

Safety Data Sheet

acc. to OSHA HCS

Printing date 07/29/2013

Version number 2

Reviewed on 07/26/2013

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**



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· **Signal word** Warning

· **Hazard-determining components of labeling:**

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· **Hazard statements**

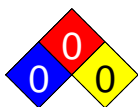
May cause damage to organs through prolonged or repeated exposure.

· **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.

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3 Composition/information on ingredients

· **Chemical characterization:** Mixtures

· **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**

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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.

· **After swallowing:** Seek medical treatment.

· **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.

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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:**

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PEL 1/2 value from respirable dust formulae for Quartz

REL Long-term value: 0.05* mg/m³
*respirable dust; See Pocket Guide App. A

TLV Long-term value: 0.025* mg/m³
*as respirable fraction

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· **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.

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Upper:	Not determined.
· Vapor pressure:	Not determined.
· Density at 20 °C (68 °F):	1.0 - 1.6 g/cm ³ (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)**

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- **NTP (National Toxicology Program)**

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12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.

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- **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.
- **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 | |
| · 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 MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | - |

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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)*

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· *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:*

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· *Hazard statements*

May cause damage to organs through prolonged or repeated exposure.

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· **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.**

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