

SAFETY DATA SHEET according to Regulation (EU) 2015/830

Page 1/7

Universal Composite.

Revision 4 Revision date 2022-10-31

| | | Revision date 2022-10-31 | | |
|--|--|--|--|--|
| SECTION 1: Identification of | the substance/mixture and of the company/underta | aking | | |
| 1.1. Product identifier | | | | |
| Product name | 300102 / 300103 - Fortis Nano Universal Composite. | | | |
| 1.2. Relevant identified uses of the substance or mixture and uses advised against | | | | |
| Product Use | [SU22] Professional uses: Public domain (administration craftsmen); | on, education, entertainment, services, | | |
| Restricted use | [SU21] Consumer uses: Private households (= general public = consumers); | | | |
| Description | Dental product. | | | |
| 1.3. Details of the supplier of the | e safety data sheet | | | |
| Company | Precision Dental Products | | | |
| Address | Care House, | | | |
| | Chester Road, | | | |
| | Borehamwood, | | | |
| | Hertfordshire, | | | |
| | WD6 1LP | Manufactured by: | | |
| Web | www.precisiondental.co.uk | Advanced Healthcare Ltd Units 2-4 Leavers Estate, | | |
| Telephone | +44 (0) 208 2360606 (Use for Emergency also) | Chiddingstone | | |
| Fax | +44 (0)1208 2360070 | Causeway, Tonbridge, | | |
| Email | sales@precisiondental.co.uk | Kent, TN11 8JU, UK | | |
| | | | | |
| 1.4. Emergency telephone num | ber | | | |

| Emergency telephone number | +44(0)1892870500 | |
|----------------------------|-------------------------------|--|
| | (8.00 am - 4.30 pm Mon - Fri) | |

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

| 2.1.2. Classification - EC 1272/2008 | Skin Sens. 1: H317; |
|---|--|
| 2.2. Label elements | |
| Hazard pictograms | |
| Signal Word | Warning |
| Hazard Statement | Skin Sens. 1: H317 - May cause an allergic skin reaction. |
| Precautionary Statement: Prevention | P272 - Contaminated work clothing should not be allowed out of the workplace. P280 - Wear protective gloves/protective clothing/eye protection/face protection. |



| 2.2. Label elements | | | |
|--------------------------------------|--|--|--|
| Precautionary Statement: Response | P302+P352 - IF ON SKIN: Wash with plenty of water/ . P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. | | |
| 2.3. Other hazards | | | |
| Other hazards | PBT. vPvB. Not applicable. | | |
| Further information | | | |
| | Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user. | | |

SECTION 3: Composition/information on ingredients

3.2. Mixtures

EC 1272/2008

| Chemical Name | Index No. | CAS No. | EC No. | REACH Registration Number | Conc. (%w/w) | Classification |
|---|-----------|-----------|-----------|------------------------------|-----------------|--|
| Bisphenol A glycerolate dimethacrylate | | 1565-94-2 | 216-367-7 | 01-2119485287-26 | 1 - 10% | Skin Irrit. 2: H315; Skin Sens. 1: H317; Eye Irrit. 2: H319; |
| Triethylene Glycol Dimethacrylate | | 109-16-0 | 203-652-6 | 01-2119969287-21 | 1 - 10% | Skin Sens. 1: H317; |
| Dioctyltin dilaurate | | 3648-18-8 | 222-883-3 | | 0 - 0.5% | Eye Irrit. 2: H319; Repr. 1B: H360D; Repr. 2: H361; STOT RE 1: H372; Aquatic Chronic 4: H413; |
| SECTION 4: First aid me | asures | | | | | |

4.1 Description of first aid measures

| 4.1. Description of first aid measures | | |
|--|---|--|
| Inhalation | Move the exposed person to fresh air. | |
| Eye contact | Rinse immediately with plenty of water for 15 minutes holding the eyelids open. | |
| Skin contact | Wash off immediately with plenty of soap and water. Remove contaminated clothing. | |
| Ingestion | Do NOT induce vomiting. | |
| 4.2. Most important symptoms and effects, both acute and delayed | | |
| Inhalation | May cause irritation to mucous membranes. | |
| Eye contact | May cause irritation to eyes. | |
| Skin contact | May cause irritation to skin. May cause allergic reactions in susceptible people. | |
| Ingestion | May cause irritation to mucous membranes. | |
| 4.3. Indication of any immediate | medical attention and special treatment needed | |
| Inhalation | Seek medical attention if irritation or symptoms persist. | |
| Eye contact | Seek medical attention if irritation or symptoms persist. | |
| Skin contact | Seek medical attention if irritation or symptoms persist. | |
| Ingestion | Seek medical attention if irritation or symptoms persist. | |
| General information | | |
| | If you feel unwell, seek medical advice (show the label where possible). | |
| SECTION 5: Firefighting me | asures | |
| 5.1. Extinguishing media | | |
| | Use extinguishing media appropriate to the surrounding fire conditions. | |
| 5.2. Special hazards arising from | n the substance or mixture | |
| | Burning produces irritating, toxic and obnoxious fumes. | |
| | | |

5.3. Advice for firefighters



Revision 4

Revision date 2022-10-31

| 5.3. Advice for firefighters | | | | |
|---|---|--|--|--|
| | Wear suitable respiratory equipment when necessary. | | | |
| SECTION 6: Accidental release measures | | | | |
| 6.1. Personal precautions, protective equipment and emergency procedures | | | | |
| | Ensure adequate ventilation of the working area. Wear suitable protective equipment. | | | |
| 6.2. Environmental precautions | | | | |
| | Do not allow product to enter drains. Prevent further spillage if safe. | | | |
| 6.3. Methods and material for co | ntainment and cleaning up | | | |
| | Sweep up. Transfer to suitable, labelled containers for disposal. Clean spillage area thoroughly with plenty of water. | | | |
| 6.4. Reference to other sections | | | | |
| | See Section 13 for disposal information. See Section 8 for exposure controls/personal protection. | | | |
| SECTION 7: Handling and st | lorage | | | |
| | | | | |
| 7.1. Precautions for safe handlin | 9 | | | |
| 7.1. Precautions for safe handlin | 9 Avoid contact with eyes and skin. Ensure adequate ventilation of the working area. Adopt best Manual Handling considerations when handling, carrying and dispensing. | | | |
| 7.1. Precautions for safe handlin7.2. Conditions for safe storage, | Avoid contact with eyes and skin. Ensure adequate ventilation of the working area. Adopt best Manual Handling considerations when handling, carrying and dispensing. | | | |
| | Avoid contact with eyes and skin. Ensure adequate ventilation of the working area. Adopt best Manual Handling considerations when handling, carrying and dispensing. | | | |
| | Avoid contact with eyes and skin. Ensure adequate ventilation of the working area. Adopt best Manual Handling considerations when handling, carrying and dispensing. including any incompatibilities | | | |
| 7.2. Conditions for safe storage, | Avoid contact with eyes and skin. Ensure adequate ventilation of the working area. Adopt best Manual Handling considerations when handling, carrying and dispensing. including any incompatibilities | | | |
| 7.2. Conditions for safe storage, | Avoid contact with eyes and skin. Ensure adequate ventilation of the working area. Adopt best Manual Handling considerations when handling, carrying and dispensing. including any incompatibilities Keep in a cool, dry, well ventilated area. Keep containers tightly closed. Store in original container. See section 1.2. Relevant identified uses of the substance or mixture and uses advised against for further information. | | | |

8.1.1. Exposure Limit Values

| Aluminium Oxide (Aluminium oxides) | WEL 8-hr limit ppm: - | WEL 8-hr limit mg/m3: - |
|------------------------------------|-------------------------------|--------------------------------|
| 0,1400) | WEL 15 min limit ppm: - | WEL 15 min limit mg/m3: - |
| | WEL 8-hr limit mg/m3 total 10 | WEL 15 min limit mg/m3 total - |
| | inhalable dust: | inhalable dust: |
| | WEL 8-hr limit mg/m3 total 4 | WEL 15 min limit mg/m3 total - |
| | respirable dust: | respirable dust: |

8.2. Exposure controls

| 8.2.1. Appropriate engineering controls | Ensure adequate ventilation of the working area. |
|---|---|
| 8.2.2. Individual protection measures | Wear chemical protective clothing. |
| Eye / face protection | Approved safety goggles. |
| Skin protection - Handprotection | Chemical resistant gloves. |
| Respiratory protection | Wear suitable respiratory equipment when necessary. |



Revision 4 **Revision date** 2022-10-31

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| Appearance | Paste |
|---------------------------|-------------------|
| Odour | |
| Odour threshold | No data available |
| рH | No data available |
| Melting point | No data available |
| Freezing Point | No data available |
| Initial boiling point | No data available |
| Flash point | No data available |
| Evaporation rate | No data available |
| Flammability (solid, gas) | No data available |
| Vapour pressure | No data available |
| Vapour density | No data available |
| Relative density | No data available |
| Fat Solubility | No data available |
| Partition coefficient | No data available |
| Autoignition temperature | No data available |
| Viscosity | No data available |
| Oxidising properties | No data available |
| Solubility | No data available |

9.2. Other information

| Conductivity its | |
|-----------------------|-------------------|
| Conductivity | No data available |
| Surface tension | No data available |
| Gas group | No data available |
| Benzene Content | No data available |
| Lead content | No data available |
| VOC (Volatile organic | |
| compounds) | |
| | |

SECTION 10: Stability and reactivity

| 10.1. Reactivity | | |
|--|---|--|
| | No data available. | |
| 10.2. Chemical stability | | |
| | Stable under normal conditions. | |
| 10.3. Possibility of hazardous re | actions | |
| | No data is available on this product. | |
| 10.4. Conditions to avoid | | |
| | Heat. Moisture. Direct sunlight. | |
| 10.5. Incompatible materials | | |
| | Reducing agents. Strong acids. Strong bases. Strong oxidising agents. | |
| 10.6. Hazardous decomposition | products | |
| | No data available. | |
| SECTION 11: Toxicological information | | |
| 11.1. Information on toxicological effects | | |
| Acute toxicity | No data available. | |
| Skin corrosion/irritation | May cause irritation to skin. May cause allergic reactions in susceptible people. | |



| 11.1. Information on toxicological effects | | |
|--|---|--|
| Serious eye damage/irritation | Causes serious eye irritation. | |
| Respiratory or skin sensitisation | May cause irritation to mucous membranes. | |
| Germ cell mutagenicity | No mutagenic effects reported. | |
| Carcinogenicity | No carcinogenic effects reported. | |
| Reproductive toxicity | No teratogenic effects reported. | |
| STOT-single exposure | No data available. | |
| STOT-repeated exposure | No data available. | |
| Aspiration hazard | May cause irritation to mucous membranes. | |
| Repeated or prolonged exposure | No data available. | |
| 11.1.4. Toxicological Information | | |
| Triethylene Glycol Dimethacrylate | Oral Rat LD50: 10837 mg/kg | |
| SECTION 12: Ecological information | | |
| 12.1. Toxicity | | |
| Triethylene Glycol Dimethacrylate | Fish LC50/96h: 16.4000 mg/l | |
| 12.2. Persistence and degradability | | |
| | No data is available on this product. | |
| 12.3. Bioaccumulative potential | | |
| | | |
| | No data is available on this product. | |
| Partition coefficient | | |
| | Universal Composite. No data available | |
| 12.4. Mobility in soil | | |
| | No data is available on this product. | |
| 12.5. Results of PBT and vPvB assessment | | |
| | No data is available on this product. | |
| 12.6. Other adverse effects | | |
| | No data is available on this product. | |
| SECTION 13: Disposal considerations | | |
| 13.1. Waste treatment methods | | |
| | Dispose of in compliance with all. local and national regulations. | |
| General information | | |
| | 18 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND /OR RELATED RESEARCH(except kitchen and restaurant wastes not arising from immediate health care). 18 01 wastes from natal care, diagnosis, treatment or prevention of disease in humans. 18 01 06 chemicals consisting of or containing dangerous substances. | |
| Disposal methods | | |
| | Do not empty into drains. For disposal within the EC, the appropriate code according to the European Waste Catalogue (EWC) should be used. | |



| Disposal of packaging | | |
|--|---|--|
| | Do NOT reuse empty containers. Empty containers can be sent for disposal or recycling. | |
| SECTION 14: Transport information | | |
| 14.1. UN number | | |
| | The product is not classified as dangerous for carriage. | |
| 14.2. UN proper shipping name | | |
| | The product is not classified as dangerous for carriage. | |
| 14.3. Transport hazard class(es) | | |
| | The product is not classified as dangerous for carriage. | |
| 14.4. Packing group | | |
| | The product is not classified as dangerous for carriage. | |
| 14.5. Environmental hazards | | |
| | The product is not classified as dangerous for carriage. | |
| 14.6. Special precautions for use | | |
| | The product is not classified as dangerous for carriage. | |
| 14.7. Transport in bulk according | g to Annex II of MARPOL 73/78 and the IBC Code | |
| | The product is not classified as dangerous for carriage. | |
| SECTION 15: Regulatory information | | |
| 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture | | |
| Regulations | COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 1999/45/EC and repealing Council Regulation (EC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. | |
| 15.2. Chemical safety assessme | | |
| | No data available. | |
| SECTION 16: Other information | | |
| Other information | | |
| Text of Hazard Statements in Section 3 | Skin Irrit. 2: H315 - Causes skin irritation. Skin Sens. 1: H317 - May cause an allergic skin reaction. Eye Irrit. 2: H319 - Causes serious eye irritation. Repr. 1B: H360D - May damage the unborn child. Repr. 2: H361 - Suspected of damaging fertility or the unborn child . STOT RE 1: H372 - Causes damage to organs through prolonged or repeated exposure . Aquatic Chronic 4: H413 - May cause long lasting harmful effects to aquatic life. | |
| Further information | | |

The information supplied in this Safety Data Sheet is designed only as guidance for the safe use, storage and handling of the product. This information is correct to the best of our knowledge and belief at the date of publication however no guarantee is made to its accuracy. This information relates only to the specific material designated and may not be valid for such material used in



 Revision
 4

 Revision date
 2022-10-31

combination with any other materials or in any other process.

