

**SYLC  
SAFETY DATA SHEET  
AQUACARE DESENSITISING BIOGLASS**

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

**1.1 Product identifier**

Product Name SYLC 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**

Class 1 Medical Device - Under Directive 93/42 EEC

**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 <sup>3</sup>       |
| 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

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Revision GHS1

### Disclaimer

This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. Such information is, to the best of the company's knowledge and belief, accurate and reliable as of the date indicated. However, no warranty guarantee or representation is made to its accuracy, reliability or completeness. It is the users' responsibility to satisfy themselves as to the suitability of such information for their own particular use.