1 Identification

- Product identifier
  - Trade name: EXABITE III Base
  - Relevant identified uses of the substance or mixture and uses advised against
    No further relevant information available.
  - Application of the substance / the mixture Auxillary for dental technology

- Details of the supplier of the safety data sheet
  - Manufacturer/Supplier: GC Australasia Dental Pty Ltd
    1753 Botany Road
    Banksmeadow, NSW 2019
    Tel: +61 2 9301 8200

- Further information obtainable from: Regulatory affairs

2 Hazard(s) Identification

- Classification of the substance or mixture
  - The product is not classified, according to the Globally Harmonised System (GHS).

- Label elements
  - GHS label elements Void
  - Exemptions
    - The product, regulated as an invasive medical device by the Regulation (EC) 2017/745, is exempted from
      labelling requirements for substances and mixtures (according to the provision of the Art 1.5).
  - Hazard pictograms Void
  - Signal word Void
  - Hazard statements Void
  - Other hazards
  - Results of PBT and vPvB assessment
    - PBT: Not applicable.
    - vPvB: Not applicable.

3 Composition and Information on Ingredients

- Chemical characterisation: Mixtures
- Description:
  - Only substances required to be mentioned according to Annex II of regulation 1907/2006 are listed. Information
    on the other substances that may be present can be obtained upon request.

- Dangerous components:
  - 112926-00-8 silicon dioxide, amorphous 50-<75%
Trade name: EXABITE III Base

68037-59-2 Methylhydrogen dimethylpolysiloxane

Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335

2.5-<5%

· Additional information: For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

· Description of first aid measures
  · General information:
    No special measures required.
    If symptoms persist consult doctor.
  · After inhalation: Take affected persons into fresh air and keep quiet.
  · After skin contact: Immediately rinse with water.
  · After eye contact:
    Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
  · After swallowing:
    Rinse out mouth and then drink plenty of water.
    If symptoms persist consult doctor.
  · Information for doctor:
    · Most important symptoms and effects, both acute and delayed No further relevant information available.
    · Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 Fire Fighting Measures

· Extinguishing media
  · Suitable extinguishing agents:
    CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
    Use fire extinguishing methods suitable to surrounding conditions.
  · For safety reasons unsuitable extinguishing agents: Water with full jet

· Special hazards arising from the substance or mixture
  Formation of toxic gases is possible during heating or in case of fire.
  No further relevant information available.

· Advice for firefighters
  · Protective equipment: Wear self-contained respiratory protective device.

· Additional information
  Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

6 Accidental Release Measures

· Personal precautions, protective equipment and emergency procedures Remove persons from danger area.

· Environmental precautions:
  Do not allow product to reach sewage system or any water course.
  Inform respective authorities in case of seepage into water course or sewage system.
  Do not allow to penetrate the ground/soil.
  In case of seepage into the ground inform responsible authorities.

· Methods and material for containment and cleaning up:
  Absorb liquid components with liquid-binding material.
  Dispose of the material collected according to regulations.

· Reference to other sections
  See Section 7 for information on safe handling.
7 Handling and Storage

- **Handling:**
  - **Precautions for safe handling:** No special precautions are necessary if used correctly.
  - **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
  - **Requirements to be met by storerooms and receptacles:** Store only in unopened original receptacles.
  - **Information about storage in one common storage facility:** Store away from foodstuffs.
  - **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**
  - **Ingredients with limit values that require monitoring at the workplace:**
    - 112926-00-8 silicon dioxide, amorphous
      - WES Long-term value: 10 mg/m³
  - **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
  - **Personal protective equipment:**
    - **General protective and hygienic measures:**
      - The usual precautionary measures are to be adhered to when handling chemicals.
      - Wash hands before breaks and at the end of work.
    - **Respiratory protection:** Suitable respiratory protective device recommended.
    - **Protection of hands:** Protective gloves
    - **Material of gloves**
      - The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
      - **Penetration time of glove material**
        - The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
    - **Eye protection:** Safety glasses

* 9 Physical and Chemical Properties

- **Information on basic physical and chemical properties**
  - **General Information**
  - **Appearance:**
    - **Form:** Pasty
    - **Colour:** Green
    - **Odour:** Odourless
• Odour threshold: Not determined.
• pH-value: Not determined.
• Change in condition
  Melting point/freezing point: Undetermined.
  Initial boiling point and boiling range: Undetermined.
• Flash point: Not applicable.
• Flammability (solid, gas): Not applicable.
• Ignition temperature: Undetermined.
• Decomposition temperature: Not determined.
• Auto-ignition temperature: Product is not selfigniting.
• Explosive properties: Product does not present an explosion hazard.
• Explosion limits: Not determined.
  Lower: Not determined.
  Upper: Not determined.
• Vapour pressure: Not determined.
• Density: Not determined.
  2.56 g/cm³
  1.18 g/ml
• Relative density Not determined.
• Vapour density Not determined.
• Evaporation rate Not determined.
• Solubility in / Miscibility with water: Insoluble.
• Partition coefficient: n-octanol/water: Not determined.
• Viscosity:
  Dynamic: Not determined.
  Kinematic: Not determined.
• Solvent content:
  VOC (EC) 0.0 g/l
• Other information No further relevant information available.

10 Stability and Reactivity

• Reactivity No further relevant information available.
• Chemical stability
• Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
• Possibility of hazardous reactions No dangerous reactions known.
• Conditions to avoid No further relevant information available.
• Incompatible materials: No further relevant information available.
• Hazardous decomposition products: No dangerous decomposition products known.
### 11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity**
  - LD/LC50 values relevant for classification: No further relevant information available.
- **Primary irritant effect:**
  - Skin corrosion/irritation: No irritant effect.
  - Serious eye damage/irritation: No irritating effect.
- **Respiratory or skin sensitisation:**
  - No sensitising effects known.
- **Additional toxicological information:**
  - The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
- **Repeated dose toxicity:**
  - No further relevant information available.
- **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
  - No further relevant information available.

### 12 Ecological Information

- **Toxicity**
  - Aquatic toxicity: No further relevant information available.
- **Persistence and degradability**
  - No further relevant information available.
- **Behaviour in environmental systems:**
  - Bioaccumulative potential: No further relevant information available.
  - Mobility in soil: No further relevant information available.
- **Additional ecological information:**
  - General notes:
    - Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water
    - Do not allow product to reach ground water, water course or sewage system, even in small quantities.
    - Danger to drinking water if even extremely small quantities leak into the ground.
- **Results of PBT and vPvB assessment**
  - PBT: Not applicable.
  - vPvB: Not applicable.
- **Other adverse effects**
  - No further relevant information available.

### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
  - Must not be disposed together with household garbage. Do not allow product to reach sewage system.
  - Contact waste processors for recycling information.
- **Uncleaned packaging:**
  - **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- **UN-Number**
- **ADG, ADN, IMDG, IATA**
  - not regulated
Trade name: EXABITE III Base

- UN proper shipping name: not regulated
- ADG, ADN, IMDG, IATA

- Transport hazard class(es)
  - ADG, ADN, IMDG, IATA
  - Class: not regulated

- Packing group
  - ADG, IMDG, IATA
  - not regulated

- Environmental hazards:
  - Marine pollutant: No

- Special precautions for user
  - Not applicable.

- Transport in bulk according to Annex II of Marpol and the IBC Code
  - Not applicable.

- UN "Model Regulation": not regulated

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15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture

  - Australian Inventory of Chemical Substances
    - 68083-19-2 Vinylethylsiloxane
    - 68037-59-2 Methylhydrogen dimethylpolysiloxane
    - 81-77-6 C.I. Pigment Blue 60
    - 5580-57-4 C.I. Pigment Yellow 93

  - Standard for the Uniform Scheduling of Medicines and Poisons
    - None of the ingredients is listed.

  - Australia: Priority Existing Chemicals
    - None of the ingredients is listed.

  - GHS label elements
    - Void
  - Hazard pictograms
    - Void
  - Signal word
    - Void
  - Hazard statements
    - Void

  - Directive 2012/18/EU

  - Named dangerous substances - ANNEX I
    - None of the ingredients is listed.

  - Chemical safety assessment
    - A Chemical Safety Assessment has not been carried out.

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16 Other information

- Relevant phrases
  - H315 Causes skin irritation.
  - H319 Causes serious eye irritation.
  - H335 May cause respiratory irritation.

- Department issuing SDS
  - Regulatory affairs

- Contact: msds@gc.dental

(Contd. on page 7)
Trade name: EXABITE III Base

· Abbreviations and acronyms:
  ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
  IMDG: International Maritime Code for Dangerous Goods
  IATA: International Air Transport Association
  EINECS: European Inventory of Existing Commercial Chemical Substances
  ELINCS: European List of Notified Chemical Substances
  CAS: Chemical Abstracts Service (division of the American Chemical Society)
  VOC: Volatile Organic Compounds (USA, EU)
  LC50: Lethal concentration, 50 percent
  LD50: Lethal dose, 50 percent
  PBT: Persistent, Bioaccumulative and Toxic
  vPvB: very Persistent and very Bioaccumulative
  Skin Irrit. 2: Skin corrosion/irritation – Category 2
  Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
  STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

· Sources
  • ECHA (http://echa.europa.eu/)
  • EnviChem (www.echemportal.org)

  * Data compared to the previous version altered.
  This version replaces all previous versions.

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