

Safety Data Sheet

Kit summary

Following components used as mixtures in the kit are defined as hazardous chemical according to the Regulation (EC) N° 1272/2008.

Component	Identification	Classification	Hazard class pictograms (pure ingredient)	% weight	Hazard Statements
ProClin 300	CAS : - EC : 932-593-5	H302 Cat 4 H312 Cat 4 H314 Cat 1A H317 Cat 1 H332 Cat 4 H411Cat 2	GHS05 GHS07 GHS09	0.001-0.5%	H317 Cat 1
2-Pyrrolidinone	CAS :616-45-5 EC : 210-483-1	H319 Cat 2 H360 Cat 1B	GHS08	<10%*	H319 Cat 2 H360 Cat 1B

* The exact percentage has been withheld as a trade secret

Other chemicals contained within these products do not meet definition of a hazardous chemical according to CLP Regulation.

Section 1 – Identification

Product Identification: **ELISA kits High Sensitivity using Amplification Steps**

Product Code: **Cat- n° 850 810.xxx/ 850 870.xxx/ 850 880.xxx/ 850 890.xxx/ 850.900.xxx**

Product Application: **For Research Use Only**

Manufacturer:

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Section 2 – Hazard Identification

2.1 Classification of the substance or Mixture according to (EC) No 1272/2008

Skin Sens.1 - Eye Irrit.2 - Repr.1B

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008:

Hazard pictograms:



GHS07

GHS08

Signal word: Danger

Hazard statements:

H317: May cause an allergic skin reaction
 H319: Causes serious eye irritation
 H360: May damage fertility or the unborn child

Precautionary Statements:

P201: Obtain special instructions before use.
 P202: Do not handle until all safety precautions have been read and understood.
 P261: Avoid breathing dust/fume/gas/mist/vapors/spray.
 P264: Wash hands thoroughly after handling.
 P272: Contaminated work clothing should not be allowed out of the workplace.
 P280: Wear protective gloves/protective clothing/eye protection/face protection
 P281: Use personal protective equipment as required.

**Response:**

P302+352: IF ON SKIN: Wash with plenty of water.
 P333+313: If skin irritation or rash occurs: Get medical advice/attention.
 P363: Wash contaminated clothing before reuse.
 P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P337+313: If eye irritation persists: Get medical advice/attention.
 P308+313: IF exposed or concerned: Get medical advice/attention.
 P405: Store locked up.
 P501: Dispose of contents/container to a hazardous waste collection point or special requirements in accordance with local regulation.

Section 3 –Composition / Information on Ingredients

3.2 Mixtures

Component	Contains	Identification	Classification	Hazard class Pictograms (pure ingredient)	% weight	Hazard Statements
Coated Microwell strips	-	-	-	NA	-	NA
Standards	-	-	-	NA	-	NA
Biotinylated Antibody	ProClin 300	CAS : - EC : 932-593-5	H302 Cat 4 H312 Cat 4 H314 Cat 1A H317 Cat 1 H332 Cat 4 H411Cat 2	GHS06 GHS05 GHS09	0.1%	H317 Cat 1
Streptavidin- HRP					0.001%	
Standard diluent Serum					0.5%	
HRP Diluent					0.1%	
Standard diluent Buffer 10X	NaN ₃	CAS : 26628-22-8 EC : 247-852-1	H300 Cat 2 H400 Cat 1 H410 Cat 1 EUH032	GHS06 GHS09	0.09%	Not Hazardous at this concentration
Biotinylated Antibody Diluent						
Wash Buffer	-	-	-	NA	-	NA
Amplifier	Sodium tetraborate decahydrate	CAS : 1303-96-4 EC : 215-540-4	H360FD Cat 1B	GHS08	< 1.9%	Not Hazardous at this concentration
Amplifier Diluent	Hydrogen peroxyde	CAS : 7722-84-1 EC : 231-765-0	H271 Cat 1 H332 Cat 4 H302 Cat 4 H314 Cat 1A	GHS03 GHS05 GHS07	< 0.01%	Not Hazardous at this concentration
TMB Substrate	2-Pyrrolidinone	CAS : 616-45-5 EC : 210-483-1	H319 Cat 2 H360 Cat 1B	GHS08	The exact percentage has been withheld as a trade secret	H319 Cat 2 H360 Cat 1B
	Urea hydrogen peroxide	CAS : 124-43-6 EC : 204-701-4	H272 Cat 3 H314 Cat 1B H318 Cat 1	GHS03 GHS05	<0.5 %	
Stop Reagent	Sulfuric Acid	CAS : 7664-93-9 EC : 231-639-5	H314 Cat 1A	GHS05	4.2%	Not Hazardous at this concentration

For the full text of the H-Statements mentioned in this Section, see Section 16.

Additional information

The data and advice relate to the concentrations not of the lyophilized powder, but of the prepared solution.

Section 4 - First Aid Measures

4.1 Description of first aid measures

General information: Consult a doctor if necessary and provide this SDS.

After inhalation: remove victim to fresh air and keep at rest in a position comfortable for breathing. Consult doctor or poison center if irritation or symptoms persist.

After skin contact: Remove contaminated clothing. Rinse with plenty of water and soap.

After eye contact: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. If eye irritation persists get medical advice/attention.

After ingestion: Call a poison center. Rinse mouth thoroughly

4.2 Most important symptoms or effects

TMB substrate may cause:

- Irritation to respiratory system if inhaled.
- Skin or eye irritation if contact
- Ingestion may cause nausea and vomiting. May damage fertility or the unborn child

Section 5 – Fire Fighting Measures

Suitable extinguishing agents: CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Specific hazards due to combustion products: Do not breathe fumes. Smoke from fires is toxic. Take precautions to protect personnel from exposure. Decomposition products may include carbon oxides.

Protective equipment for firefighters: Wear chemical protection suit and positive-pressure breathing apparatus. Wear protective clothing.

Section 6 – Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Wear respiratory protection. Ensure adequate ventilation. Avoid prolonged or repeated exposure.

Measures for environmental protections: Do not allow to enter sewers / surface or ground water.

Measures for cleaning / collecting: Soak up with inert absorbent material and dispose of as hazardous waste. Avoid splashing.

Section 7 – Handling and storage

7.1 Handling

Information for safe handling: wash parts of the body in contact with substance thoroughly after handling; wear protective gloves and/or clothing, and eye and/or face protection. Avoid breathing dust, vapour, mist or gas. Avoid contact with eyes, skin and clothing. Take off contaminated clothing and wash before reuse. Keep container tightly closed. Use with adequate ventilation. Avoid release to the environment.

Information about fire - and explosion protection:

No data available

7.2 Storage

Requirement to be met by storerooms and receptacles: Store in a cool, dry, well ventilated area away from incompatible substances. Keep away from metal ions.

Storage class: Store product and all components at 2-8°C. Store TMB substrate locked up.

Section 8 – Exposure Controls / Personal Protection

8.1 Control of exposition

2-pyrrolidone (pure ingredient):

Inhalation exposure:

Systemic effects: long term (DNEL) 29.62 mg/m³ developmental toxicity/teratogenicity

Dermal exposure:

Systemic effects: long term (DNEL) 4.2 mg/kg bw/day developmental toxicity/ teratogenicity

8.2 Personal protective equipment

General protective and hygienic measures: The usual precautionary measures are to be adhered to when handling chemicals.

Respiratory protection: Wear respiratory protection or use in a chemical hood.

Hand protection: Wear protective gloves.

Eye protection: Wear eye or face protection

Skin and body protection: Wear suitable protective clothing

8.3 Environmental exposure controls

No data available

Section 9 - Physical and Chemical Properties

Form: Liquid

Colour:

Components	Ingredients	Colour
Biotinylated Antibody	ProClin 300 (0.1%)	Colourless
Standard diluent Buffer	NaN ₃ (0.09%)	Red
Standard diluent Serum	ProClin 300 (0.5%)	Opaque Yellow
Biotinylated Antibody Diluent	NaN ₃ (0.09%)	Blue
Streptavidin-HRP	ProClin 300 (0.001%)	Clear amber
HRP Diluent	ProClin 300 (0.1%)	Green
Amplifier	Sodium Tetraborate decahydrate (<1.9%)	Colourless
Amplifier Diluent	Hydrogen peroxyde (< 0.01%)	Colourless
TMB Substrate	Not communicated (<5%)	Colourless
Stop reagent	Sulfuric Acid (4.2%)	Colourless

Odour: Odourless

pH: N/A

Melting point/Melting range: N/A

Boiling point/Boiling range: N/A

Flash point: N/A

Evaporation rate: N/A

Autoignition temperature: N/A

Danger of explosion: Product does not present an explosion hazard

Density: N/A

Viscosity: N/A

Solubility in / Miscibility with water: Fully miscible

Section 10 - Stability and Reactivity

10.1 Reactivity

No available data

10.2 Chemical stability

Thermal decomposition: No decomposition if used according to specifications.

Light: TMB tinge in blue under light exposition.

10.3 Others

Hazardous reactions:

Sulfuric acid: produces hydrogen when contact of metals.

Reagents containing NaN₃: Toxic fumes when contact with acid.

Incompatibilities:

Sulfuric acid: with strong bases, alkali metals, organic materials, organic solvents, peroxides, permanganates, hydrides, phosphorus and phosphorous oxides.

Streptavidin-HRP: strong oxidising agents.

Reagents containing NaN_3 : acid, metal, acid chloride.

Reagents containing Proclin 300: strong oxidising or reducing materials, amines.

Reagent containing Sodium tetraborate decahydrate: strong oxidising or reducing materials.

Reagent containing H_2O_2 : zinc, powdered metals, copper, nickel, brass, iron and iron salts.

TMB: with some common metals ions (such as iron).

Hazardous decomposition products:

Sulfuric acid: Toxic fumes of oxides of sulphur when heated. Reacts with carbonates to generate carbon dioxide gas, and with cyanide and sulfides to form poisonous hydrogen cyanide and hydrogen sulphide respectively. (concentrated Sulfuric Acid).

TMB: Decomposition products may include carbon oxides.

Section 11 - Toxicological Information

Acute toxicity: No data available

Skin corrosion/irritation: May cause an allergic skin reaction

Eye damage/irritation: May cause serious eye irritation

Respiratory or skin sensitization: Harmful if inhaled, swallowed or absorbed through the skin.

Germ cell mutagenicity: TMB possibly mutagenic, not proved

Carcinogenicity: No component of this product presents at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity: Toxic for reproduction category 1. May damage fertility or the unborn child

Specific Target Organ Toxicity – single exposure: May cause allergy or asthma symptoms or breathing difficulties if inhaled. Acute poisoning may cause gastrointestinal irritation and renal failure.

Specific Target Organ Toxicity – repeated exposure: Chronic ingestion may result in salicylism which is characterized by nausea, vomiting, gastrointestinal ulcers, and hemorrhagic strokes. Laboratory experiments have shown some mutagenic effects. Target organs: Kidneys and central nervous system.

Section 12 – Ecological Information

Toxicity: No data available

Persistence and degradability: Not available

Bioaccumulative potential: Not available

Mobility in soil: Not available

Results of PBT and vPvB: Not available

Others harmful effects: Hazardous for water

Section 13 – Disposal Considerations

Waste disposal: dispose of in accordance with local official environmental regulations.
Do not reuse or refill this container

Section 14 – Transport Information

This product does not require a classification for transport.

Section 15 – Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture
No data available.

Chemical safety assessment

No data available

Section 16 – Other Information

This document is writing in accordance to Regulation (EC) No 1272/2008 and commission Regulation (EU) 2020/878.

Revision:

This document differs from the previous version:

- 2- Hazard identification
- 3- Composition/information
- 4- First Aid Measures
- 6- Accidental Release Measures
- 7- Safe handling
- 8- Control of exposition
- 11- Toxicological information
- 12- Ecological information
- 15- Regulatory Information

Abbreviations:

CAS: Chemical Abstracts Service

CLP: Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures

IARC: International Agency for Research on Cancer

PBT: Persistent, Bioaccumulativ, Toxic

vPvB: very Persistent, very Bioaccumulativ.

REACH: Registration, Evaluation, Authorization and restriction of CHemicals

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

Full text of any Hazard statements under Section 3:

H271: May cause fire or explosion; strong oxidizer

H272: May intensify fire; oxidizer

H300: Fatal if swallowed

H302: Harmful if swallowed

H312: Harmful in contact with skin

H314: Causes severe skin burns and eye damage

H317: May cause an allergic skin reaction

H318: Causes serious eye damage

H319: Causes serious eye irritation

H332: Harmful if inhaled

H360: May damage fertility or the unborn child

H360FD: May damage fertility; May damage the unborn child

H400: Very toxic to aquatic life

H410: Very toxic to aquatic life with long lasting effects

H411: Toxic to aquatic life with long lasting effects

EUH032: Contact with acids liberates very toxic gaz

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. DIACLONE SAS shall not be liable for any damages resulting from handling or from contact with the above products.