01.03.2024	Kit components
Product code	Description
B024-112	AutoDELFIA Neonatal 17a-OH-progesterone kit B024-104Z, B024-112, B024-112Z, B024-112J, B024- 01C
Components:	
13806174	17-OHP-Eu (~40 nmol/L)
13806175	17-OHP Antiserum

17-OHP assay buffer

13802021



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

Printing date 01.03.2024

Version number 8

Revision: 01.03.2024

SECTION 1: Identification of the substance/mixture and of the company/undertaking · 1.1 Product identifier · Trade name: 17-OHP-Eu (~40 nmol/L) · Article number: 13806174 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 Acute Tox. 4 H302 Harmful if swallowed. Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects. · 2.2 Label elements · Labelling according to Regulation (EC) No 1272/2008 and 98/79 The product is labelled according to the IVD regulation The product is classified and labelled according to the GB CLP regulation. · Hazard pictograms GHS07 · Signal word Warning · Hazard-determining components of labelling: sodium azide (Contd. on page 2) GB

Printing date 01.03.2024

Version number 8

Revision: 01.03.2024

Trade name: 17-OHP-Eu (~40 nmol/L)

	(Conta: of page 1)
· Hazard statements	
H302 Harmful if swallowed.	

H412 Harmful to aquatic life with long lasting effects.

· Precautionary statements

P264 Wash thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P273 Avoid release to the environment.

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

- *P330 Rinse mouth.*
- *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 compone	ents:	
CAS: 26628-22-8	sodium azide	≥0.25-<1%
EINECS: 247-852-1	\bigotimes Acute Tox. 2, H300; Acute Tox. 1, H310; \bigotimes Aquatic Acute 1, H400; Aquatic Chronic 1, H410	
• Other ingredients		
CAS: 9004-54-0	Dextran 10	50-75%
EINECS: 232-677-5		
CAS: 7647-14-5	sodium chloride	10-15%
EINECS: 231-598-3		
CAS: 77-86-1	trometamol	5-10%
EINECS: 201-064-4		
CAS: 90604-29-8	Albumins, blood plasma, Cohn fraction V	1-2.5%
EINECS: 292-322-5		
. Additional informat	ion. For the wording of the listed hazard phrases refer to section 16	

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:

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

· 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: Call for a doctor immediately.

• 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.

(Contd. on page 3)

(Contd. of page 1)

GB

Printing date 01.03.2024

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(Contd. of page 2)

Trade name: 17-OHP-Eu (~40 nmol/L)

· 5.3 Advice for firefighters

· Protective equipment: No special measures required.

SECTION 6: Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- · 6.2 Environmental precautions:
- Inform respective authorities in case of seepage into water course or sewage system.
- 6.3 Methods and material for containment and cleaning up:
- Dispose contaminated material as waste according to section 13.
- · 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 precautions are necessary if used correctly.

- · 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.

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:

26628-22-8 sodium azide

WEL Short-term value: 0.3 mg/m³ Long-term value: 0.1 mg/m³

(as $NaN\Box$), Sk

• 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.
- Wash hands before breaks and at the end of work.
- **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.

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GB

Printing date 01.03.2024

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Revision: 01.03.2024

Trade name: 17-OHP-Eu (~40 nmol/L)

· 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 cl	hemical properties
• General Information • Appearance:	
Form:	Solid material
Colour:	White
· Odour:	Characteristic
• Odour threshold:	Not determined.
· pH-value:	Not applicable.
· Change in condition	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range.	
· 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
· 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:	100.0 %
• 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.

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GB

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Printing date 01.03.2024

Version number 8

Revision: 01.03.2024

(Contd. of page 4)

Trade name: 17-OHP-Eu (~40 nmol/L)

· 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 Harmful if swallowed.

· LD/LC50 values relevant for classification:

26628-22-8 sodium azide

Oral	LD50 (dynamic)	27 mg/kg (rat)
Dermal		20 mg/kg (rabbit)

· Primary irritant effect:

• Skin corrosion/irritation Based on available data, the classification criteria are not met.

· Serious eye damage/irritation Based on available data, the classification criteria are not met.

• Respiratory or skin sensitisation Based on available data, the classification criteria are not met.

· Additional toxicological information:

· CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)

- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- *Carcinogenicity* Based on available data, the classification criteria are not met.

• *Reproductive toxicity Based on available data, the classification criteria are not met.*

• **STOT-single exposure** Based on available data, the classification criteria are not met.

• STOT-repeated exposure Based on available data, the classification criteria are not met.

· Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity: No further relevant information available.

• 12.2 Persistence and degradability No further relevant information available.

• 12.3 Bioaccumulative potential No further relevant information available.

· 12.4 Mobility in soil No further relevant information available.

• Ecotoxical effects:

• **Remark:** Harmful to fish

• Additional ecological information:

· General notes:

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

- Harmful to aquatic organisms
- · 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.*

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Printing date 01.03.2024

Version number 8

Revision: 01.03.2024

Trade name: 17-OHP-Eu (~40 nmol/L)

(Contd. of page 5)

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

SECTION 15: Regulatory information

· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

· Directive 2012/18/EU

· Named dangerous substances - ANNEX I None of the ingredients is listed.

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

SECTION 16: Other information

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

· Relevant phrases

H300 Fatal if swallowed. H310 Fatal in contact with skin. H400 Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects.

· Department issuing SDS: Product safety department.

· Contact: MSDS Turku@revvity.com

· Abbreviations and acronyms: ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European List of Notified Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Acute Tox. 2: Acute toxicity – Category 2 Acute Tox. 4: Acute toxicity - Category 4 Acute Tox. 1: Acute toxicity - Category 1 Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard - Category 1 Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard - Category 3 * Data compared to the previous version altered.

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

Printing date 01.03.2024

Version number 7

Revision: 01.03.2024

SECTION 1: Identification of the substance/mixture and of the company/undertaking · 1.1 Product identifier • Trade name: 17-OHP Antiserum · Article number: 13806175 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) GB

Printing date 01.03.2024

Version number 7

Revision: 01.03.2024

Trade name: 17-OHP Antiserum

		(Contd. of page 1)
• Other ingredients		
CAS: 7732-18-5 EINECS: 231-791-2	water	95-100%
CAS: 7647-14-5 EINECS: 231-598-3	sodium chloride	<1%
CAS: 77-86-1 EINECS: 201-064-4	trometamol	<1%
CAS: 90604-29-8 EINECS: 292-322-5	Albumins, blood plasma, Cohn fraction V	<0.1%
CAS: 26628-22-8 EINECS: 247-852-1	sodium azide Sodium Tox. 2, H300; Acute Tox. 1, H310; (Solutional Acute 1, H400; Aquatic Chronic 1, H410	≥0.025-<0.1%
· Additional informat	ion: For the wording of the listed hazard phrases refer to section 16.	

SECTION 4: First aid measures

• 4.1 Description of first aid measures

· General information: No special measures required.

- After inhalation: Supply fresh air; consult doctor in case of complaints.
- After skin contact: Generally the product does not irritate the skin.
- · After eye contact: Rinse opened eye for several minutes under running water.
- · After swallowing: If symptoms persist consult doctor.

• 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.

· 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

• 5.1 Extinguishing media

• Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.

• 5.2 Special hazards arising from the substance or mixture No further relevant information available.

• 5.3 Advice for firefighters

· Protective equipment: No special measures required.

SECTION 6: Accidental release measures

• 6.1 Personal precautions, protective equipment and emergency procedures Not required.

· 6.2 Environmental precautions: Dilute with plenty of water.

· 6.3 Methods and material for containment and cleaning up:

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

• 6.4 Reference to other sections

No dangerous substances are released.

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling No special measures required.

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

· 7.2 Conditions for safe storage, including any incompatibilities

· Storage:

• Requirements to be met by storerooms and receptacles: No special requirements.

(Contd. on page 3)

GB

Printing date 01.03.2024

Version number 7

Revision: 01.03.2024

Trade name: 17-OHP Antiserum

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

SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- Additional information about design of technical facilities: No further data; see section 7.
- · Ingredients with limit values that require monitoring at the workplace:
- The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- Personal protective equipment:
- General protective and hygienic measures:
- The usual precautionary measures are to be adhered to when handling chemicals.
- · Respiratory protection: Not required.
- Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection: Goggles recommended during refilling

9.1 Information on basic physical and ch	hemical properties	
General Information		
Appearance:	T · · · 1	
Form:	Liquid	
Colour:	Colourless	
Odour:	Sulfurous	
Odour threshold:	Not determined.	
pH-value at 20 °C:	7.75	
Change in condition		
Melting point/freezing point:	0 °C	
Initial boiling point and boiling range.	: 100 °C	
Flash point:	Not applicable.	
Flammability (solid, gas):	Not applicable.	
Decomposition temperature:	Not determined.	
Ignition temperature:	Product is not selfigniting.	
Explosive properties:	Product does not present an explosion hazard.	

(Contd. of page 2)

Printing date 01.03.2024

Version number 7

Revision: 01.03.2024

Trade name: 17-OHP Antiserum

	(Contd. of pag
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure at 20 °C:	23 hPa
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:	98.0 %
Solids content:	0.0 %
9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

· 10.2 Chemical stability

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

- · 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: No dangerous decomposition products known.

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects

• Acute toxicity Based on available data, the classification criteria are not met.

• Primary irritant effect:

- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- Serious eye damage/irritation Based on available data, the classification criteria are not met.
- Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- Additional toxicological information:

· CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)

- Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- *Reproductive toxicity Based on available data, the classification criteria are not met.*
- STOT-single exposure Based on available data, the classification criteria are not met.
- STOT-repeated exposure Based on available data, the classification criteria are not met.

• Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity: No further relevant information available.

(Contd. on page 5)

Printing date 01.03.2024

Version number 7

Revision: 01.03.2024

(Contd. of page 4)

Trade name: 17-OHP Antiserum

- · 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- 12.4 Mobility in soil No further relevant information available.
- Additional ecological information:
- General notes: Not hazardous for water.
- 12.5 Results of PBT and vPvB assessment
- *PBT*: Not applicable.

• **vPvB:** Not applicable.

• 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

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

SECTION 14: Transport information

· 14.1 UN-Number · ADR, ADN, IMDG, IATA	Void	
	, 014	
 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.

· Relevant phrases

H300 Fatal if swallowed.

(Contd. on page 6)

GB

Printing date 01.03.2024

Version number 7

Revision: 01.03.2024

Trade name: 17-OHP Antiserum

(Contd. of page 5)
H310 Fatal in contact with skin.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
• Department issuing SDS: Product safety department.
• Contact: MSDS Turku@revvity.com
Abbreviations and acronyms:
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the
International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
* * Data compared to the previous version altered.



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GB

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

Printing date 01.03.2024

Version number 8

Revision: 01.03.2024

SECTION 1: Identification of the substance/mixture and of the company/undertaking · 1.1 Product identifier • Trade name: 17-OHP assay buffer · Article number: 13802021 1.2 Relevant identified uses of the substance or mixture and uses advised against · Product category PC21 Laboratory chemicals · Application of the substance / the mixture In vitro diagnostics Laboratory chemicals • 1.3 Details of the supplier of the safety data sheet · Manufacturer/Supplier: Revvity Inc. Wallac Oy P.O. Box 10 FI-20101 Turku Finland +358 2 2678 111 • Further information obtainable from: Product safety department. MSDS Turku@revvity.com • 1.4 Emergency telephone number: CHEMTREC (whithin U.S.) 800 424-9300 CHEMTREC (from outside U.S.) +1-703-572-3887 **SECTION 2: Hazards identification** · 2.1 Classification of the substance or mixture Classification according to Regulation (EC) No 1272/2008 The product is not classified, according to the GB CLP regulation. · 2.2 Label elements · Labelling according to Regulation (EC) No 1272/2008 and 98/79 The product is labelled according to the IVD regulation · Hazard pictograms Void · Signal word Void · Hazard statements Void · 2.3 Other hazards · Results of PBT and vPvB assessment · PBT: Not applicable. · vPvB: Not applicable. **SECTION 3: Composition/information on ingredients** · 3.2 Chemical characterisation: Mixtures • Description: Mixture of substances listed below with nonhazardous additions. · Dangerous components: Void (Contd. on page 2)

Printing date 01.03.2024

Version number 8

Revision: 01.03.2024

Trade name: 17-OHP assay buffer

		(Contd. of page 1)
· Other ingredients		
CAS: 7732-18-5 EINECS: 231-791-2	water	95-100%
CAS: 9048-46-8 EINECS: 232-936-2	Albumins, bovine serum	1-2.5%
CAS: 7647-14-5 EINECS: 231-598-3	sodium chloride	<1%
CAS: 77-86-1 EINECS: 201-064-4	trometamol	<1%
CAS: 25322-68-3 NLP: 500-038-2	Polyethylene glycol	<1%
CAS: 64-17-5 EINECS: 200-578-6	ethanol 🚯 Flam. Liq. 2, H225	<0.1%
CAS: 26628-22-8 EINECS: 247-852-1	sodium azide Sodium azide Acute Tox. 2, H300; Acute Tox. 1, H310; Solaritic Acute 1, H400; Aquatic Chronic 1, H410	≥0.025-<0.1%
· Additional informat	ion: For the wording of the listed hazard phrases refer to section 16.	

SECTION 4: First aid measures

• 4.1 Description of first aid measures

- · General information: No special measures required.
- After inhalation: Supply fresh air; consult doctor in case of complaints.
- After skin contact: Generally the product does not irritate the skin.
- · After eye contact: Rinse opened eye for several minutes under running water.
- · After swallowing: If symptoms persist consult doctor.
- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

• 5.1 Extinguishing media

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

SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- · 6.2 Environmental precautions: Dilute with plenty of water.
- · 6.3 Methods and material for containment and cleaning up:
- Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- 6.4 Reference to other sections
- No dangerous substances are released.
- See Section 7 for information on safe handling.
- See Section 8 for information on personal protection equipment.
- See Section 13 for disposal information.

SECTION 7: Handling and storage

• 7.1 Precautions for safe handling No special measures required.

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· 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.

SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- Additional information about design of technical facilities: No further data; see section 7.
- · Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

· Additional information: The lists valid during the making were used as basis.

- · 8.2 Exposure controls
- · Personal protective equipment:
- General protective and hygienic measures:
- The usual precautionary measures are to be adhered to when handling chemicals.
- · Respiratory protection: Not required.
- · Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection: Goggles recommended during refilling

9.1 Information on basic physical a General Information	nd chemical properties	
Appearance: Form:	Solution	
Form. Colour:	Red	
Odour:	Characteristic	
Odour threshold:	Not determined.	
pH-value at 20 °C:	7.75	
Change in condition		
Melting point/freezing point:	$0 \ ^{\circ}C$	
Initial boiling point and boiling r	ange: 100 °C	
Flash point:	Not applicable.	
Flammability (solid, gas):	Not applicable.	

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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	
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:		
Organic solvents:	0.1 %	
Water:	96.5 %	
Solids content:	0.0 %	
9.2 Other information	No further relevant information available.	

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- Acute toxicity Based on available data, the classification criteria are not met.
- Primary irritant effect:
- Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · Additional toxicological information:
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- \cdot 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.

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· Aspiration hazard Based on available data, the classification criteria are not met.

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SECTION 12: Ecological information

· 12.1 Toxicity

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

SECTION 13: Disposal considerations

• 13.1 Waste treatment methods

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

SECTION 14: Transport information	tion	
· 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 Ann. Marpol and the IBC Code	ex II of 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.

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· 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.
H300 Fatal if swallowed.
H310 Fatal in contact with skin.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

· Department issuing SDS: Product safety department.

· Contact: MSDS_Turku@revvity.com

 Abbreviations and acronyms: ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European List of Notified Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative * **Data compared to the previous version altered.** GB