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1 Identification of the substance/mixture and of the company

- 1.1 Trade Name (As Labeled): Enzyme Conjugate
- 1.2 Product Use: Used as Enzyme Conjugate for HCP ELISA. For in-vitro use only
- 1.3 Manufacturer's Name: BioGenes GmbH
Address: Köpenicker Str. 325, 12555 Berlin, Germany
Business Phone: +49 30-65762378 (Product information)
E-Mail (competent person): service@biogenes.de
- 1.4 Emergency telephone number: +49 30-19 24 0

2 HAZARD IDENTIFICATIONS

2.1 Classification of the substance or mixture Classification according to Regulation (EC) No. 1272/2008 [CLP]


This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP].

2.2 Label elements Labelling according to Regulation (EC) No 1272/2008 [CLP]

According to EC directives or the corresponding national regulations the product does not have to be labelled.

2.3 Other hazards

No ingredients are PBT/vPvB, according to the criteria in REACH Annex XIII.

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3 COMPOSITION AND INFORMATION ON INGREDIENTS

3.1 Substance

This substance is a mixture.

3.2 Mixture

Streptavidin-conjugated peroxidase in stabilized solution.

HAZARDOUS INGREDIENTS: Enzyme Conjugate	CAS No./ EC No./ Registration No. (REACH)	Amount	Hazard Classification; Hazard Statements
Ethanediol	107-21-1/ 203-473-3/ 01-2119456816- 28-XXXX	≤5%	Acute Tox. 4, H302 STOT RE 2, H373
5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2- methyl-2H - isothiazol-3-one [EC no. 220-239-6] (3:1)	55965-84-9 Not applicable/ Not applicable	<0.0014%	Acute Tox. 3, H331; Acute Tox. 3; H311, Acute Tox. 3, H301; Skin Corr. 1B, H314; Skin Sens. 1, H317; Aquatic Acute 1, H400; Aquatic Chronic 1, H410 Skin Corr. 1B; H314: C ≥ 0.6%; Skin Irrit. 2; H315: 0.06% ≤ C < 0.6%; Eye Irrit. 2; H319: 0.06% ≤ C < 0.6%; Skin Sens. 1; H317: C ≥ 0.0015% M-factor=10
Each of the other components is present in less than 1 percent concentration (0.1% concentration for potential carcinogens, reproductive toxins, respiratory tract sensitizers, and mutagens)			Hazard Classification: Not Classified Hazard Statements: None

4 FIRST-AID MEASURES

4.1 Description of first aid measures

General information:

Remove contaminated, saturated clothing immediately. In the case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

Following inhalation:

Remove casualty to fresh air and keep at rest.

Following skin contact:

Wash immediately with soap and water. In case of skin irritation consult a physician.

Following eye contact:

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

Following ingestion: If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention.

Self-protection of the first aider:


First aider: Pay attention to self-protection!

4.2 Most important symptoms and effects, both acute and delayed symptoms and effects:

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

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5 FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Carbon dioxide (CO₂), foam, water, extinguishing powder.

5.2 Special hazards arising from the substance or mixture Hazardous combustion products:

None.

5.3 Advice for fire-fighters

Co-ordinate fire-fighting measures to the fire surroundings.

6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: Use personal protective equipment, see Section 8. For emergency responders: Use personal protective equipment, see Section 8.

6.2 Environmental precautions

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

6.3 Methods and material for containment and cleaning up

Clear contaminated areas thoroughly.

7 HANDLING AND STORAGE

7.1 Precautions for safe handling

Protective measures:

Use in well-ventilated areas. Handle and open container with care. Always close containers tightly after the removal of product. Wear personal protective clothing (see Section 8).

Measures to prevent fire:

This product is not flammable. No special fire protection measures are necessary.

Advice on general occupational hygiene:

Avoid contact with skin, eyes and clothes. Provide eye shower and label its location conspicuously. Wash hands before breaks and after work. When using do not eat, drink, smoke, sniff. Remove contaminated, saturated clothing immediately. Wash contaminated clothing prior to re-use.


7.2 Conditions for safe storage, including any incompatibilities

No special measures are necessary.

8 EXPOSURE CONTROLS – PERSONAL PROTECTION

8.1 Control parameters

value type (country of origin)	Substance name	EC-No/ CAS No.	Occupational exposure limit value		Monitoring and observation processes	Peak limitation	Source
			Long term	Short term			
IOELV (EU)	Ethanediol	203-473-3/ 107-21-1	52 mg/m ³ , 20 ppm	104 mg/m ³ , 40 ppm	N/A	N/A	2000/39 /EC
AGW (DE)	Ethanediol	203-473-3/ 107-21-1	26 mg/m ³ , 10 ppm	52 mg/m ³ , 20 ppm	N/A	N/A	TRGS 900

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8.2 Exposure controls

Personal Protection General protective and hygienic measures: Keep away from foodstuffs, beverages and feed. Wash hands before breaks and at the end of work. Change contaminated clothing. Eye/face protection: Safety glasses Skin protection: Full contact: Glove material: Nitrile rubber Glove thickness: 0.11 mm Break through time: > 480 min Splash contact: Glove material: Nitrile rubber Glove thickness: 0.11 mm Break through time: > 480 min The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374. This recommendation applies only to the product stated in this safety data sheet and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves.

9 PHYSICAL and CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

- (a) Appearance: liquid (at 20°C and 101.3 kPa)
- (b) Odour: Odourless
- (c) Odour threshold: Does not apply, as substance is odourless
- (d) pH: 7-8
- (e) Melting point / freezing point: No data available
- (f) Initial boiling point and boiling range: No data available
- (g) Flash point: No data available
- (h) Evaporation rate: No data available
- (i) Flammability (solid, gas): Does not apply
- (j) Upper/lower flammability or explosive limits: Does not apply, mixture is not flammable
- (k) Vapour pressure: No data available
- (l) Vapour density: No data available
- (m) Relative density: No data available
- (n) Solubility(ies): Does not apply
- (o) Partition coefficient: n-octanol/water: No data available
- (p) Auto-ignition temperature: No data available
- (q) Decomposition temperature: No data available
- (r) Viscosity: No data available
- (s) Explosive properties: Does not apply, mixture is not explosive
- (t) Oxidising properties: None

9.2 Other information

No additional information relevant to safe use of the mixture.

10 STABILITY AND REACTIVITY

10.1 Reactivity

No specific test data related to reactivity available for this product or its ingredients.

10.2 Chemical stability


The mixture is chemically stable under recommended conditions of storage, use and temperature.

10.3 Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

10.4 Conditions to avoid

No specific conditions to avoid.

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10.5 Incompatible materials

No data available.

10.6 Hazardous decomposition products

Does not decompose when used for intended uses.

11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Mixture

No data available.

Acute toxicity: Ingredients:

Ethanediol: Oral LD50 >4700 mg/kg (rat), Dermal LD50 > 3500 mg/kg (mouse)

Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2- methyl-2H - isothiazol-3-one [EC no. 220-239-6] (3:1): LD50 53mg/kg (rat)

Skin corrosion/irritation: Mixture

No data available.

Skin corrosion/irritation: Ingredients

Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2- methyl-2H - isothiazol-3-one [EC no. 220-239-6] (3:1):

Skin - Rabbit; Result: Corrosive

Serious eye damage/irritation: Mixture

No data available.

Serious eye damage/irritation: Ingredients

Ethanediol: Slight irritation

Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2- methyl-2H - isothiazol-3-one [EC no. 220-239-6] (3:1):

Eyes – Rabbit; Result: Corrosive to eyes

Respiratory or skin sensitisation: Mixture

No data available.

Respiratory or skin sensitisation: Ingredients

Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2- methyl-2H - isothiazol-3-one [EC no. 220-239-6] (3:1):

SCL: Skin Corr. 1B; H314: C ≥ 0.6 %; Skin Irrit. 2; H315: 0.06 % ≤ C < 0.6 %; Eye Irrit. 2; H319: 0.06 % ≤ C < 0.6 %; Skin Sens. 1; H317: C ≥ 0.0015 %

Germ cell mutagenicity:

There are no data available for the ingredients.

Carcinogenicity:

There are no data available for the ingredients.

Reproductive toxicity:

There are no data available for the ingredients.

Specific target organ toxicity (single exposure):


There are no data available for the ingredients.

Specific target organ toxicity (repeated exposure):

There are no data available for the ingredients.

Aspiration hazard:

There are no data available for the ingredients.

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12 ECOLOGICAL INFORMATION

12.1 Toxicity

There are no data available for the ingredients.

12.2 Persistence and degradability

There are no data available for the ingredients.

12.3 Bioaccumulative potential

There are no data available for the ingredients.

12.4 Mobility in soil

There are no data available for the ingredients.

12.5 Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

12.6 Other adverse effects

There are no data available for the ingredients.

13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations. Product / Packaging disposal: Handle uncleaned containers like the product itself.

14 TRANSPORTATION INFORMATION

14.1 UN number (ADR, RID, ADN, IMDG, IATA)

Not applicable.

14.2 UN proper shipping name (ADR, RID, ADN, IMDG, IATA)

Not applicable.

14.3 Transport hazard class(es) (ADR, RID, ADN, IMDG, IATA)

Not applicable.

14.4 Packing group (ADR, RID, ADN, IMDG, IATA)

Not applicable.

14.5 Environmental hazards


None.

14.6 Special precautions for user

Not applicable.

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

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15 REGULATORY INFORMATION

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

Authorisations and/or restrictions on use:

None Water Hazard Class 1, (Self-classification carried out according to VwVwS, 4. German Regulation).

15.2 Chemical Safety Assessment

For this mixture a chemical safety assessment has not been carried out.

16 OTHER INFORMATION

All chemicals may pose unknown hazards and should be used with cautions. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide for experienced personnel. BioGenes GmbH assumes no responsibility for the completeness or accuracy of the information contained herein. Users should consider these data only as a supplement to other information gathered by them and must make independent determinations of suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees and customers and protection of the environment.

Full text of H-Statements referred to under section 3

Acute Tox.	Acute toxicity
Aquatic Acute	Acute aquatic toxicity
Aquatic Chronic	Chronic aquatic toxicity
Eye Irrit.	Eye irritation
H301	Toxic if swallowed
H302	Toxic if swallowed
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H331	Toxic if inhaled
H373	May cause damage to organs (kidney) through prolonged or repeated exposure (if ingested)
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
Skin Corr.	Skin corrosion
Skin Irrit.	Skin irritation
Skin Sens.	Skin sensitisation

End of SDS Sheet