

SAFETY DATA SHEETS

This SDS packet was issued with item:

077703911

N/A

ZHERMACK S.P.A.**Safety Data Sheet according to the Dir. 2001/58/EEC****ELITE GLASS**

Revision date: 11/02/08

Print Date: 15/02/08

1. IDENTIFICATION OF THE PREPARATION AND OF THE COMPANY**1.1 Identification of the preparation:**

Trade name: ELITE GLASS
Trade code: C401610/C410611

1.2 Utilization of the substance or of the preparation:

Addition silicone for make transparent matrices directly in mouth

1.3 Identification of the company:

Supplier: ZHERMACK S.p.A. via Bovazecchino, 100 – 45021 - Badia Polesine (RO) ITALY
Emergency telephone number of the company: 0039 0425 597611

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous components in accordance with EEC directive 67/548 and successive amendments or components with a recognised exposure limit: None

3. IDENTIFICATION OF HAZARDS

PREPARATION NOT CLASSIFIED DANGEROUS

No specific hazards are encountered under normal use of the product. Contact with the eyes may cause slight irritation and reddening of the conjunctiva.

4. FIRST AID MEASURES

4.1 Contact with skin: Wash with water and soap.

4.2 Contact with eyes: Wash immediately with water for at least 10 minutes.

4.3 Swallowing: Induce vomiting. SEEK MEDICAL ATTENTION IMMEDIATELY and present the safety-data sheet. A suspension of activated charcoal in water or medicinal mineral Vaseline oil may be administered.

4.4 Inhalation: Ventilate the premises.

5. FIRE-FIGHTING MEASURES

5.1 Recommended extinguishers: water, CO₂, foam, or chemical powders, depending on the materials involved in the fire.

5.2 Extinguishers not to be used: direct water on the flames.

5.3 Risks arising from combustion: avoid inhaling the fumes.

5.4 Protective equipment: use protection for the respiratory tract.

6. ACCIDENTAL RELEASE MEASURES

6.1 Measures for personal safety: none in particular

6.2 Environmental measures: limit leakage with earth or sand. If the product has escaped into a water course, into the drainage system, or has contaminated the ground or vegetation, notify the competent authorities.

6.3 Cleaning methods: recover the product for re-use if possible, or for elimination. The product may, where appropriate, be absorbed by inert material. After the product has been recovered, rinse the area and materials involved with water.

7. HANDLING AND STORAGE

7.1 Handling precautions: refer to point 8 below. Do not eat or drink while working.

7.2 Incompatible materials: none in particular. Also see point 10 below.

7.3 Storage conditions: keep in a cool, dry place at a temperature of 5°C to 27°C (41-80°F).

7.4 Technical measures: adequately ventilated premises.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Precautionary measures: ensure adequate ventilation of the premises where the product is stored and/or handled.

8.2 Respiratory protection: not needed for normal use

8.3 Protection for hands: not needed for normal use

8.4 Eye protection: not needed for normal use. Always apply proper working practices.

8.5 Protection for skin: no special precaution required for normal use

8.6 Exposure limit(s) (ACGIH): none

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Appearance and colour: Bicomponent fluid, with the two parts are transparent.

9.2 Odour: odourless

9.3 Relative density: 1.08 g/cm³

9.4 Solubility in water: insoluble

Page 1 of 2

| REVISIONE | DATA | DESCRIZIONE | EMISSIONE | APPROVAZIONE |
|-----------|----------|----------------|-----------|--------------|
| 1 | 11/02/08 | First emission | R&S | RSGQA |

ZHERMACK S.P.A.

Safety Data Sheet according to the Dir. 2001/58/EEC

ELITE GLASS

Revision date: 11/02/08

Print Date: 15/02/08

10. STABILITY AND REACTIVITY

10.1 Conditions to avoid: stable under normal conditions.

10.2 Substances to avoid: none.

10.3 Hazardous decomposition products: none

11. TOXICOLOGICAL INFORMATION

The product itself has no cytotoxic effects on the L929 cellular line.

12. ECOLOGICAL INFORMATION

Adopt sound working practices, ensuring that the product is not released into the environment.

13. DISPOSAL CONSIDERATIONS

Recover if possible. In so doing, comply with the local and national regulations currently in force.

14. TRANSPORT INFORMATION

Not classified as dangerous under transport regulations.

15. REGULATORY INFORMATION

The preparation is not considered hazardous under dir. 88/379/EEC.

Medical Device CE marked according to the Directive 93/42/EEC.

16. OTHER INFORMATION

The information contained herein is based on our state of knowledge on the date specified above. It refers solely to the product indicated and constitutes no guarantee of particular quality. It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended. This MSDS cancels and replaces any preceding release.

| REVISIONE | DATA | DESCRIZIONE | EMISSIONE | APPROVAZIONE |
|-----------|----------|----------------|-----------|--------------|
| 1 | 11/02/08 | First emission | R&S | RSGQA |

C401610/C401611 - ELITE GLASS**Safety Data Sheet****1. Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Code: C401610/C401611
Product name: ELITE GLASS

1.2. Relevant identified uses of the substance or mixture and uses advised against

Intended use: Addition silicone for impression material

1.3. Details of the supplier of the safety data sheet

Name: Zhermack S.p.a
Full address: Via Bovazecchino
District and Country: 45021 Badia Polesine (RO)
Italy
Tel. +39 0425-597611
Fax +39 0425-53596

e-mail address of the competent person responsible for the Safety Data Sheet: tania.demetri@zhermack.com

1.4. Emergency telephone number

For urgent inquiries refer to: +39 0425-597611

2. Hazards identification.**2.1. Classification of the substance or mixture.**

The product is not classified as hazardous pursuant to the provisions set forth in Directives 67/548/EEC and 1999/45/EC and/or EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).

2.2. Label elements.

Pictograms: --
Warning: --
Hazard indication: --
Caution recommendations: --

2.3. Other hazards.

Information not available.

3. Composition/information on ingredients.**3.1. Substances.**

Information not relevant.

3.2. Mixtures.

The product does not contain substances classified as being hazardous to human health or the environment pursuant to the provisions set forth in Directives 67/548/EEC and/or EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).

4. First aid measures.**4.1. Description of first aid measures.**

No harm to the staff authorised to use has been reported. However, in case of contact, inhalation or ingestion, the following general measures provided for a first aid shall be taken.

INHALATION: remove to open air. If respiration is difficult, administer artificial respiration and seek medical advice.

INGESTION: seek medical attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person.

EYES and SKIN: wash with plenty of water; if the irritation persists, seek medical advice.

C401610/C401611 - ELITE GLASS**4.2. Most important symptoms and effects, both acute and delayed.**

No episodes of damage to health ascribable to the product have been reported.

4.3. Indication of any immediate medical attention and special treatment needed.

Follow doctor's orders.

5. Firefighting measures.**5.1. Extinguishing media.**

SUITABLE EXTINGUISHING MEDIA

The extinction equipment should be of the conventional kind: carbon dioxide, foam, powder and nebulised water.

EXTINGUISHING MEDIA WHICH SHALL NOT BE USED FOR SAFETY REASONS

None in particular.

5.2. Special hazards arising from the substance or mixture.

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products (carbon oxide, toxic pyrolysis products, etc).

5.3. Advice for firefighters.

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health.

Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Hardhat with visor, fireproof clothing (fireproof jacket and trousers with straps around arms, legs and waist), work gloves (fireproof, cut proof and dielectric), a depressurised mask with facemask covering the whole of the operator's face or a self-respirator (self-protector) in the event of large quantities of fume.

6. Accidental release measures.**6.1. Personal precautions, protective equipment and emergency procedures.**

Eliminate all sources of ignition (cigarettes, flames, sparks, etc.) from the leakage site. If there are no contraindications, spray solid products with water to prevent the formation of dust. Use breathing equipment if fumes or powders are released into the air. Block the leakage if there is no hazard. Do not handle damaged containers or the leaked product before donning appropriate protective gear. For information on risks for the environmental and health, respiratory tract protection, ventilation and personal protection equipment, see the other sections of this sheet.

6.2. Environmental precautions.

The product must not penetrate the sewers, surface water, ground water and neighbouring areas.

6.3. Methods and material for containment and cleaning up.

Use inert absorbent material (sand, vermiculite, diatomaceous earth, Kieselguhr, etc.) to soak up leaked product. Collect the majority of the remaining material and deposit it in containers for disposal. If there are no contraindications, use jets of water to eliminate product residues. Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections.

Any information on personal protection and disposal is given in sections 8 and 13.

7. Handling and storage.**7.1. Precautions for safe handling.**

Store in closed, labelled containers.

7.2. Conditions for safe storage, including any incompatibilities.

Normal storage conditions without particular incompatibilities.

7.3. Specific end use(s).

Information not available.

8. Exposure controls/personal protection.**8.1. Control parameters.**

Information not available.

8.2. Exposure controls.

Observance of safety measures used in handling chemical substances.

RESPIRATORY PROTECTION

None required.

EYE PROTECTION

None required.

C401610/C401611 - ELITE GLASS**HAND PROTECTION**

None required.

SKIN PROTECTION

None required.

9. Physical and chemical properties.**9.1. Information on basic physical and chemical properties.**

| | |
|--|--------------------|
| Appearance | viscous liquid |
| Colour | transparent |
| Odour | odourless |
| Odour threshold. | Not available. |
| pH. | Not available. |
| Melting or freezing point. | Not available. |
| Boiling point. | Not available. |
| Distillation range. | Not available. |
| Flash point. | Not available. |
| Evaporation Rate | Not available. |
| Flammability of solids and gases | Not available. |
| Lower inflammability limit. | Not available. |
| Upper inflammability limit. | Not available. |
| Lower explosive limit. | Not available. |
| Upper explosive limit. | Not available. |
| Vapour pressure. | Not available. |
| Vapour density | Not available. |
| Specific gravity. | Not available. |
| Solubility | insoluble in water |
| Partition coefficient: n-octanol/water | Not available. |
| Ignition temperature. | Not available. |
| Decomposition temperature. | Not available. |
| Viscosity | Not available. |
| Reactive Properties | Not available. |

9.2. Other information.

| | |
|------------------------------|---|
| VOC (Directive 1999/13/EC) : | 0 |
| VOC (volatile carbon) : | 0 |

10. Stability and reactivity.**10.1. Reactivity.**

There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability.

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions.

No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4. Conditions to avoid.

None in particular, however the usual precautions used for chemical products should be respected.

10.5. Incompatible materials.

Information not available.

10.6. Hazardous decomposition products.

In the event of thermal decomposition or fire, vapours potentially dangerous to health may be released.

11. Toxicological information.

According to currently available data, this product has not yet produced health damages. Anyway, it must be handled carefully according to good industrial practices. This product may have slight health effects on sensitive people, by inhalation and/or cutaneous absorption and/or contact with eyes and/or ingestion.

11.1. Information on toxicological effects.

Information not available.

12. Ecological information.

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or sewers or contaminate soil or vegetation.

C401610/C401611 - ELITE GLASS**12.1. Toxicity.**

Information not available.

12.2. Persistence and degradability.

Information not available.

12.3. Bioaccumulative potential.

Information not available.

12.4. Mobility in soil.

Information not available.

12.5. Results of PBT and vPvB assessment.

Information not available.

12.6. Other adverse effects.

Information not available.

13. Disposal considerations.**13.1. Waste treatment methods.**

Reuse, when possible. Neat product residues should be considered special non-hazardous waste. Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

14. Transport information.

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

15. Regulatory information.**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture.**

Seveso category. None.

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006.
None.

Substances in Candidate List (Art. 59 REACH).
None.

Substances subject to authorisation (Annex XIV REACH).
None.

Healthcare controls.
Information not available.

15.2. Chemical safety assessment.

No chemical safety assessment has been processed for the mixture and the substances it contains.

16. Other information.

GENERAL BIBLIOGRAPHY

1. Directive 1999/45/EC and following amendments
2. Directive 67/548/EEC and following amendments and adjustments
3. Regulation (EC) 1907/2006 (REACH) of the European Parliament
4. Regulation (EC) 1272/2008 (CLP) of the European Parliament
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EC) 453/2010 of the European Parliament
7. The Merck Index. - 10th Edition
8. Handling Chemical Safety
9. Niosh - Registry of Toxic Effects of Chemical Substances
10. INRS - Fiche Toxicologique (toxicological sheet)
11. Patty - Industrial Hygiene and Toxicology

C401610/C401611 - ELITE GLASS

12. N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product .

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.