

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

077703606

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

077704554

## **1. IDENTIFICATION OF THE PREPARATION AND OF THE COMPANY**

*Trade name:* OCCLUFAST ROCK

*Trade code:* C200726

*Supplier:* ZHERMACK S.p.A. via Bovazecchino, 100 -45021- Badia Polesine (RO) ITALY

*Emergency telephone number of the company:* 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**

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**

*Contact with skin:* Wash with plenty of water and soap.

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

*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.

*Inhalation:* Ventilate the premises.

## **5. FIRE-FIGHTING MEASURES**

*Recommended extinguishers:* water, CO<sub>2</sub>, foam, or chemical powders, depending on the materials involved in the fire.

*Extinguishers not to be used:* none in particular.

*Risks arising from combustion:* avoid inhaling the fumes.

*Protective equipment:* use protection for the respiratory tract.

## **6. ACCIDENTAL RELEASE MEASURES**

*Measures for personal safety:* none in particular

*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.

*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**

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

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

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

*Technical measures:* adequately ventilated premises.

## **8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

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

*Respiratory protection:* not needed for normal use

*Protection for hands:* not needed for normal use

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

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

*Exposure limit(s) (ACGIH):* none

## **9. PHYSICAL AND CHEMICAL PROPERTIES**

*Appearance and colour:* Bicomponent fluid, of which one part (base) is coloured (violet).

*Odour:* odourless

*Relative density:* 1.40 g/cc

*Solubility in water:* insoluble

## **10. STABILITY AND REACTIVITY**

*Conditions to avoid:* stable under normal conditions.

*Substances to avoid:* the "base" component may produce hydrogen in contact with alkaline and acid substances.

*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**

*88/379/EEC (Classification and Labelling):* 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.

|                                                                                  |                                   |                                                          |
|----------------------------------------------------------------------------------|-----------------------------------|----------------------------------------------------------|
|  | Zhermack S.p.a                    | Revision nr. 1                                           |
|                                                                                  | C200726_B - OCCLUFAST ROCK - BASE | Dated 21/11/2013<br>Printed on 26/11/2013<br>Page n. 1/9 |

## Safety data sheet

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

#### 1.1. Product identifier

Code: C200726\_B  
Product name: OCCLUFAST ROCK - BASE

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

Intended use Addition silicone for bite registration.

#### 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

CAV Italia: Centro Antiveleni di Milano: 02 66101029; Centro Antiveleni di Pavia: 0382 24444; Centro Antiveleni di Bergamo: 800 883300; Centro Antiveleni di Firenze: 055 7947819; Centro Antiveleni di Roma: 06 3054343; Centro Antiveleni di Roma: 06 49978000; Centro Antiveleni di Napoli: 081 7472870

Servicio de Información Toxicológica (España): + 34 91 562 04 20 (24h/365 días)

Numéro ORFILA (INRS-France): + 33 (0)1 45 42 59 59 (24h/ 7 jours sur 7)

UK Emergency number: 844 892 0111 (24 hours)

Deutschland Notruf: BERLIN Tel.: 030/19240; HOMBURG Tel.: 06841/19240; BONN Tel.: 0228/19240; MAINZ Tel.: 06131/19240; ERFURT Tel.: 0361/730 730; MÜNCHEN Tel.: 089/19240; FREIBURG Tel.: 0761/19240; NÜRNBERG Tel.: 0911/398-2451; GÖTTINGEN Tel.: 0551/19 240

### 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). However, since the product contains hazardous substances in concentrations such as to be declared in section no. 3, it requires a safety data sheet with appropriate information, compliant to EC Regulation 1907/2006 and subsequent amendments.

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

Hazard classification and indication:

|                                                                                  |                                   |                                                          |
|----------------------------------------------------------------------------------|-----------------------------------|----------------------------------------------------------|
|  | Zhermack S.p.a                    | Revision nr. 1                                           |
|                                                                                  | C200726_B - OCCLUFAST ROCK - BASE | Dated 21/11/2013<br>Printed on 26/11/2013<br>Page n. 2/9 |

## 2.2. Label elements.

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms: --

Signal words: --

Hazard statements: --

Precautionary statements: --

**Contains:** CRISTOBALITE

Safety data sheet available for professional users on request.

## 2.3. Other hazards.

There is no exposure to breathable free crystalline silica during normal use of this product. For more information see section 11.

# SECTION 3. Composition/information on ingredients.

## 3.1. Substances.

Information not relevant.

## 3.2. Mixtures.

Contains:

| Identification.     | Conc. %. | Classification 67/548/EEC. | Classification 1272/2008 (CLP). |
|---------------------|----------|----------------------------|---------------------------------|
| <b>CRISTOBALITE</b> |          |                            |                                 |
| CAS. 14464-46-1     | 10 - 20  | Xn R48/20                  | STOT RE 1 H372                  |
| EC. 238-455-4       |          |                            |                                 |
| INDEX. -            |          |                            |                                 |

Note: Upper limit is not included into the range.

The full wording of the Risk (R) and hazard (H) phrases is given in section 16 of the sheet.

# SECTION 4. First aid measures.

## 4.1. Description of first aid measures.

**EYES:** Remove contact lenses, if present Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice

**SKIN:** Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.

**INHALATION:** Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.

**INGESTION:** Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorised by a doctor.

|                                                                                  |                                   |                                                          |
|----------------------------------------------------------------------------------|-----------------------------------|----------------------------------------------------------|
|  | Zhermack S.p.a                    | Revision nr. 1                                           |
|                                                                                  | C200726_B - OCCLUFAST ROCK - BASE | Dated 21/11/2013<br>Printed on 26/11/2013<br>Page n. 3/9 |

#### 4.2. Most important symptoms and effects, both acute and delayed.

For symptoms and effects caused by the contained substances, see chap. 11.

#### 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

Extinguishing substances are: carbon dioxide, foam, chemical powder. For product loss or leakage that has not caught fire, water spray can be used to disperse flammable vapours and protect those trying to stem the leak.

##### UNSUITABLE EXTINGUISHING EQUIPMENT

Do not use jets of water. Water is not effective for putting out fires but can be used to cool containers exposed to flames to prevent explosions.

#### 5.2. Special hazards arising from the substance or mixture.

##### HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Excess pressure may form in containers exposed to fire at a risk of explosion. Do not breathe combustion products.

#### 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).

### SECTION 6. Accidental release measures.

#### 6.1. Personal precautions, protective equipment and emergency procedures.

Block the leakage if there is no hazard.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. 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.

Collect the leaked product into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

Make sure the leakage site is well aired. Check incompatibility for container material in section 7. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

|                                                                                  |                                   |                                                          |
|----------------------------------------------------------------------------------|-----------------------------------|----------------------------------------------------------|
|  | Zhermack S.p.a                    | Revision nr. 1                                           |
|                                                                                  | C200726_B - OCCLUFAST ROCK - BASE | Dated 21/11/2013<br>Printed on 26/11/2013<br>Page n. 4/9 |

#### 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.

Keep away from heat, sparks and naked flames; do not smoke or use matches or lighters. Without adequate ventilation, vapours may accumulate at ground level and, if ignited, catch fire even at a distance, with the danger of backfire. Avoid bunching of electrostatic charges. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat. Avoid leakage of the product into the environment.

#### 7.2. Conditions for safe storage, including any incompatibilities.

Store only in the original container. Store in a well ventilated place, keep far away from sources of heat, naked flames and sparks and other sources of ignition. Keep containers away from any incompatible materials, see section 10 for details.

#### 7.3. Specific end use(s).

Information not available.

## SECTION 8. Exposure controls/personal protection.

#### 8.1. Control parameters.

Regulatory References:

|                |                                                                                                                                                                            |
|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| United Kingdom | EH40/2005 Workplace exposure limits. Containing the list of workplace exposure limits for use with the Control of Substances Hazardous to Health Regulations (as amended). |
| Éire           | Code of Practice Chemical Agent Regulations 2011.                                                                                                                          |
| OEL EU         | Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC.                                                                                   |
| TLV-ACGIH      | ACGIH 2012                                                                                                                                                                 |

#### CRISTOBALITE

##### Threshold Limit Value.

| Type      | Country | TWA/8h |     | STEL/15min |     |
|-----------|---------|--------|-----|------------|-----|
|           |         | mg/m3  | ppm | mg/m3      | ppm |
| TLV-ACGIH |         | 0,025  |     |            |     |
| OEL       | IRL     | 0,1    |     |            |     |

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.

|                                                                                  |                                   |                                                          |
|----------------------------------------------------------------------------------|-----------------------------------|----------------------------------------------------------|
|  | Zhermack S.p.a                    | Revision nr. 1                                           |
|                                                                                  | C200726_B - OCCLUFAST ROCK - BASE | Dated 21/11/2013<br>Printed on 26/11/2013<br>Page n. 5/9 |

## 8.2. Exposure controls.

As the use of adequate technical equipment must always take priority over personal protection equipment, make sure that the workplace is well aired through effective local aspiration. Personal protection equipment must comply with the rules in force indicated below.

### HAND PROTECTION

Protect hands with category III (ref. Directive 89/686/EEC and standard EN 374) work gloves, such as those in PVA, butyl, fluoroelastomer or equivalent. The following should be considered when choosing work glove material: degradation, breakage times and permeation. Work glove resistance to preparations should be checked before use, as it can be unpredictable. Gloves` limit depends on the duration of exposure.

### EYE PROTECTION

Wear hood visor or protective visor together with airtight goggles (ref. standard EN 166).

### SKIN PROTECTION

Wear category III professional long-sleeved overalls and safety footwear (ref. Directive 89/686/CEE and standard EN 344). Wash body with soap and water after removing overalls.

### RESPIRATORY PROTECTION

If the threshold value (if available) for one or more of the substances present in the preparation for daily exposure in the workplace or to a fraction established by the company`s prevention and protection service is exceeded, wear a mask with an B or universal filter, the class (1, 2 or 3) of which must be chosen according to the limit concentration of use (ref. standard EN 141).

The use of respiratory tract protection equipment, such as masks like that indicated above, is necessary to reduce worker exposure in the absence of technical measures. The protection provided by masks is in any case limited.

If the substance in question is odourless or its olfactory threshold is higher than the relative exposure limit and in the event of an emergency, or when exposure levels are unknown or the concentration of oxygen in the workplace is less than 17% volume, wear self-contained, open-circuit compressed air breathing apparatus (ref. standard EN 137) or fresh air hose breathing apparatus for use with full face mask, half mask or mouthpiece (ref. standard EN 138).

In the presence of risks of exposure to splashes or squirts during work, adequate mouth, nose and eye protection should be used to prevent accidental absorption.

Exposure levels must be kept as low as possible to avoid significant build-up in the organism; consequently, personal protective equipment must be managed so as to guarantee maximum protection (e.g. by reducing the replacement times for used PPE).

### ENVIRONMENTAL EXPOSURE CONTROLS.

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                           | violet         |
| 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                 | NA             |
| 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. |

|                                                                                  |                                   |                                                          |
|----------------------------------------------------------------------------------|-----------------------------------|----------------------------------------------------------|
|  | Zhermack S.p.a                    | Revision nr. 1                                           |
|                                                                                  | C200726_B - OCCLUFAST ROCK - BASE | Dated 21/11/2013<br>Printed on 26/11/2013<br>Page n. 6/9 |

|                                        |                    |
|----------------------------------------|--------------------|
| Solubility                             | insoluble in water |
| Partition coefficient: n-octanol/water | NA                 |
| 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.

#### 11.1. Information on toxicological effects.

CRISTOBALITE  
LD50 (Oral). > 2000 mg/kg (OECD 401, rat, MSDS supplier)  
LC50 (Inhalation). > 2,6 mg/l (OECD 403, rat, MSDS supplier)

*"For the purposes of classification of health hazards (part 3), the route of exposure, information on mechanisms and metabolism studies are useful for determining the relevance of effects in humans. If this information raises doubts as to their relevance in humans, in spite of the indisputable data legitimacy and quality, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified (annex I, section 1.1.1.5, EC Regulation 1272/2008)".*

Monitoring activities conducted at the company related to possible inhalation exposure, in accordance with industrial hygiene standards for paste and fluid products, showed levels of exposure to free crystalline silica (breathable part) below the limit of quantification of the method, therefore exposure is

|                                                                                  |                                   |                                                          |
|----------------------------------------------------------------------------------|-----------------------------------|----------------------------------------------------------|
|  | Zhermack S.p.a                    | Revision nr. 1                                           |
|                                                                                  | C200726_B - OCCLUFAST ROCK - BASE | Dated 21/11/2013<br>Printed on 26/11/2013<br>Page n. 7/9 |

not expected during the use indicated in section 1.2 for this specific product.  
However, the actual levels of free crystalline silica (breathable part) present in the workplace must be obtained through monitoring as required by regulations for the safety and health of workers.

## SECTION 12. Ecological information.

### 12.1. Toxicity.

Information not available.

### 12.2. Persistence and degradability.

CRISTOBALITE  
NOT rapidly biodegradable.

### 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.

## SECTION 13. Disposal considerations.

### 13.1. Waste treatment methods.

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.

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.

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.

|                                                                                  |                                   |                                                          |
|----------------------------------------------------------------------------------|-----------------------------------|----------------------------------------------------------|
|  | Zhermack S.p.a                    | Revision nr. 1                                           |
|                                                                                  | C200726_B - OCCLUFAST ROCK - BASE | Dated 21/11/2013<br>Printed on 26/11/2013<br>Page n. 8/9 |

Seveso category. None.

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006.

Product.  
Point. 3

Substances in Candidate List (Art. 59 REACH).

None.

Substances subject to authorisation (Annex XIV REACH).

None.

Substances subject to exportation reporting pursuant to (EC) Reg. 689/2008:

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.

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

**STOT RE 1** Specific target organ toxicity - repeated exposure, category 1  
**H372** Causes damage to organs through prolonged or repeated exposure.

Text of risk (R) phrases mentioned in section 2-3 of the sheet:

**R48/20** HARMFUL: DANGER OF SERIOUS DAMAGE TO HEALTH BY PROLONGED EXPOSURE THROUGH INHALATION.

### 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

|                                                                                  |                                          |                                                          |
|----------------------------------------------------------------------------------|------------------------------------------|----------------------------------------------------------|
|  | Zhermack S.p.a                           | Revision nr. 1                                           |
|                                                                                  | <b>C200726_B - OCCLUFAST ROCK - BASE</b> | Dated 21/11/2013<br>Printed on 26/11/2013<br>Page n. 9/9 |

- 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.

#### 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. The Merck Index. - 10th Edition
9. Handling Chemical Safety
10. Niosh - Registry of Toxic Effects of Chemical Substances
11. INRS - Fiche Toxicologique (toxicological sheet)
12. Patty - Industrial Hygiene and Toxicology
13. N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
14. ECHA website

#### 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.

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

|                                                                                  |                                       |                                                          |
|----------------------------------------------------------------------------------|---------------------------------------|----------------------------------------------------------|
|  | Zhermack S.p.a                        | Revision nr. 1                                           |
|                                                                                  | C200726_C - OCCLUFAST ROCK - CATALYST | Dated 21/11/2013<br>Printed on 26/11/2013<br>Page n. 1/9 |

## Safety data sheet

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

#### 1.1. Product identifier

Code: C200726\_C  
Product name: OCCLUFAST ROCK - CATALYST

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

Intended use Addition silicone for bite registration.

#### 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

CAV Italia: Centro Antiveleni di Milano: 02 66101029; Centro Antiveleni di Pavia: 0382 24444; Centro Antiveleni di Bergamo: 800 883300; Centro Antiveleni di Firenze: 055 7947819; Centro Antiveleni di Roma: 06 3054343; Centro Antiveleni di Roma: 06 49978000; Centro Antiveleni di Napoli: 081 7472870

Servicio de Información Toxicológica (España): + 34 91 562 04 20 (24h/365 días)

Numéro ORFILA (INRS-France): + 33 (0)1 45 42 59 59 (24h/ 7 jours sur 7)

UK Emergency number: 844 892 0111 (24 hours)

Deutschland Notruf: BERLIN Tel.: 030/19240; HOMBURG Tel.: 06841/19240; BONN Tel.: 0228/19240; MAINZ Tel.: 06131/19240; ERFURT Tel.: 0361/730 730; MÜNCHEN Tel.: 089/19240; FREIBURG Tel.: 0761/19240; NÜRNBERG Tel.: 0911/398-2451; GÖTTINGEN Tel.: 0551/19 240

### 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). However, since the product contains hazardous substances in concentrations such as to be declared in section no. 3, it requires a safety data sheet with appropriate information, compliant to EC Regulation 1907/2006 and subsequent amendments.

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

Hazard classification and indication:

|                                                                                  |                                       |                                                          |
|----------------------------------------------------------------------------------|---------------------------------------|----------------------------------------------------------|
|  | Zhermack S.p.a                        | Revision nr. 1                                           |
|                                                                                  | C200726_C - OCCLUFAST ROCK - CATALYST | Dated 21/11/2013<br>Printed on 26/11/2013<br>Page n. 2/9 |

## 2.2. Label elements.

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms: --

Signal words: --

Hazard statements: --

Precautionary statements: --

**Contains:** CRISTOBALITE

Safety data sheet available for professional users on request.

## 2.3. Other hazards.

There is no exposure to breathable free crystalline silica during normal use of this product. For more information see section 11.

# SECTION 3. Composition/information on ingredients.

## 3.1. Substances.

Information not relevant.

## 3.2. Mixtures.

Contains:

| Identification.     | Conc. %. | Classification 67/548/EEC. | Classification 1272/2008 (CLP). |
|---------------------|----------|----------------------------|---------------------------------|
| <b>CRISTOBALITE</b> |          |                            |                                 |
| CAS. 14464-46-1     | 5 - 10   | Xn R48/20                  | STOT RE 1 H372                  |
| EC. 238-455-4       |          |                            |                                 |
| INDEX. -            |          |                            |                                 |

Note: Upper limit is not included into the range.

The full wording of the Risk (R) and hazard (H) phrases is given in section 16 of the sheet.

# SECTION 4. First aid measures.

## 4.1. Description of first aid measures.

**EYES:** Remove contact lenses, if present Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice

**SKIN:** Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.

**INHALATION:** Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.

**INGESTION:** Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorised by a doctor.

|                                                                                  |                                       |                                                          |
|----------------------------------------------------------------------------------|---------------------------------------|----------------------------------------------------------|
|  | Zhermack S.p.a                        | Revision nr. 1                                           |
|                                                                                  | C200726_C - OCCLUFAST ROCK - CATALYST | Dated 21/11/2013<br>Printed on 26/11/2013<br>Page n. 3/9 |

#### 4.2. Most important symptoms and effects, both acute and delayed.

For symptoms and effects caused by the contained substances, see chap. 11.

#### 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

Do not use jets of water. Water is not effective for putting out fires but can be used to cool containers exposed to flames to prevent explosions.

### 5.2. Special hazards arising from the substance or mixture.

#### HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Excess pressure may form in containers exposed to fire at a risk of explosion. Do not breathe combustion products.

### 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).

## SECTION 6. Accidental release measures.

### 6.1. Personal precautions, protective equipment and emergency procedures.

Block the leakage if there is no hazard.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. 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.

Collect the leaked product into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

Make sure the leakage site is well aired. Check incompatibility for container material in section 7. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

|                                                                                  |                                       |                                                          |
|----------------------------------------------------------------------------------|---------------------------------------|----------------------------------------------------------|
|  | Zhermack S.p.a                        | Revision nr. 1                                           |
|                                                                                  | C200726_C - OCCLUFAST ROCK - CATALYST | Dated 21/11/2013<br>Printed on 26/11/2013<br>Page n. 4/9 |

#### 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.

Keep away from heat, sparks and naked flames; do not smoke or use matches or lighters. Without adequate ventilation, vapours may accumulate at ground level and, if ignited, catch fire even at a distance, with the danger of backfire. Avoid bunching of electrostatic charges. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat. Avoid leakage of the product into the environment.

### 7.2. Conditions for safe storage, including any incompatibilities.

Store only in the original container. Store in a well ventilated place, keep far away from sources of heat, naked flames and sparks and other sources of ignition. Keep containers away from any incompatible materials, see section 10 for details.

### 7.3. Specific end use(s).

Information not available.

## SECTION 8. Exposure controls/personal protection.

### 8.1. Control parameters.

Regulatory References:

|                |                                                                                                                                                                            |
|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| United Kingdom | EH40/2005 Workplace exposure limits. Containing the list of workplace exposure limits for use with the Control of Substances Hazardous to Health Regulations (as amended). |
| Éire           | Code of Practice Chemical Agent Regulations 2011.                                                                                                                          |
| OEL EU         | Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC.                                                                                   |
| TLV-ACGIH      | ACGIH 2012                                                                                                                                                                 |

#### CRISTOBALITE

##### Threshold Limit Value.

| Type      | Country | TWA/8h |     | STEL/15min |     |
|-----------|---------|--------|-----|------------|-----|
|           |         | mg/m3  | ppm | mg/m3      | ppm |
| TLV-ACGIH |         | 0,025  |     |            |     |
| OEL       | IRL     | 0,1    |     |            |     |

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.

VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified.

|                                                                                  |                                       |                                                          |
|----------------------------------------------------------------------------------|---------------------------------------|----------------------------------------------------------|
|  | Zhermack S.p.a                        | Revision nr. 1                                           |
|                                                                                  | C200726_C - OCCLUFAST ROCK - CATALYST | Dated 21/11/2013<br>Printed on 26/11/2013<br>Page n. 5/9 |

## 8.2. Exposure controls.

As the use of adequate technical equipment must always take priority over personal protection equipment, make sure that the workplace is well aired through effective local aspiration. Personal protection equipment must comply with the rules in force indicated below.

### HAND PROTECTION

Protect hands with category II (ref. Directive 89/686/EEC and standard EN 374) work gloves, such as those in PVC, neoprene, nitril or equivalent. The following should be considered when choosing work glove material: degradation, breakage times and permeation. Work glove resistance to preparations should be checked before use, as it can be unpredictable. Gloves' limit depends on the duration of exposure.

### EYE PROTECTION

Wear protective airtight goggles (ref. standard EN 166).

### SKIN PROTECTION

Wear category II professional long-sleeved overalls and safety footwear (ref. Directive 89/686/CEE and standard EN 344). Wash body with soap and water after removing overalls.

### RESPIRATORY PROTECTION

If the threshold value (if available) for one or more of the substances present in the preparation for daily exposure in the workplace or to a fraction established by the company's prevention and protection service is exceeded, wear a mask with an B or universal filter, the class (1, 2 or 3) of which must be chosen according to the limit concentration of use (ref. standard EN 141).

The use of respiratory tract protection equipment, such as masks like that indicated above, is necessary to reduce worker exposure in the absence of technical measures. The protection provided by masks is in any case limited.

If the substance in question is odourless or its olfactory threshold is higher than the relative exposure limit and in the event of an emergency, or when exposure levels are unknown or the concentration of oxygen in the workplace is less than 17% volume, wear self-contained, open-circuit compressed air breathing apparatus (ref. standard EN 137) or fresh air hose breathing apparatus for use with full face mask, half mask or mouthpiece (ref. standard EN 138).

In the presence of risks of exposure to splashes or squirts during work, adequate mouth, nose and eye protection should be used to prevent accidental absorption.

Exposure levels must be kept as low as possible to avoid significant build-up in the organism; consequently, personal protective equipment must be managed so as to guarantee maximum protection (e.g. by reducing the replacement times for used PPE).

### ENVIRONMENTAL EXPOSURE CONTROLS.

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                           | white          |
| 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                 | NA             |
| 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. |

|                                                                                  |                                       |                                                          |
|----------------------------------------------------------------------------------|---------------------------------------|----------------------------------------------------------|
|  | Zhermack S.p.a                        | Revision nr. 1                                           |
|                                                                                  | C200726_C - OCCLUFAST ROCK - CATALYST | Dated 21/11/2013<br>Printed on 26/11/2013<br>Page n. 6/9 |

|                                        |                    |
|----------------------------------------|--------------------|
| Solubility                             | insoluble in water |
| Partition coefficient: n-octanol/water | NA                 |
| 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.

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

## SECTION 11. Toxicological information.

### 11.1. Information on toxicological effects.

CRISTOBALITE  
LD50 (Oral). > 2000 mg/kg (OECD 401, rat, MSDS supplier)  
LC50 (Inhalation). > 2,6 mg/l (OECD 403, rat, MSDS supplier)

*"For the purposes of classification of health hazards (part 3), the route of exposure, information on mechanisms and metabolism studies are useful for determining the relevance of effects in humans. If this information raises doubts as to their relevance in humans, in spite of the indisputable data legitimacy and quality, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified (annex I, section 1.1.1.5, EC Regulation 1272/2008)".*

Monitoring activities conducted at the company related to possible inhalation exposure, in accordance with industrial hygiene standards for paste and fluid products, showed levels of exposure to free crystalline silica (breathable part) below the limit of quantification of the method, therefore exposure is

|                                                                                  |                                       |                                                          |
|----------------------------------------------------------------------------------|---------------------------------------|----------------------------------------------------------|
|  | Zhermack S.p.a                        | Revision nr. 1                                           |
|                                                                                  | C200726_C - OCCLUFAST ROCK - CATALYST | Dated 21/11/2013<br>Printed on 26/11/2013<br>Page n. 7/9 |

not expected during the use indicated in section 1.2 for this specific product.  
However, the actual levels of free crystalline silica (breathable part) present in the workplace must be obtained through monitoring as required by regulations for the safety and health of workers.

## SECTION 12. Ecological information.

### 12.1. Toxicity.

Information not available.

### 12.2. Persistence and degradability.

CRISTOBALITE  
NOT rapidly biodegradable.

### 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.

## SECTION 13. Disposal considerations.

### 13.1. Waste treatment methods.

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.  
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.  
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.

|                                                                                  |                                       |                                                          |
|----------------------------------------------------------------------------------|---------------------------------------|----------------------------------------------------------|
|  | Zhermack S.p.a                        | Revision nr. 1                                           |
|                                                                                  | C200726_C - OCCLUFAST ROCK - CATALYST | Dated 21/11/2013<br>Printed on 26/11/2013<br>Page n. 8/9 |

Seveso category. None.

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006.

Product.  
Point. 3

Substances in Candidate List (Art. 59 REACH).

None.

Substances subject to authorisation (Annex XIV REACH).

None.

Substances subject to exportation reporting pursuant to (EC) Reg. 689/2008:

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.

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

**STOT RE 1**                      Specific target organ toxicity - repeated exposure, category 1  
**H372**                              Causes damage to organs through prolonged or repeated exposure.

Text of risk (R) phrases mentioned in section 2-3 of the sheet:

**R48/20**                              HARMFUL: DANGER OF SERIOUS DAMAGE TO HEALTH BY PROLONGED EXPOSURE THROUGH INHALATION.

### 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)

|                                                                                  |                                       |                                                          |
|----------------------------------------------------------------------------------|---------------------------------------|----------------------------------------------------------|
|  | Zhermack S.p.a                        | Revision nr. 1                                           |
|                                                                                  | C200726_C - OCCLUFAST ROCK - CATALYST | Dated 21/11/2013<br>Printed on 26/11/2013<br>Page n. 9/9 |

- 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.

#### 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. The Merck Index. - 10th Edition
9. Handling Chemical Safety
10. Niosh - Registry of Toxic Effects of Chemical Substances
11. INRS - Fiche Toxicologique (toxicological sheet)
12. Patty - Industrial Hygiene and Toxicology
13. N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
14. ECHA website

#### 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.

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