1 Identification

- **Product identifier**
- **Trade name:** EQUIA FORTE Fil (Powder)
- **Application of the substance / the mixture** Dental filling material
- **Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:**
    GC America Inc.
    3737 W. 127th Street
    Alsip, IL 60803
    USA
    sds@gcamerica.com
  - **Information department:** Regulatory Affairs
  - **Emergency telephone number:**
    During normal opening times (Mon.-Fri. 8:00 AM-5:00 PM CST): +1 (708) 597-0900
    Transportation (CHEMTREC®) Emergency Telephone No. +1 (800) 424-9300

2 Hazard(s) identification

- **Classification of the substance or mixture**
  Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- **Additional information:**
  The information provided is in regards to the toxicity and hazard rating(s) of the individual component(s) in the formulation. The associated risk(s) depends on the route(s) of exposure. The hazard rating system is based entirely on the existence of the risk(s) and does not take into account the likelihood of reduced risk(s) through proper usage and handling.
- **Label elements**
- **GHS label elements**
  The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**

![GHS08](image)

- **Signal word** Danger
- **Hazard-determining components of labeling:**
  iron(III) oxide
- **Hazard statements**
  May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- **Precautionary statements**
  [In case of inadequate ventilation] wear respiratory protection.
  Avoid breathing dust/fume/gas/mist/vapors/spray
  If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
  If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.
  Dispose of contents/container in accordance with local/regional/national/international regulations.

(Contd. on page 2)
**Trade name:** EQUIA FORTE Fil (Powder)

### 3 Composition/information on ingredients

- **Chemical characterization:** Mixtures
- **Description:** Mixture of the substances listed below with nonhazardous additions.

#### Dangerous components:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>iron(III) oxide</td>
<td>&lt; 0,5%</td>
</tr>
</tbody>
</table>

**Additional information:**
If a substance is marked with **, then substance is a trade secret. This is allowed under OSHA’s Hazard Communication Standard (HCS) as a trade secret and under GHS as Confidential Business Information (CBI).

### 4 First-aid measures

- **Description of first aid measures**
- **General information:** If symptoms persist consult doctor.
- **After inhalation:**
  - Supply fresh air; consult doctor in case of complaints.
  - In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**
  - Generally the product does not irritate the skin.
  - Rinse with warm water.
  - If symptoms persist consult doctor.
- **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.

(Contd. of page 1)
Trade name: EQUIA FORTE Fil (Powder)

- 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, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
    Use fire fighting measures that suit the environment.
  - 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.

- 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.
  Avoid formation of dust.
  Wear protective clothing.
  - 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:
  Ensure adequate ventilation.
  Pick up mechanically.
  Prevent formation of dust.
  Dispose of the collected material according to regulations.

- Reference to other sections
  See Section 7 for information on safe handling.
  See Section 8 for information on personal protection equipment.
  See Section 13 for disposal information.

7 Handling and storage

- Handling:
  - Precautions for safe handling
    Observe instructions for use.
    Ensure good ventilation/exhaustion at the workplace.
    Prevent formation of dust.
    Do not inhale dust / smoke / mist.
    Any deposit of dust which cannot be avoided must be regularly removed.
  - Information about protection against explosions and fires:
    Dust can combine with air to form an explosive mixture.
8 Exposure controls/personal protection

- Additional information about design of technical systems: No further data; see item 7.
- Control parameters
- Components with limit values that require monitoring at the workplace:
  The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- Additional information: The lists that were valid during the creation were used as basis.
- Exposure controls
- Personal protective equipment:
  General protective and hygienic measures:
  The usual precautionary measures for handling chemicals should be followed.
  Do not inhale dust / smoke / mist.
  Wash hands before breaks and at the end of work.
- Breathing equipment: 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: Powder
  Color: According to product specification
  Odor: Odorless
  Odor threshold: Not determined.
- pH-value: Not applicable.
- Change in condition
  Melting point/Melting range: Undetermined.
  Boiling point/Boiling range: Undetermined.
10 Stability and reactivity

- **Reactivity**: No further relevant information available.
- **Chemical stability**: Stable at ambient temperature.
- **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 that are relevant for classification**: No further relevant information available.
Trade name: EQUIA FORTE Fil (Powder)

- Primary irritant effect:
  - on the skin: No irritant effect.
  - on the eye: No irritating effect.
- Sensitization: Sensitization possible through inhalation.
- Additional toxicological information:

  - Carcinogenic categories

    - IARC (International Agency for Research on Cancer)
      poly(acrylic acid) 3
      iron(III) oxide 3
    - NTP (National Toxicology Program)
      None of the ingredients is listed.
    - OSHA-Ca (Occupational Safety & Health Administration)
      None of the ingredients is listed.

  - Carcinogenic categories' legend:
    IARC Group 1: The agent is carcinogenic to humans.
    IARC Group 2A: The agent is probably carcinogenic to humans.
    IARC Group 2B: The agent is possibly carcinogenic to humans.
    IARC Group 3: The agent is not classifiable as to its carcinogenicity to humans.
    IARC Group 4: The agent is probably not carcinogenic to humans.
    NTP K: Known to be human carcinogen.
    NTP R: Reasonably anticipated to be human carcinogen.

- Repeated dose toxicity. No further relevant information available.

- CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
  No further relevant information available.

  - Toxicity
  - Aquatic toxicity: No further relevant information available.
  - Persistence and degradability No further relevant information available.
  - Behavior 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 (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 of together with household garbage. Do not allow product to reach sewage system.

- **Uncleaned packagings**:
  - **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **UN-Number**
  - DOT, ADR, ADN, IMDG, IATA: Void

- **UN proper shipping name**
  - DOT, ADR, ADN, IMDG, IATA: Void

- **Transport hazard class(es)**
  - DOT, ADR, ADN, IMDG, IATA: Void

- **Packing group**
  - DOT, ADR, IMDG, IATA: Void

- **Environmental hazards**:
  - Marine pollutant: No

- **Special precautions for user**
  - Not applicable.

- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**
  - Not applicable.

- **UN "Model Regulation"**
  - Void

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - **SARA (Superfund Amendments and Reauthorization Act)**
    - **Section 355 (extremely hazardous substances):**
      - None of the ingredients is listed.
    - **Section 313 (Specific toxic chemical listings):**
      - None of the ingredients is listed.
  
  - **TSCA (Toxic Substances Control Act):**
    - poly(acrylic acid)
    - silane**
    - iron hydroxide oxide
    - iron(III) oxide
    - triiron tetraoxide

(Contd. on page 8)
Trade name: EQUIA FORTE Fil (Powder)

- Carcinogenic categories
  
  - EPA (Environmental Protection Agency)
    None of the ingredients is listed.
  
  - TLV (Threshold Limit Value established by ACGIH)
    iron(III) oxide A4
  
  - NIOSH-Ca (National Institute for Occupational Safety and Health)
    None of the ingredients is listed.

- GHS label elements
  The product is classified and labeled according to the Globally Harmonized System (GHS).

- Hazard pictograms
  
  ![GHS08]

- Signal word: Danger

- Hazard-determining components of labeling:
  iron(III) oxide

- Hazard statements
  May cause allergy or asthma symptoms or breathing difficulties if inhaled.

- Precautionary statements
  [In case of inadequate ventilation] wear respiratory protection.
  Avoid breathing dust/fume/gas/mist/vapors/spray
  If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
  If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.
  Dispose of contents/container in accordance with local/regional/national/international regulations.

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

**16 Other information**

- Department issuing SDS: Regulatory Affairs
- Contact:
  Regulatory Affairs
  Telephone No. +1 (708) 597-0900
  sds@gcamerica.com
- Date of preparation / last revision 10/22/2015 / -
- Abbreviations and acronyms:
  GHS: Globally Harmonized System of Classification and Labelling of Chemicals
  HCS: Hazard Communication Standard (USA)
  MSDS: Material Safety Data Sheet
  SDS: Safety Data Sheet
  ADN: Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures
  (European Agreement Concerning the International Carriage of Dangerous Goods by Inland Waterways)
  ECHA: European Chemicals Agency
  OSHA: Occupational Safety and Health Administration (USA)
  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
  DOT: US Department of Transportation
  IATA: International Air Transport Association
  ACGIH: American Conference of Governmental Industrial Hygienists
Trade name: EQUIA FORTE Fil (Powder)

<table>
<thead>
<tr>
<th>Source</th>
<th>Details</th>
</tr>
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<tbody>
<tr>
<td>CAS: Chemical Abstracts Service (division of the American Chemical Society)</td>
<td></td>
</tr>
<tr>
<td>NFPA: National Fire Protection Association (USA)</td>
<td></td>
</tr>
<tr>
<td>HMIS: Hazardous Materials Identification System (USA)</td>
<td></td>
</tr>
<tr>
<td>LC50: Lethal concentration, 50 percent</td>
<td></td>
</tr>
<tr>
<td>LD50: Lethal dose, 50 percent</td>
<td></td>
</tr>
<tr>
<td>PBT: Persistent, Bioaccumulative and Toxic</td>
<td></td>
</tr>
<tr>
<td>vPvB: very Persistent and very Bioaccumulative</td>
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</tr>
<tr>
<td>Resp. Sens. 1: Sensitisation - Respirat., Hazard Category 1</td>
<td></td>
</tr>
</tbody>
</table>

**Sources**
- Manufacturers' MSDSs/SDSs
- TOXNET (http://toxnet.nlm.nih.gov/)
- ECHA (http://echa.europa.eu/)
- EnviChem (www.echemportal.org)

**Notes:**
- CAS Registry Number is a Registered Trademark of the American Chemical Society.
- CHEMTREC® is a registered service mark of the American Chemistry Council, Inc.
- * Data compared to the previous version altered. This version replaces all previous versions.

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