20.02.2024	Kit components
Product code	Description
D0/7 101	A A DELEIA LA ED/E L CCO D. 11.4

B067-101	AutoDELFIA hAFP/Free hCGβ Dual kit
	B067-101, B067-201

Components:

13803301	hAFP/hCGß standards
13803302	Anti-hAFP-Eu, stock solution
13803303	Anti-hCGβ-Sm, stock solution
13802700	DELFIA-2 Buffer





Printing date 20.02.2024 Version number 4 Revision: 20.02.2024

1 Identification

· Product identifier

· Trade name: hAFP/hCG\beta standards

· Article number: 13803301

- · 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

- 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

· Emergency telephone number:

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

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

2 Hazard identification

· Classification of the substance or mixture

Acute Tox. 5 H303 May be harmful if swallowed.

Acute Tox. 5 H313 May be harmful in contact with skin.

Skin Corr. 3 H316 Causes mild skin irritation.

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

· Classification according to Directive 67/548/EEC or Directive 1999/45/EC



Xn; Harmful

R22: Harmful if swallowed.

R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

- · Information concerning particular hazards for human and environment: Not applicable.
- · Classification system:

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

- · Label elements
- · GHS label elements

The product is labelled according to the IVD regulation

The product is classified and labelled according to the Globally Harmonised System (GHS).

- · Hazard pictograms Void
- · Signal word Warning
- · Hazard-determining components of labelling:

sodium azide

(Contd. on page 2)

Printing date 20.02.2024 Version number 4 Revision: 20.02.2024

Trade name: hAFP/hCG\beta standards

(Contd. of page 1)

· Hazard statements

May be harmful if swallowed or in contact with skin.

Causes mild skin irritation.

Harmful to aquatic life with long lasting effects.

· Precautionary statements

Avoid release to the environment.

Call a POISON CENTER/doctor if you feel unwell.

If skin irritation occurs: Get medical advice/attention.

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

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

3 Composition / information on ingredients

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

7647-14-5	sodium chloride	5-109
	Acute Tox. 5, H303	
7647-01-0	hydrogen chloride	1-2.5
	C R34; ★ Xi R37	
	Skin Corr. 1B, H314; Eye Dam. 1, H318; $\textcircled{1}$ STOT SE 3, H335 Specific concentration limits: Skin Corr. 1B; H314: $C \ge 25 \%$	
	Skin Irrit. 2; H315: 10 % ≤ C < 25 %	
	Eye Irrit. 2; H319: 10 % ≤ C < 25 %	
	STOT SE 3; H335: C ≥ 10 %	
26628-22-8	sodium azide	≥0.25-<
	<i>R32</i> T+ R28; ¥₂ N R50/53	
	Acute Tox. 2, H300; Acute Tox. 1, H310; 🕓 Aquatic Acute 1, H400; Aquatic Chronic 1, H410	
Other ingre	dients	
9048-46-8	Albumins, bovine serum	75-6
77-86-1	trometamol	5-1
10035-04-8	calcium chloride, dihydrate	<

4 First-aid measures

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

No further relevant information available.

Printing date 20.02.2024 Version number 4 Revision: 20.02.2024

Trade name: hAFP/hCG\beta standards

(Contd. of page 2)

5 Fire-fighting measures

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

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- · Environmental precautions:

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

· Methods and material for containment and cleaning up:

Dispose contaminated material as waste according to section 13.

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.

7 Handling and storage

- · Handling:
- · Precautions for safe handling No special precautions are necessary if used correctly.
- · Information about fire and explosion protection: No special measures required.
- · Conditions for safe storage, including any incompatibilities
- 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.
- · Specific end use(s) No further relevant information available.

8 Exposure controls / personal protection

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

7647-01-0 hydrogen chloride

PEL (USA)	Ceiling limit: 7 mg/m³, 5 ppm
REL (USA)	Ceiling limit: 7 mg/m³, 5 ppm Ceiling limit: 7 mg/m³, 5 ppm
TLV (USA)	Ceiling limit: 2 ppm A4
	A4

26628-22-8 sodium azide

DEL /IICA)	Cailing limit, 0.2** mg/m3 0.1* mm
KEL (USA)	Celling limit: 0.5 · · mg/m², 0.1 · ppm
	Ceiling limit: 0.3** mg/m³, 0.1* ppm *as HN3; **as NaN3; Skin
TLV (USA)	Ceiling limit: 0.29** mg/m³, 0.11* ppm *as HN3 vapor **as NaN3, A4
	*as HN3 vapor **as NaN3, A4

- · Additional information: The lists valid during the making were used as basis.
- · Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

Immediately remove all soiled and contaminated clothing

(Contd. on page 4)

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Trade name: hAFP/hCG\beta standards

(Contd. of page 3)

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.

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.

Information on basic physical and ca	hemical properties	
General Information		
Appearance:		
Form:	Solid	
Colour:	According to product specification	
Odour: Odour threshold:	Characteristic Not determined.	
pH-value:	Not applicable.	
Change in condition		
Melting point/freezing point:	Undetermined.	
Initial boiling point and boiling ra	nge: 1,461 °C	
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.	
Density at 20 °C:	1.12 g/cm³	
Relative density	Not determined.	
Vapour density	Not applicable.	
Evaporation rate	Not applicable.	
Solubility in / Miscibility with		
water:	Soluble.	
Partition coefficient: n-octanol/wate	r: Not determined.	
Viscosity:		
Dynamic:	Not applicable.	
Kinematic:	Not applicable.	

Printing date 20.02.2024 Version number 4 Revision: 20.02.2024

Trade name: hAFP/hCG\beta standards

· Solvent content:		(Contd. of page 4)
Solids content:	10.2 %	
· Other information	No further relevant information available.	

10 Stability and reactivity

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

11 Toxicological information

- Information on toxicological effects
- · Acute toxicity

· LD/LC5	LD/LC50 values relevant for classification:		
26628-2	26628-22-8 sodium azide		
Oral	LD50 (dynamic)	27 mg/kg (rat)	
Dermal	LD50	20 mg/kg (rabbit)	

- · Primary irritant effect:
- · Skin corrosion/irritation No irritant effect.
- · Serious eye damage/irritation No irritating effect.
- · Respiratory or skin sensitisation No sensitising effects known.
- · Additional toxicological information:

The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · 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

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

Printing date 20.02.2024 Version number 4 Revision: 20.02.2024

Trade name: hAFP/hCG\beta standards

(Contd. of page 5)

13 Disposal considerations

- · 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.

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

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Philippines Inventory of Chemicals and Chemical Substances

All ingredients are listed.

· GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

- · Hazard pictograms Void
- · Signal word Warning
- Hazard-determining components of labelling:

sodium azide

· Hazard statements

May be harmful if swallowed or in contact with skin.

Causes mild skin irritation.

Harmful to aquatic life with long lasting effects.

· Precautionary statements

Avoid release to the environment.

Call a POISON CENTER/doctor if you feel unwell.

If skin irritation occurs: Get medical advice/attention.

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

- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.

(Contd. on page 7)

Printing date 20.02.2024 Version number 4 Revision: 20.02.2024

Trade name: hAFP/hCG\beta standards

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

(Contd. of page 6)

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.
- H303 May be harmful if swallowed.
- H310 Fatal in contact with skin.
- H314 Causes severe skin burns and eye damage.
- H318 Causes serious eye damage.
- H335 May cause respiratory irritation.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.
- R28 Very toxic if swallowed.
- R32 Contact with acids liberates very toxic gas.
- R34 Causes burns.
- R37 Irritating to respiratory system.
- R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
- · 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
- 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. 5: Acute toxicity Category 5
- Acute Tox. 1: Acute toxicity Category 1
- Skin Corr. 1B: Skin corrosion/irritation Category 1B
- Skin Corr. 3: Skin corrosion/irritation Category 3
- Eye Dam. 1: Serious eye damage/eye irritation Category 1
- STOT SE 3: Specific target organ toxicity (single exposure) Category 3
- 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





Printing date 20.02.2024 Version number 4 Revision: 20.02.2024

1 Identification

· Product identifier

· Trade name: Anti-hAFP-Eu, stock solution

· Article number: 13803302

· 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

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

· Emergency telephone number:

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

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

2 Hazard identification

· Classification of the substance or mixture

The product is not classified, according to the Globally Harmonised System (GHS).

- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC Not applicable.
- · Information concerning particular hazards for human and environment:

The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

· Classification system:

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

- · Label elements
- · GHS label elements The product is labelled according to the IVD regulation
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

3 Composition / information on ingredients

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

(Contd. on page 2)

Printing date 20.02.2024 Version number 4 Revision: 20.02.2024

Trade name: Anti-hAFP-Eu, stock solution

(Contd. of page 1)

· Dangerous components: Void

· Other ingre	dients	
7732-18-5	water	95-100%
7647-14-5	sodium chloride Acute Tox. 5, H303	<1%
77-86-1	trometamol	<1%
7647-01-0	hydrogen chloride C R34; Xi R37 Skin Corr. IB, H314; Eye Dam. 1, H318; \bigcirc STOT SE 3, H335 Specific concentration limits: Skin Corr. 1B; H314: C ≥ 25 % Skin Irrit. 2; H315: 10 % ≤ C < 25 % Eye Irrit. 2; H319: 10 % ≤ C < 25 % STOT SE 3; H335: C ≥ 10 %	<0.25%
90604-29-8	Albumins, blood plasma, Cohn fraction V	<0.1%
26628-22-8	sodium azide T+ R28; N R50/53 R32 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.

4 First-aid measures

- · 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.
- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.
- · Indication of any immediate medical attention and special treatment needed
- No further relevant information available.

5 Fire-fighting measures

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

6 Accidental release measures

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

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

· 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.

(Contd. on page 3)

Printing date 20.02.2024 Version number 4 Revision: 20.02.2024

Trade name: Anti-hAFP-Eu, stock solution

(Contd. of page 2)

See Section 13 for disposal information.

7 Handling and storage

- · Handling:
- · Precautions for safe handling No special measures required.
- · Information about fire and explosion protection: No special measures required.
- · 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.
- · Specific end use(s) No further relevant information available.

8 Exposure controls / personal protection

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

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

- · Additional information: The lists valid during the making were used as basis.
- · 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 Physical and chemical properties

- · Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Fluid

Colour: According to product specification

• Odour: Characteristic
• Odour threshold: Not determined.

(Contd. on page 4)

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Trade name: Anti-hAFP-Eu, stock solution

	(Contd. of page
pH-value at 20 °C:	7.75
Change in condition Melting point/freezing point: Initial boiling point and boiling range	0 °C : 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.
Explosion limits: Lower: Upper:	Not determined. Not determined.
Vapour pressure at 20 °C:	23 hPa
Density at 20 °C: Relative density Vapour density Evaporation rate	1.02 g/cm³ Not determined. Not determined. Not determined. Not determined.
Solubility in / Miscibility with water:	Fully miscible.
Partition coefficient: n-octanol/water:	Not determined.
Viscosity: Dynamic at 20°C: Kinematic:	0.952 mPas Not determined.
Solvent content: Water:	98.0 %
Solids content:	0.9 %
Other information	No further relevant information available.

10 Stability and reactivity

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

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity
- Primary irritant effect:
- · Skin corrosion/irritation No irritant effect.
- · Serious eye damage/irritation No irritating effect.
- · Respiratory or skin sensitisation No sensitising effects known.

(Contd. on page 5)

Printing date 20.02.2024 Version number 4 Revision: 20.02.2024

Trade name: Anti-hAFP-Eu, stock solution

(Contd. of page 4)

· Additional toxicological information:

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12 Ecological information

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

13 Disposal considerations

- · 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.

UN-Number ADR, ADN, IMDG, IATA	Void	
UN proper shipping name ADR, ADN, IMDG, IATA	Void	
Transport hazard class(es)		
ADR, ADN, IMDG, IATA Class	Void	
Packing group ADR, IMDG, IATA	Void	
Environmental hazards: Marine pollutant:	Not applicable	
Special precautions for user	Not applicable.	
Transport in bulk according to Annex Is and the IBC Code	I of Marpol Not applicable.	
UN "Model Regulation":	Void	

Printing date 20.02.2024 Version number 4 Revision: 20.02.2024

Trade name: Anti-hAFP-Eu, stock solution

(Contd. of page 5)

15 Regulatory information

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

	Philippines Inventory of Chemicals and Chemical Substances		
7732-18-5	water		
7647-14-5	sodium chloride		
77-86-1	trometamol		
7647-01-0	hydrogen chloride		
26628-22-8	sodium azide		

- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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.
- H303 May be harmful if swallowed.
- H310 Fatal in contact with skin.
- H314 Causes severe skin burns and eye damage.
- H318 Causes serious eye damage.
- H335 May cause respiratory irritation.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.
- R28 Very toxic if swallowed.
- R32 Contact with acids liberates very toxic gas.
- R34 Causes burns.
- R37 Irritating to respiratory system.
- R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
- · 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

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

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

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative





Printing date 20.02.2024 Version number 4 Revision: 20.02.2024

1 Identification

· Product identifier

· Trade name: Anti-hCGβ-Sm, stock solution

· Article number: 13803303

· 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

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

· Emergency telephone number:

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

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

2 Hazard identification

· Classification of the substance or mixture

The product is not classified, according to the Globally Harmonised System (GHS).

- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC Not applicable.
- · Information concerning particular hazards for human and environment:

The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

Classification system:

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

- · Label elements
- · GHS label elements The product is labelled according to the IVD regulation
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

3 Composition / information on ingredients

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

(Contd. on page 2)

Printing date 20.02.2024 Version number 4 Revision: 20.02.2024

Trade name: Anti-hCG\u03b3-Sm, stock solution

(Contd. of page 1)

· Dangerous components: Void

· Other ingre	· Other ingredients		
7732-18-5	water	95-100%	
7647-14-5	sodium chloride	<1%	
	Acute Tox. 5, H303		
77-86-1	trometamol	<1%	
90604-29-8	Albumins, blood plasma, Cohn fraction V	<0.1%	
	sodium azide	≥0.025-<0.1%	
	₩ T+ R28; ₩ N R50/53 R32		
	Acute Tox. 2, H300; Acute Tox. 1, H310; 🍑 Aquatic Acute 1, H400; Aquatic Chronic 1, H410		

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

4 First-aid measures

- · 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.
- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.
- $\cdot \textit{Indication of any immediate medical attention and special treatment needed}$

No further relevant information available.

5 Fire-fighting measures

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

6 Accidental release measures

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

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

· 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.

7 Handling and storage

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

(Contd. on page 3)

Printing date 20.02.2024 Version number 4 Revision: 20.02.2024

Trade name: Anti-hCG\u03b3-Sm, stock solution

(Contd. of page 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.
- · Specific end use(s) No further relevant information available.

8 Exposure controls / personal protection

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

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

- · Additional information: The lists valid during the making were used as basis.
- · 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 Physical and chemical properties

- · Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Fluid
Colour: Clear

• Odour: Characteristic
• Odour threshold: Not determined.

• **pH-value at 20 °C:** 7.75

· Change in condition

Melting point/freezing point: 0 °C Initial boiling point and boiling range: 100 °C

· Flash point: Not applicable.

· Flammability (solid, gas): Not applicable.

(Contd. on page 4)

Printing date 20.02.2024 Version number 4 Revision: 20.02.2024

Trade name: Anti-hCG\u03b3-Sm, stock solution

	(Contd. of page 3)
· 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/cm³
· Relative density	Not determined.
· Vapour density	Not determined.
Evaporation rate	Not determined.
· Solubility in / Miscibility with	
water:	Fully miscible.
Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic at 20 °C:	0.952 mPas
Kinematic:	Not determined.
· Solvent content:	
Water:	98.0 %
Solids content:	0.9 %
· Other information	No further relevant information available.

10 Stability and reactivity

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

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity
- Primary irritant effect:
- · Skin corrosion/irritation No irritant effect.
- · Serious eye damage/irritation No irritating effect.
- · Respiratory or skin sensitisation No sensitising effects known.
- · Additional toxicological information:

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

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Trade name: Anti-hCG\beta-Sm, stock solution

(Contd. of page 4)

12 Ecological information

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

13 Disposal considerations

- · 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.

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

15 Regulatory information

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

Philippines Inventory of Chemicals and Chemical Substances	
7732-18-5	water
7647-14-5	sodium chloride
77-86-1	trometamol
	(Contd. on page 6)

- PH

Printing date 20.02.2024 Version number 4 Revision: 20.02.2024

Trade name: Anti-hCG\u03b3-Sm, stock solution

(Contd. of page 5)

26628-22-8 sodium azide

- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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.

H303 May be harmful if swallowed.

H310 Fatal in contact with skin.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

R28 Very toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

- · 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

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

PH





Printing date 20.02.2024 Version number 4 Revision: 20.02.2024

1 Identification

· Product identifier

· Trade name: <u>DELFIA-2 Buffer</u>

· Article number: 13802700

- · 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

- 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

· Emergency telephone number:

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

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

2 Hazard identification

· Classification of the substance or mixture

The product is not classified, according to the Globally Harmonised System (GHS).

- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC Not applicable.
- · Information concerning particular hazards for human and environment:

The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

· Classification system:

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

- · Label elements
- · GHS label elements The product is labelled according to the IVD regulation
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

3 Composition / information on ingredients

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

(Contd. on page 2)

Printing date 20.02.2024 Version number 4 Revision: 20.02.2024

Trade name: DELFIA-2 Buffer

(Contd. of page 1)

· Dangerous components: Void

Other ingre	dients	
7732-18-5	water	95-100%
7647-14-5	sodium chloride Acute Tox. 5, H303	<1%
9048-46-8	Albumins, bovine serum	<1%
7647-01-0	hydrogen chloride C R34; Xi R37 Skin Corr. IB, H314; Eye Dam. 1, H318; STOT SE 3, H335 Specific concentration limits: Skin Corr. 1B; H314: $C \ge 25$ % Skin Irrit. 2; H315: 10 % ≤ $C < 25$ % Eye Irrit. 2; H319: 10 % ≤ $C < 25$ % STOT SE 3; H335: $C \ge 10$ %	<0.25%
26628-22-8	sodium azide T+ R28; N R50/53 R32 Acute Tox. 2, H300; Acute Tox. 1, H310; Aquatic Acute 1, H400; Aquatic Chronic 1, H410	≥0.025-<0.1%
9007-83-4	Globulins	<0.1%
9005-64-5	Polysorbate 20	<0.1%

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

4 First-aid measures

- 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.
- Information for doctor:
- Most important symptoms and effects, both acute and delayed No further relevant information available.
- · Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 Fire-fighting measures

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

6 Accidental release measures

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

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

· 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.

(Contd. on page 3)

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Trade name: DELFIA-2 Buffer

See Section 13 for disposal information.

(Contd. of page 2)

7 Handling and storage

- · Handling:
- · Precautions for safe handling No special measures required.
- · Information about fire and explosion protection: No special measures required.
- · 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.
- · Specific end use(s) No further relevant information available.

8 Exposure controls / personal protection

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

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

- · Additional information: The lists valid during the making were used as basis.
- · 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 Physical and chemical properties

- · Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Fluid
Colour: Red

• Odour: Characteristic
• Odour threshold: Not determined.

(Contd. on page 4)

Printing date 20.02.2024 Version number 4 Revision: 20.02.2024

Trade name: DELFIA-2 Buffer

	(Contd. of pag
pH-value at 20 °C:	7.75
Change in condition	
Melting point/freezing point:	$0~^{\circ}C$
Initial boiling point and boiling range	2: 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
Density at 20 °C:	1.01 g/cm³
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.
Solubility in / Miscibility with	
water:	Fully miscible.
Partition coefficient: n-octanol/water:	Not determined.
Viscosity:	
Dynamic at 20 °C:	0.952 mPas
Kinematic:	Not determined.
Solvent content:	
Water:	97.5 %
Other information	No further relevant information available.

10 Stability and reactivity

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

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity
- · Primary irritant effect:
- · Skin corrosion/irritation No irritant effect.
- · Serious eye damage/irritation No irritating effect.
- · Respiratory or skin sensitisation No sensitising effects known.

(Contd. on page 5)

Printing date 20.02.2024 Version number 4 Revision: 20.02.2024

Trade name: DELFIA-2 Buffer

(Contd. of page 4)

· Additional toxicological information:

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12 Ecological information

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

13 Disposal considerations

- · 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.

UN-Number ADR, ADN, IMDG, IATA	Void	
UN proper shipping name ADR, ADN, IMDG, IATA	Void	
Transport hazard class(es)		
ADR, ADN, IMDG, IATA Class	Void	
Packing group ADR, IMDG, IATA	Void	
Environmental hazards: Marine pollutant:	Not applicable	
Special precautions for user	Not applicable.	
Transport in bulk according to Annex Is and the IBC Code	I of Marpol Not applicable.	
UN "Model Regulation":	Void	

Printing date 20.02.2024 Version number 4 Revision: 20.02.2024

Trade name: DELFIA-2 Buffer

(Contd. of page 5)

15 Regulatory information

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

	Philippines Inventory of Chemicals and Chemical Substances		
7732-18-5	water		
7647-14-5	sodium chloride		
9048-46-8	Albumins, bovine serum		
	hydrogen chloride		
26628-22-8	sodium azide		
	Polysorbate 20		
1310-73-2	sodium hydroxide		
915-67-3	trisodium 3-hydroxy-4-(4'-sulphonatonaphthylazo)naphthalene-2,7-disulphonate		
67-43-6	N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)		

- GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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.
- H303 May be harmful if swallowed.
- H310 Fatal in contact with skin.
- H314 Causes severe skin burns and eye damage.
- H318 Causes serious eye damage.
- H335 May cause respiratory irritation.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.
- R28 Very toxic if swallowed.
- R32 Contact with acids liberates very toxic gas.
- R34 Causes burns.
- R37 Irritating to respiratory system.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

- · 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

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