DENFOTEX

SAFETY DATA SHEET

1. Identification of the substance and of the company	
1.1 Product Identifier/Trade name	Sylc Original SR (V1.0 July 2015)
1.2. Relevant Identified Use(s) and uses advised against.	Only for use by a dental professional, for the treatment of dental hypersensitivity and prophylaxis treatment.
1.3 Details of Manufacturer/supplier.	Denfotex Research Ltd., Floor 5, Henriette Raphael House, Kings College London, Guys Hospital Campus, London, SE11UL, United Kingdom.
1.4 Emergency telephone and contact information.	Tel: +44 (0) 7802439204 Email: david.clements@denfotexresearch.com
2. Hazards identification	
2.1 Classification of substance	Not a hazardous substance or mixture according to Regulation no. 1272/2008. This substance is not classified as dangerous according to directive 67/548/EEC.
2.2.Label elements	As required by Medical Device Directive
2.3 Other hazard information	
Ingestion	This material is unlikely to be hazardous by ingestion.
Skin contact	Not absorbed through skin. No evidence of adverse effects.
Eye contact	May cause irritation, redness and pain.
Inhalation	Inhaling very large quantities (overexposure to particles) may cause temporary irritation to mucous membranes.
Enviroment: vPvB/PBT	No known effect
Additional information	No other risks known.
3.Information on ingredients	
3.1 Substances	calcium sodium phosphosilicate Elemental Component Wt.% Silicon 21 Calcium 18 Sodium 18 Phosphorus 3 Oxygen 40
3.2 Mixtures	Not a mixture – Fused Glass
Other information	
Description:	White powder
Hazardous components:	
CAS Number	359684-27-8
REACH Number	A registration number is not available as the substance or its uses are exempted from registration, the annual tonnage does not require registration or the registration is envisaged

	for a later registration deadline.
Synonyms	Bioactive Glass NovaMin 45S5 Bioglass calcium sodium phosphosilicate
Formula Molecular Weight EC-No. :	n/a n/a n/a
4. First Aid Measures	
4.1 Description of First Aid measures	
Ingestion	Induce vomiting in a conscious person, get medical attention
Skin	Wash with plenty of soap and water.
Eyes	Flush with water for several minutes. Get medical attention. Take care not to rub eyes as glass particles may scratch surface of eye.
Inhalation	Remove from exposure. Get medical attention if experiencing over exposure effects
4.2 Most important symptoms and effects, both acute and delayed	
Ingestion	Irritation and inflammation are unlikely but possible symptoms
Skin	Irritation and inflammation are unlikely but possible symptoms
Eyes	Irritation and inflammation are unlikely but possible symptoms
Inhalation	Irritation and inflammation are unlikely but possible symptoms
4.3 Indication of immediate medical attention and special treatment	Irritation and inflammation.
5.Fire Fighting Measures	
5.1 Extinguishing media	
Small fires	Non-combustible. Use extinguishing media appropriate to surrounding fire conditions.
Large fires	Non-combustible. Use extinguishing media appropriate to surrounding fire conditions.
5.2 Special hazards arising from substance	None.
5.3.Special protective actions for fire-fighters	None
6. Accidental release measures	
6.1 Personal precautions, protective equipment and emergency procedures	Avoid ingestion and contact with eyes. For personal protection see section 8.
6.2.Environmental precautions	None

6.3 Methods and materials for containment and cleaning up	Spills should be cleaned up with a broom and dust pan or vacuum depending on size of spill. Take care not to inhale or ingest dust. Waste can be placed in a plastic trash bag to be disposed of according to applicable regulations.
7. Handling & storage	
7.1 Precautions for safe handling	Dust mask class FFP1 or higher Protective safety glasses Disposable examination gloves
7.2 Conditions for safe storage, including any incompatibilities	No special precautions necessary. It is recommended that material be stored in unopened containers at ambient temperature and humidity (rH<70%).
7.3 Specific End Uses:	Waste can be placed in a plastic trash bag to be disposed of according to applicable regulations.
8. Exposure controls and personal protection	
8.1 Control parameters	Dust mask class FFP1 or higher Protective safety glasses Disposable examination gloves
8.2 Exposure Controls	Use with adequate ventilation
8.3 Additional information	
9. Physical and chemical properties	
9.1 Information on basic physical and chemical properties	
Appearance/Form:	Powder
Colour:	White
Odour/odour threshold	None/none.
Change in condition	none
Melting point/melting range	1300 ºC
Boiling point/boiling range:	n/a
Freezing point	700ºC
Evaporation rate	Not applicable
Flash point	Not applicable
Auto ignition temperature	Not applicable
Explosive properties	Not applicable
Upper/lower flammability	Not applicable
Oxidising properties	Not applicable
Decomposition temperature	Not applicable
Density:	2.73g/cm^3
Vapour pressure:	Not applicable

Viscosity:	Not applicable
pH	7-14 in aqueous environment
Solubility in/miscibility with water:	Not soluble
Content of solvents	None
Organic content:	None
Water content:	None
Other information	None
10. Stability and reactivity	
10.1 Reactivity	None
10.2 Chemical stability	Highly Stable
10.3 Possibility of hazardous reactions	None
10.4 Conditions to avoid:	mositure
10.5 Incompatible materials	None
10.6 Hazardous decomposition products:	None
Other information	
11. Toxicological information	
11.1 Information on toxicological effect	
Acute toxicity:	None.
Skin corrosion/irritation	Irritant
Serious eye damage/irritanion	Irritant
Respiratory/skin sensitisation:	Irritant
Germ cell mutagenicity	None known
Carginogenicity	None known
Reproductive toxicity	None known
STOT – single exposure	None known
STOT – repeated exposure	None known
Aspiration hazard	None
12. Ecological information	
12.1 Toxicity	None known
12.2 Persistence and degradability	Stable to decomposition. Long term effects may include slight leaching of Na, Ca and P
12.3 Bioaccumulative potential	None known.
12.4 Mobility in soil	None known
12.5 Results of PBT and vPvB assessment	Not applicable to medical device.

12.6 Other adverse effects	None known.
13. Disposal instructions	
13.1 Waste treatment methods	Glass recycling or land fill.
14. Transport information	No special precautions
14.1 UN Number	ADR/RID: Not applicable IMDG: Not applicable IATA: Not applicable
14.2 UN Proper Shipping Name	ADR/RID: Not dangerous goods. IMDG: Not dangerous goods. IATA: Not dangerous goods
14.3 Transport Hazard Classes	ADR/RID: Not applicable. IMDG: Not applicable IATA: Not applicable
14.4 Packing group	ADR/RID: Not applicable. IMDG: Not applicable IATA: Not applicable
14.5 Environmental hazards	ADR/RID: Not applicable. IMDG: Not applicable IATA: Not applicable
14.6 Special precautions for user	Follow instructions in Directions For Use
14.7 Transport in bulk	Not applicable
15. Regulatory information	
15.1 Safety, health and environmental regulations/legislation specific for substance	This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006
Chemical safety assessment	Contains no known hazard.
16. Other information	The above information is based on our present day knowledge and relates solely to the safety requirements of the product. It does not constitute a guarantee for any specific property users of the product should satisfy themselves that the information is sufficient for their specific circumstances of use