1 Identification

- **Product identifier**

- **Trade name:** Virtual XD: Putty Fast Set, Putty Regular Set, Heavy Body Fast Set, Heavy Body Regular Set, Virtual XD 380: Fast Set, Regular Set

- **Relevant identified uses of the substance or mixture and uses advised against**
  No further relevant information available.

- **Application of the substance / the preparation** Dental impression material

- **Details of the supplier of the safety data sheet**

- **Manufacturer/Supplier:**
  Ivoclar Vivadent Inc.
  175 Pineview Drive, Amherst, N.Y. 14228
  USA
  Tel. +1 800 533 6825
  Fax +1 716 691 2285

  Ivoclar Vivadent Inc.
  1-6600 Dixie Road
  Mississauga, Ontario
  L5T 2Y2
  Canada
  Phone: +1 905 670 8499
  Fax: +1 905 670 3102

- **Information department:** Quality Assurance / Regulatory Affairs

- **Emergency telephone number:**
  24 Hour Emergency Assistance:
  Emergency-Call USA - Infotrac: 1-800-535-5053
  Emergency-Call Canada - Canutec: 1-613-996-6666

  General MSDS Assistance:
  US: 1-800-533-6825
  Canada: 1-800-263-8182

2 Hazard(s) identification

- **Classification of the substance or mixture**
  H373 May cause damage to organs through prolonged or repeated exposure.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** Not applicable.

- **Classification system:**
  The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

- **Label elements**

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

- **Hazard pictograms**

  GHS08
Trade name: Virtual XD: Putty Fast Set, Putty Regular Set, Heavy Body Fast Set, Heavy Body Regular Set, Virtual XD 380: Fast Set, Regular Set

- Signal word Warning
- Hazard-determining components of labeling: cristobalite
- Hazard statements
  May cause damage to organs through prolonged or repeated exposure.
- Precautionary statements
  Get medical advice/attention if you feel unwell.
- Classification system:
  - NFPA ratings (scale 0 - 4)
    - Health = 0
    - Fire = 0
    - Reactivity = 0
  - HMIS-ratings (scale 0 - 4)
    - Health = *0
    - Fire = 0
    - Reactivity = 0
- Other hazards
- Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.

3 Composition/information on ingredients

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

3 Dangerous components:

| 14464-46-1 cristobalite | 2.5-%10% |

4 First-aid measures

- Description of first aid measures
- After inhalation: Supply fresh air; consult doctor in case of complaints.
- After skin contact:
  Immediately rinse with water.
  If skin irritation continues, consult a doctor.
- After eye contact: Rinse opened eye for several minutes under running water. Then consult a 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, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- Special hazards arising from the substance or mixture: No further relevant information available.
- Advice for firefighters
- Protective equipment: No special measures required.

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures: Not required.
- Environmental precautions: Do not allow to enter sewers/surface or ground water.
- Methods and material for containment and cleaning up: Pick up mechanically.
- 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
    - Only adequately trained personnel should handle this product.
    - For use in dentistry only.
  - Information about protection against explosions and fires: No special measures required.
- Conditions for safe storage, including any incompatibilities
- Storage:
  - Requirements to be met by storerooms and receptacles: Store only in the original receptacle.
  - Information about storage in one common storage facility: Not required.
- Further information about storage conditions:
  - Keep receptacle tightly sealed.
  - Protect from heat and direct sunlight.
- Specific end use(s) No further relevant information available.

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:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Limit Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>14464-46-1 cristobalite</td>
<td>PEL 1/2 value from respirable dust formulae for Quartz</td>
</tr>
<tr>
<td></td>
<td>REL Long-term value: 0.05 mg/m³</td>
</tr>
<tr>
<td></td>
<td>*respirable dust; See Pocket Guide App. A</td>
</tr>
<tr>
<td></td>
<td>TLV Long-term value: 0.025 mg/m³</td>
</tr>
<tr>
<td></td>
<td>*as respirable fraction</td>
</tr>
</tbody>
</table>

(Contd. on page 4)
Additional information: The lists that were valid during the creation were used as basis.

- Exposure controls
- Personal protective equipment:
  - General protective and hygienic measures:
    - Usual hygienic measures for dental practice.
    - Keep away from foodstuffs, beverages and feed.
    - Wash hands before breaks and at the end of work.
    - Avoid contact with the eyes and skin.
- Breathing equipment: Not required.
- Protection of hands:
  - The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
  - Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
  - Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- 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
  - Goggles recommended during refilling.

9 Physical and chemical properties

- Information on basic physical and chemical properties
  - General Information
    - Appearance:
      - Form: Viscous
      - Color: Different according to coloring
      - Odor: like peppermint
    - Odour threshold: Not determined.
  - pH-value: Not applicable.
  - Change in condition
    - Melting point/Melting range: Undetermined.
    - Boiling point/Boiling range: Undetermined.
  - Flash point: Not applicable.
  - Flammability (solid, gaseous): Not applicable.
  - Auto igniting: Product is not selfigniting.
  - Danger of explosion: Product does not present an explosion hazard.
  - Explosion limits:
    - Lower: Not determined.
Trade name: Virtual XD: Putty Fast Set, Putty Regular Set, Heavy Body Fast Set, Heavy Body Regular Set, Virtual XD 380: Fast Set, Regular Set

Upper:
- Vapor pressure: Not determined.
- Density at 20 °C (68 °F): 1.0 - 1.6 g/cm³ (8.345 - 13.352 lbs/gal)
- Relative density: Not determined.
- Vapour density: Not determined.
- Evaporation rate: Not determined.

- Solubility in / Miscibility with Water: Nearly insoluble.
- Partition coefficient (n-octanol/water): Not determined.
- Viscosity:
  - Dynamic: Not determined.
  - Kinematic: Not determined.
- Other information: No further relevant information available.

10 Stability and reactivity
- Reactivity: No further relevant information available.
- Chemical stability: Stable under normal handling and storage conditions.
- 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: None under normal conditions of storage and use.

11 Toxicological information
- Information on toxicological effects:
- Acute toxicity:
- Primary irritant effect:
  - on the skin: No irritant effect.
  - on the eye: No irritating effect.
- Sensitization: No sensitizing effects known.
- Additional toxicological information:
- Carcinogenic categories:
  - IARC (International Agency for Research on Cancer)
    - 14464-46-1 cristobalite
  - NTP (National Toxicology Program)
    - 14464-46-1 cristobalite

12 Ecological information
- Toxicity:
- Aquatic toxicity: No further relevant information available.
- Persistence and degradability: No further relevant information available.
Trade name: Virtual XD: Putty Fast Set, Putty Regular Set, Heavy Body Fast Set, Heavy Body Regular Set, Virtual XD 380: Fast Set, Regular Set

- 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 1 (Self-assessment): slightly hazardous for water
    Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
  - 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:
    Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- uncleared 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
  - Class: 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 MARPOL 73/78 and the IBC Code
  - Not applicable.
- UN "Model Regulation": -
15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
  - Sara
    - 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):
      All ingredients are listed.
  - Proposition 65
    - Chemicals known to cause cancer:
      All ingredients are listed.
    - Chemicals known to cause reproductive toxicity for females:
      None of the ingredients is listed.
    - Chemicals known to cause reproductive toxicity for males:
      None of the ingredients is listed.
    - Chemicals known to cause developmental toxicity:
      None of the ingredients is listed.
  - Carcinogenic categories
  - EPA (Environmental Protection Agency)
    None of the ingredients is listed.
  - TLV (Threshold Limit Value established by ACGIH)
    cristobalite
    - A2
  - NIOSH-Ca (National Institute for Occupational Safety and Health)
    All ingredients are listed.
  - OSHA-Ca (Occupational Safety & Health Administration)
    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 Warning
    - Hazard-determining components of labeling:
      cristobalite
    - Hazard statements
      May cause damage to organs through prolonged or repeated exposure.

(Contd. on page 8)
Precautionary statements
Get medical advice/attention if you feel unwell.

National regulations:
Other regulations, limitations and prohibitive regulations
The product is a medical device according to the EC-directive 93/42/EEC.
This product is classified as a medical device under US and Canadian regulations and has been reviewed by
the US Food and Drug Administration and Health Canada.

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

16 Other information
This information is based on our present knowledge. However, this shall not constitute a guarantee for any
specific product features and shall not establish a legally valid contractual relationship.

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
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
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)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)

* Data compared to the previous version altered.