

SAFETY DATA SHEETS

This SDS packet was issued with item:

077143977

N/A

Material Safety Data Sheet

according to NOHSC:2011(2003)



Product name : Ivoclar Vivadent IPS Classic V Powder
Statement of Hazardous Nature : This product is classified as: Non Hazardous according to criteria of National Occupational Health and Safety Commission.
Revision : 10.10.2009 **Version :** 1.0.0
Print date : 10109.2009

01. Identification of substance, preparation and company

Product name : Ivoclar Vivadent IPS Classic V Powder
Use of the substance / preparation : Ceramic
Incisal, Dentin, IDentin modifier, Opaque Dentin Opaque Dentin modifier, Transparent, Opaquer Opaquer modifier, Fill Opaquer, Add-on material
Manufacturer/Supplier : Ivoclar Vivadent AG
Street/P.O.Box : Bendererstrasse 2, FL -9494 Schaan
Country code/Postal code/Town/City : Fürstentum Liechtenstein
Telephone : +(716) 691-0010
Telefax : +423 / 235 35 35 or 373 40 40
Distributor : Ivoclar Vivadent P/L (Australia), 1-5 Overseas Drive, Noble Park North, Victoria 3174
Phone No.: +61-3 9795 9599, Tele fax No.: +61-3 9795 9645
Emergency information : Poisons Information Centre: Dial 13 11 26
24 hours a day, 7 days a week Australia wide

02. Hazards identification

Statement of Hazardous Nature

This product is not classified as: Hazardous according to criteria of National Occupational Health and Safety Commission.
Non-Dangerous Goods according to ADG.

Hazard designation

Classification : Xi: Irritant. F: Highly flammable. Contains Ethyl acetate, Cellulose nitrate
ADG Classification: not classified
UN Number: not classified

Particular information pertaining specific risk for human and environment

None, if handled according to order.

03. Composition/information on ingredients

Ceramic powder made of > 98 % SiO₂, BaO, Al₂O₃, CaO, CeO₂, Na₂O, K₂O, B₂O₃, MgO, ZrO₂, P₂O₅ < 2 % TiO₂ and pigments

Hazardous components

Dust generation. Avoid breathing dust. Grinding dust

Other ingredients determined not be hazardous

Non hazardous ingredients

04. First-aid measures

General

Immediately remove all contaminated clothing.

After inhalation

Let in fresh air. Call a doctor, should the air passages be affected.

After skin contact

Flush with plenty of water. Melted material presents a special hazard of deep thermal burns. If burn occurs, treat as any thermal burn

After eye contact

Flush with plenty of water (10 - 15 min.). Contact a doctor immediately.

After ingestion

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Drink plenty of water. Do not induce vomiting. Contact a doctor immediately.

05. Fire-fighting measures

Suitable extinguishing media

Not combustible under normal conditions. Adapt extinguishing measures to suit the environment.

Unsuitable extinguishing media

Waterjet. Do not use direct water stream.

Special risk posed by the substance or by the actual preparation, its combustion products or gases discharged

Cool containers in the vicinity of the blaze using a water spray. Highly flammable liquid. Keep possible ignition sources away from vapours. Risk of explosion if heated under confinement.

Special protective equipment

When extinguishing fires, use breathing apparatus with an independent source of air.

06. Accidental release measures

Personal precautions

Wear suitable protective clothing, gloves and eye/face protection.

Environmental precautions

Prevent from flowing into surface water/ground water.

Methods for cleaning up/collecting

Take up with a mechanical source and proceed according to the waste disposal regulations.

Additional information

Remove according to regulations.

07. Handling and storage

Information for safe handling

Containers to be opened and handled with care. Make sure that ventilation is adequate. Only adequately trained personnel should handle this product. Keep out of reach of children.

Information about protection against explosions and fires

No anti-explosion measures necessary.

Requirements to be met by storerooms and containers

Keep only in the original container. Store at 12-28 °C . Store in a dry place

Information about separation of incompatible products

Store the foodstuffs separately. Sensitive to cold below < 2 °C

08. Exposure controls and personal protection

Additional information about engineering measures

During mixing it is recommended to apply local exhaust ventilation.

Components with critical values that require monitoring at the workplace (exposure limits)

Dust exposure limit: 1.5 mg/m³. Control airborne concentration below the exposure guideline. Producer Industry recommends an exposure limit of 1.5 mg/m³.

Specification : TWA (AUS)

Value : MAK

Personal protective equipment

Do not eat or drink during work - no smoking. Keep away from food, drink and animal feeding stuff.. Avoid contact with skin and eyes. Respiratory protection In dusty atmospheres, use an approved dust respirator P2. If metal fumes are present, use an approved high-efficiency particulate respirator (P3).

Respiratory protection

Provide for good ventilation.

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Hand protection

Short-term exposure (< 30 min): disposable gloves, e.g. nitrile rubber, material thickness 0.1 mm (Australian Standard 2161).
Long-term exposure (Level 6: < 480 min): protective gloves, e.g. nitrile rubber, material thickness 0.7 mm (Australian Standard 2161). Solvent resistant gloves

Eye protection

Use tightly fitting safety glasses (Australian Standard AS 1336 and AS/NZS 1337).

Body protection

No particular measures required.

09. Physical and chemical properties

Image

Form : powder
Colour : different
Odour : odourless

Relevant safety data

| | | | | | |
|--------------------------------|--------------|-----|----------------|-------------------|-----------|
| Melting point / range : | (1013 hPa) | ca. | not applicable | °C | |
| Casting point / range : | (1013 hPa) | | not applicable | °C | |
| Flash point : | | | not applicable | °C | DIN 51755 |
| Ignition temperature : | | | not determined | °C | |
| Lower explosion limit : | | | not applicable | % b.v. | |
| Upper explosion limit : | | | not applicable | % b.v. | |
| Density : | (20 °C) | | not applicable | g/cm ³ | |
| Solubility in water : | (20 °C) | | not determined | % b.w. | |
| pH value : | | | not determined | | |

10. Stability and reactivity

Conditions to avoid

None, if handled according to order.

Materials to avoid

None known.

Hazardous decomposition products

None if used in accordance with instructions.

11. Toxicological information

Toxicological tests

Primary irritant effect

No data available

Sensitization

No data available.

Experience on practice

No data available

12. Ecological information

The product must not enter effluent, ground water, surface water or the soil.

Details on elimination (persistence / degradability)

Abiotical elimination

No data available.

Biological degradation / elimination

No data available.

Fate in environmental compartments

There are no data available on the preparation itself.

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Ecotoxical effects

Performance in sewage-treatment plants
No data available.

13. Disposal considerations

Product EU waste key 08 02 99

Concentrate: The cleaned-up material must be disposed of in accordance with Federal, State or Local regulations.

Contaminated packaging

Contaminated packaging must be emptied of all residues and, following appropriate cleaning, may be sent to a recycling plant.
Un cleaned packaging must be disposed of in the same manner as the medium.

14. Transport information

Land transport ADG

Classification

| | | |
|---------|----------------------|---------------|
| Class : | ADR | RID |
| | UN Number | Kemler Number |
| | Packing Group | |
| | Proper shipping name | |

Maritime transport IMDG

Classification

| | |
|------------------------------------|------|
| ADNR | IMDG |
| EMS UN Number | |
| Packing Group Proper shipping name | MFAG |

Air transport ICAO-TI and IATA-DGR

Classification

| | |
|---------|--------------------------------|
| Class : | ICAO / IATA-DGR |
| | Proper shipping name UN Number |
| | Subsidiary Risk |
| | Labels |

15. Regulatory information

Classification This product does not require classification according to the criteria of the EC. The product is a medical device according to the EC-directive 93/42

Danger symbol and danger designation



Not required.

Hazard-determining components of labelling

None : MAK value (ppm)

R-phrases

R: 11-36-66-67

11 Highly flammable.

36 Irritating to eyes.

66 Repeated exposure may cause skin dryness or cracking

67 Vapours may cause drowsiness and dizziness

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| | | | |
|--|---|------------------|-------|
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| Print date : | 10109.2009 | | |

S-phrases

S: 2-16-23-26-29-33

- 2 Keep out of the reach of children.
- 16 Keep away from sources of ignition -No smoking.
- 23 Do not breathe vapour.
- 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advise.
- 29 Do not empty into drains.
- 33 Take precautionary measures against static discharge.

16. Other information

Processing instructions / technical data sheets

Please observe the label/directions for use!

Further information

This is a medical device classified under the requirements of EU and TGA . Complies with ISO 8891, ISO 9693

Contact

Dr. Peter Lobo

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

1 Identification

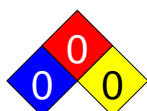
- **Product identifier**
- **Trade name:** **IPS Classic / IPS Classic V: Dentin, Intensive Dentin, Incisal, Opal Incisal, Transparent, Correction Powder**
- **CAS Number:**
66402-68-4
- **EC number:**
266-340-9
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture**
Metal-ceramic
Manufacture of dental prothesis
- **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 SDS Assistance:
US: 1-800-533-6825
Canada: 1-800-263-8182

2 Hazard(s) identification

- **Classification of the substance or mixture**
The substance is not classified according to the Globally Harmonized System (GHS).
- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



Health = 0
Fire = 0
Reactivity = 0

(Contd. on page 2)

CA

Material Safety Data Sheet

acc. to ISO 11014

Printing date 05/20/2015

Version number 7

Reviewed on 04/11/2015

Trade name: **IPS Classic / IPS Classic V: Dentin, Intensive Dentin, Incisal, Opal Incisal, Transparent, Correction Powder**

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· **HMIS-ratings (scale 0 - 4)**

| | | |
|------------|---|----------------|
| HEALTH | 0 | Health = 0 |
| FIRE | 0 | Fire = 0 |
| REACTIVITY | 0 | Reactivity = 0 |

· **Other hazards**

Dust generation

Particular danger of slipping on leaked/spilled product.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Substances**

· **CAS No. Description**

66402-68-4 ceramic materials

· **Identification number(s)**

· **EC number:** 266-340-9

4 First-aid measures

· **Description of first aid measures**

· **General information:** No special measures required.

· **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:**

Rinse with water.

Generally the product does not irritate the skin.

· **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

Mechanical effects only.

· **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.

· **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

5 Fire-fighting measures

· **Extinguishing media**

· **Suitable extinguishing agents:** The product is not flammable.

· **Special hazards arising from the substance or mixture** No further relevant information available.

· **Advice for firefighters**

· **Protective equipment:** No special measures required.

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acc. to ISO 11014

Printing date 05/20/2015

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Reviewed on 04/11/2015

Trade name: *IPS Classic / IPS Classic V: Dentin, Intensive Dentin, Incisal, Opal Incisal, Transparent, Correction Powder*

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6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Particular danger of slipping on leaked/spilled product.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:**
Pick up mechanically.
Ensure adequate ventilation.
- **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.
Prevent formation of dust.
Ensure good ventilation/exhaustion at the workplace.
- **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.
Store in dry conditions.
- **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:** Not required.
- **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.
Wash hands before breaks and at the end of work.
Keep away from foodstuffs, beverages and feed.
Vacuum clean contaminated clothing. Do not blow or brush off contamination.
Do not inhale dust / smoke / mist.
- **Breathing equipment:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- **Recommended filter device for short term use:** Filter P2
- **Protection of hands:** Not required.

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Trade name: IPS Classic / IPS Classic V: Dentin, Intensive Dentin, Incisal, Opal Incisal, Transparent, Correction Powder

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· **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.

· **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

· **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):** Product is not flammable.

· **Auto igniting:** Not determined.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

Lower: Not determined.

Upper: Not determined.

· **Vapor pressure:** Not applicable.

· **Density:** Not determined.

· **Relative density** Not determined.

· **Vapour density** Not applicable.

· **Evaporation rate** Not applicable.

· **Solubility in / Miscibility with**

Water: Nearly insoluble.

· **Partition coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

Dynamic: Not applicable.

Kinematic: Not applicable.

· **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.

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Material Safety Data Sheet

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Reviewed on 04/11/2015

Trade name: **IPS Classic / IPS Classic V: Dentin, Intensive Dentin, Incisal, Opal Incisal, Transparent, Correction Powder**

(Contd. of page 4)

- **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:** Mechanical effects only.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:** No further relevant information available.

- **Carcinogenic categories**

- **NTP (National Toxicology Program)**

Substance is not listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

Substance is not listed.

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.
- **Additional ecological information:**
- **General notes:** Generally not hazardous for water
- **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.

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Material Safety Data Sheet

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Reviewed on 04/11/2015

Trade name: **IPS Classic / IPS Classic V: Dentin, Intensive Dentin, Incisal, Opal Incisal, Transparent, Correction Powder**

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14 Transport information

| | |
|---|--|
| · UN-Number | |
| · DOT, TDG, ADN, IMDG, IATA | Void |
| · UN proper shipping name | |
| · DOT, TDG, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · DOT, TDG, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT, TDG, 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. |
| · Transport/Additional information: | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · UN "Model Regulation": | - |

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture

· Sara

· Section 355 (extremely hazardous substances):

Substance is not listed.

· Section 313 (Specific toxic chemical listings):

Substance is not listed.

· TSCA (Toxic Substances Control Act):

Substance is listed.

· Proposition 65

· Chemicals known to cause cancer:

Substance is not listed.

· Chemicals known to cause reproductive toxicity for females:

Substance is not listed.

· Chemicals known to cause reproductive toxicity for males:

Substance is not listed.

· Chemicals known to cause developmental toxicity:

Substance is not listed.

· Carcinogenic categories

· EPA (Environmental Protection Agency)

Substance is not listed.

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· **TLV (Threshold Limit Value established by ACGIH)**

Substance is not listed.

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

Substance is not listed.

· **GHS label elements** Void

· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations**

The product is a medical device according to the 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.

· **Date of preparation / last revision** 05/20/2015 / 6

· **Abbreviations and acronyms:**

ICAO: International Civil Aviation Organisation

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

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.**

CA