



Trade name: Certolizumab Pegol ELISA

Article number: IG-AB109

1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product identifier

Trade name: **Certolizumab Pegol ELISA (mAb-based)**

Article number: **: IG-AB109**

1.2 Relevant identified uses of the substance or mixture and uses advised against

The Certolizumab Pegol (mAb-based) Assay is an enzyme immunoassay for the specific and quantitative in vitro measurement of free Certolizumab Pegol in human serum and plasma.

Kit content (name and label reference):

Microtiterplate	MTP
Assay Buffer	ASSAYBUF
Dilution Buffer	DILBUF 5X
Biotinylated TNF	BIOTINTNF
Enzyme Conjugate	ENZCONJ
TMB-Substrate Solution	TMBSUBS
Stop Solution	STOP
Wash Buffer Concentrate	WASHBUF 20x
Standard A-E	STD A-E 10x

1.3 Details of the supplier of the safety data sheet

Distributor:

Eagle Biosciences, Inc.
10 Columbia Drive Amherst NH 03031
Phone: 617-409-2019

E-mail: info@eaglebio.com
<http://www.eaglebio.com>

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Due to the low concentration of hazardous ingredients none of the listed components of this product may be classified as dangerous according to Directive 1999/45/EC, 67/548/EEC and Regulation (EC) 1272/2008.

2.2 Label elements

This product is not under labelling according to Regulation (EC) n. 1272/2008.

2.3 Other hazards

No one.

Note: this product is intended for laboratory use by professional uses only. Use appropriate personal protective equipment while working with the reagents provided.

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3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

<i>Stop Solution</i>							
Ingrediente	CAS No [EC No]	Con- taining Conc. (%)	Classification according to regulation (EC) No 1272/2008 (CLP) (related to the concentrated form)		Pictogram, Signal Word Code(s)	Specific Conc. Limits, M-factors	Dir. 67/548/EEC
			Hazard Class and Category Code(s)	Hazard statement Code(s)			
Hydro-chloric Acid (HCl) Index-No. 017-002-01-X	7647-01-0 [231-595-7]	< 5.0 %*	Skin Corr. 1B STOT SE 3	H314 H335	GHS05 GHS07 Dgr	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 %	C; R34-37: C ≥ 25 % Xi; R36/37/38: 10 % ≤ C < 25 %

*Dilution is not classified as hazardous according to the European Regulation 67/548/EEC and 1999/45/EC or 1272/2008/EC.

3.2 Mixtures

<i>Enzyme Conjugate, Wash Buffer Concentrate, Sample Diluent, Control 1&2</i>							
Ingrediente	CAS No [EC No]	Containing Conc. (%)	Classification according to regulation (EC) No 1272/2008 (CLP) (related to the concentrated form)		Pictogram, Signal Word Code(s)	Specific Conc. Limits, M-factors	Dir. 67/548/EEC
			Hazard Class and Category Code(s)	Hazard statement Code(s)			
Proclin 300* Index-No. 613-167-00-5	55965-84-9	< 0.0015 %*	Acute Tox. 3 * Acute Tox. 3 * Acute Tox. 3 * Skin Corr. 1B Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H331 H311 H301 H314 H317 H400 H410	GHS06 GHS05 GHS09 Dgr	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 %	T; N R: 23/24/25- 34-43- 50/53 S: (2-)26-28- 36/37/ 39-45-60-61

* Proclin 300 is a mixture of substances of the components, 5-chloro-2-methyl-2H-isothiazol-3-one (EG-nr 247-500-7) and 2-methyl-2H-isothiazol-3-one (3:1).

*Dilution is not classified as hazardous according to the European Regulation 67/548/EEC and 1999/45/EC or 1272/2008/EC.

Note: See section 16 for the detailed text of the above stated R-, H-, P- and S-phrases.

4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice: No special measures required. Consult physician in case of complaints.

If inhaled: supply fresh air.

In case of skin contact: Immediately flush skin with plenty of water. Cold water may be used.
Remove contaminated clothing and shoes.

In case of eye contact: Check for and remove any contact lenses. Immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used.

If swallowed: If swallowed, rinse mouth with plenty of water.

4.2 Most important symptoms and effects, both acute and delayed

To our present state of knowledge no symptoms or risks are known.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

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Use dry chemical powder, water spray or alcohol resistant foam.

5.2 Special hazards arising from the substance or mixture

To the best of our knowledge, no special hazards can be defined.

5.3 Advice for firefighters

No data available.

6. ACCIDENTAL RELEASE MEASURES**6.1 Personal precautions, protective equipment and emergency procedures**

Wear appropriate protective gloves and clothes.

6.2 Environmental precautions

Dilute with plenty of water.

Do not allow to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

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

Dispose contaminated material as waste according to item 13.

6.4 Reference to other sections

For personal protection see section 8.

For disposal see section 13.

7. HANDLING AND STORAGE**7.1 Precautions for safe handling**

Use all reagents in accordance with the relevant package insert provided with the product.

Do not smoke, eat, drink or apply cosmetics in areas where kit reagents are handled.

Wear disposable latex gloves when handling reagents.

Never pipet by mouth and avoid contact of reagents and specimens with skin and mucous membranes.

Handling should be done in accordance with the procedures defined by an appropriate national biohazard safety guideline or regulation.

7.2 Conditions for safe storage, including any incompatibilities

Store all reagents as directed in the relevant package insert provided with the product.

Protect TMB-Substrate Solution from UV light.

7.3 Specific end use(s)

This product is intended for laboratory use by professional users only.

(For research use only)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION**8.1. Control parameters**

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

8.2. Exposure controls

General hygiene directives should be considered.

Keep away from foodstuffs and beverages. Wash hands before breaks and at the end of the working day.

Personal protective equipment

Respiratory protection: Not required.

Skin Protection: Protective gloves of nitril rubber or nature latex, satisfying the norm DIN EN 455

Eye / face protection: Safety glasses with side shields conforming to EN 166 (EU), NIOSH (US)

Body protection: Impenetrable protective clothing

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9. PHYSICAL AND CHEMICAL PROPERTIES
9.1 Information on basic physical and chemical properties

Component	(a) Appearance	(b) Odour	(d) pH
Standards and Controls	liquid, colorless	odorless	7.2 ± 0.2
Enzyme Conjugate	liquid, red	odorless	6.5 ± 0.2
Microtiterplate	solid, white	odorless	not applicable
TMB-Substrate Solution	liquid, colorless	odorless	3.55 ± 0.2
Stop Solution	liquid, colorless	odorless	<1
Wash Buffer Concentrate	liquid, colorless	odorless	7.2 ± 0.2
Dilution Buffer	liquid, orange	odorless	7.2 ± 0.2
Assay Buffer	liquid, blue	odorless	7.2 ± 0.2

For all components

(c) Odour threshold	no data available
(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)	no data available
(j) Upper/lower flammability or explosive limits	no data available
(k) Vapour pressure	no data available
(l) Vapour density	no data available
(m) Relative density	no data available
(n) Solubility(ies)	Fully miscible
(o) Partition coefficient: n-octanol/water	no data available
(p) Auto-ignition temperature	Product is not self igniting
(q) Decomposition temperature	no data available
(r) Viscosity	no data available
(s) Explosive properties	Product does not present an explosion hazard
(t) Oxidising properties	no data available

9.2 Other informations

No other information available.

10. STABILITY AND REACTIVITY

10.1 Reactivity: Some reagents contain sodium azide (NaN₃) as preservatives. In case of contact with eyes or skin, flush immediately with water. NaN₃ may react with lead and copper plumbing to form explosive metal azides. When disposing reagents, flush with large volume of water to avoid azide build-up.

10.2 Chemical stability: no data available.

10.3 Possibility of hazardous reactions: no data available.

10.4 Conditions to avoid

TMB Substrate Solution: Protect from direct UV light, avoid elevated temperatures.

10.5 Incompatible materials: no data available.

10.6 Hazardous decomposition products: No dangerous decomposition products known.

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(a) Acute toxicity	no data available
(b) Skin corrosion/irritation	Stop Solution: May cause irritation of the skin.
(c) Serious eye damage / irritation	Stop Solution: May cause irritation of the eyes.
(d) Respiratory or skin sensitisation	no data available
(e) Germ cell mutagenicity	no data available
(f) Carcinogenicity	no data available
(g) Reproductive toxicity	no data available
(h) STOT-single exposure	no data available
(i) STOT-repeated exposure	no data available
(j) Aspiration hazard	no data available

Additional Informations

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**12.1 Toxicity:** no data available.**12.2 Persistence and degradabilità:** no data available.**12.3 Bioaccumulative potential:** no data available.**12.4 Mobility in soil:** no data available.**12.5 Results of PBT and vPvB assessment:** no data available.**12.6 Other adverse effects:** no data available.**13. DISPOSAL CONSIDERATIONS****13.1. Waste treatment methods****Product:**

Waste should be disposed of in accordance with federal, state and local environmental control regulations. Must not be composed together with household garbage.

Uncleaned packaging:

Waste should be disposed of in accordance with federal, state and local environmental control regulations. Must not be composed together with household garbage.

General notes:

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

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.



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14. TRANSPORT INFORMATION

No hazardous material as defined by the transport regulations (ADR/RID, IMDG Code, ICAO TI/IATA DGR).

14.1 UN number: None

14.2 UN proper shipping name: None

14.3 Transport hazard class(es): None

14.4 Packing group: None

14.5 Environmental hazards: None

14.6 Special precautions for user: Not applicable.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable.

15. REGULATORY INFORMATION

This Safety Data Sheet is according to:

1907/2006/EC Registration, evaluation and authorization of chemicals regulation (REACH)

1272/2008/EC Classification, labelling and packaging regulation (CLP, globally harmonized system GHS) replaces 67/548/EEC and 1999/45/EC, amending 1907/2006/EC

453/2010/EC Compilation of safety data sheets regulation (SDS), amending 1907/2006/EC

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

No data available.

15.2 Chemical safety assessment

No data available.

16. OTHER INFORMATION

"H code" and "R Phrases" used in this Safety data sheet

Reg. 1272/2008	Dir. 67/548/EEC	
H301	/	Toxic if swallowed.
H311	/	Toxic in contact with skin.
H314	/	Causes severe skin burns and eye damage.
H315	/	Cause skin irritation.
H317	/	May cause an allergic skin reaction.
H319	/	Cause serious eye irritation.
H331	/	Toxic if inhaled.
H335	/	May cause respiratory irritation.
H400	/	Very toxic to aquatic life.
H410	/	Very toxic to aquatic life with long lasting effects.
/	R23/24/25	Toxic by inhalation, in contact with skin and if swallowed.
/	R34	Causes burns.
/	R37	Irritating to respiratory system.
/	R36/37/38	Irritating to eyes, respiratory system and skin.
/	R43	May cause sensitisation by skin contact.
/	R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.



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“P statements” and “S Phrases” used in this Safety data sheet

<i>Reg. 1272/2008</i>	<i>Dir. 67/548/EEC</i>	
/	S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
/	S28	After contact with skin, wash immediately with plenty of ... (to be specified by the manufacturer)
/	S36/37	Wear suitable protective clothing and gloves.
/	S39	Wear eye/face protection.
/	S45	In case of accident or if you feel unwell, seek medical advice immediately. (Show the label where possible.)
/	S60	This material and/or its container must be disposed of as hazardous waste
/	S61	Avoid release to the environment. Refer to special instructions safety data sheet

Department issuing MSDS: Product Management

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.