



SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH), Annex II

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1 Product identifier**
Trade name D Dimer Controls
DM900A, DM900MA, DM901A, DM902A
Reference No. DM900X, DM900MX, DM901X, DM902X
- 1.2 Relevant identified uses of the substance or mixture and uses advised against**
Identified use(s) In vitro diagnostic reagent. For professional use only.
- 1.3 Details of the supplier of the safety data sheet**
Company Identification Techno-path Manufacturing Ltd
Fort Henry Business Park
Ballina
County Tipperary
Ireland
Telephone +353 (0) 61 525700
E-Mail (competent person) qcsupport@technopathcd.com
- 1.4 Emergency telephone number**
Emergency Phone No. +353 (0) 61 525700

SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture Regulation (EC) No. 1272/2008 (CLP)** Not classified as dangerous for supply/use.
- 2.2 Label elements** No measures required.
- 2.3 Other hazards** Contains materials of human origin.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.2 Mixtures**
Description: In vitro diagnostic reagent. Aqueous solution. Stabilised human serum with adjusted levels of defined analytes.
Dangerous components: The product does not contain reportable quantities of dangerous components.
- 3.3 Additional Information** Each donor unit used in the preparation of this material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV, and non-reactive for HBsAg.

SECTION 4: FIRST AID MEASURES



- 4.1 Description of first aid measures**



T E C H N O P A T H

SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH), Annex II

Inhalation	Supply fresh air; consult doctor in case of complaint.
Skin Contact	Wash skin with soap and water. Remove contaminated clothing.
Eye Contact	Rinse cautiously with water for several minutes. Consult a doctor in case of complaint.
Ingestion	Wash out mouth with water. Consult a doctor in case of complaint.
4.2 Most important symptoms and effects, both acute and delayed	None.
4.3 Indication of the immediate medical attention and special treatment needed	None.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media	Suitable Extinguishing Media	CO ₂ , powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
5.2 Special hazards arising from the substance or mixture		In case of fire, the following can be released: Carbon oxides (CO _x), nitrogen oxides (NO _x).
5.3 Advice for fire-fighters		Use fire-extinguishing methods suitable to surrounding conditions. Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures		Isolate spillage and clean up immediately. Refer to Section 8 for protective measures when handling the spillage.
6.2 Environmental precautions		Do not allow to enter drains, sewers or watercourses.
6.3 Methods and material for containment and cleaning up		Absorb with liquid-binding material (paper towelling, sand, diatomite, acid binders, universal binders, sawdust). Dispose of contaminated material as waste according to Section 13. Swab down area with Chlorox or other disinfecting agent.
6.4 Reference to other sections		8, 13

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling		This product should be handled as a potentially infectious material, as no known test method procedure can offer complete assurance that products derived from materials of human origin will not transmit infectious agents. Refer to Directive 2000/54/EC for information on handling biohazardous materials. Avoid contact with the eyes, skin and mucous membranes. Keep out of reach of children. Wash hands before breaks and after work. Clean work areas with hypochlorite or other disinfecting agent.
7.2 Conditions for safe storage, including any incompatibilities		Store frozen.
7.3 Specific end use(s)		Controls for D Dimer assays



T E C H N O P A T H

SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH), Annex II

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Occupational Exposure Limits

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Not relevant for this material.

8.2.2 Personal protection equipment

Eye/face protection

Safety glasses recommended. (EN166).

Hand protection

Disposable gloves. (EN374).



Material of gloves:

Latex / natural rubber, Nitrile rubber.

Penetration time of glove material:

Gloves resistance is not critical when the product is handled according to the instructions for use.

Body protection

Laboratory coat.

Respiratory protection

Not normally required.

8.2.3 Environmental Exposure Controls

No special measures are required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance

Liquid.

Colour

Yellow - Brown.

Odour

Light.

Odour Threshold (ppm)

Not determined.

pH (Value)

6.8 – 7.5.

Melting Point (°C) / Freezing Point (°C)

Similar to water, approximately 0°C.

Boiling point/boiling range (°C):

Similar to water, approximately 100°C.

Flash Point (°C)

Not applicable.

Evaporation rate (BA = 1)

Not determined.

Flammability (solid, gas)

Not applicable.

Explosive limit ranges

Not applicable.

Vapour Pressure (mm Hg)

Similar to water, approximately 23 hPa.

Vapour Density (Air=1)

Not determined.

Density (g/ml)

~ 1

Solubility (Water)

Completely miscible with water.

Solubility (Other)

Not determined.

Partition Coefficient (n-Octanol/water)

Not determined.

Auto Ignition Temperature (°C)

Not determined.

Decomposition Temperature (°C)

Not determined.

Viscosity (mPa.s)

Not determined.

Explosive properties

Not explosive.

Oxidising properties

Not oxidising

9.2 Other information

Not available.



T E C H N O P A T H

SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH), Annex II

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity	None known.
10.2 Chemical stability	The product is stable in accordance with the recommended storage conditions.
10.3 Possibility of hazardous reactions	Hazardous polymerisation will not occur.
10.4 Conditions to avoid	None.
10.5 Incompatible materials	None known.
10.6 Hazardous Decomposition Product(s)	None known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects	
11.1.2 Mixtures	
Acute toxicity	Based upon the available data, the classification criteria are not met.
Skin corrosion/irritation	Based upon the available data, the classification criteria are not met.
Serious eye damage/irritation	Based upon the available data, the classification criteria are not met.
Respiratory/skin sensitization	Based upon the available data, the classification criteria are not met.
Germ cell mutagenicity	Based upon the available data, the classification criteria are not met.
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Reproductive toxicity	Based upon the available data, the classification criteria are not met.
STOT-single exposure	Based upon the available data, the classification criteria are not met.
STOT-repeated exposure	Based upon the available data, the classification criteria are not met.
Aspiration hazard	Based upon the available data, the classification criteria are not met.
Health Effects and Symptoms	
Skin Contact	No significant harmful effects anticipated.
Eye Contact	No significant harmful effects anticipated.
Ingestion	No significant harmful effects anticipated.
11.2 Other information	Not applicable.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity	The product does not contain significant quantities of ingredients that are environmentally toxic.
12.2 Persistence and degradability	The product is readily biodegradable.
12.3 Bioaccumulative potential	None anticipated.
12.4 Mobility in soil	The product is predicted to have high mobility in soil.
12.5 Results of PBT and vPvB assessment	Not applicable.
12.6 Other adverse effects	Not applicable.



T E C H N O P A T H

SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH), Annex II

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods	
Product:	Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
European waste catalogue:	18 01 03.
Packaging:	Disposal should be in accordance with local, state or national legislation. Contaminated packaging must be disposed of in the same manner as the product. Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

SECTION 14: TRANSPORT INFORMATION

14.1 UN number	Not applicable
14.2 UN Proper Shipping Name	Not applicable
14.3 Transport hazard class(es)	Not classified as dangerous for transport.
14.4 Packing Group	Not applicable
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user	Not applicable
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture	None.
15.2 Chemical Safety Assessment	Not applicable.

SECTION 16: OTHER INFORMATION

LEGEND

STOT Specific Target Organ Toxicity

References:

Raw material safety data sheets.

Additional Information

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To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.