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

1.1. Product identifier

Product name: Citrullinated Protein Antibodies ELISA Kit
Product code: GD110

Contains – Antigen Coated Plate, Standards and Control, Sample Diluent Concentrate (x15), Conjugate, Wash Buffer x 10 concentrate, TMB Substrate Solution, Stop Solution

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

Use of substance / mixture: This product is intended for IN VITRO diagnostic use only. NOT FOR USE IN HUMANS. Only blood from donors proven to have no antibodies against HIV I, HIV II, HCV and HBsAg, with the FDA-licensed tests, is used in the manufacture of this product. Since, nevertheless, the risk of infection cannot be fully precluded, the product must be handled with the same care as a patient sample.

The substance contains small quantities of Sodium Azide and are not classed as hazardous at these product concentrations, however, buildups of Sodium Azide can react with lead and copper plumbing to form explosive oxides so upon disposal of the product, flush with large volumes of water to prevent buildup in plumbing.

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1.3. Details of the supplier of the safety data sheet

Company name: Genesis Diagnostics Ltd
Eden Research Park,
Henry Crabb Road,
Littleport,
Cambridgeshire,
CB6 1SE,
United Kingdom

www.omegadiagnostics.com

Tel: + 44 (0) 1353 862220

Fax: + 44 (0) 1353 863330

Email: genesis@elisa.co.uk

1.4. Emergency telephone number

Emergency tel: +44 (0) 1353 862220 (office hours only)

Section 2: Hazards identification

2.1. Classification of the substance or mixture

Classification under CLP: Not classed as hazardous under EC Directives but contains following hazardous ingredients:

Antigen coated plate -A polystyrene microplate, coated with dried antigen and a proprietary blocking/stabilizing agent contained in a foil pouch with drying agent.

Standards and Control - 10mM Tris-buffered saline containing human serum and sodium azide @ 0.09%

Conjugate - Rabbit anti-human Ig conjugated to horseradish peroxidase in protein stabilising solution containing Proclin 300 @ 20ppm.

Sample Diluent Concentrate (x15) -10mM Tris-buffered saline containing a blocking agent and sodium azide @0.09%

Wash Buffer x 10 Concentrate - 100mM Tris-buffered saline containing 0.2% Triton X-100.

TMB Substrate Solution- A mildly acidic aqueous solution of 3,3',5,5'-tetramethylbenzidine and hydrogen peroxidase.

Stop Solution - Sulphuric acid 0.25mol/l (0.5N) solution (<5%)

Chemical name	**CAS (Chemical Abstracts Service) Number** **EiNECS (European List of Notified Chemical Substances) EC Number**	**Amount (%) in the mixture**	**Classification according Regulation (EC) No 1272/2008 [CLP] (relating to the 100% form)**	
			Hazard class/ Hazard categories	**Hazard-statement**

Component:	**Proclin300**	**Tris-buffered saline**	**Triton X-100**	**Sodium Azide**
Content:	≤ 0.05%	10mM	≤ 0.02%	≤0.09%
CAS number:	55965-84-9	None	9002-93-1	026628-22-8
Symbol:		N/A		
Hazard Statements:	H314, H315, H318	N/A	H312, H315, H318, H320, H335	H300, H310, H410, EUH032
Precautionary Statements:	P280, P305, P338, P351,	N/A	P260, P262, P280	P264, P273, P301, P310, EUH032

Component:	**3,3',5,5'-tetramethylbenzidine**	**Hydrogen peroxide**	**Sulphuric Acid 0.25M**
Content:	≤ 0.05%	<0.02%	(<5%)
CAS number:	54827-17-7	7722-84-1	7664-93-9
Symbol:			
Hazard Statements:	H319, H335, H315	H270; H314	H290, H314
Precautionary Statements:	P260, P262, P280,	P220, P305, P351, P338, P80 P391	P280, P305, P310, P351, P338, P390,

2.2. Label elements

Label elements: Not classed as hazardous under EC Directives.

2.3. Other hazards

PBT: This product is not identified as a PBT/vPvB substance.

Section 3: Composition/information on ingredients

3.1. Substances

Chemical identity: Conjugate contains Rabbit anti-human Ig conjugated to horseradish peroxidase in protein stabilising solution containing Proclin 300 @ 20ppm

Contains: Contains no hazardous substances in reportable quantities under the CLP.

3.2. Mixture

Chemical name	**CAS (Chemical Abstracts Service) Number** **EiNECS (European List of Notified Chemical Substances) EC Number**	**Amount (%) in the mixture**	**Classification according Regulation (EC) No 1272/2008 [CLP] (relating to the 100% form)**	
			Hazard class/ Hazard categories	**Hazard-statement**
Stop Solution				
Sulphuric Acid 0.25m	7664-93-9	<5%	Skin Irritant (Cat 2)	H315

TMB Reagent				
3,3',5,5'-Tetramethylbenzidine	54827-17-7 259-364-6	< 0.05%	Skin Irrit. 2 Eye Irrit 2 STOT SE 3	H315 H319 H335
Hydrogen Peroxide.	7722-84-1	< 3.65%		H314 H335
Reference Standards **Conjugate** **Assay Buffer**				
Proclin 300 - modified alkyl carboxylate Mixture of: 5-chloro-2-methyl-2H-isothiazolin-3-one	26172-55-4 247-500-7	< 0.1%	Skin Corrosive. 1B Resp. Sensitation. 1 Skin Sensitation. 1 Aquatic Acute 1 Aquatic Chronic 1	H314 H317 H334 H410
2-methyl-2H isothiazolin-3-one Ratio 3:1	2682-20-4 220-239-6	< 0.05%	Acute Toxicity. 4 Skin Corrosive. 1B Skin Sensitation. 1 STOT SE 3 Aquatic Acute 1 Aquatic Chronic 1	H302 H314 H317 H331 H335 H400

Section 4: First aid measures

4.1. Description of first aid measures

Skin contact: Wash immediately with plenty of soap and water.

Eye contact: Flush with copious amounts of water or eyewash saline for at least 15 minutes. Remove contact lenses, if present and easy to do so. Continue rinsing. If eye irritation persists, seek medical advice/attention.

Ingestion: Rinse mouth with water provided person is conscious
Do not induce vomiting. Wash mouth with water and give plenty of water or a cup of milk to drink immediately. Obtain medical attention if necessary and show label on container.

Inhalation: Irritation is unlikely to occur but in the event of discomfort, provide plenty of fresh air and if necessary seek medical assistance.

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

Skin contact: There may be mild irritation at the site of contact.

Eye contact: There may be irritation and redness.

Ingestion: There may be irritation of the throat.

Inhalation: No symptoms.

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

Immediate / special treatment: Not applicable.

Section 5: Fire-fighting measures

5.1. Extinguishing media

Extinguishing media: Suitable extinguishing media for the surrounding fire should be used. Use water spray to cool containers.

5.2. Special hazards arising from the substance or mixture

Exposure hazards: No known specific hazards

5.3. Advice for fire-fighters

Advice for fire-fighters: Do not enter fire without proper protective equipment, including respiratory protection.

Section 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Refer to section 8 of SDS for personal protection details.

Turn leaking containers leak-side up to prevent the escape of liquid.

6.2. Environmental precautions

Environmental precautions: Do not discharge into drains or rivers.

6.3. Methods and material for containment and cleaning up

Clean-up procedures: For small spills, clean up with paper/cloth, or mop up, and dispose of safely.
Clean area of spillage down with plenty of water.

6.4. Reference to other sections

Reference to other sections: Refer to section 8 of SDS.

Section 7: Handling and storage

7.1. Precautions for safe handling

Handling requirements: Avoid contact with skin and wash hands after use.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: Store at 2- 8ºC

Suitable packaging:

7.3. Specific end use(s)

Specific end use(s): No data available.

Section 8: Exposure controls/personal protection

8.1. Control parameters

Workplace exposure limits: No data available.

DNEL/PNEC Values

DNEL / PNEC No data available.

8.2. Exposure controls

Engineering measures: Ensure all engineering measures mentioned in section 7 of SDS are in place.

Respiratory protection: Respiratory protection not required.

Hand protection: Protective gloves. Wash hands after working with substance.

Eye protection: No specific measures are required when using good safe practice.

Skin protection: Protective clothing not required in normal use.

Section 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Wash Buffer x 10 Concentrate
Standards - Liquid, blue (standards) green (control); odourless
Sample Diluent Concentrate (x15) - Liquid, blue odourless
Conjugates - Liquid, red (IgG), green (IgM), yellow(IgA); odourless
Stop Solution – Liquid, colourless, odourless

9.2 Other information

Other information: No data available.

Section 10: Stability and reactivity

10.1. Reactivity

Reactivity: No reactivity data.

10.2. Chemical stability

Chemical stability: Stable at 2 –8ºC until expiry date if unopened; once opened stable for 3 months if stored at 2 –8ºC.

10.3. Possibility of hazardous reactions

Hazardous reactions: Hazardous reactions will not occur under normal transport or storage conditions.

10.4. Conditions to avoid

Conditions to avoid: Save under storage conditions outlined in Section 7 of this SDS.

10.5. Incompatible materials

Materials to avoid: None known.

10.6. Hazardous decomposition products

Decomposition products: No known specific hazards

Section 11: Toxicological information

11.1. Information on toxicological effects

Toxicity values: No data available.

Symptoms / routes of exposure

Skin contact: There may be mild irritation at the site of contact.

Eye contact: There may be irritation and redness.

Ingestion: There may be irritation of the throat.

Inhalation: No symptoms.

Section 12: Ecological information

12.1. Toxicity

Ecotoxicity values: No data available.

12.2. Persistence and degradability

Persistence and degradability: Biodegradable.

12.3. Bioaccumulative potential

Bioaccumulative potential: No bioaccumulation potential.

12.4. Mobility in soil

Mobility: **Reagents** - Readily absorbed into soil.

Plate -Not readily absorbed into soil.

12.5. Results of PBT and vPvB assessment

PBT identification: This product is not identified as a PBT/vPvB substance.

12.6. Other adverse effects

Other adverse effects: Negligible ecotoxicity.

Section 13: Disposal considerations

13.1. Waste treatment methods

Disposal operations: Dispose of in accordance with current legislation and local authority regulations.

If outside the U.K, comply with local waste disposal regulations.

NB: The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

Section 14: Transport information

14.1. UN number

UN number: Not applicable.

14.2. UN proper shipping name

Shipping name: This product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/RID).

14.3. Transport hazard class(es)

Hazard Class: Product is not classified as hazardous

14.4. Packing group

Group: Product is not classified as dangerous goods

14.5. Environmental hazards

Environmentally hazardous: No harmful effects at use concentration **Marine pollutant:** No

14.6. Special precautions for user

Special precautions: No special precautions.

Section 15: Regulatory information

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

Specific regulations: Not applicable.

15.2. Chemical Safety Assessment

CSA: Not applicable - product not subject to registration under REACH

Section 16: Other information

Other information

Other information: This safety data sheet is prepared in accordance with Commission Regulation (EU) No 453/2010.

Legal disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This company shall not be held liable for any damage resulting from handling or from contact with the above product.

H302	Harmful if swallowed.
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
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.