

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: Light Fast Set, Light 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**
H372 Causes damage to organs through prolonged or repeated exposure.
H319 Causes serious eye irritation.
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
Harmful
Harmful: danger of serious damage to health by prolonged exposure through inhalation.
Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
- **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).

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Trade name: **Virtual XD: Light Fast Set, Light Regular Set**

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· **Hazard pictograms**

GHS07 GHS08

· **Signal word** *Danger*· **Hazard-determining components of labeling:***Quartz (SiO₂)*· **Hazard statements***Causes serious eye irritation.**Causes damage to organs through prolonged or repeated exposure.*· **Precautionary statements***Wear protective gloves/protective clothing/eye protection/face protection.**Avoid release to the environment.**Wash thoroughly after handling.**IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.**Get medical advice/attention if you feel unwell.*· **Classification system:**· **NFPA ratings (scale 0 - 4)**

Health = 2

Fire = 0

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**

Health = *2

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.· **Dangerous components:**

| | | |
|------------|----------------------------|----------|
| 14808-60-7 | Quartz (SiO ₂) | ≤10% |
| 14464-46-1 | cristobalite | 2.5-<10% |
| 27306-78-1 | polysiloxane | 2.5-<5% |

4 First-aid measures

· **Description of first aid measures**· **After inhalation:** Supply fresh air; consult doctor in case of complaints.

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- **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.

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.

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· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

14808-60-7 Quartz (SiO₂)

| | |
|-----|---|
| PEL | see Quartz listing |
| REL | Long-term value: 0.05* mg/m ³ *respirable dust; See Pocket Guide App. A |
| TLV | Long-term value: 0.025* mg/m ³ *as respirable fraction |

14464-46-1 cristobalite

| | |
|-----|---|
| PEL | ½ value from respirable dust formulae for Quartz |
| REL | Long-term value: 0.05* mg/m ³ *respirable dust; See Pocket Guide App. A |
| TLV | Long-term value: 0.025* mg/m ³ *as respirable fraction |

· **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: | Light red |
| Odor: | like peppermint |

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| | |
|---|---|
| · 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. |
| Upper: | Not determined. |
| · Vapor pressure: | Not determined. |
| · Density at 20 °C (68 °F): | 1.260 - 1.270 g/cm ³ (10.515 - 10.598 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. |
| · Solvent content: | |
| Solids content: | 30,7 % |
| · 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.

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· **Additional toxicological information:**

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

| | | |
|------------|----------------------------|---|
| 14808-60-7 | Quartz (SiO ₂) | I |
| 14464-46-1 | cristobalite | I |

· **NTP (National Toxicology Program)**

| | | |
|------------|----------------------------|---|
| 14808-60-7 | Quartz (SiO ₂) | K |
| 14464-46-1 | cristobalite | K |

12 Ecological information

· **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.

· **Ecotoxicological effects:**

· **Remark:** Harmful to fish

· **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.

Harmful to aquatic organisms

· **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

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- | | |
|--|-----------------|
| · 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": | - |

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:

14808-60-7 Quartz (SiO₂)

14464-46-1 cristobalite

· 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)

14808-60-7 Quartz (SiO₂)

A2

14464-46-1 cristobalite

A2

· NIOSH-Ca (National Institute for Occupational Safety and Health)

14808-60-7 Quartz (SiO₂)

14464-46-1 cristobalite

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· **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**



GHS07 GHS08

· **Signal word** *Danger*

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

Quartz (SiO₂)

· **Hazard statements**

Causes serious eye irritation.

Causes damage to organs through prolonged or repeated exposure.

· **Precautionary statements**

Wear protective gloves/protective clothing/eye protection/face protection.

Avoid release to the environment.

Wash thoroughly after handling.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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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1 Identification

- **Product identifier**
- **Trade name:** **Virtual XD: Extra Light Fast Set, Extra Light 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**
H372 Causes damage to organs through prolonged or repeated exposure.
H319 Causes serious eye irritation.
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
Harmful
Harmful: danger of serious damage to health by prolonged exposure through inhalation.
Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
- **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).

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· **Hazard pictograms**



GHS07 GHS08

· **Signal word** *Danger*

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

Quartz (SiO₂)

· **Hazard statements**

Causes serious eye irritation.

Causes damage to organs through prolonged or repeated exposure.

· **Precautionary statements**

Wear protective gloves/protective clothing/eye protection/face protection.

Avoid release to the environment.

Wash thoroughly after handling.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Get medical advice/attention if you feel unwell.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 2

Fire = 0

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = *2

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.

· **Dangerous components:**

| | | |
|------------|----------------------------|---------|
| 14808-60-7 | Quartz (SiO ₂) | 25-50% |
| 27306-78-1 | polysiloxane | 2.5-<5% |

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.

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- **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.

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.

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· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

14808-60-7 Quartz (SiO₂)

| | |
|-----|---|
| PEL | see Quartz listing |
| REL | Long-term value: 0.05* mg/m ³ *respirable dust; See Pocket Guide App. A |
| TLV | Long-term value: 0.025* mg/m ³ *as respirable fraction |

· **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

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Viscous

Color: Yellow

· **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.

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| | |
|---|--|
| · Auto igniting: | Product is not selfigniting. |
| · Danger of explosion: | Product does not present an explosion hazard. |
| · Explosion limits: | |
| Lower: | Not determined. |
| Upper: | Not determined. |
| · Density at 20 °C (68 °F): | 1.316 g/cm ³ (10.982 lbs/gal) |
| · Relative density | Not determined. |
| · Vapour density | Not determined. |
| · Evaporation rate | Not determined. |
| · Solubility in / Miscibility with Water: | Not miscible or difficult to mix. Nearly insoluble. |
| · Partition coefficient (n-octanol/water): | Not determined. |
| · Viscosity: | |
| Dynamic: | Not determined. |
| Kinematic: | Not determined. |
| · Solvent content: | |
| Solids content: | 35.46 % |
| · 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)**

14808-60-7 Quartz (SiO₂)

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· **NTP (National Toxicology Program)**

14808-60-7 Quartz (SiO₂)

K

12 Ecological information

- **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.
- **Ecotoxicological effects:**
- **Remark:** Harmful to fish
- **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.
 Harmful to aquatic organisms
- **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 |

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Safety Data Sheet

acc. to OSHA HCS

Printing date 07/29/2013

Version number 2

Reviewed on 07/26/2013

Trade name: **Virtual XD: Extra Light Fast Set, Extra Light Regular Set**

(Contd. of page 6)

· **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:**

14808-60-7 Quartz (SiO₂)

· **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)**

14808-60-7 Quartz (SiO₂)

A2

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

14808-60-7 Quartz (SiO₂)

· **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**



GHS07 GHS08

· **Signal word** Danger

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USA

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(Contd. of page 7)

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

Quartz (SiO₂)

· **Hazard statements**

Causes serious eye irritation.

Causes damage to organs through prolonged or repeated exposure.

· **Precautionary statements**

Wear protective gloves/protective clothing/eye protection/face protection.

Avoid release to the environment.

Wash thoroughly after handling.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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.**

USA