## **SAFETY DATA SHEETS**

## This SDS packet was issued with item:

077176985

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

077143571 077175359 077176811 077176829 077176837 077176845 077176852 077176860 077176878 077176894 077176902 077176910 077176928 077176936 077176944 077176951 077176969 077176977 077176993 077177009 077177017



Printing date 11/08/2012

Version number 3

Reviewed on 11/08/2012

### 1 Identification of the substance/mixture and of the company/undertaking

- · Product identifier
- · Trade name: IPS e.max ZirPress
- · 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 preparation

Manufacture of dental prothesis

Fluorapatite glass-ceramic ingot for the PRESS-ON technology

- · 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 Hazards identification

· Classification of the substance or mixture

The substance is not classified according to the Globally Harmonized System (GHS).

- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC Not applicable.
- · Information concerning particular hazards for human and environment: Not applicable.
- · Label elements
- · Labelling according to EU guidelines:

The substance is not subject to classification according to the sources of literature known to us.

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



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Trade name: IPS e.max ZirPress

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· HMIS-ratings (scale 0 - 4)

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

- · Other hazards Avoid breathing sanding dust /swarf.
- · 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
- · Description: Fluorapatite glass-ceramic ingot

#### 4 First aid measures

- · Description of first aid measures
- · General information: No special measures required.
- · After inhalation: Grinding dust: Supply fresh air; consult doctor in case of complaints.
- · After skin contact: Generally the product does not irritate the skin.
- · After eye contact:

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

Mechanical effects only.

· After swallowing:

Grinding dust: 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: 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.

### 6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- · Environmental precautions: No special measures required.
- · Methods and material for containment and cleaning up: Pick up mechanically.

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Trade name: IPS e.max ZirPress

(Contd. of page 2)

· 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: None.
- · 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.
- · Breathing equipment: Use respiratory protective device against the effects of dust.
- · Protection of hands: Not required.
- · Material of gloves -
- · Penetration time of glove material -
- · Eye protection:

Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

### 9 Physical and chemical properties

- · Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form:

Solid

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.

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## Trade name: IPS e.max ZirPress

(Contd. of page 3)

· 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: Upper: Not determined. Not determined.

· Vapor pressure:

Not applicable.

Density:
Relative density
Vapour density
Evaporation rate

Not determined. Not determined. Not applicable. Not applicable.

· Solubility in / Miscibility with

Water:

Insoluble.

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

· Viscosity:

Dynamic: Kinematic: Not applicable.
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.
- · 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: The substance is not subject to classification.
- · Carcinogenic categories
- · NTP (National Toxicology Program)

Substance is not listed.

USA

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Printing date 11/08/2012

Version number 3

Reviewed on 11/08/2012

Trade name: IPS e.max ZirPress

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#### 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.

#### 14 Transport information

· L	JΝ	-N	un	nb	er
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· 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":

USA (Contd. on page 6)

Printing date 11/08/2012

Version number 3

Reviewed on 11/08/2012

Trade name: IPS e.max ZirPress

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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):

Substance is not listed.

· Section 313 (Specific toxic chemical listings):

Substance is not listed.

· TSCA (Toxic Substances Control Act):

Substance is not 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.

· TLV (Threshold Limit Value established by ACGIH)

Substance is not listed.

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

Substance is not listed.

· OSHA-Ca (Occupational Safety & Health Administration)

Substance is not listed.

· Product related hazard informations:

The substance is not subject to classification according to the sources of literature known to us.

- · 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:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

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Reviewed on 11/08/2012

## Trade name: IPS e.max ZirPress

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ICAO: International Civil Aviation Organization

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
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

USA



Printing date 05/20/2015

Version number 4

Reviewed on 04/13/2015

### 1 Identification

- · Product identifier
- · Trade name: IPS e.max ZirPress
- · 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

Manufacture of dental prothesis

Fluorapatite glass-ceramic ingot for the PRESS-ON technology

- · 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)



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Trade name: IPS e.max ZirPress

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· HMIS-ratings (scale 0 - 4)



- · Other hazards Avoid breathing sanding dust /swarf.
- · 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
- · Description: Fluorapatite glass-ceramic ingot

### 4 First-aid measures

- · Description of first aid measures
- · General information: No special measures required.
- · After inhalation: Grinding dust: Supply fresh air; consult doctor in case of complaints.
- · After skin contact: Generally the product does not irritate the skin.
- · After eye contact:

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

Mechanical effects only.

· After swallowing:

Grinding dust: 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.

### 6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- · Environmental precautions: No special measures required.
- · Methods and material for containment and cleaning up: Pick up mechanically.

(Contd. on page 3)

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Trade name: IPS e.max ZirPress

(Contd. of page 2)

· 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: None.
- · 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.
- · Breathing equipment: Use respiratory protective device against the effects of dust.
- · Protection of hands: Not required.
- · Material of gloves -
- · Penetration time of glove material -
- · Eye protection:

Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

### 9 Physical and chemical properties

- · Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Solid

Color: According to product specification

Odor: OdorlessOdour threshold: Not determined.

· pH-value: Not applicable.

· Change in condition

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

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-US

Printing date 05/20/2015 Version number 4 Reviewed on 04/13/2015

Trade name: IPS e.max ZirPress

	(Contd. o	f page
· 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:	Insoluble.	
Partition coefficient (n-octanol/wa	ter): 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.
- $\cdot \textit{Chemical stability} \ \textit{Stable under normal handling and storage conditions}.$
- · 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: 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.

US

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Trade name: IPS e.max ZirPress

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### 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.

· 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.		
· Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).		
· UN ''Model Regulation'':	_		

– US

(Contd. on page 6)

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Trade name: IPS e.max ZirPress

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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):

Substance is not listed.

· Section 313 (Specific toxic chemical listings):

Substance is not listed.

· TSCA (Toxic Substances Control Act):

Substance is not 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.

· 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 / 3
- · Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

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Printing date 05/20/2015

Version number 4

Reviewed on 04/13/2015

## Trade name: IPS e.max ZirPress

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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.