SAFETY DATA SHEETS

This SDS packet was issued with item:

077703911

N/A

Information Sheet

SECTION 1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Code:	**C401610**
Product name	**ELITE GLASS - BASE**

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

Intended use **For professional use only. Addition silicone for transparent matrices.**

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	**msds@zhermack.com**

1.4. Emergency telephone number

For urgent inquiries refer to **0039 0425597611**

SECTION 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 EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).

2.1.1. Regulation 1272/2008 (CLP) and following amendments and adjustments.

The Regulation EC 1272/2008, on classification, labelling and packaging of substances and mixtures (CLP), shall not apply to a medical device in the finished state used in direct physical contact with the human body according to art. 5.1, letter d). Therefore the product is exempted from the CLP labeling requirements.

Hazard classification and indication:

2.2. Label elements.

Hazard pictograms: --

Signal words: --

Hazard statements: --

Precautionary statements: --

2.3. Other hazards.

Information not available.

SECTION 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).

SECTION 4. First aid measures.

4.1. Description of first aid measures.

Not specifically necessary. Observance of good industrial hygiene is recommended.

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.

Information not available.

SECTION 5. Firefighting measures.

5.1. Extinguishing media.

SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
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. The product is combustible and, when the powder is released into the air in sufficient concentrations and in the presence of a source of ignition, it can create explosive mixtures with air. Fires may start or get worse by leakage of the solid product from the container, when it reaches high temperatures or through contact with sources of ignition.

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
Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

Obtained by Global Safety Management, www.globalsafetynet.com, (877) 683-7460

SECTION 6. Accidental release measures.

6.1. Personal precautions, protective equipment and emergency procedures.

Use breathing equipment if fumes or powders are released into the air. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions.

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up.

Confine using earth or inert material. Collect as much material as possible and eliminate the rest using jets of water. 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.

SECTION 7. Handling and storage.

7.1. Precautions for safe handling.

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use.

7.2. Conditions for safe storage, including any incompatibilities.

Keep the product in clearly labelled containers. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s).

See section 1.2

SECTION 8. Exposure controls/personal protection.

8.1. Control parameters.

During the risk assessment process, it is essential to take into consideration the ACGIH occupational exposure levels for inert particulate otherwise classified (PNOC respirable fraction: 3 mg/m3; PNOC inhalable fraction: 10 mg/m3). For values above these limits, use a P type filter, whose class (1, 2 or 3) must be chosen according to the outcome of risk assessment.

8.2. Exposure controls.

Comply with the safety measures usually applied when handling chemical substances.

HAND PROTECTION
None required.

SKIN PROTECTION
None required.

EYE PROTECTION
None required.

RESPIRATORY PROTECTION
Use a type P filtering facemask, whose class (1, 2 or 3) and effective need, must be defined according to the outcome of risk assessment (see standard EN 149).

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties.

9.1. Information on basic physical and chemical properties.

Appearance	fluid
Colour	transparent
Odour	odourless
Odour threshold.	Not available.
pH.	Not available.
Melting point / freezing point.	Not available.
Initial boiling point.	Not available.
Boiling range.	Not available.
Flash point.	Not available.
Evaporation Rate	Not applicable.
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.
Relative density.	Not available.
Solubility	partially soluble in water
Partition coefficient: n-octanol/water	Not applicable.
Auto-ignition temperature.	Not available.
Decomposition temperature.	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidising properties	Not available.

9.2. Other information.

Information not available.

SECTION 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.

Information not available.

SECTION 11. Toxicological information.

According to currently available data, this product has not yet produced health damages. Anyway, it must be handled according to good industrial practices.

11.1. Information on toxicological effects.

Information not available.

SECTION 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.

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.

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

12.6. Other adverse effects.

Information not available.

Obtained by Global Safety Management, www.globalsafetynet.com, (877) 683-7460

SECTION 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.
Avoid littering. Do not contaminate soil, sewers and waterways.
Solid residues may be suitable for disposal in an authorised landfill site.
CONTAMINATED PACKAGING
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 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.

SECTION 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 authorisarion (Annex XIV REACH).

None.

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

None.

Substances subject to the Rotterdam Convention:

None.

Substances subject to the Stockholm Convention:

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.

SECTION 16. Other information.

LEGEND:
- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

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. Regulation (EC) 286/2011 (II Atp. CLP) of the European Parliament
8. Regulation (EC) 618/2012 (III Atp. CLP) of the European Parliament
9. The Merck Index. - 10th Edition
10. Handling Chemical Safety
11. Niosh - Registry of Toxic Effects of Chemical Substances
12. INRS - Fiche Toxicologique (toxicological sheet)
13. Patty - Industrial Hygiene and Toxicology
14. N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
15. ECHA website

Note for users:
A safety data sheet is not required for this product under article 31 of Regulation 1907/2006/EC.
This safety data sheet has been created on a voluntary basis.

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.
Provide appointed staff with adequate training on how to use chemical products.

Changes to previous review:
The following sections were modified:
01 / 02 / 03 / 04 / 08 / 09 / 11 / 12 / 14 / 15 / 16.

Obtained by Global Safety Management, www.globalsafetynet.com, (877) 683-7460

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.

Obtained by Global Safety Management, Inc. -Tel: 1-813-435-5161 - www.globalsafetynet.com

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, diatomeous 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.

Obtained by Global Safety Management, Inc. -Tel: 1-813-435-5161 - www.globalsafetynet.com

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.

Obtained by Global Safety Management, Inc. -Tel: 1-813-435-5161 - www.globalsafetynet.com

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 authorisarion (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

Obtained by Global Safety Management, Inc. -Tel: 1-813-435-5161 - www.globalsafetynet.com

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.

Obtained by Global Safety Management, Inc. -Tel: 1-813-435-5161 - www.globalsafetynet.com