

Material Safety Datasheet for Monoclonal Antibodies (SAF0002_D) (Unconjugated and conjugated)

Please note:

The substance/mixture supplied is **not** classified as hazardous.
The delivery of a Safety Data Sheet is **not** a mandatory requirement under REACH.

1. Identification of the substance//mixture and of the company/undertaking

1.1 Product Identifier: Monoclonal antibodies, unconjugated or conjugated

Product Group Code: Various (AF....., AM....., BM....., CL....., DM....., DRM....., PM....., SM.....)

1.2 Relevant identified uses of the substance or mixture

Used as a component in immunological reactions

1.3 SupplierDetails of the supplier of the safety data sheet

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2. Hazards identification

The following safety datasheet identifies the hazards related to the monoclonal antibody product, and constituent chemicals in undiluted form that make up the buffer. Where the ingredients are used in a diluted form the risk of harm being caused by certain ingredients during handling of this product may be reduced compared with the undiluted ingredient. However, the hazards are still present and users should handle the product with care accordingly. This assessment should be used as a guide only and does not represent an all inclusive study of the product.

This product contains material of animal origin (from cell cultures), as specified on product datasheet, and should be handled as a potential biohazard. As with all biological material, reduce direct handling to a minimum and wear appropriate protective clothing.

A chemical hazard may be associated with this product where a preservative has been added (see individual product datasheet for information and refer to guidance below).

3. Composition/ Information on ingredients

This product contains monoclonal antibodies of animal origin (as specified on the product datasheet), mostly in buffered solution.

Bovine serum albumin (BSA) is added to some purified monoclonal antibodies, and a chemical preservative is also usually added (see individual product datasheet for information and refer to guidance below).

Where a monoclonal antibody is conjugated refer to specific hazard data below (16. "Additional notes regarding monoclonal antibody conjugates").

Buffers

All constituents of the buffers in which monoclonal antibodies are supplied contain chemicals designated as non-regulated (NR) by BDH Hazard Class System that corresponds to UN Hazard Classification.

Bovine Serum Albumin (BSA) (CAS No. 9048-46-8) is added to some purified monoclonal antibody preparations as a preservative/stabilizing agent - usually at a level of 1% w/v. Eye contact may cause transient eye irritation. Ingestion may cause allergic reaction characterized by a rash. Low hazard for industrial handling.

Preservatives:

Sodium azide (NaN₃, CAS No.: 26628-22-8) - Most monoclonal antibodies contain sodium azide as a preservative at a maximum level of 0.09% w/v (see individual product datasheet).

Sodium azide is highly toxic if swallowed (R28): Causes irritation of mouth, pharynx, gullet and gastro-intestinal tract.

Health warning:

Skin:	Causes skin irritation. May be fatal if absorbed through the skin.
Eye:	Causes eye irritation.
Inhalation:	Mucosal irritation, cough, dyspnea, pulmonary edema after lag time.

Sensitizing effects: Not known.

Additional toxicological advice:

Systemic effects:	Disorders of CNS, circulatory failure, low blood pressure, cough, dyspnea, spasms, headache, dizziness, nausea, vomiting, collapse, unconsciousness.
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Stability and Reactivity:

Thermal decomposition: > 275°C (527 deg F).

Conditions to avoid: Humidity; Contact with water, acids, heavy metals (lead, copper), metal salts, bromine, methylene chloride, carbon disulfide, sulfuric acid, halogenated hydrocarbons.

Hazardous reactions: May liberate toxic gas.

Hazardous decomposition products: Nitrous gas.

Thiomersal - Also referred to as Thimerosal (SIGMA) and Merthiolate (Eli Lilly and Co)

Some monoclonal antibody products (eg peroxidase conjugates) contain thiomersal as a preservative at a level of 0.01% w/v; see individual product datasheet.

Thiomersal is a toxic substance and an irritant to eyes and skin. Avoid ingestion or contact with skin and eyes.

Wear appropriate protective clothing.

Bronidox - Bronidox is suitable for use in surface cosmetics which do not remain in contact with the skin including child shampoos and cleansing creams and that the toxicological risk associated with this chemical is low. It is advised that direct contact of the concentrated chemical with the skin and mucous membrane should be avoided. The level present in our products is usually 0.02% w/v.

'Stabilzyme' HRP Conjugate Stabiliser - Some peroxidase conjugates are supplied in the aqueous 'Stabilzyme' HRP Conjugate Stabiliser - Though complete toxicity information on 'Stabilzyme' HRP Conjugate Stabiliser is not available, none of its components are known to be toxic or hazardous at use concentrations. 'Stabilzyme' contains three preservatives: ProClin 300 (20 ppm), methylisothiazolone (0.02%) and bromonitrodioxane (0.02%), all of which can produce adverse health effects in their concentrated form. Undiluted ProClin 300 can cause eye damage, skin burns and allergic skin reaction.

For more specific toxicity data refer to supplier safety data on these components from Boehringer Mannheim Corporation and Rohm and Haas respectively.

4. First-aid measures

Skin	In case of contact dab off with absorbent cloth and wash off skin thoroughly with soap and water. If discomfort persists obtain medical attention.
Lungs	If inhaled, remove from exposure, rest and keep warm. Seek medical attention.
Mouth	If ingested, wash out mouth thoroughly with water and give plenty of water to drink. DO NOT induce vomiting. Obtain medical.
Eyes	Flush eyes with plenty of water for at least 10 minutes, occasionally lifting the upper and lower eyelids. Get medical help.

5. Fire fighting measures

Suitable extinguishing media: Water (Attention for sodium azide: do not use water directly on fire), dry chemical powder, appropriate foam, carbon dioxide (CO₂).

Hazardous combustion products: 'Stabilzyme' HRP Conjugate Stabiliser emits toxic fumes in fire.

6. Accidental release measures

Wear appropriate protective clothing! Mop up with absorbent cloth. Wash site of spillage thoroughly with water and detergent. Dispose cloth in accordance with local disposal guidelines.

7. Handling and storage

Store monoclonal antibody as directed on individual product datasheet.

8. Exposure controls / personal protection

Gloves: Rubber or plastic

Eye protection: Use goggles or face shield.

Other protection: Use long sleeved laboratory coat.

9. Physical and chemical properties

Form: Monoclonal antibodies and their conjugates are supplied either as a liquid or lyophilized powder.

Colour: Unconjugated - colourless to pale yellow. (For conjugated products see "Additional notes regarding monoclonal antibody conjugates" (16.).

Odour: Almost odourless.

Solubility in water: Miscible in all proportions.

No further data available

10. Stability and reactivity

Stable under normal handling conditions.

11. Toxicological information

See information under "Preservatives". (3.)

12. Ecological information

Sodium azide and Proclin 300 contained are toxic to fish and wildlife and therefore should not be discharged where treated effluent will leak into lakes, streams and ponds or public water.

13. Disposal considerations

This product should be disposed of in accordance with local waste disposal authority guidelines or passed to a chemical disposal company.

14. Transport information

Observe storage requirements.

ICAO/IATA class: None

15. Regulatory information

For research and in vitro use only. Not for diagnostic or therapeutic work.

The information contained in this safety datasheet is believed to provide relevant information that will aid the safe handling and use of all these products and their related conjugates. However, it does not claim to be an all inclusive assessment and should be used as a guide only.

Please note that Safety Datasheets have been formulated in accordance with EU directives, without regard to national current chemical acts. Special national regulations must be observed by the user!

OriGene Technologies GmbH shall not be held liable for any damage resulting from contact with this product.

16. Additional notes regarding monoclonal antibody conjugates

Monoclonal antibodies may be found conjugated to the following labels and the hazard assessment for each label can be found below:

Fluorescein Isothiocyanate (FITC)

Hazard class: NR + UN NO / CAS No. 27072-45-3 in pure crystalline powder form.

Supplied as: Pale fluorescent green/yellow colour conjugate in solution.

Fluorescein isothiocyanate is present in conjugated products at very low levels (less than 0.002% w/v maximum) at 1 mg/ml concentration. There are no extra special requirements for product handling of fluorescein conjugates other than those already listed for unconjugated antibody.

Phycoerythrin (PE)

Hazard class: NR / CAS No. 11016-17-4. Non-hazardous phycobilliprotein extracted from seaweed.

Supplied as: Fluorescent pink colour conjugate in solution.

There are no extra special requirements for product handling.

Alkaline Phosphatase (AP)

Hazard class: NR / CAS No. 9001-78-9 in cream powder form.

Supplied as: Pale yellow colour conjugate in solution.

Alkaline phosphatase is present in the product at very low levels.

In concentrated powder form alkaline phosphatase may irritate eyes and cause allergic reactions in sensitive individuals therefore it is advisable to be aware of this information and avoid contact of these conjugates with eyes and skin and wear protective disposable gloves.

Horseradish peroxidase (HRP)

Hazard class: NR / CAS No. 9003-99-0

Supplied as: Pale brown colour conjugate in solution.

Horseradish peroxidase is present in conjugated products at very low levels. In powder form it is a possible irritant therefore it is advisable to be aware of this information and avoid contact of these conjugates with eyes and skin and wear protective disposable gloves.

Biotin

Hazard class: NR / CAS No. 58-85-5 as white crystalline powder form.

Supplied as: Colourless conjugate solution.

Biotin is present in conjugated products at very low levels. There are no extra special requirements for product handling.

Allophycocyanine (APC)

Supplied as: Lyophilized pale blue powder or blue conjugate solution.

APC is present in the conjugated product at very low levels (less than 0.1%).

Cy5 / PE-Cy5

Supplied as: Straw coloured conjugate solution.

The concentrated unconjugated Cy5 dye (CAS No. 146368-14-1) is a harmful irritant. Therefore, although PE-Cy5 is present in the conjugated product at very low levels, it is advisable to be aware of this information and avoid contact with skin, eyes and respiratory system, or by inhalation or ingestion.

Texas red™ (TR)

Supplied as: pale red conjugate solution.

Texas red (CAS No. 82345-19-6) is present in the conjugated product at very low levels.

In concentrated solid form, Texas red is toxic and a possible carcinogen, therefore although Texas red is present in the conjugated product at very low levels, it is advisable to be aware of this information, and avoid contact by inhalation, eyes, skin or ingestion and wear protective disposable gloves.

Reference

This document has been produced to provide health and safety information in accordance with:

Control of Substances Hazardous to Health Regulations (1999) COSHH, Personal Protective Equipment (PPE) Regulations (1992) and Management of Health and Safety at Work Regulations (1999).

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on Classification, Labelling and Packaging of substances and mixtures (CLP), amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

Material Safety Datasheets are available at www.acris-antibodies.com or on request.