

Printing date 03/08/2013 Version number 4 Reviewed on 03/07/2013

I Identification of the substance/mixture and of the company/undertaking

- · Product identifier
- · Trade name: IPS Shade / IPS Shade V / IPS Stains-P
- · Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the preparation Auxiliary for manufacture of dental prothesis
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

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USA

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· 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 Hazards identification

- · Classification of the substance or mixture
- · 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
- · Labelling according to EU guidelines:

The product is not subject to identification regulations according to directives on hazardous materials.

- · Classification system:
- · NFPA ratings (scale 0 4)



(Contd. on page 2)

Printing date 03/08/2013 Version number 4 Reviewed on 03/07/2013

Trade name: IPS Shade / IPS Shade V / IPS Stains-P

(Contd. of page 1)

· HMIS-ratings (scale 0 - 4)



- · Other hazards
- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.

3 Composition/information on ingredients

· Chemical characterization: Mixtures

· Description: dental ceramic

· Dangerous components: Void

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 Firefighting 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.

(Contd. on page 3)

Printing date 03/08/2013 Version number 4 Reviewed on 03/07/2013

Trade name: IPS Shade / IPS Shade V / IPS Stains-P

(Contd. of page 2)

- · 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.

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:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- · 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.

- · Breathing equipment: Not required.
- · Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. After use of gloves apply skin-cleaning agents and skin cosmetics.

· Material of gloves

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

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.

(Contd. on page 4)

Printing date 03/08/2013 Version number 4 Reviewed on 03/07/2013

Trade name: IPS Shade / IPS Shade V / IPS Stains-P

(Contd. of page 3)

· Eye protection: Safety glasses

9 Physical and chemical properties

· Information	on basia	nhysical	and	chemical	nronerties
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· General Information

· Appearance:

Form: Pasty

Color: According to product specification

Odor: CharacteristicOdour threshold: Not determined.

· pH-value: Not determined.

· Change in condition

Melting point/Melting range: Undetermined.
Boiling point/Boiling range: Undetermined.

· Flash point: Undetermined.

· 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: Not determined.
 Relative density Not determined.
 Vapour density Not determined.
 Evaporation rate Not determined.

· Solubility in / Miscibility with

Water: Partly soluble.

· 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.

USA

Printing date 03/08/2013 Version number 4 Reviewed on 03/07/2013

Trade name: IPS Shade / IPS Shade V / IPS Stains-P

(Contd. of page 4)

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:

The product is not subject to classification according to internally approved calculation methods for preparations:

- · Carcinogenic categories
- · NTP (National Toxicology Program)

None of the ingredients is 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:
- $\cdot \textit{Recommendation:} \ \textit{Disposal must be made according to official regulations.}$

14 Transport information

- · UN-Number
- · DOT, ADR, ADN, IMDG, IATA Void
- · UN proper shipping name
- · DOT, ADR, ADN, IMDG, IATA Void

(Contd. on page 6)

Printing date 03/08/2013 Version number 4 Reviewed on 03/07/2013

Trade name: IPS Shade / IPS Shade V / IPS Stains-P

	(Contd. of page 5)
· 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 MARPOL73/78 and the IBC Code	of Not applicable.

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:

None of the ingredients is 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)

None of the ingredients is listed.

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

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

· Product related hazard informations:

The product is not subject to identification regulations according to directives on hazardous materials.

(Contd. on page 7)

Printing date 03/08/2013 Version number 4 Reviewed on 03/07/2013

Trade name: IPS Shade / IPS Shade V / IPS Stains-P

(Contd. of page 6)

- · 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.

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