4 Packing group · ADR, IMDG, IATA 	<p style="margin: 0;">II</p>
<ul style="list-style-type: none"> · 14.5 Environmental hazards: · Marine pollutant: · Special marking (ADR): 	<p style="margin: 0;">Product contains environmentally hazardous substances: Zinc sulfate heptahydrate</p> <p style="margin: 0;">Not applicable</p> <p style="margin: 0;">Symbol (fish and tree)</p> <p style="margin: 0;">Symbol (fish and tree)</p>
<ul style="list-style-type: none"> · 14.6 Special precautions for user · Hazard identification number (Kemler code): · EMS Number: · Stowage Category 	<p style="margin: 0;">Warning: Flammable liquids.</p> <p style="margin: 0;">33</p> <p style="margin: 0;">F-E,S-E</p> <p style="margin: 0;">B</p>
<ul style="list-style-type: none"> · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code 	<p style="margin: 0;">Not applicable.</p>
<ul style="list-style-type: none"> · Transport/Additional information: 	<p style="margin: 0;">ADR</p> <p style="margin: 0;">Limited quantities (LQ) 1L</p> <p style="margin: 0;">Excepted quantities (EQ) Code: E2</p> <p style="margin: 0;">Maximum net quantity per inner packaging: 30 ml</p> <p style="margin: 0;">Maximum net quantity per outer packaging: 500 ml</p> <p style="margin: 0;">Transport category 2</p> <p style="margin: 0;">Tunnel restriction code D/E</p>

(Contd. on page 8)

GB

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

Printing date 22.02.2024

Version number 7

Revision: 07.11.2023

Trade name: Neonatal Extraction Solution

(Contd. of page 7)

<ul style="list-style-type: none"> · IMDG · Limited quantities (LQ) · Excepted quantities (EQ) 	<p>IL Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml</p>
<ul style="list-style-type: none"> · UN "Model Regulation": 	<p>UN 1993 FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL (ISOPROPYL ALCOHOL)), 3, II, ENVIRONMENTALLY HAZARDOUS</p>

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
- **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**
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
- **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.**

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

Printing date 22.02.2024

Version number 4

Revision: 07.11.2023

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

- **1.1 Product identifier**
- **Trade name:** 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 (within U.S.) 800 424-9300
CHEMTREC (from outside U.S.) +1-703-572-3887

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The product is not classified, according to the GB CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008 and 98/79**
The product is labelled according to the IVD regulation
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

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

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.02.2024

Version number 4

Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Enzyme Reagent

(Contd. of page 1)

· Other ingredients		
CAS: 9048-46-8 EINECS: 232-936-2	Albumins, bovine serum	85-90%
CAS: 9001-18-7 EINECS: 232-587-6	Dehydrogenase, lipoamide	5-10%
CAS: 10049-21-5	phosphoric acid, monosodium salt, monohydrate	2.5-5%
CAS: 62758-13-8	7-sodiooxy-3H-phenoxazin-3-one 10-oxide	1-2.5%
CAS: 69403-12-9	L-Phenylalanine Dehydrogenase	<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:** 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.

GB

(Contd. on page 3)

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

Printing date 22.02.2024

Version number 4

Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Enzyme Reagent

(Contd. of page 2)

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Additional information about design of technical facilities:** No further data; see section 7.
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Not required.

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Solid
Colour:	Blue
Odour:	Sulfurous
Odour threshold:	Not determined.
- **pH-value:** Not applicable.
- **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not determined.
- **Decomposition temperature:** Not determined.
- **Ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.
- **Vapour pressure at 20 °C:** 23 hPa

(Contd. on page 4)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.02.2024

Version number 4

Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Enzyme Reagent

(Contd. of page 3)

· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with water:	Soluble.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Solvent content:	
Solids content:	3.8 %
· 9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Not hazardous for water.

(Contd. on page 5)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.02.2024

Version number 4

Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Enzyme Reagent

(Contd. of page 4)

- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Hand over to hazardous waste disposers.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

SECTION 14: Transport information

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

SECTION 15: Regulatory information

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

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
- **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

(Contd. on page 6)

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

Printing date 22.02.2024

Version number 4

Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Enzyme Reagent

(Contd. of page 5)

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.**

GB

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

Printing date 22.02.2024

Version number 6

Revision: 07.11.2023

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 GB CLP regulation.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008 and 98/79**
The product is labelled according to the IVD regulation
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

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

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31



Printing date 22.02.2024

Version number 6

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	sodium azide  Acute Tox. 2, H300; Acute Tox. 1, H310;  Aquatic Acute 1, H400; Aquatic Chronic 1, H410	≥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.

GB

(Contd. on page 3)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.02.2024

Version number 6

Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Assay Buffer

(Contd. of page 2)

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Additional information about design of technical facilities:** No further data; see section 7.
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Goggles recommended during refilling

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Fluid
Colour:	Colourless
Odour:	Sulfurous
Odour threshold:	Not determined.
- **pH-value at 20 °C:** 9.6
- **Change in condition**

Melting point/freezing point:	0 °C
Initial boiling point and boiling range:	Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not applicable.
- **Decomposition temperature:** Not determined.
- **Ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.
- **Vapour pressure at 20 °C:** 23 hPa

(Contd. on page 4)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.02.2024

Version number 6

Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Assay Buffer

(Contd. of page 3)

· Density at 20 °C:	1.02 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with water:	Fully miscible.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic at 20 °C:	0.952 mPas
Kinematic:	Not determined.
· Solvent content:	
Water:	96.3 %
VOC (EC)	0.00 %
Solids content:	0.0 %
· 9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.

(Contd. on page 5)

GB

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

Printing date 22.02.2024

Version number 6

Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Assay Buffer

(Contd. of page 4)

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

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Hand over to hazardous waste disposers.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

SECTION 14: Transport information

- | | |
|---|-----------------|
| · 14.1 UN-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. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Void |

SECTION 15: Regulatory information

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

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**
H300 Fatal if swallowed.
H310 Fatal in contact with skin.
H400 Very toxic to aquatic life.

(Contd. on page 6)

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

Printing date 22.02.2024

Version number 6

Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Assay Buffer

(Contd. of page 5)

H410 Very toxic to aquatic life with long lasting effects.

- **Department issuing SDS:** Product safety department.
- **Contact:** MSDS_Turku@revvity.com

· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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

GB

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

Printing date 22.02.2024

Version number 5

Revision: 07.11.2023

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 GB CLP regulation.*
- **2.2 Label elements**
 - **Labelling according to Regulation (EC) No 1272/2008 and 98/79**
 - The product is labelled according to the IVD regulation*
 - **Hazard pictograms** *Void*
 - **Signal word** *Void*
 - **Hazard statements** *Void*
- **2.3 Other hazards**
 - **Results of PBT and vPvB assessment**
 - **PBT:** *Not applicable.*
 - **vPvB:** *Not applicable.*

SECTION 3: Composition/information on ingredients

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

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.02.2024

Version number 5

Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Substrate Reagent

(Contd. of page 1)

· 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.

GB

(Contd. on page 3)

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

Printing date 22.02.2024

Version number 5

Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Substrate Reagent

(Contd. of page 2)

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Additional information about design of technical facilities:** No further data; see section 7.
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Not required.

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Solid
Colour:	White
Odour:	Sulfurous
Odour threshold:	Not determined.
- **pH-value:** Not applicable.
- **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not determined.
- **Decomposition temperature:** Not determined.
- **Ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.
- **Vapour pressure:** Not applicable.

(Contd. on page 4)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.02.2024

Version number 5

Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Substrate Reagent

(Contd. of page 3)

· Density:	<i>Not determined.</i>
· Relative density	<i>Not determined.</i>
· Vapour density	<i>Not applicable.</i>
· Evaporation rate	<i>Not applicable.</i>
· Solubility in / Miscibility with water:	<i>Soluble.</i>
· Partition coefficient: n-octanol/water:	<i>Not determined.</i>
· Viscosity:	
Dynamic:	<i>Not applicable.</i>
Kinematic:	<i>Not applicable.</i>
· Solvent content:	
Solids content:	<i>100.0 %</i>
· 9.2 Other information	<i>No further relevant information available.</i>

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** *Based on available data, the classification criteria are not met.*
- **Primary irritant effect:**
- **Skin corrosion/irritation** *Based on available data, the classification criteria are not met.*
- **Serious eye damage/irritation** *Based on available data, the classification criteria are not met.*
- **Respiratory or skin sensitisation** *Based on available data, the classification criteria are not met.*
- **Additional toxicological information:**
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** *Based on available data, the classification criteria are not met.*
- **Carcinogenicity** *Based on available data, the classification criteria are not met.*
- **Reproductive toxicity** *Based on available data, the classification criteria are not met.*
- **STOT-single exposure** *Based on available data, the classification criteria are not met.*
- **STOT-repeated exposure** *Based on available data, the classification criteria are not met.*
- **Aspiration hazard** *Based on available data, the classification criteria are not met.*

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** *No further relevant information available.*
- **12.2 Persistence and degradability** *No further relevant information available.*
- **12.3 Bioaccumulative potential** *No further relevant information available.*
- **12.4 Mobility in soil** *No further relevant information available.*
- **Additional ecological information:**
- **General notes:** *Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water*

(Contd. on page 5)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.02.2024

Version number 5

Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Substrate Reagent

(Contd. of page 4)

- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Hand over to hazardous waste disposers.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

SECTION 14: Transport information

- | | |
|---|-----------------|
| <ul style="list-style-type: none"> · 14.1 UN-Number · ADR, ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · 14.3 Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class | Void |
| <ul style="list-style-type: none"> · 14.4 Packing group · ADR, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · 14.5 Environmental hazards: · Marine pollutant: | Not applicable |
| <ul style="list-style-type: none"> · 14.6 Special precautions for user | Not applicable. |
| <ul style="list-style-type: none"> · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| <ul style="list-style-type: none"> · UN "Model Regulation": | Void |

SECTION 15: Regulatory information

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

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
- **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

(Contd. on page 6)

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

Printing date 22.02.2024

Version number 5

Revision: 07.11.2023

Trade name: Neonatal Phenylalanine Substrate Reagent

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

(Contd. of page 5)

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

GB