

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

Revision date: 07/02/2011

Print Date: 14/02/11

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

Trade name: COLORBITE D

Trade code: C200750

1.2 Utilization of the substance or of the preparation:

Thermochromic Addition silicone for occlusion bite.

1.3 Identification of the company:

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

Emergency telephone number of the company: 0039 0425 597611

2. COMPOSITION/INFORMATION ON INGREDIENTS

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

3. IDENTIFICATION OF HAZARDS

PREPARATION NOT CLASSIFIED DANGEROUS

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

4. FIRST AID MEASURES**4.1 Contact with skin:** 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, or chemical powders, depending on 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 leakage with earth or sand. If the product has escaped into a water course, into the drainage system, or has contaminated the ground or vegetation, notify the competent authorities.**6.3 Cleaning methods:** recover the product for re-use if possible, or for elimination. The product may, where appropriate, be absorbed by inert material. After the product has been recovered, rinse the area and materials involved with water.**7. HANDLING AND STORAGE****7.1 Handling precautions:** refer to point 8 below. Do not eat or drink while working.**7.2 Incompatible materials:** none in particular. Also see point 10 below.**7.3 Storage conditions:** keep in a cool, dry place at a temperature of 5°C to 27°C (41-80°F).**7.4 Technical measures:** adequately ventilated premises.**8. EXPOSURE CONTROLS / PERSONAL PROTECTION****8.1 Precautionary measures:** ensure adequate ventilation of the premises where the product is stored and/or handled.

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REVISIONE	DATA	DESCRIZIONE	EMISSIONE	APPROVAZIONE
1	11/10/05	First emission	R&S	RSGQA
2	16/05/06	Name modification (colorbite / colorbite D)	R&S	RSGQA
3	07/02/2011	Riemesso con nessuna modifica	R&D	HSEQ

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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. Always apply proper working practices.
8.5 Protection for skin: no special precaution required for normal use
8.6 Exposure limit(s) (ACGIH): none

9. PHYSICAL AND CHEMICAL PROPERTIES

- 9.1 Appearance and colour:** Bicomponent fluid, of which one part (base) is coloured (green at 23°C / yellow > 30°C).
9.2 Odour: lime flavour
9.3 Relative density: 1.61 g/cc
9.4 Solubility in water: insoluble

10. STABILITY AND REACTIVITY

- 10.1 Conditions to avoid:** stable under normal conditions.
10.2 Substances to avoid: the "base" component may produce hydrogen in contact with alkaline and acid substances.
10.3 Hazardous decomposition products: none

11. TOXICOLOGICAL INFORMATION

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

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

Not classified as dangerous under transport regulations.

15. REGULATORY INFORMATION

Danger labelling under regulations 67/548/CEE and 1999/45/CE and following amendments and adjustments.

Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/CE regulation is respected.

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.

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