

Scheda di Dati di Sicurezza

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

1.1. Product identifier

Name Cubi Orth Primer **HS Code: 3209 10 00**

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

Description / Use Cubes Orth Primer of the safety data sheet of the supplier information

Company Megadental Italy Address Via Caprera, 16 District and Country 91028 Partanna (TP) Italy

e-mail address of the person responsible info@megadentalitalia.it

1.4. Emergency telephone number

For urgent inquiries refer to Poison Centre - Ospedale di Firenze (24/24)

Phone: +39 55 794 7819

SECTION 2. Hazards identification.

2.1. Classification of the substance or mixture.

The product is not classified as hazardous pursuant to the provisions of Directives 67/548 / EEC and 1999/45 / EC. The product, however, contains dangerous substances in concentrations that must be declared in section No. 3 and requires a safety data sheet containing all the information required under the Regulation (EC) No. 1907/2006, as amended.

2.2. Label elements.

The product is not subject to hazard labeling under the 67/548 / EEC and 1999/45 / EC and following amendments and adjustments.

Warning symbols: None Hazard sentences (R): None safety advice (S): None.

Safety data sheet available on request for professional users.

2.3. Other hazards. Based on available data, the product does not contain any PBT or vPvB substances as a percentage greater than 0.1%.



SECTION 3. Composition / information on ingredients.

3.2. Mixtures. It contains:

Identification. Conc.%. Classification 67/548 / EEC. Classification 1272/2008 (CLP).

2-Butoxyethanol

Xn R20 / 21/22 Xi R36 / 38 Acute Tox. 4 H302, Acute Tox. 4 H312, Acute Tox. 4 H332, Eye Irrit. 2 H319, Skin Irrit. 2 H315

INDEX. 603-014-00-0

Nr. Reg. 01-2119475108-36 2- (2-butoxyethoxy) ethanol

CAS. 112-34-5 1 to 1.5 Xi R36 Eye Irrit. 2 H319

THERE IS. 203-961-6 INDEX. 603-096-00-8

Nr. Reg. 01-2119475104-44

Note: Higher value of the excluded range.

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

T + = Very Toxic (T +), T = Toxic (T), Xn = Harmful (Xn), C = Corrosive (C), Xi = Irritating (Xi), O = Oxidizing (O), E = Explosive (E), F + = Extremely Flammable (F +), F = Highly Flammable (F), N = Dangerous for the Environment (N)

SECTION 4. First aid measures.

4.1. Description of first aid measures.

EYES: Remove contact lenses. Wash immediately with plenty of water for at least 15 minutes, opening her eyelids. Consult a doctor if the problem persists.

SKIN: Take off contaminated clothing. Wash immediately with plenty of water. If irritation persists, consult a doctor. Wash contaminated clothing before reuse.

Inhalation: Move to fresh air. If breathing is difficult, seek medical attention.

Ingestion: Consult a physician immediately. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person and if indicated by the doctor.

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.

SECTION 5. Fire-fighting measures.

5.1. Extinguishing.

SUITABLE EXTINGUISHING MEDIA

The extinction equipment should be of the conventional kind: carbon dioxide, foam, powder and nebulised water. EXTINGUISHING MEDIA NOT SUITABLE

No one 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.
- 5.3. Advice for firefighters.

GENERAL INFORMATIONS

Cool down with water jets 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. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

EQUIPMENT

normal clothing to fight the fire, such as a compressed air breathing apparatus open circuit (EN 137), complete with flame retardant (EN469), flame-resistant gloves (EN 659) and boots for the fire brigade (HO A29 or A30).



SECTION 6. Measures in case of accidental release.

6.1. Personal precautions, protective equipment and procedures in case of emergency devices.

Stop leak if safe to do so.

Wear suitable protective equipment (including personal protective equipment referred to in section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These directions are valid both for the workers to work which for emergency interventions.

6.2. Environmental precautions.

Prevent product from entering into drains, surface water, ground water.

6.3. Methods and materials for containment and cleaning up.

Vacuum the spilled product into a suitable container. Assess the compatibility of the container to be used with the product, verifying section 10. Absorb the remainder with inert absorbent material.

Ensure adequate ventilation of the place affected by the loss. Verify the compatibility of the material of the containers in section 7. The disposal of contaminated material must be made in accordance with point 13.

6.4. Reference to other sections.

SECTION 7. Handling and storage.

7.1. Precautions for safe handling.

Keep away from heat, sparks and open flames, do not smoke, use matches or lighters. Without adequate ventilation, the vapors may accumulate on the ground and ignite at a distance, if triggered off with the risk of flashback. Avoid the accumulation of electrostatic charges. Do not eat, drink or smoke while handling it. Remove contaminated clothing and protective equipment before entering areas where you eat. Avoid dispersal into the environment.

7.2. Conditions for safe storage, including any incompatibilities.

Store only in the original container. Store in a cool, well-ventilated place, away from heat sources, open flames, sparks and other ignition sources. Store containers away from any incompatible materials, checking section 10.

07:02:01 - Keep from freezing. Store at temperatures between 5 $^{\circ}$ C and 35 $^{\circ}$ C.

7.3. Specific end uses.

See section 1.2.Per more information please see data sheet.

SECTION 8. Exposure controls / personal protection.

8.1. Control parameters.

Normative requirements:

EU OEL EU Directive 2009/161 / EU; Directive 2006/15 / EC; Directive 2004/37 / EC; Directive 2000/39 / EC.



Section 8 Exposure control / personal protection

OEL EU 98 20 246 50 SKIN.

Concentration expected not to impact on the environment - PNEC.

reference value in fresh water 8.8 mg/l

reference value in marine water 0,88 mg / I

reference value for sediments in freshwater 34.6 mg / kg

reference value for sediment in seawater 3.46 mg /

reference value for the terrestrial compartment 3.13 mg / kg

Oral. VND 3.2

mg / kg

Inhalation. VND 49 VND 98

mg / m3 mg / m3

Dermal. VND 38 VND 75

mg / kg mg / kg

OEL EU 67,5 10 101,2 (C) 15 (C)

Concentration expected not to impact on the environment - PNEC.

reference value in fresh water 1 mg / I

reference value in sea water 0.1 mg / I

reference value for sediment in fresh water 4 mg / kg

reference value for sediment in seawater 0.4 mg / kg

reference value for the terrestrial compartment 0.4 mg / kg

Oral. VND 1.25

mg / kg

Inhalation. 50.6 VND 34 VND 101.2 VND 67.5 67.5

mg / m3 Dermal. VND 10 VND 20

legend:

(C) = CEILING; INALAB = Inhalable fraction; RESPIR = Respirable fraction; Torac = Fraction Thoracic.

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

8.2. Exposure controls.

As the use of adequate technical equipment must always take priority over personal protection equipment, ensure good ventilation in the workplace through effective local aspiration.

HAND PROTECTION

Protect your hands with work gloves, category III (ref. Standard EN 374).

For the final choice of work glove material must be considered: compatibility, degradation, breakage times and permeation.

In the case of preparations the resistance of protective gloves to chemicals should be checked before use, as it expected. The Gloves' limit depends on the duration and method of use.

SKIN PROTECTION

Wear work clothes with long sleeves and safety footwear for professional use category I (ref. Directive 89/686 / EEC and standard EN ISO 20344). Wash with soap and water after removing protective clothing.

EYE PROTECTION

You should wear protective airtight goggles (ref. Standard EN 166). RESPIRATORY PROTECTION

In case of exceeding the threshold value (eg. TLV-TWA) of the substance or one or more of the substances present in the product, you should wear a Type A, the class mask with filter (1, 2 or 3) must be chosen according to the limit concentration of use.

EPY 9.0.8 - SDS 1003



Section 8 personal control / Individual protection

(Ref. Standard EN 14387). In the case were present gas or of a different nature vapors and / or gases or vapors with particles (aerosols, fumes, mists, etc.) Should be provided for combined type filters.

The use of respiratory protective equipment is necessary in case the technical measures are not sufficient to limit the exposure of the worker to the threshold values considered. The protection provided by masks is in any case limited.

In the case where the substance in question is odorless or its olfactory threshold is higher than the related TLV-TWA, and in case of emergency, wear a compressed air breathing apparatus open circuit (ref. Standard EN 137) or a respirator in socket d'outdoor air (ref. standard EN 138). For the correct choice of protective breathing equipment, refer to EN 529. ENVIRONMENTAL EXPOSURE CONTROLS. Emissions from production processes, including those from ventilation should be checked for compliance of environmental protection legislation.

SECTION 9. Physical and chemical properties.

9.1. Information on basic physical and chemical properties.

Appearance liquid

milky color

characteristic odor

olfactory threshold. Not available.

pH. 7.2000

melting or freezing point. Not available. Initial boiling point. > 100 ° C. boiling range. Not available. Flash point. > 60 ° C.

Evaporation rate Not available.

Flammability of solids and gases Not available.

lower flammable limit. Not available.

upper flammable limit. Not available.

lower explosive limit. Not available.

upper explosive limit. Not available.

Vapor pressure. Not available.

Vapour density Not applicable.

Relative density. 1.04 kg / I

Solubility Soluble in water

Partition coefficient: n-octanol / water: Not available. auto-ignition temperature. Not available.

decomposition temperature. Not available.

Viscosity Not available.

Explosive properties Not available.

oxidant properties Not available.

9.2. Further information.

VOC (Directive 1999/13 / EC): 5,24% - 54,53 g / liter.

VOC (volatile carbon): 3,20% - 33,28 g / liter.

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 under normal conditions of use and storage.

10.3. Possibility of hazardous reactions.

Vapors may form explosive mixtures with air.

10.4. Conditions to avoid.

Avoid overheating. Avoid the accumulation of electrostatic charges. Avoid all sources of ignition.

10.5. Incompatible materials.

Information not available.

10.6. Hazardous decomposition products.

When heated or in case of fire can be released vapors potentially dangerous to health.



SECTION 11. Toxicological information.

No episodes of damage to health due to exposure to the product. In any case it must be handled in accordance with good industrial practices. This product may have sensitive people, cause minor health effects by inhalation and / or cutaneous absorption and / or contact with eyes and / or ingestion.

11.1. Information on toxicological effects.

2- (2-butoxyethoxy) ethanol LD50 (Oral). > 6000 mg / kg Rat

LD50 (Dermal). > 4000 mg / kg Rabbit

2-Butoxyethanol LD50 (Oral). 1746 mg / kg Rat LD50 (Dermal). 6411 mg / kg Pig LC50 (inhalation). 450 ppm Rat

SECTION 12. Ecological information.

No specific data are available on the preparation, use according to good working practices, avoiding release of the product in the environment. Never allow to enter soil, sewers or waterways. Inform the competent authorities, should the product reach waterways or sewers or contaminate soil or vegetation. Take steps to minimize the effects on ground water.

12.1. Toxicity.

2- (2-butoxyethoxy) ethanol

LC50 - Fish. 100 mg / I / 96h Fish

EC50 - Crustaceans. 100 mg / l / 48h Algae

2-Butoxyethanol

LC50 - Fish. 1474 mg / I / 96h Fish

EC50 - Crustaceans. 1550 mg / I / 48h Daphnia

EC50 - Algae / Aquatic Plants. 911 mg / I / 72h Algae

12.2. Persistence and degradability.

2-Butoxyethanol Readily Biodegradable.

12.3. Potential for bioaccumulation.

Information not available.

12.4. Mobility in soil.

Information not available.

12.5. Results of PBT and vPvB.

Based on available data, the product does not contain any PBT or vPvB substances as a percentage greater than 0.1%.

12.6. Other adverse effects.

SECTION 13. Disposal considerations.

13.1. Methods of waste treatment.

Reuse, when possible. The product residues should be considered special non-hazardous waste.

Disposal must be performed through an authorized 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.



SECTION 14. Transport information.

14.1. UN number.

Not applicable.

14.2. UN proper shipping name.

Not applicable.

14.3. hazard class transport.

Not applicable.

14.4. Packaging group. Not applicable.

14.5. Environmental hazards.

Not applicable.

14.6. Special precautions for user.

Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code.

- REACH: EU Regulation 1907/2006
- RID: Regulations for the international carriage of dangerous goods by rail
- TLV: TLV
- TLV CEILING: Concentration which must not be exceeded during any time of occupational exposure.
- TWA STEL: Short Term Exposure Limit
- TWA: Medium exposure limit weighed
- VOC: Volatile Organic Compound
- VPvB: Very persistent and very bioaccumulative according to REACH
- WGK: Water hazard class (Germany).

GENERAL BIBLIOGRAPHY

- 1. Directive 1999/45 / EC as amended
- 2. Directive 67/548 / EEC and following amendments and adjustments
- 3. Regulation (EU) 1907/2006 of the European Parliament (REACH)

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 Regulation (EC) 1907/2006. ACGIH.

Point. 55 2- (2-butoxyethoxy) ethanol

Nr. Reg .: 01-2119475104-44

Substances in Candidate List (Art. 59 REACH).

NONE

Substances subject to authorization (Annex XIV REACH).

Substances subject to the obligation of export notification Reg. (EC) 649/2012:

NONE

Substances subject to the Rotterdam Convention: NONE

Substances subject to the Stockholm Convention:

Sanitary checks.

nformation not available.

Legislative Decree no. 152/2006 and subsequent amendments.

EMMISSIONI:

TAB. C Class 4 00.30%

TAB. D Class 3 06.24%

WATER 59.60%

Classification for water pollution in Germany (VwVwS 2005).



SECTION 15. Regulatory information.

WGK 3: Dangerous Water

15.2. Chemical safety assessment. Test Report N $^\circ$ 615-16en and N $^\circ$ 618-16en Pag. 1/6 Time Schedule Of Study The study was started on the 28/02/16 and was completed on the 04/03/16 Test carried out by: Barbara Gottardi



ACCREDIA accreditation N° 1337

Lab4LIFE S.R.L. P.IVA e C.F: 03096401207 Capitale Sociale €45.000 i.v. N. REA: BO – 491522 - Sede legale Via dei Fornaciai 21 g/h 40129 Bologna Tel. 051323039 FAX. 0514170410

SECTION 16. Other information.

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

Acute toxicity, category 4

Eye irritation, Category 2

Skin irritation, category 2

Harmful if swallowed. Harmful in contact with skin.

Harmful if inhaled Causes serious eye irritation.

It causes skin irritation.

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

HARMFUL BY INHALATION, IN CONTACT WITH SKIN AND IF SWALLOWED.

Irritating to eyes.

Irritating to eyes and skin.

LEGEND:

- ADR: European Agreement concerning the Carriage of Dangerous Goods by Road
- CAS NUMBER: Number of the Chemical Abstract Service
- EC50: Concentration that gives effect to 50% of the population subject to testing
- EC NUMBER: Number identifier in ESIS (European database of existing substances)
- CLP: Regulation EC 1272/2008
- DNEL: Derived no effect level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of Classification and Labeling of Chemicals
- IATA DGR: Regulation for the transport of dangerous goods by the International Air Transport Association
- IC50: Concentration of immobilization of 50% of the population subject to testing
- IMDG: International Maritime Code for Dangerous Goods
- IMO: International Maritime Organization
- INDEX NUMBER: identification number in Annex VI of the CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal Dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent, bioaccumulative and toxic according to REACH
- PEC: Predicted Environmental Concentration
- PEL: Predicted Exposure Level
- PNEC: Predicted No Effect Concentration
- REACH: EU Regulation 1907/2006
- RID: Regulations for the international carriage of dangerous goods by rail
- TLV: TLV
- TLV CEILING: Concentration which must not be exceeded during any time of occupational exposure.
- TWA STEL: Short Term Exposure Limit
- TWA: Medium exposure limit weighed
- VOC: Volatile Organic Compound
- VPvB: Very persistent and very bioaccumulative according to REACH
- WGK: Water hazard class (Germany).

GENERAL BIBLIOGRAPHY

- 1. Directive 1999/45 / EC as amended
- 2. Directive 67/548 / EEC and following amendments and adjustments
- 3. Regulation (EU) 1907/2006 of the European Parliament (REACH)
- 4. Regulation (EU) 1272/2008 of the European Parliament (CLP)
- 5. Regulation (EU) 790/2009 of the European Parliament (I Atp. CLP) 6. Regulation (EU) 453/2010 of the European Parliament
- 7. Regulation (EU) 286/2011 of the European Parliament (II ATP. CLP)



SECTION 16. Other information.

8. Regulation (EU) 618/2012 of the European Parliament (ATP III. CLP)

9. Regulation (EU) 487/2013 of the European Parliament (IV ATP. CLP)

10. Regulation (EU) 944/2013 of the European Parliament (V Atp. CLP)

11. Regulation (EU) 605/2014 of the European Parliament (VI Atp. CLP)

- The Merck Index. - 10th Edition

Handling Chemical Safety

Niosh - Registry of Toxic Effects of Chemical Substances

INRS - Fiche Toxicologique (toxicological sheet)

- Patty - Industrial Hygiene and Toxicology

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

- Web Site ECHA Agency

Note for users:

The information contained in this 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.

It should not be construed 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 the laws and the current regulations on hygiene and safety. Do not assume responsibility for improper use.

Provide appropriate training of staff involved in the operation of chemicals.

Changes to previous review.

Changes were made to the following sections: 02/14.

Changes compared with the previous version:

Adaptation according to 1907/2006/EG, Article 31

The above information is based on our present day knowledge and relates solely to the safety requirements of the product. The data do not signify any warranty with regards to products properties. However users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.