Safety Data Sheet - SDS

according to Regulation (EC) No.1907/2006

Micronised Silica Platelet Substitute

1. IDENTIFICATION OF SUBSTANCE / PREPARATION AND COMPANY.

1.1 Product Identifiers.

Product name	:	**Micronised Silica Platelet Substitute.**
Product codes	:	MSPS060/061.
Index Number	:	Not indexed in regulation (EC) No.1272/2008.
REACH No.	:	Not required due to exemption from registration (below the annual tonnage for downstream user).
CAS Number	:	Not indexed.

1.2 Identified uses: Blood coagulation testing reagent with high sensitivity to both Heparin and the Lupus anticoagulant. Activated Partial Thromboplastin Time (APTT) Reagent.

1.3 Company :

Diagnostic Reagents Ltd.
Wenman Road,
Thame,
Oxon, OX9 3NY,
UK.

Telephone : +44(0)1844 212426
Fax : +44(0)1844 216162
Email : sds@diagen.co.uk

1.4 Emergency Tel: **+44(0)1844 212426** **(Monday to Friday, 09.00 to 17.00)**

2. HAZARDS IDENTIFICATION.

2.1 Classification of the substance or mixture according to regulation (EC) No 1272/2008 (EU-GHS/CLP).

Not a dangerous substance according to GHS.

2.2 Label Elements :

Labelling according to Regulation (EC) No 1272/2008 (CLP).

The product does not need to be labelled in accordance with EC directives or respective national laws.

2.3 Other hazards

Micronised Silica Platelet Substitute contains ingredients derived from bovine brain. All materials have been processed from animals passed fit for human consumption, it is however recommended that standard precautions are taken, as for any potentially infectious material. See section 16 for further details.

3. COMPOSITION / INFORMATION ON INGREDIENTS.

3.1 N/A.

3.2 Mixtures.
Synonyms : Micronised Silica and Bovine Phospholipid Suspension.

Component	Classification	Concentration
Bovine Phospholipid CAS No. 93384-34-0 EC No. N/A	Not classified.	≤4%
Micronised Silica CAS No. 7631-86-9 EC No. 310-194-1	Not classified.	≤1%

4. FIRST AID MEASURES.

4.1 Description of first aid measures.

General Advice.
Consult a physician. Show this SDS to the doctor in attendance.

If inhaled.
Move the person into fresh air. If not breathing give artificial respiration. Consult a physician.

In case of skin contact.
Wash the area with soap and plenty of water. If a reaction occurs consult a physician.

In case of eye contact.
Rinse the eye thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed.
Rinse mouth with water. Never give anything by mouth to an unconcious person. Consult a physician.

4.2 Most important symptoms and effects, both accute and delayed.
Micronised Silica Platelet Substitute is used in blood clotting assays. There are currently no chemical, physical or toxicological properties that have been thoroughly investigated.

4.3 Indication of any immediate medical attension and special treatment needed.
No data available.

5. FIRE FIGHTING MEASURES.

5.1 Extinguishing media.

Suitable extinguishing media.
Water Spray, alcohol-resistant foam, dry chemical or Carbon dioxide.

5.2 Special Hazards arising from the substance or mixture.
Nature of decomposition products not known.

5.3 Advice for firefighters.
When entering any fire, please ensure the correct protective clothing and self contained breathing apparatus are worn.

5.4 Further information.
No data available.

6. ACCIDENTAL RELEASE MEASURES.

6.1 Personal Precautions, protective equipment and emergency procedures.
Use personal protective equipment. Avoid dust formation. Avoid inhailing dust. Ensure adequate ventilation. Evacuate personel to a safe area if necessary.

6.2 Environmental precautions.
Don not allow product to enter the drains.

6.3 Methods and materials for containment and cleaning up.
Sweep up and shovel, or vaccum, creating as little dust as possible. Once contained, hold in suitable, closed container for disposal.

6.4 Reference to other sections.
For disposal see section 13.

7. HANDLING AND STORAGE.

7.1 Precautions for safe handling.
Avoid skin and eye contact. Avoid dust and aerosol formation. Provide appropriate exhaust ventilation at places where dust is formed.

7.2 Conditions for safe storage, including any incompatibilities.
Store according to manufacturers instruction in a cool place. Keep container tightly closed when storing. The recommended storage temperature is -20°C.

7.3 Specific end use(s).
Apart from those uses mentioned in section 1.2 no other specific uses are stipulated.

8. EXPOSURE CONTROL / PERSONAL PROTECTION.

8.1 Control Parameters.

Components with workplace control parameters.
Contains no substance with Workplace Exposure Limits (WELs).

8.2 Exposure controls.

Appropriate engineering controls.
Handle in accordance with good laboratory practice. Wash hands before breaks and immediately after handling this product.

8.3 Personal protective equipment.

Eye/face protection.
A face shield or safety glasses. Use equipment tested and approved by government standards such as EN 166 (EU) or NIOSH (US).

Skin protection.
Handle with gloves. Gloves should be thouroughly checked before use. Use correct glove removal technique to avoid skin contact with this product. Dispose of any used gloves in accordance with applicable laws and Good Laboratory Practice (GLP).

Wash and dry hands thouroughly after use.

Protective gloves should adhere to the specifications detailed in EU directive 89/686/EEC and the derived standard EN374. A experienced Safety Officer should conduct a thourough assessment of any procedure using this product before proceeding.

Body Protection.
Wear impervious protective clothing, including boots, gloves, lab coat, apron or overalls as appropriate, to prevent skin contact. The extend of the protective equipment must be selected according to the concentration and the amount of substance being used.

Respiratory protection.
For nusiance eposures use type N95 (US) or type P1 (EU EN143). Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

9. PHYSICAL AND CHEMICAL PROPERTIES.

9.1 Information on basic chemical and physical properties.

a) Physical state:	Powder, white, lyophilised.	**m) Relative density:**	Not available.
b) Odour:	Not available.	**n) Water solubility:**	Not available.
c) pH:	Not available.	**o) Partition coefficient:**	Not available.
d) Melting/freezing point	Not available.	**p) Auto ignition temp.**	Not available.
e) Boiling point/range:	Not available.	**q) Decomposition**	Not available.
g) Flash point:	Not available.	**temperature**	Not available.
h) Evaporation rate:	Not available.	**r) Viscosity**	Not available.
i) Flammability:	Not available.		
j) Explosive properties:	Not available.		
k) Vapour pressure	Not available.		
l) Vapour density	Not available.		

Other information: Not available.

10. STABILITY AND REACTIVITY.

10.1 Reactivity
No data available

10.2 Chemical Stability
Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions
No data available.

10.4 Conditions to avoid:
No data available.

10.5 Materials to avoid:
Strong oxidising agents..

10.6 Hazardous decomposition products
Other decomposition products - no data available.

11. TOXICOLOGICAL INFORMATION.

11.1 Information on toxicological effects

Acute toxicity:
No data available.

Skin corrosion/irritation
No data available.

Serious eye damage/irritation.
No data available.

Respiratory or skin sensitisation.
No data available.

Germ cell mutagenicity.
No Data Available.

Carcinogenicity.
IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity.
No data available.

Specific target organ toxicity - single exposure.
No data available.

Specific target organ toxicity - repeated exposure.
No data available.

Aspiration hazard.
No data available.

Potential health effects.

Inhalation	May be harmful if inhaled. May cause respiratory tract irritaion.
Ingestion	May be harmful if swallowed.
Skin	May cause skin irritation.
Eyes	May cause eye irritation.

Signs and Symptoms of Exposure.
Micronised Silica Platelet Substitute is used in blood clotting assays. There are currently no chemical, physical and toxicological properties that have been thoroughly investigated.

Additional information.
RTECS: VV7310000

12. ECOLOGICAL INFORMATION

12.1 Toxicity.
No data available.

12.2 Persistence/Biodegradability.
No data available.

12.3 Bioaccumulation potential.
No data available.

12.4 Mobility in soil.
No data available.

12.5 Other adverse effects.
No data available.

13. DISPOSAL CONSIDERATIONS.

13.1 Waste Treatment methods.

Product.
Offer surplus and non-recyclable solutions to a licensed disposal company. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator with an afterburner and scrubber.

Contaminated Packaging.
Dispose of as an unused product.

14. TRANSPORT INFORMATION.

RID/ADR:

UK Road Class:	-	**UK Road Packaging Group:**	-
UN No. (Road):	-	**RID Class No.**	-
Proper Shipping Name:	Not dangerous goods.	**RID Pack Group:**	-
		CEFIC TEC-R No.	-
Hazchem Code:	-	**ADR Class:**	-
ADR Class No.	-	**ADR Label No:**	-
ADR Pack Group:	-		

IMDG:

IMDG Class:	-	**IMDG Pack Group:**	-
UN No. (Sea):	-	**MFAG:**	-
Proper Shipping Name:	Not dangerous goods.	**IMDG Page No:**	-
EMS:	-		
Marine pollutant:	-		

IATA:

Air Class:	-	**Air Pack Group:**	-
UN Air No.	-		
Proper Shipping Name:	Not dangerous goods.		

14.6 Special precautions for user:
No data available.

15. REGULATORY INFORMATION.

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture.
No data available.

15.2 Chemical Safety Assessment.
A chemical safety assessment has not been carried out for this product.

16. OTHER INFORMATION

Further Information

Cattle used in the production of Bovine Phospholipid have passed both ante and post mortem inspection and have been passed fit for human consumption. Normal precautions should still be observed for potentially infectious material. All the above information is based on current knowledge at the time of publication and follows stipulated regulations. Diagnostic Reagents Ltd is not responsible for any errors or lack of information give in the above literature. The information contained in this SDS does not constitute an assessment of work place risks and is intended only as a guide to the appropriate precautionary handling of a material by a trained person using this product. The customer should undertake a formal COSHH assessment which should ensure that employees are aware of the hazards / precautions detailed in this SDS. The COSHH assessment should ensure that the recommended safety equipment is available and where applicable, that the exposure limits are not being exceeded. Diagnostic Reagents Ltd will not therefore be responsible for damages resulting from use of or reliance upon this information.