



ZHERMACK S.P.A

Safety data sheet in agreement with EC DIRECTIVE 2001/58/EC

ZETAFLW CATALYST

Review date: 22/02/07

Print date: 12/06/08

1. IDENTIFICATION OF THE PRODUCT AND THE COMPANY

1.1 Identification of the preparation:

Commercial name ZETAFLW CATALYST

Commercial code: C100890 / C100850

1.2 Use of the substance or the preparation:

Catalyser for malleable condensation silicon impression material.

1.3 Identification of the company:

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

Emergency telephone number to contact the company: 0425/597611

2. COMPOSITION AND INFORMATION ON THE INGREDIENTS

The substances contained are dangerous to health pursuant to directive 67/548/EC and later adjustments or for which recognised limits of exposure exist: alkylstannosiloxane

| Ingredient | Percentage< | CAS | Danger symbol | Risk phrases |
|---------------------|-------------|------------|---------------|------------------------|
| alkylstannosiloxane | 5% - 7% | 93925-42-9 | Xi Irritant | R36 Irritating to eyes |

3. HAZARDS IDENTIFICATION

The preparation is not classified dangerous according to the dispositions of directives 67/548/EC and 1999/45/EC and subsequent changes and adjustments.

No specific danger can be found in its normal usage.

4. FIRST-AID MEASURES

4.1 Skin contact: Wash with plenty of hot water and soap.

4.2 Eye contact: Wash immediately with water for at least 10 minutes.

4.3 Ingestion: Do not induce vomit. SEEK MEDICAL ASSISTANCE IMMEDIATELY showing the safety data sheet. It is possible to administer active carbon suspended in water or medicinal mineral Vaseline oil.

4.4 Inhalation: Ventilate the room. Remove the patient immediately from the contaminated area and keep him at rest in a well ventilated area. In case of indisposition seek medical advice.

5. FIRE-FIGHTING MEASURES

5.1 Recommended extinguishers: Water, CO₂, foam, chemical powders according to the materials involved in the fire.

5.2 Forbidden extinguishers: None in particular.

5.3 Combustion risks: Avoid inhaling the fumes.

5.4 Protection equipment: Use protection equipment for the respiratory tract.

6. ACCIDENTAL RELEASE MEASURES

6.1 Individual precautions: Wear protective gloves and clothing.

6.2 Environmental precautions: Contain leaks with soil or sand. If the product has flown into waterways, sewage works or contaminated the ground or vegetation, advise the competent authorities.

6.3 Cleaning: Collect the product for reuse, if possible, or elimination. If necessary absorb it with inert material. Subsequent to collection, wash the area and interested materials with water.

7. HANDLING AND STORAGE

7.1 Handling precautions: See also paragraph B below. Refrain from eating or drinking at work.

7.2 Incompatible materials: None in particular. See also paragraph 10 below.

7.3 Storage conditions: Keep in a fresh dry place at a temperature of between 5 and 27°C (41-80°F).

7.4 Indications for rooms: Should be adequately ventilated.

Page 1 di 3

| REVIEW | DATE | DESCRIPTION | ISSUED BY | APPROVED BY |
|--------|----------|--------------|---------------------|------------------------|
| 1 | 22/02/07 | First issue | R&S | RSGQA |
| 2 | 12/06/08 | Agg.point 11 | Quality Coordinator | HSEQ Executive Manager |

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ITALY - GERMANY - POLAND - UNITED STATES - UNITED KINGDOM - RUSSIA - CHINA



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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

- 8.1 **Precaution measures:** Ventilate the rooms where the product is stored and/or handled adequately.
8.2 **Respiratory protection:** Not necessary for normal usage.
8.3 **Hand protection:** Not necessary for normal usage.
8.4 **Eye protection:** Not necessary for normal usage. Work, in any case, using good work practises.
8.5 **Skin protection:** No particular precaution must be adopted for normal use.
8.6 **Exposure limits of substances contained:** None

9. PHYSICAL AND CHEMICAL PROPERTIES

- 9.1 **Physical state and colour:** Yellow gel
9.2 **Odour:** Ethylic
9.3 **Boiling point:** 110°C at 1013MBARS
9.4 **Igniting temperature:** 62°C with closed vase
9.5 **Vapour tension:** at 20°C < at 42 MBAR
9.6 **Relative density:** at 25°C 1.05 g/cc
9.7 **Solubility in water:** Insoluble, it disperses in aromatic and chlorinated solvents

10. STABILITY AND REACTIVITY

- 10.1 **Conditions to avoid:** Stable in normal conditions.
10.2 **Substances to avoid:** None in particular.
10.3 **Dangers from decomposition:** None.

11. TOXICOLOGICAL INFORMATION

Toxicological data on the preparation as is are not available: similar products have highlighted DL50 pc (rodent) > 2000 mg/Kg, DL 50 po (rodent) > 2000 mg/Kg.

Below is the toxicological information regarding the principal substances:

CAS 78-10-4 LD 50 (rodent) 6270 mg/Kg: it can cause eye, skin and mucous irritation.

CAS 93925-42-9 TWA as tin 0.1 mg/m³; for some composites of tin like CAS 1067-33-0, LD 50 (mouse, oral) 160 mg/Kg, (rabbit, cutaneous) 2320 mg/Kg.

Cytotoxicity tests performed on the product with silicon tested on cellular line L929 have given negative results. Skin irritation tests on the rabbit performed on the product as is have not given negative result.

12. ECOLOGICAL INFORMATION

Use according to good work practises, avoiding dispersion of the product in the environment.

13. DISPOSAL CONSIDERATIONS

Recycle if possible. Work according to the current local and national laws in force.

14. TRANSPORT INFORMATION

Goods are not dangerous according to transport regulations.

15. REGULATORY INFORMATION

Leg. Dec.65/03 (classification, packing and labelling of dangerous preparations): The preparation is not considered dangerous according to directive 67/548/EC and 1999/45/EC and subsequent adjustments.

Medical Device marked EC in agreement with Directive 93/42/EC on Medical Devices.

16. OTHER INFORMATION

Page 2 di 3

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The information contained here is based on the knowledge available to us at the date shown above. It refers solely to the named product and is no guarantee of specific qualities. The user must ensure suitability and completeness of this information in relation to the specific use he must make of it. This safety data sheet cancels and replaces any previous edition. The product has been treated to cancel the fraction of respirable dust.

Page 3 di 3

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ITALY - GERMANY - POLAND - UNITED STATES - UNITED KINGDOM - RUSSIA - CHINA

zetaflow



POLYSILOXANE
(CONDENSATION SILICONE)
IMPRESSION MATERIAL

zetaflow putty
zetaflow light
zetaflow catalyst

Zhermack[®]
CLINICAL 



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Via Bovazecchino, 100
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HYDROCOMPATIBLE CONDENSATION SILICONES (POLYSILOXANES) FOR HIGH-PRECISION IMPRESSIONS

USE

Zetaflow Putty: Polysiloxane for the first impression characterised by initial flow in the working phase and high rigidity after setting. Recommended for the two stage technique (double impression).

Zetaflow Light: Low viscosity, extremely fluid, hydrocompatible, polysiloxane. Recommended for the two stage technique (double impression).

Zetaflow Catalyst: Specific catalyst for Zetaflow Putty and Zetaflow Light.

IMPRESSION TRAY: All rigid types; Hi-Tray (Zhermack) stainless steel impression trays are particularly recommended. Use Universal Tray Adhesive (Zhermack) with impression trays without perforations or rim locks.

ZETAFLAW PUTTY
INSTRUCTIONS FOR USE:

Dosage: Use the measuring scoop to dose the required quantity of ZETAFLAW Putty and spread it out over your hand (note: for the correct dosage the putty should be level with the top of the measuring scoop). Press the rim of the measuring scoop onto the putty once for each measure dosed. For each measure of material, apply one strip of ZETAFLAW Catalyst as long the measuring scoop (4 cm.) (1).

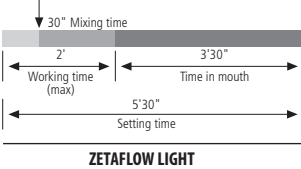
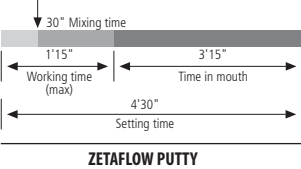
Mixing: Fold and knead the putty energetically with your fingertips for about 30 sec., until the colour is even, without any stripes (2).
Spread out the putty over the impression tray. The working time including mixing time is about 1 min. 15 sec. (3).
Put into the mouth and wait until it is set, which will take about 3 min. 15 sec. (4).

ZETAFLAW LIGHT
INSTRUCTIONS FOR USE:

Dosage: Extrude the required quantity, observing the dosage scale on the mixing pad. Then dose a quantity of ZETAFLAW Catalyst equal to the length of the fluid (5).

Mixing: Mix energetically with the spatula, and then carefully spread the mixture out, pressing it over the mixing block to eliminate any air which may have been incorporated into the mixture. Repeat this operation until the mix is even in colour. Mixing time should ideally be about 30 sec. (6). Apply the mixture to the impression tray with a spatula or a syringe for elastomers. Working time including mixing time is about 2 min. (7).
Put into the oral cavity and wait for the mix to set, which will take about 3 min. 30 sec. (8).

TIMES FOR CLINICAL USE



WARNING: In sensitive subjects, polysiloxanes may cause irritation or other allergic reactions.

CLEANING AND DISINFECTION OF THE IMPRESSION

After rinsing well under running water, the impression can be immediately disinfected. Ideal disinfecting is achieved by immersing the impression in **Zeta 7 solution** or spraying it with **Zeta 7 spray** (Zhermack). When using other disinfectants, always follow the manufacturer's instructions.

CASTING MODELS: the impression must be cast 30 min. to 72 hours after setting. To reduce surface tension and therefore the risk of bubble formation (with dental stone materials) we recommend treating the impression by spraying with Zhermack Tensilab. The material is compatible with all quality commercially available dental stone. We recommend Zhermack gypsum, type 4 die stone: **Elite Rock/Elite Rock Fast** (Zhermack) and type 3: **Elite Model/Elite Model Fast** (Zhermack).

WARNING / CAUTION

- Before making the wash impression, remove all remaining traces of oral fluids by rinsing thoroughly and drying.
- The times given are for mix starting at 23°C/73°F. High temperatures or overuse of catalysts will speed up setting, whereas low temperatures or insufficient use of catalysts will slow it down.
- Close all setting substances properly after use.
- Use of gloves is recommended. Prevent catalyst from coming into contact with skin and eyes; wash well with soap and water in the event of accidental skin contact. In the event of eye contact, rinse thoroughly with running water and seek medical attention. If substance is ingested, seek medical attention immediately.
- Do not stain garments.

GALVANISATION: The impressions may be galvanised with copper or silver.

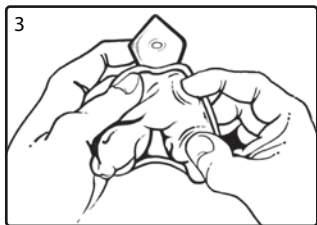
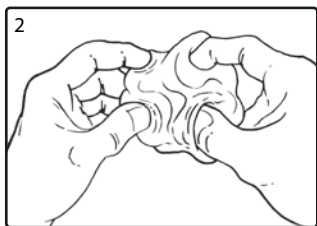
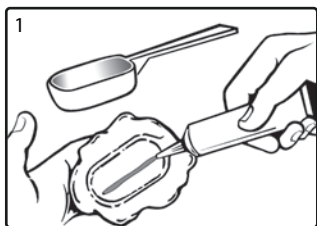
CONSERVATION: Guaranteed for 36 months at 5°C to 27°C (41°F – 80°F)

| TECHNICAL DATA | ZETAFLAW PUTTY | ZETAFLAW LIGHT |
|------------------------------------|-----------------------------|------------------------------------|
| ISO 4823 / ADA 19 | Type 0 Putty Consistency | Type 3 Light-bodied Consistency |
| Mixing time | 30" | 30" |
| Total working time* | 1'15" | 2' |
| Time in mouth* | 3'15" | 3'30" |
| Setting time* | 4'30" | 5'30" |
| Strain in compression (min - max) | 2-5% | 2-8% |
| Recovery from deformation | >98% | >99% |
| Linear dimensional change 24 hours | <-0,2% | <-0,7% |

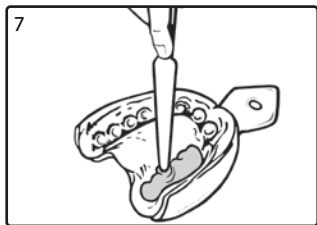
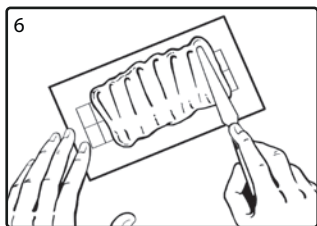
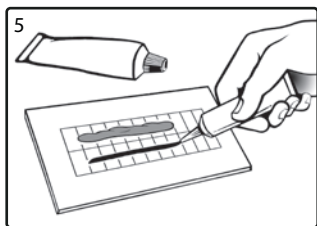
*The times mentioned must be intended from the start of mixing at 23°C – 73°F. Higher temperatures reduce the times, lower temperatures increase them.

IMPORTANT REMARKS: Consulting services on the use of our products, provided in any form, be that verbal, written or through demonstrations, are based upon the current state of dentistry and of our know-how. They are to be considered as non-binding information, also in relation to possible third party claims, and do not exonerate the user from personally checking whether the product is suitable for the planned use. Use and application by the user take place under no possible control by the Company, and are therefore under the user's responsibility. Possible liability for damages is limited to the value of goods supplied by the Company and utilized by the user.

zetaflow putty



zetaflow light



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ZETAFLW LIGHT

Revision date:20/02/07

Print Date: 21/08/07

1. IDENTIFICATION OF THE PREPARATION AND OF THE COMPANY

1.1 Identification of the preparation:

Trade name: ZETAFLW LIGHT

Trade code: C100810 / C100850

1.2 Utilization of the substance or of the preparation:

Condensation silicone for second impression.

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: 0425/597611

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous components within the meaning of EEC directive 67/548 and corresponding classification: None.

3. HAZARDS IDENTIFICATION

PREPARATION NOT CLASSIFIED DANGEROUS

No specific hazards are encountered under normal product use. The contact with eyes can to cause a highly trouble and subjunctive's redding.

4. FIRST AID MEASURES

4.1 Contact with skin: The specific indications will not cause of irritation.

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

4.3 Swallowing: If swallowed in a small quantity the product is harmless, otherwise consult a doctor.

4.4 Inhalation: Ventilate the premises.

5. FIRE-FIGHTING MEASURES

5.1 Recommended extinguishers: water, CO₂, foam, chemical powders, according to the materials involved in the fire.

5.2 Extinguishers not to be used: none in particular.

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 leakages with earth or sand.

6.3 Cleaning methods: recover the product for re-use if possible, or for elimination. The product might, 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: avoid contact and inhalation of the vapours. See, too, paragraph 8 below. Do not eat or drink while working.

7.2 Incompatible materials: none in particular.

7.3 Storage conditions: keep the closed container a temperature varying from 5°C to 27°C (41-80°F).

7.4 Technical measures: satisfactory room ventilation.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

| REVISIONE | DATA | DESCRIZIONE | EMISSIONE | APPROVAZIONE |
|-----------|----------|--------------------------------|-----------|--------------|
| 2 | 15/04/98 | Aggiornamento | | |
| 3 | 18/01/99 | Aggiornamento formato scheda | RCP | RS/RQA |
| 4 | 12/12/02 | Aggiornamento Dir. 2001/58/CEE | R&S | RSGQA |

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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

8.5 Protection for skin: no special precaution must be adopted for normal use

8.6 Exposure limit(s) (ACGIH): none

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Appearance and colour: blue fluid

9.2 Odour: inodore

9.3 Relative density: 1.10 g/cc

9.4 Solubility in water: insoluble

The mixing of base and catalyst causes a elastic product.

10. STABILITY AND REACTIVITY

10.1 Conditions to avoid: stable under normal conditions.

10.3 Substances to avoid: none in particular.

10.4 Hazardous decomposition products: none

11. TOXICOLOGICAL INFORMATION

The exactly product doesn't have citotossic effects on the L929 cellular line.

12. ECOLOGICAL INFORMATION

Adopt sound working practices, so 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 in the meaning of transport regulations.

15. REGULATORY INFORMATION

The preparation should not be considered as dangerous accordingly to 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 at the above-specified date. 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.

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| 4 | 12/12/02 | Aggiornamento Dir. 2001/58/CEE | R&S | RSGQA |

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Print Date: 21/08/07

1. IDENTIFICATION OF THE PREPARATION AND OF THE COMPANY

1.1 Identification of the preparation:

Trade name: ZETAFLOW PUTTY

Trade code: C100800/C100850

1.2 Utilization of the substance or of the preparation:

Condensation silicone for first impression.

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: 0425/597611

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous components within the meaning of EEC directive 67/548 and corresponding classification: None.

3. HAZARDS IDENTIFICATION

PREPARATION NOT CLASSIFIED DANGEROUS

No specific hazards are encountered under normal product use. The contact with eyes can to cause a little trouble and conjunctive's reddening.

4. FIRST AID MEASURES

4.1 Contact with skin: The specific indications will not cause of irritation.

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

4.3 Swallowing: If swallowed in a small quantity the product is harmless, otherwise consult a doctor.

4.4 Inhalation: Ventilate the premises.

5. FIRE-FIGHTING MEASURES

5.1 Recommended extinguishers: water, CO₂, foam, chemical powders, according to the materials involved in the fire.

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7.2 Incompatible materials: none in particular.

7.4 Storage conditions: keep the closed container a temperature varying from 5°C to 27°C (41-80°F).

7.5 Technical measures: satisfactory room ventilation.

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8.3 Protection for hands: not needed for normal use

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|-----------|----------|-----------------|-----------|--------------|
| 1 | 22/02/07 | Prima emissione | | |

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8.4 Eye protection: not needed for normal use

8.5 Protection for skin: no special precaution must be adopted for normal use

8.6 Exposure limit(s) (ACGIH): none

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Appearance and colour: ocrea paste

9.2 Odour: lampone

9.3 Relative density: 1.70 g/cc

9.4 Solubility in water: insoluble

The mixing of base and catalyst causes a elastic product.

10. STABILITY AND REACTIVITY

10.1 Conditions to avoid: stable under normal conditions.

10.2 Substances to avoid: none in particular.

10.3 Hazardous decomposition products: none

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| 1 | 22/02/07 | Prima emissione | | |