



1. Identification Of The Substance / Preparation & Of The Company / Undertaking

Identification of the product: Daratumumab ELISA Kit (Catalog No: KBI1028)

1. Anti-Daratumumab Coated Microtiter Plate (12x8 wells) – 1 no
2. Daratumumab Standard, (0.5 ml/vial) – 0, 10, 20, 40, 80, 160, 320 and 640 ng/ml
3. Anti-Daratumumab:HRP Conjugate – 12 ml
4. Sample Diluent – 50 ml
5. Wash Buffer (20X) – 25 ml
6. TMB Substrate – 12 ml
7. Stop Solution – 12 ml
8. Instruction Manual

Use of the Product: For Research Use Only. The test is a rapid and easy method for the quantitative determination of Daratumumab in human serum, plasma and cell culture supernatant.

Company / Undertaking: EAGLE BIOSCIENCES

Identification:

20A NW Blvd, Suite 112, Nashua, NH 03063 USA

617-419-2019

info@eaglebio.com

Emergency: 911

2. Hazards Identification

Health: The product is not judged to be hazardous to health, although it may cause sensitization by skin contact. May have a slight irritating effect on skin and eye contact as well as by inhalation- see further section 11.

Environment: The product is not judged to be dangerous for the environment but the product contains very small amounts of a substance very toxic to the aquatic organisms and may cause long-term adverse effects in the aquatic environment.

Fire: The product is not classified as flammable.

3. Composition / Information on Ingredients

Water based buffers containing the following hazardous substance (-s):

Hazardous ingredients:	CAS-No	EC-No	Conc %	Symbol	Risk-phrases
Tris-(hydroxymethyl)-aminomethane	77-86-1	201-064-4	1-5	Xi	R36/38
Tris-(hydroxymethyl)Aminomethane hydrochloride salt	1185-53-1	214-684-5	1-5	Xi	R36/37/38
Sulphuric acid	7664-93-9	231-639-5	1-5	C	R35

1) Hazardous components are 5-chloro-2-methyl-2H-isothiazol-3-one (EG-nr 247-500-7) and 2-methyl-2H-isothiazol-3-one (EG-nr 220-239-6) as a 3:1 mixture, CAS No 55965-84-9

2) See further description in section 16

Risk Phrases Interpretation -

R 22 = Harmful if swallowed

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R 23/24/25	= Toxic by inhalation, contact with skin and if swallowed
R 34	= Causes burns
R 35	= Causes severe burns
R 36/37/38	= Irritating to eyes, respiratory system and skin
R 36/38	= Irritating to eyes and skin
R 43	= May cause sensitization by skin contact
R 50/53	= Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic Environment

4. First Aid Measures

Inhalation: Breathe fresh air and rest. If breathing is difficult, give oxygen.

Skin contact: Remove contaminated clothing. Wash the affected area with soap and water.

Eye contact: Rinse immediately with copious amount of water for at least 15 minutes with the eyelid held wide open. Consult a doctor if symptoms persist.

Ingestion: Rinse mouth and throat with water. Consult a doctor if symptoms persist. Never give anything to drink / eat to an unconscious person.

Information to physician:

5. Fire-Fighting Measures

Extinguishing media:

Specific hazards:

Protective equipment for fire fighters:

The product will not burn. The choice of extinguishing media depends on the surroundings, preferably water spray, carbon dioxide, powder or foam. Remove if possible adjacent containers or keep cool by spraying with water in case of heat / fire, harmful oxides may evolve.

Suitable protective equipment:

Self-contained breathing apparatus may be needed in confined spaces.

6. Accidental Release Measures

Personal precautions: See "Handling", section 7 and "personal protection" section 8.

Environmental precautions: No special precaution is necessary, although discharge in sewerage systems, surface and ground water should be prevented.

Methods for cleaning up: Clean up with absorbent paper and dispose of in a sealed container according to current waste regulations, see section 13.

Remarks:-

7. Handling & Storage

Handling: Ensure good ventilation. Direct physical contact with all components in this product should be avoided and avoid ingestion.

Storage: Keep container tightly closed and in a cool place. Keep from freezing. Protect from light.

Specific use (-s): -

8. Exposure Control / Personal Protection

Exposure limit values: Exists for the following substances:

Occupational exposure Limits: (acc. to EH40/2002 Occupational Exposure Limits incl. Supplement 2003)

Substance (Unit)		ppm mg/m ³
Sulphuric acid	-	1
Butylated hydroxytoluene	-	10

OEL*

*long-term exposure limit (8 hours TWA)

Note: -

Exposure controls: Ensure good ventilation. Avoid, if possible, direct contact with the product. An emergency shower and/or an eye bath should be available in the workplace.

Occupational exposure controls:

Respiratory protection: Not normally necessarily. If any, respiratory protective equipment suitable for the specific conditions may be used.

Hand protection: Chemical resistant gloves (butyl rubber, PE or PVC) may be used if risk of direct contact may occur.

Eye protection: Use chemical safety goggles where splashing is possible

Skin protection: Laboratory coat.

Other: Not relevant

Environmental exposure controls: None known.

9. Physical & Chemical Properties

Appearance: B), C), D), F), G), H), I) and J) Liquid, A), E), K) and L) Solid

Color: B), F), G) and H)

Colorless C)Blue D), E) J) K) and L)Yellow and I)Red.

Odor: Odorless

Relative Density (g/cm³) B), C), D), E), F), G), I), J), K) and L) 1,0 and H)1,1

Flash Point (°C) N.A. = Not Applicable

Boiling Point (°C) N.A

Ignition temperature (°C) appr. 100

Explosive Limits (vol%): N.A

Solubility in Water: Soluble

pH: B), C), D), E) G), I), J), K)and L) appr. 7 F)appr. 3,3 and H)appr. 0,5

10. Stability & Reactivity

Stability: Stable under normal conditions.

Conditions to avoid: None known

Materials to avoid: None known

Hazardous decomposition Products: Insufficient combustion may form harmful oxides such as sulphur oxides, carbon oxides, nitrogen oxides, chloro oxides, phospho oxides etc.

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11. Toxicological Information

General: Data is lacking on the product.

Inhalation: The product is not judged to be hazardous to health.

Skin contact: It might have a slight irritating effect on skin contact.

Eye contact: Certain risk for severe eye damages cannot entirely be excluded. The product is also judged on the basis of content, as possible risk for skin sensitization.

Ingestion: Relatively harmless.

Others: Certain mild irritation may occur in the respiratory systems. May cause mild irritation. Certain risk for an allergic reaction may occur. Splash and steam may cause mild pain and irritation. Certain risk for severe eye damages can not entirely be excluded. Certain risk for mild irritation in mucous membranes in stomach and intestine may occur. May be harmful if ingested in quantity.

Sulphuric acid 96 %:LD50(oral, rat) 2.140 mg/kg

The product is diluted. The content of hazardous component is small. A minor irritating effect still remains, in spite of the dilution. The content of Kathon CG cause the product its classification as a skin sensitizer.

12. Ecological Information

Ecotoxicity: Data is lacking on the product. Is judged to be of low toxicity to aquatic organism.

Mobility: None known.

Persistence and degradability: Data is lacking. The product is soluble in water. Data is lacking. The product contains mainly of water. For the inorganic substances, existing in very small amount, there are no criteria for biodegradability.

Bioaccumulative potential: Data is lacking. The product is judged not to be potential bioaccumulated.

Other adverse effects: The organic part is judged to be easily biodegradable.

Note! The product contains a small amount of a complex binder (EDTA) in the amount of 1,5 % which slowly biodegrades in the nature.

Remarks:

Relevant data of analysis on the product is lacking. The information given above is based on knowledge of the ecotoxicology of the components. The product is judged neither to be dangerous for the environment, nor to cause long-term adverse effects in the aquatic environment. The low pH might harm the aquatic organisms.

13. Disposal Considerations

The product: Discarded product (incl. Contaminated packaging) and related waste is not hazardous waste acc. to current waste legislation. For disposal contact approved waste Management Company. Requirements for certain permission exists - see current waste legislation.

Propose EWC-code: 18 01 07 Wastes from natural care, diagnosis, treatment or prevention of disease in humans, chemicals other than those mentioned in 18 01 06.

Emptied packaging: Glass bottles exclusive of lids and fiberboard boxes may be send to material recycling - see "Emptying instruction" below.

Emptying instruction: Glass bottles emptied well, made free of drip and handed over to glass recycling while fiberboard boxes are handed over to relevant material recycling.

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14. Transport Information

The product is not classified as Dangerous Goods according to current transport legislation (ADR/RID, DGR and IMDG code) as per IATA.

15. Regulatory Information

(According to 2001/58/EC)

Classification and Labeling: The product is not classified as health- and/or environmentally hazardous according to current legislation.

Other national regulations: Relevant Workplace legislation due to the Occupational Exposure Limit

16. Other Information

The above information is believed to be correct and may not be all conclusive; however, it should only be used as a guide. Eagle Biosciences shall not be held liable for any damage resulting from handling or contact with this above product.