1. **Product and manufacturer information**

   **Product name:** Chromaspeed ortho  
   **Product description:** Dental Alginate Impression Material  
   **Utilization:** For dental use only  

   **Manufacturer:**  
   ITENA CLINICAL  
   83, Avenue Foch  
   75116 Paris –France  
   Phone: +33 1 45 91 30 06 – Fax: + 33 1 45 91 61 31

2. **Hazard identification:**

   **2.1 Classification of the substance/preparation :**

   The preparation fulfils the classification criteria of Directive 1999/45. The preparation therefore requires a safety data sheet in compliance with the requirements of Regulation 1907/2006/EC as amended.

   **Hazard symbol:** HARMFUL  
   **R phrase:** R48/20  
   R20/22

   **Hazard identification:**
   Harmful: danger of serious damage to health by prolonged exposure  
   Harmful by inhalation

   **2.2 Elements of labelling:**

   For the preparation:  
   **Hazard symbol:**

   ![Xn](image)

   **R phrases:**
   - R48/20: Harmful: danger of serious damage to health by prolonged exposure
   - R20/22: Harmful by inhalation and ingestion

   **S phrases:**
   - S36/37/39: Wear suitable protective clothing, gloves and eye / face protection

   **2.3. Other hazards :**

   At the date of compilation of the present sheet, none known.
3. **Composition / information on ingredients:**

*Preparations:*

Classification of the substances in the preparation according to Directive 67/548/EEC as amended and Regulation 1272/2008/EC

<table>
<thead>
<tr>
<th>Name</th>
<th>Conc. (C)</th>
<th>Clas. 67/548/EEC</th>
<th>Clas. 1272/2008/EC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diatomaceous earth</td>
<td>65&lt;C≤75</td>
<td>Xn</td>
<td>R48/20 STOT RE 2</td>
</tr>
<tr>
<td>Cas No. 68855-54-9</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC No. 272-489-0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Index No. -</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>REACH No. 01-2119488518-22-0005</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium hexafluorotitanate</td>
<td>1&lt;C≤3</td>
<td>Xn</td>
<td>R20 / R22 Acute Tox. 4</td>
</tr>
<tr>
<td>Cas No. 16919-27-0</td>
<td></td>
<td></td>
<td>H332 Acute Tox. 4</td>
</tr>
<tr>
<td>EC No. 240-969-9</td>
<td></td>
<td></td>
<td>H302</td>
</tr>
<tr>
<td>Index No. -</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>REACH No. -</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Full text of relevant R and H phrase is listed in the Section 16 of this Safety Data Sheet.

4. **First aid measures:**

4.1 **First aid measures description**

4.1.1 **Inhalation:** Remove the subject from the contaminated area and have him breathe fresh air and blow his nose. In case of persistent symptoms consult a doctor.

**Skin contact:** Remove all contaminated clothing and use soap and water to wash the skin that has come into contact with the product.

**Eye contact:** Rinse with plenty of running water while holding the eyelids open. Consult a doctor in case of symptoms attributable to contact with the product.

**Ingestion:** No significant effects or critical dangers are known. In case of symptoms consult a doctor.

4.2 **Most important symptoms and effects, both acute and delayed,**

The product may cause serious damage to health in case of prolonged exposure by inhalation.

4.3 **Indication of any immediate medical attention and special treatment needed.**

In the event of consulting a doctor refer to Section 4.1.1.

5. **Fire fighting measures:**

5.1 **Extinguishing media:**

**Suitable extinguishing media:** not applicable, the product is not inflammable

Extinguishing media which must not be used for safety reasons: not applicable, the product is not inflammable.
5.2 Special hazards arising from the substance or mixture: not applicable.

5.3 Advice for firefighters:
Special protective equipment for fire-fighters: Always use suitable protective devices while working. Use a protective helmet with a visor, fire-resistant clothing, protective gloves for fire fighters, a mask under positive pressure with a face shield that covers the operator’s entire face or a self-contained breathing apparatus if there is a significant amount of smoke. Collect the water used to fight the fire; this water must not be discharged into the sewer system. Dispose of the contaminated water used to fight the fire and of the residues of the fire according to the regulations in effect.

6. Accidental release measures:

6.1 Personal precautions, protective equipment and emergency procedures:
6.1.1. For persons who do not take any direct action: evacuate the release area. Do not take any action unless trained for the operations to be carried out.
6.1.2. For persons who take direct action: Avoid contact with eyes and skin. Remove all persons who are not involved in the operations. Do not handle damaged containers or released product without first putting on suitable protective equipment.

6.2 Environmental precautions: Prevent the product from entering sewers, surface waters, groundwater and confined areas. If the product has entered a watercourse or the sewer network, or if it has contaminated the soil or vegetation, inform the competent authorities.

6.3 Methods and material for containment and cleaning up: Use suitable mechanical means to remove the powder without raising it, and dispose of the powder according to the specific regulations in effect.

6.4 Reference to other sections (see 8 and 13) The contaminated material must be disposed of in compliance with the regulations indicated in Section 13.

7. Handling and storage:

7.1 Precautions for safe handling: Avoid contact with skin and eyes and inhalation of the powder. Contaminated clothing must be replaced. Do not eat or drink during work. Avoid the formation of dust. See Section 8 for recommended protective equipment.

7.2 Conditions for safe storage, including any incompatibilities:
a. No risks are known with respect to explosive atmospheres, corrosive conditions, flammability dangers, incompatible substances and mixtures, evaporation conditions, potential ignition sources
b. Keep the container in a cool and dry place. Avoid exposure to direct sunlight.
c. The product is stable under normal conditions of use and storage.
d. Use the original and undamaged containers

7.3 Specific end use(s): not known.
8. Exposure control / Personal protections

8.1 Control parameters:

<table>
<thead>
<tr>
<th>Description</th>
<th>Type</th>
<th>State</th>
<th>TWA/8h mg/m³</th>
<th>STEL/15min mg/m³</th>
<th>ppm</th>
<th>ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inorganic powder</td>
<td>TLV-ACGIH</td>
<td>3</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Inorganic powder</td>
<td>OEL</td>
<td>IT</td>
<td>3</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Inorganic powder</td>
<td>TLV-ACGIH</td>
<td>10</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Inorganic powder</td>
<td>OEL</td>
<td>IT</td>
<td>10</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

8.2 Exposure controls: Considering that the use of suitable technical means should always have priority over the use of personal protective equipment, ensure good ventilation of the workplace by means of efficient local aspiration or discharge of the polluted air. Operate and handle according to the usual precautionary measures for the handling of chemical products. Do not eat, drink or smoke during use. Accurately wash the hands with water and soap before meals and take a shower at the end of the work shift.

Appropriate engineering controls:

Individual protection measures, such as personal protective equipment:

General information: Use a suitable respiratory device; a P3 filter is suggested.

Eye/face protection: Protective devices for eyes/face: hermetic protective goggles are recommended (acc. to norm EN 166).

Skin protection:

Hand protection: Work gloves (acc. to norm EN 374).

Other: Protective work clothes, work clothes (acc. to norm EN 344).

Respiratory Protection: Mask with universal filter.

Thermal hazard: Not applicable.

Environmental Exposure Controls: Based on the use of the product in the various environmental compartments, compliance with any national or community regulations for environmental protection is required.

9. Physical/chemical properties:

9.1 Information on basic physical and chemical properties:

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Green powder</td>
</tr>
<tr>
<td>Odour</td>
<td>Characteristic</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>Not determined</td>
</tr>
<tr>
<td>pH</td>
<td>8 at 20°C (suspension of 10 g of powder per litre of water after 2 min.)</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>Not pertinent</td>
</tr>
<tr>
<td>Initial boiling point and boiling range °C</td>
<td>Not pertinent</td>
</tr>
<tr>
<td>Flash point °C</td>
<td>Not pertinent</td>
</tr>
</tbody>
</table>
Solubility in water | Reacts by forming a hydrophilic gel
--- | ---
Evaporation rate | Not pertinent
Flammability (solid/gas) | Not flammable
Upper/lower flammability or explosive limits | Not flammable or explosive
Vapour pressure | mmHg | Not pertinent
Vapour density | Not pertinent
Relative density | g/cm³ | 2.3
Apparent density | g/l | 300
Partition coefficient: n-octanol/water | Not pertinent
Auto-ignition temperature | °C | Not pertinent
Decomposition temperature | °C | Not pertinent
Explosive properties | Not explosive
Oxidising properties | Not oxidising

10. Stability and reactivity:

10.1 Reactivity: The product reacts with water by forming a hydrogel.

10.2 Chemical stability: The products do not decompose if used according to the instructions for used and stored according to the instructions provided by the manufacturer.

10.3 Possibility of hazardous reactions: There is no possibility of any hazardous reactions.

10.4 Conditions to avoid: Heat, humidity.

10.5 Incompatible materials: None known.

10.6 Hazardous decomposition products: None.

11. Toxicological information

11.1 Information on toxicological effects:

No episodes of damages to health due to exposure to the product are known. It is advisable in any case to work in compliance with the rules of good industrial hygiene.

*Indication of LD50 or LC50:*

<table>
<thead>
<tr>
<th>Diatomaceous earth</th>
<th>Oral</th>
<th>LD50</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>&gt; 2000 mg/Kg (rat)</td>
</tr>
</tbody>
</table>

Potassium hexafluorotitanate

<table>
<thead>
<tr>
<th>Oral</th>
<th>LD50</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>169 mg/kg (rat)</td>
</tr>
</tbody>
</table>

Information on likely routes of exposure: the likely routes of exposure are by inhalation, via the skin and, much less likely, by ingestion.

Symptoms related to the physical, chemical and toxicological characteristics: the mixture is harmful by inhalation.

Delayed and immediate effects as well as chronic effects from short and long term exposure: the product is harmful by inhalation. Danger of serious damage to health in case of prolonged exposure by inhalation.

Interactive effects: unknown
Further information: none known

12. Ecological information

12.1 Ecotoxicity

Acute toxicity (fish, aquatic invertebrates, aquatic plants, micro-organisms): No effect up to the solubility limit.

12.2 Persistence and degradability:

Not applicable for inorganic substances.

12.3 Bioaccumulative potential:

Not applicable, not organic.

12.4 Mobility in soil:

No data available.

12.5 Results of PBT and vPvB Assessment:

Not pertinent, not organic.

12.6 Other adverse effects:

Harmful for aquatic organisms (potassium hexafluorotitanate).

13. Disposal considerations:

13.1 Disposal treatment methods:

a. containers and treatment methods: seeing the nature of the product, its containers cannot be cleaned and recycled; they must be sent to a special decontamination system or be disposed of as hazardous waste.

b. physical/chemical properties that may affect waste treatment: the Product is stable under normal conditions.

c. sewage disposal is discouraged: disposal may take place via biological treatment systems.

d. special precautions during treatment: none in particular

14. Transport Information:

The product is not subject to transport regulations

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 according to Annex XVII to Regulation (EC) 1907/2006: none

Substances in Candidate List (art.59 REACH): none

Substances subject to authorization (Annex XIV REACH): none

D. Lgs. 152/2006 and subsequent amendments:
Emissions into the atmosphere: not applicable

15.1 Chemical safety assessment:

No assessment of chemical safety was made for the mixture.

16. Other information

This edition of the safety data sheet replaces each point of the previous versions.

Key and legend to abbreviations and acronyms used in the safety data sheet
ADR: Accord européen relatif au transport international des marchandises dangereuses par route (European agreement regarding the international road transport of hazardous goods)
ASTM: ASTM International, originally known as American Society for Testing and Materials (ASTM)
ATE: Acute toxicity estimate
EINECS: European Inventory of Existing Commercial Chemical Substances
EC50: Effective Concentration 50
LC50: Lethal Concentration 50
IC50: Inhibitor Concentration 50
NOEL: No Observed Effect Level
DNEL: Derived No Effect Level
DMEL: Derived Minimum Effect Level
CLP: Classification, Labelling and Packaging
CSR: Chemical Safety Report
IATA: International Air Transport Association
ICAO: International Civil Aviation Organization
IMDG: International Maritime Dangerous Goods code
PBT: Persistent, bioaccumulative and toxic
vPvB: Very persistent very bioaccumulative
RID: Regulation regarding the international rail transport of hazardous goods
STEL: Short term exposure limit
TLV: Threshold limit value
TWA: Time Weighted Average
EU: European Union

For mixtures, explanation of the classification assessment methods according to 1272/2008:

The mixture has not been classified according to the criteria of Regulation 1272/2008/EC but based on Directive 1999/45/EC.

List of R phrases:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>R48/20</td>
<td>Harmful: Danger of serious damage to health in case of prolonged exposure by inhalation</td>
</tr>
<tr>
<td>R20/22</td>
<td>Harmful by inhalation and if swallowed</td>
</tr>
</tbody>
</table>

List of H phrases:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>H373</td>
<td>May cause damage to organs through prolonged or repeated exposure</td>
</tr>
<tr>
<td>H332</td>
<td>Harmful if inhaled</td>
</tr>
<tr>
<td>H302</td>
<td>Harmful if swallowed</td>
</tr>
</tbody>
</table>
Abbreviations used:

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Tox. 4</td>
<td>Acute toxicity of category 4</td>
</tr>
<tr>
<td>STOT RE 2</td>
<td>Specific toxicity by target organ - repeated exposure, hazard category 2</td>
</tr>
</tbody>
</table>

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