

Material Safety Data Sheet

1. Product Identification

Identification of the products: IMUCLONE® Annexin V
Product no.: ADG650

Manufacturer:

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Application / Intended use

It must be used according strictly to the instructions of package insert, and for the indicated purpose.

2. HEALTH HAZARDS IDENTIFICATION

All the above listed chemicals or biologicals may be harmful by inhalation, ingestion, or skin adsorption. Nasal irritation, eye reddening, and allergic reactions may result from overexposure.

TMB has possible mutagenic effects on experimental animals (mice).

Viral Safety: Purified human factors are extracted from human plasma, which has been tested for HIV Antibodies, HBsAg and HCV Antibodies, with registered methods. BSA and purified bovine factors were prepared from bovine plasma; which was tested for the absence of infectious agents, and collected from animals free from BSE. However, no biological test may totally exclude the presence of any infectious agent. All biological material should be treated as potentially hazardous and the appropriate handling and disposal procedures must be adhered to.

Miscellaneous: Handle the aluminium pouch containing the plate with great care, when open, the aluminium pouch can cut or damage fingers. Take all required cautions.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Reagents	Chemical compounds	CAS N°	% or weight	Classification	LD50 (oral) rat
Plate	Dessicant	NA	3 g	NA	NA
	Plate Polystyrene	NA	NA	NA	NA
	Aluminium pouch	N	NA	NA	NA
Sample Diluent	Sodium H phosphate	13472-35-0	< 50%	NA	8,29 g/Kg
	Sodium chloride	7647-14-5	< 50%	NA	3 g/Kg
	BSA	NA	< 50%	NA	NA
	Tween 20	9005-64-5	< 20%	NA	38, 9 g/kg
	Kathon CG	26172-55-4	< 20 %	R22-R34-R43-S26-S36/37/39-S45	862 mg/kg
	PAB	2682-20-4		R21/22-R23-R34-R42/43-R43-R53	
	Ciprofloxacin	555-06-6	< 20 %	R36/37/38 S26-36	2760 mg/kg
Annexin V Calibrator	Rh-Annexin V	85721-33-1	< 10%	NA	NA
	Glycine	56-40-6	< 50%	NA	7,9g/kg
	Ciprofloxacin	85721-33-1	< 10%	NA	NA
Plasma Control I & II (UTA)	Human plasma	NA	< 75%	NA	NA
	Glycine	56-40-6	< 50%	NA	7,9g/kg
	Ciprofloxacin	85721-33-1	< 10%	NA	NA
Immunoconjugate	MoAbs	NA	< 10 %	NA	NA
	Peroxydase	9003-99-0	< 10 %	R42/43 S22-S24-S37-S45	NA
	BSA	NA	< 75 %	NA	NA
	Sodium H phosphate	13472-35-0	< 50 %	NA	8,29 g/kg
Wash Solution	Sodium H phosphate	13472-35-0	< 30%	NA	8,29 g/kg
	Sodium chloride	7647-14-5	< 75 %	NA	3 g/Kg
	Tween 20	9005-69-5	< 20%	NA	38,9 g/kg
	Kathon CG	26172-55-4	< 20%	R22-R34-R43-S26-S36/37/39-S45	862 mg/kg
	PAB	2682-20-4		R21/22-R23-R34-R42/43-R43-R53	
	Ciprofloxacin	85721-33-1	< 10%	NA	NA
Conjugate Diluent	Sodium H phosphate	13472-35-0	< 50%	NA	8,29 g/kg
	Sodium chloride	7647-14-5	< 50%	NA	3 g/Kg
	BSA	NA	< 50%	NA	NA
	Tween 20	9005-64-5	< 20%	NA	38, 9 g/kg
	Kathon CG	26172-55-4	< 20 %	R22-R34-R43-S26-S36/37/39-S45	862 mg/kg
	PAB	2682-20-4		R21/22-R23-R34-R42/43-R43-R53	
Substrate	TMB	54827-17-7	< 10%	R36/37/38/ S26-36	NA
Sulfuric acid	Sulfuric acid H2SO4	7664-93-9	< 10%	R35 S-26-30-45	2.14 g/Kg

4. FIRST AID MEASURES

-If swallowed, wash out mouth with water provided person is conscious. Medical advice is necessary.

-In case of contact with eyes, flush with copious amounts of water, for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Seek medical advice.

-In case of inhalation, remove victim to fresh air, and seek medical advice.

-In any case of overexposure, call a physician.

-In case of contact, inhalation or ingestion of any of the components of the kit (especially TMB or sulphuric acid), seek immediately medical attention. If the victim is conscious, in case of ingestion, drink several glasses of water (or milk), to dilute contents of stomach. Do not induce vomiting.

5. FIRE AND EXPLOSION HAZARDS DATA

Flammability: Solutions are aqueous and non-flammable. Only carton boxes, dry chemical, interiors inserts are flammable.

Extinguishing media: carbon dioxide, dry chemical powder or appropriate foam.

Special fire fighting procedures: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin.

6. SPILL, LEAK AND DISPOSAL PROCEDURES

Sweep up, place in a bag and hold for waste material. Avoid raising dust. Ventilate area and wash spill site after material pickup is complete. Do not empty into drains or sinks. Comply with all federal, state and local environmental regulations on waste handling and disposal.

7. CAUTIONS TO BE TAKEN IN HANDLING AND STORAGE

Must be used only by suitable trained and informed personnel. Wear chemical resistant gloves, chemical safety goggles and protective laboratory clothing.

8. EXPOSURE CONTROLS, PERSONAL PROTECTION

Personal Protective Equipment

Eyes: Wear chemical splash goggles

Skin: Wear appropriate protective gloves to prevent skin exposure

Clothing: Wear appropriate protective clothing to prevent skin exposure.

9. PHYSICAL AND CHEMICAL PROPERTIES

Annexin V calibrator, Control I & II and immunoconjugate of the kit are lyophilized powder. Plate is a stabilized coated plate.

Sample Diluent, Conjugate Diluent, Wash Solution, TMB and Sulfuric Acid are stable liquid solutions.

Excepted for TMB substrate and sulfuric acid, they do not present any specific physical or chemical reactivity, and are stable compounds. The specific cautions for handling TMB substrate and sulfuric acid, and their chemical reactivities, are specifically outpointed in paragraph 10.

10. STABILITY AND REACTIVITY

Stability: Stable

Hazardous combustion or decomposition products: Carbon monoxide, carbon dioxide, nitrogen oxide.

Hazardous polymerisation: Does not occur.

TMB: When heated to dryness, the product may form hazardous decomposition products.

Sulfuric Acid : May cause strong oxidation reaction with reducing (possible cause of ignition) ; toxic fumes or oxides of sulphur will result ; will react with carbonates to generate carbon dioxide gas, and with cyanides and sulphides to generate poisonous hydrogen cyanide and hydrogen sulphides respectively.

11. TOXICOLOGICAL INFORMATION

All the components of the kit are intended for in vitro use only, by experienced and suitably trained personnel. There is no special risk when used in these conditions. Products may be toxic following skin or eye contact, inhalation or ingestion. For toxicity of components, refer to chapters 2 and 3.

12. ECOLOGICAL INFORMATION

Do not empty reagents into waters or drains. Comply with state and local environmental regulations. Usually wasted biological material is stocked in hermetic specific containers for incineration by specialized companies. TMB is not readily biodegradable, and is suspected to accumulate. TMB is toxic to aqueous organisms, and may cause long term adverse effects in the aquatic environment.

13. WASTE DISPOSAL CONSIDERATIONS

Any waste product or reagent must be discarded according to local considerations.

Do not reuse vials or containers.

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"Biohazard" risk is mentioned on the box

14. TRANSPORT AND STORAGE INFORMATION

The reagent must be shipped adequately packaged and protected from any break during transportation.

It can be shipped at ambient temperature for a short period, not exceeding 7 days. It must be stored in a cold room at 2-8°C upon receipt. No special regulation for transporting this product.

General rules for in vitro use should apply.

Local, State and Federal regulations for this kind of product must be respected. The kits must be stored in an appropriate refrigerated area, specifically dedicated for in vitro use kits.

All the storage constraints are indicated on the package labels and on the kits insert.

15. REGULATORY INFORMATION

These reagents are designed, manufactured, controlled and followed according to the quality management system (based on ISO 9001 and ISO 13485) developed by HYPHEN BioMed.

Risk analysis has been performed and reduced to the lowest level available from the present knowledge.

16. OTHER INFORMATION

For in vitro research use only.

Revision were made in sections: All / Uniformisation

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