SAFETY DATA SHEETS

This SDS packet was issued with item: 077173396

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

070386938 070386946 070386953 070386961 070386979 070386987 070386995 070387001 070387019 070387027 070442509 070442517 070442525 070442533 070442541 070442558 070442566 070442574 070442582 070442590 070442608 070442616 070442624 070442632 070442640 070442657 070442665 070442673 070442681 070442699 070442889 070442897 070442913 070442939 070442947 070442954 077143613 077143621 077143639 077143647 077143654 077144843 077173008 077173016 077173024 077173032 077173040 077173057 077173065 077173305 077173313 077173321 077173339 077173347 077173354 077173362 077173370 077173388 077173404 077173412 077173420 077173438 077173446 077173453 077173461 077173479 077173487 077173495 077173503 077173511 077173529 077173537 077173545 077173552 077173560 077173578 077173586 077173594 077173602 077173610 077173628 077173636 077173644 077173651 077173669 077173677 077173685 077173693 077173701 077173982 077173990 077174006 077174014 077174022 077174030 077174048 077174055 077174063 077174071 077174089 077174139 077174147 077174154 077174162 077174170 077174188 077174196 077174204 077174212 077174220 077174238 077174287 077174295 077174303 077174311 077174329 077174337 077174345 077174352 077174360 077174378 077174501 077174519 077174527 077174535 077174543 077174550 077174568 077174576 077174584 077174592 077174600 077174618 077174626 077174634 077174642 077174659 077174667 077174675 077174683 077174691 077174709 077174717 077174725 077174733 077174741 077174758 077174766 077174774 077174782 077174790 077174808 077174816 077174824 077174832 077174840 077174899 077175383 077176118 077176126 077176134 077176142 077176159 077176167 077176175 077176183 077176191 077176209 077176217 077176225 077176233 077176241 077176258 077176266 077176274 077176282 077176290 077176308 077176316 273010807

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).

070215517 077175359



Printing date 10/05/2016

Version number 6

Reviewed on 09/21/2016

1 Identification

- · Product identifier
- · Trade name: IPS e.max CAD
- · CAS Number:
- 66402-68-4
- EC number:
- 266-340-9
- Application of the substance / the mixture Manufacture of dental prothesis Lithium disilicate glass-ceramic ingot for the CAD/CAM 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)
Health = 0 Fire = 0 Reactivity = 0

(Contd. on page 2)

US

Printing date 10/05/2016

HEALTH

FIRE

Version number 6

Reviewed on 09/21/2016

Trade name: IPS e.max CAD

(Contd. of page 1)

• HMIS-ratings (scale 0 - 4)

0 Health = 00 Fire = 0**REACTIVITY O** *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: Lithium disilicate 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)

US

Printing date 10/05/2016

Version number 6

Reviewed on 09/21/2016

Trade name: IPS e.max CAD

(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 and dental laboratories.
- 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).

Information on basic physical and General Information	chemical properties	
Appearance:		
Form:	Solid	
Color:	According to product specification	
Odor:	Odorless	
Odor threshold:	Not determined.	
pH-value:	Not applicable.	
Change in condition		
Melting point/Melting range:	Undetermined.	
Boiling point/Boiling range:	Undetermined.	

Version number 6

Reviewed on 09/21/2016

Trade name: IPS e.max CAD

		(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:	Not determined.	
Upper:	Not determined.	
· Vapor pressure:	Not applicable.	
· Density:	Not determined.	
· Relative density	Not determined.	
· Vapor 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.

- · *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:
- 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.

(Contd. on page 5)

Version number 6

Reviewed on 09/21/2016

Trade name: IPS e.max CAD

(Contd. of page 4)

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,RID,ADN, ADN, IMDG, IA	TA Void
UN proper shipping name DOT, ADR,RID,ADN, ADN, IMDG, IA	TA Void
Transport hazard class(es)	
DOT, ADR, RID, ADN, ADN, IMDG, IA	ΤΑ
Class	Void
Packing group DOT, ADR,RID,ADN, 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.
Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
UN ''Model Regulation'':	Void

(Contd. on page 6)

Printing date 10/05/2016

Version number 6

Reviewed on 09/21/2016

Trade name: IPS e.max CAD

(Contd. of page 5)

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 10/05/2016 / 5

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)

US

Printing date 10/05/2016

Version number 6

Reviewed on 09/21/2016

Trade name: IPS e.max CAD

(Contd. of page 6) 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) PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative NIOSH: National Institute for Occupational Safety OSHA: Occupational Safety & Health TLV: Threshold Limit Value PEL: Permissible Exposure Limit REL: Recommended Exposure Limit • * Data compared to the previous version altered.