

Safety data sheet

Human CD3/CD28 positive control (ELISPOT)

1. Identification of the product (substance or mixture) and supplier/company

1.1 Product identifiers

Product: Human CD3/CD28 positive control (ELISPOT)
Catalogue no.: CT372
Brand: U-CyTech biosciences
REACH no.: This product is a mixture. A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

1.2 Relevant identified uses of the product and uses advised against

Identified uses: Laboratory chemicals. To be used in U-CyTech ELISPOT systems.
For professional (R&D) use only, not for food, drug, household or other uses.

1.3 Details of the supplier of the safety data sheet

Supplier: U-CyTech biosciences
Yalelaan 42
3584 CM Utrecht
The Netherlands
Phone: +31 85 073 1460
E-mail: info@ucytech.com

1.4 Emergency telephone number

Contact your local emergency number.

2. Hazard identification

2.1 Classification of the substance or mixture

The product is not a hazardous substance or mixture according to Regulation (EC) no. 1272/2008 and its amendments.

2.2 Label elements

The product is not a hazardous substance or mixture according to Regulation (EC) no. 1272/2008 and its amendments.

2.3 Other hazards - none

3. Composition/information on ingredients

3.1 Substances

Product name: Human CD3/CD28 positive control (ELISPOT)

Synonyms: Pool of lyophilized monoclonal antibodies.

Ingredients - product is lyophilized, when reconstituted:

Cas no.	EC no.	Index no.	Classification	Concentration
Protein (antibodies)				
-	-	-	-	< 1% (v/v)
Trehalose, dihydrate (C₁₂H₂₂O₁₁ • 2H₂O)				
6138-23-4	202-739-6	-	-	< 5% (w/v)
Fetal Calf Serum (FCS)				
-	-	-	-	10% (v/v)
RPMI medium 1640				
-	-	-	-	> 85% (v/v)

No further components need to be disclosed according to the applicable regulations.

4. First aid measures

4.1 Description of first aid measures

General advice: Consult physician and show this SDS.

After contact with skin: Remove contaminated clothing and shoes. Wash contaminated area with water / shower.

After swallowing: If the person is conscious, rinse mouth with plenty of water and make the person drink water (two glasses at most). Consult a physician if not feeling well.

After contact with eyes: Rinse continuously with plenty of water for several minutes. Confirm adequate flushing by separating the eyelids. Remove contact lenses if present and easy to do - continue rinsing.

After inhalation: Provide fresh air. Not expected to be an inhalation hazard under anticipated conditions of normal use of this material. Consult a physician if necessary.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in section 2 and 11.

4.3 Indication of any immediate medical attention and special treatment needed

No further data available. Note to physician: treat symptomatically.

5. Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media: Water spray, foam, carbon dioxide (CO₂), dry powder.

Unsuitable extinguishing media: No limitations of extinguishing agents are given.

5.2 Special hazards arising from substance or mixture

No data available.

5.3 Advice for fire fighters

Stay in danger area only with self-contained breathing apparatus and protective clothing.

5.4 Further information

Prevent fire extinguishing water from contaminating surface water or the ground water system.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment to avoid exposure (section 8). Follow general safety rules for laboratories. Evacuate personnel to safe areas in case of an emergency.

6.2 Environmental precautions

Do not let product enter surface water, (sub)soil or drains. Prevent further leakage if safe to do so.

6.3 Methods and materials for containment and cleaning up

Cover drains. Contain spillage. Take up dry. Dispose of properly (section 13). Clean up affected area. Avoid generation of dust. Observe possible material restrictions (sections 7 and 10).

7. Handling and storage

7.1 Precautions for safe handling

Safe handling: For laboratory use only. Ensure adequate ventilation. Handle and open container with care. Always close container tightly after removal of product.

Hygiene measures: Follow general safety rules for laboratories. Wear personal protective equipment to avoid (prolonged or repeated) exposure (section 2.2 and 8). Immediately change contaminated clothing. Wash hands before breaks and after work.

7.2 Conditions for safe storage, including any incompatibilities

Safe storage: Store at 2-8°C, in dry and well-ventilated place. Keep container tightly closed.



7.3 Specific end use(s)

Use in laboratories.

8. Exposure controls/personal protection

8.1 Control parameters

This product does not contain substances above concentration limits fixing an occupational exposure limit.

8.2 Exposure controls

General protective and hygiene measures

Facilities storing or utilizing this product should be equipped with an eyewash facility, a safety shower and mechanical exhaust. Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of the workday. Immediately change contaminated clothing. Keep away from food and beverages.

Personal protective equipment

Eye protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN166 (EU). Use tightly fitting safety goggles.

Skin and body protection

Wear appropriate protective gloves and a lab coat to prevent skin exposure.

Protective gloves must satisfy the specifications of Regulation (EU) 2016/425 and the standard EN374 derived from it. Observe the instructions regarding permeability and breakthrough time which are provided by the suppliers of the gloves. Make sure the gloves are suitable for the task regarding chemical compatibility, dexterity, operational conditions and user susceptibility (e.g. sensation effects). Take also the specific local conditions under which the product is used into consideration (e.g. danger of cuts).

Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

This recommendation applies only to the product stated in this SDS and for the designed use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves.

Respiratory protection

Required when aerosols are generated, when workers are facing concentrations above the exposure limits or where risk assessment shows air-purifying respirators are appropriate.

Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

To protect the wearer, respiratory protective equipment must be the correct fit and be used and maintained properly.



Control of environmental expose

Do not let product enter drains.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

A. Appearance (at 20 °C):	Solid, clear (lyophilized).
B. Odor:	No data available.
C. Odor threshold:	No data available.
D. pH (at 20 °C):	No data available.
E. Melting/freezing point:	No data available.
F. Initial boiling and boiling range:	No data available.
G. Flash point:	No data available.
H. Evaporation rate:	No data available.
I. Flammability (solid, gas):	No data available.
J. Upper/lower flammability or explosive limits:	No data available.
K. Vapor pressure:	No data available.
L. Vapor density:	No data available.
M. Relative density:	No data available.
N. Solubility(ies):	Soluble in water.
O. Partition coefficient: n-octanol/water:	No data available.
P. Auto-ignition temperature:	No data available.
Q. Decomposition temperature:	No data available.
R. Viscosity:	No data available.
S. Explosive properties:	No data available.
T. Oxidizing properties:	No data available.

9.2 Other information

No additional information relevant to safe use of the product.

10. Stability and reactivity

10.1 Reactivity

No specific test data related to reactivity available for this product or its ingredients.

10.2 Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3 Possibility of hazardous reactions

No hazardous reaction when handled and stored according to recommended conditions of storage, use and temperature.

10.4 Conditions to avoid

No data available.

10.5 Incompatible materials

No data available.

10.6 Hazardous decomposition products

Does not decompose when used for intended uses (section 1.2).

11. Toxicological information

11.1 Information on toxicological effects

Product

Acute toxicity: No data available.
Skin corrosion/irritation: No data available.
Serous eye damage/irritation: No data available.
Respiratory/skin sensitization: No data available.
Germ cell mutagenicity: No data available.
Carcinogenicity: No data available.
Reproductive toxicity: No data available.
Specific target organ toxicity (single and repeated): No data available.
Aspiration hazard: No data available.

11.2 Additional information

Signs and symptoms of exposure:

To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Potential health effects:

Inhalation: May be harmful if inhaled and may cause respiratory tract irritation.

Skin: May be harmful if absorbed through skin and may cause skin irritation.

Eyes: May cause eye irritation.

Ingestion: May be harmful if swallowed.

Further hazardous properties cannot be excluded. The product should be handled with the care usual when dealing with chemicals.

Ingredients of Human CD3/CD28 positive control (section 3.1):

Protein (antibodies), Fetal Calf Serum and RPMI medium 1640:

Acute toxicity: There is no evidence available indicating acute toxicity.

Skin corrosion/irritation: No data available.

Serous eye damage/irritation: No data available.

Respiratory/skin sensitization: No data available.

Germ cell mutagenicity: No data available.

Carcinogenicity: No data available.

Reproductive toxicity: No data available.

Specific target organ toxicity (single and repeated): No data available.

Aspiration hazard: No data available.

U-CyTech B.V.
Yalelaan 42
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info@ucytech.com
www.ucytech.com

Trehalose, dihydrate:

Acute toxicity: LD50 oral - rat - male and female - >16,000 mg/kg.
Skin corrosion/irritation: Skin - rabbit: result: no skin irritation.
Serous eye damage/irritation: Eyes - rabbit: result: no eye irritation.
Respiratory/skin sensitization: Human - result: negative.
Germ cell mutagenicity: *In vitro* mammalian cell gene mutation test - Chinese hamster fibroblast - with and without metabolic activation - result: negative.
Mammalian bone marrow sister chromatid exchange - mouse - result: negative.
Carcinogenicity: No data available.
Reproductive toxicity: No data available.
Specific target organ toxicity (single and repeated): No data available.
Aspiration hazard: No data available.

12. Ecological information

Product

12.1 Toxicity: No data available.
12.2 Persistence and degradability: No data available.
12.3 Bio-accumulative potential: No data available.
12.4 Mobility in soil: No data available.
12.5 Results of PBT and vPvB assessment: No data available.
12.6 Other adverse effects: No data available.

Toxicity ingredient Trehalose, dihydrate:

Static test EC50 - Daphnia magna (water flea) - >100 mg/l - 48h
Static test ErC50 - Desmodesmus sunspicatus (green algae) - 30.41 mg/l - 72h

Biodegradability ingredient Trehalose, dihydrate:

Aerobic - exposure time 28d
Remarks: The 10 day time window criterion is not fulfilled. (anhydrous substance)

13. Disposal considerations

13.1 Waste treatment methods

Product: The generation of waste should be avoided or minimized wherever possible.
Waste material must be disposed in accordance with local, regional and national/federal regulations. Do not let product enter drains.

Packaging: Dispose of as unused product.

14. Transport information

14.1 UN number (ADR, RID, ADN, IMDG, IATA): Not applicable.
14.2 UN proper shipping name (ADR, RID, ADN, IMDG, IATA): Not dangerous.
14.3 Transport hazard class(es) (ADR, RID, ADN, IMDG, IATA): Not applicable.

- 14.4 Packing group (ADR, RID, ADN, IMDG, IATA):** Not applicable.
14.5 Environmental hazards: None.
14.6 Special precautions for user: Not applicable.
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code: Not applicable.

15. Regulatory information

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

Authorizations and/or restrictions on use: None.

German Water hazard class: No data available.

15.2 Chemical Safety Assessment

For this mixture a chemical safety assessment has not been carried out.

16. Other information

Reason for revision: Hazards identification.

Abbreviations and acronyms:

- ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
 ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
 CAS: Chemical Abstract Service
 CE: Conformité Européenne
 CEN: European Committee for Standardization
 CET: Central European Time
 EC: European Commission
 EC50: Effective concentration, 50%
 EC no: European Chemical number
 ErC50: Concentration with 50% reduction in growth rate
 EU: European Union
 IATA: International Air Transport Association
 IBC code: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in bulk
 ICE: Influenza A, Cytomegalovirus, Epstein-Barr virus
 IMDG: International Maritime Dangerous Goods
 LD50: Lethal dose, 50%
 Marpol: Marine Pollution
 M-factor: multiplication factor
 NIOSH: National Institute for Occupational Safety & Health
 No: Number
 PBS: Phosphate-buffered saline
 PBT: Persistent, bio-accumulative and toxic
 R&D: Research & Development
 REACH: Registration, Evaluation, Authorization and restriction of Chemicals
 RID: Regulations concerning the International Carriage of Dangerous Goods by Rail
 SDS: Safety data sheet

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UN: United Nations
US: United States
WGK: German Water Endangerment Class
vPvB: Very persistent and very bio-accumulative

Further information

The information provided in this SDS is to the best of our knowledge and present information. The information is described as a guidance for safe handling and is not considered a warranty or quality specification. The information is only applicable to the described products and may not be valid for such products used in combination with any other products, materials or in any process, unless specified in the text. U-CyTech B.V. shall not be held liable for any damage resulting from handling or from contact with the above products.

