SYLC
SAFETY DATA SHEET
VELOPEX PROSYLC

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

1.1 Product identifier

Product Name	PROSYLC I/PDR 0034F
Synonyms	(Desensitising Bioglass)

1.2 Uses of the product

Identified Uses	Only for use by a dental professional, for the treatment of dental hypersensitivity and prophylaxis treatment.
Uses Advised Against	None known

1.3 Details of the supplier of the safety data sheet

Supplier

Medivance Instruments Ltd.
Barretts Green Road
Harlesden
London
NW10 7AP
T +44 (0) 20 8965 2913
F +44 (0) 20 8963 1270
enquiries@velopex.com

1.4 Emergency telephone number

020 8965 2913

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

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.
Environment: vPvB/PBT	No known effect
Additional information	No other risks known.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Calcium Sodium Phosphosilicate

Elemental Component	Wt.%
Silicon	21
Calcium	18
Sodium	18
Phosphorus	3
Oxygen	40

3.2 Mixture

Not a mixture – Fused Glass

Description:	White powder
Hazardous components:	N/A
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	n/a
Molecular Weight	n/a
EC-No. :	n/a

SECTION 4: FIRST AID PROCEDURES

4.1 Description of first aid measures

If inhalation

Remove from exposure. Get medical attention if experiencing over exposure effects

In case of skin contact

Wash with plenty of soap and water.

In case of eye contact

Flush with water for several minutes. Get medical attention. Take care not to rub eyes as glass particles may scratch surface of eye.

If swallowed

Induce vomiting in a conscious person, get medical attention

4.2 Most important symptoms and effects, both acute and delayed

Inhalation:	Irritation and inflammation are unlikely but possible symptoms
Ingestion:	Irritation and inflammation are unlikely but possible symptoms
Skin contact:	Irritation and inflammation are unlikely but possible symptoms
Eye contact:	Irritation and inflammation are unlikely but possible symptoms

4.3 Indication of any immediate medical attention and special treatment needed

Irritation and inflammation.

SECTION 5: FIRE-FIGHTING PROCEDURES

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 the substance or mixture

None

5.3 Advice for fire-fighters

None

SECTION 6: ACCIDENTAL RELEASE PROCEDURES

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 for containment and clean-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.

SECTION 7: HANDLING AND 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 use(s)

Waste can be placed in a plastic trash bag to be disposed of according to applicable regulations.

SECTION 8: EXPOSURE CONTROLS/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

SECTION 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 °C
Boiling point/boiling range	n/a
Freezing point	700°C
Evaporation rate	Not applicable
Flash point	Not applicable
Auto ignition temperature	Not applicable
Explosive 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

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

None

10.2 Chemical stability

Highly Stable

10.3 Possibility of hazard reactions

None

10.4 Conditions to avoid

Moisture

10.5 Incompatible materials

None

10.6 Hazardous decomposition products

None

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	None.
Skin corrosion/irritation	Irritant
Serious eye damage/irritation	Irritant
Respiratory/skin sensitisation:	Irritant
Germ cell mutagenicity	None known
Carcinogenicity	None known
Reproductive toxicity	None known
STOT – single exposure	None known
STOT – repeated exposure	None known
Aspiration hazard	None

SECTION 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.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Glass recycling or land fill.

SECTION 14: TRANSPORT INFORMATION

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 class(es)

ADR/RID: Not applicable.
IMDG: Not applicable
IATA: Not applicable

14.4 Packaging 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 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

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

15.2 Chemical Safety Assessment

Contains no known hazard.

SECTION 16: OTHER INFORMATION

16.1 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.

16.2 Abbreviations and acronyms

WEL : Workplace exposure limit
ACGIH : American Conference of Industrial Hygiene
TWA : Time Weighted Average
DNEL : Derived no effect level
NOEC : No Observed Effect Concentration
PBT : Persistent, Bioaccumulative, Toxic
vPvB : very Persistent, very Bioaccumulative
PNEC : Predicted No Effect Concentration
ADR : European Agreement Concerning the International Carriage of Dangerous Goods by Road
RID : International Rule for Transport of Dangerous Substances by Rail
ADN : European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterway
IMO/IMDG : International Maritime Organization/International Maritime Dangerous Goods Code
ICAO/IATA : International Civil Aviation Organization/International Air Transport Association

16.3 Key literature references and sources of data

Data is taken from the Chemical Safety Report (CSR) and/or OECD SIDS report for sodium bicarbonate.

16.4 Further information

The substance(s) covered in this document do not legally require a Safety Data Sheet (SDS).
The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products.

Issued by Chemistry Manager
Revision Date 01/06/2017
Revision GHS1

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