## **SAFETY DATA SHEETS**

## This SDS packet was issued with item:

077089535

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

077084940 077089493

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).

077084932 077089337 077089345 077089352 077089360 077089378 077089428 077089519 077126071 077126089



Printing date 05/21/2015 Version number 4 Reviewed on 03/12/2015

### 1 Identification

- · Product identifier
- · Trade name: SR Ivocap High Impact Monomer
- · Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture Denture base material
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Ivoclar Vivadent Inc.

175 Pineview Drive, Amherst, N.Y. 14228

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

Flam. Liq. 2 H225 Highly flammable liquid and vapor.

Skin Irrit. 2 H315 Causes skin irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

STOT SE 3 H335 May cause respiratory irritation.

- · Label elements
- · GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms





GHS02 GHS07

- · Signal word Danger
- · Hazard-determining components of labeling: methyl methacrylate ethylene glycol dimethacrylate

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#### · Hazard statements

Highly flammable liquid and vapor.

Causes skin irritation.

May cause an allergic skin reaction.

May cause respiratory irritation.

#### · Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

Avoid breathing dust/fume/gas/mist/vapors/spray

Do not get in eyes, on skin, or on clothing.

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

If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

Dispose of contents/container in accordance with local/regional/national/international regulations.

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



Health = 2

Fire = 3

Reactivity = 2

· HMIS-ratings (scale 0 - 4)



2 Health = 2

Fire = 3

REACTIVITY 2 Reactivity = 2

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

## 3 Composition/information on ingredients

- · Chemical characterization: Mixtures
- $\cdot \textit{Description:} \ \textit{Mixture of the substances listed below with nonhazardous additions.}$

	· Dangero	us components:	
ſ	80-62-6	methyl methacrylate	50-100%
	97-90-5	ethylene glycol dimethacrylate	2.5-<10%

## 4 First-aid measures

- · Description of first aid measures
- · General information: Immediately remove any clothing soiled by the product.
- · 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: Immediately rinse with water.
- · After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- · After swallowing:

Rinse out mouth and then drink plenty of water.

Do not induce vomiting; immediately call for medical help.

- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.

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## Trade name: SR Ivocap High Impact Monomer

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· 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, sand, extinguishing powder. Do not use water.
- · For safety reasons unsuitable extinguishing agents: Water with full jet
- · Special hazards arising from the substance or mixture No further relevant information available.
- · Advice for firefighters
- · **Protective equipment:** No special measures required.
- · Additional information Cool endangered receptacles with water spray.

#### 6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

- · Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Ensure adequate ventilation.

Do not flush with water or aqueous cleansing agents

· 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.

Ensure good ventilation/exhaustion at the workplace.

 $\cdot \textit{Information about protection against explosions and fires:} \\$ 

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

- · Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles:

Store only in the original receptacle.

Store in a cool location.

- · Information about storage in one common storage facility: Store away from oxidizing agents.
- · Further information about storage conditions:

Store receptacle in a well ventilated area.

Keep receptacle tightly sealed.

Store in cool, dry conditions in well sealed receptacles.

· 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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## Trade name: SR Ivocap High Impact Monomer

(Contd. of page 3)

#### · Control parameters

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

#### 80-62-6 methyl methacrylate

PEL Long-term value: 410 mg/m³, 100 ppm REL Long-term value: 410 mg/m³, 100 ppm

TLV Short-term value: 410 mg/m³, 100 ppm Long-term value: 205 mg/m³, 50 ppm

(SEN) NIC-DSEN

- · 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.

Immediately remove all soiled and contaminated clothing.

Avoid contact with the eyes and skin.

#### · 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 A1

Filter A2

Filter A3

#### · Protection of hands:



Protective gloves

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

Butyl rubber, BR

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

#### · 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.

#### · Not suitable are gloves made of the following materials:

Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

· Eye protection:



Tightly sealed goggles

IIS.

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## Trade name: SR Ivocap High Impact Monomer

(Contd. of page 4)

Information on basic physical and c	hemical properties
· General Information	
· Appearance:	
Form:	Fluid
Color:	Colorless
· Odor: · Odour threshold:	Pungent Not determined.
· pH-value:	Not determined.
· Change in condition	
Melting point/Melting range:	-48 °C (-54 °F)
Boiling point/Boiling range:	101 °C (214 °F)
· Flash point:	10 °C (50 °F)
· Ignition temperature:	430 °C (806 °F)
· Auto igniting:	Product is not selfigniting.
· Danger of explosion:	Product is not explosive. However, formation of explosive air/vapo mixtures are possible.
· Explosion limits:	
Lower:	2.1 Vol %
Upper:	12.5 Vol %
· Vapor pressure at 20 °C (68 °F):	47 hPa (35 mm Hg)
· Density at 20 °C (68 °F):	$0.943 \text{ g/cm}^3 (7.869 \text{ lbs/gal})$
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with Water at 20 °C (68 °F):	1.6 g/l
· Partition coefficient (n-octanol/wate	
· 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

Forms explosive gas mixture with air.

Reacts with strong oxidizing agents.

Exothermic polymerization.

- · 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.

HS

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## Trade name: SR Ivocap High Impact Monomer

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### 11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:
- · LD/LC50 values that are relevant for classification:

80-62-6 methyl methacrylate

Oral LD50 7872 mg/kg (rat)

- · Primary irritant effect:
- · on the skin: Irritant to skin and mucous membranes.
- · on the eye: No irritating effect.
- · Sensitization: Sensitization possible through skin contact.
- · Additional toxicological information: No further relevant information available.
- · Carcinogenic categories
- · IARC (International Agency for Research on Cancer)

80-62-6 methyl methacrylate

3

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

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.
- $\cdot \textit{\textbf{Mobility in soil}} \ \textit{No further relevant information available}.$
- · 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.

- · 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:

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packagings:
- · Recommendation: Disposal must be made according to official regulations.

US

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## Trade name: SR Ivocap High Impact Monomer

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Transport information	
UN-Number	
DOT, ADR, IMDG, IATA	UN1247
UN proper shipping name	
DOT	Methyl methacrylate monomer, stabilized
ADR	1247 Methyl methacrylate monomer, stabilized
IMDG, IATA	METHYL METHACRYLATE MONOMER, STABILIZED
Transport hazard class(es)	
DOT	
Class	3 Flammable liquids
Label	3
ADR	
Class	3 (F1) Flammable liquids
Label	3
Class	3 Flammable liquids
Label	3
Packing group	
DOT, ADR, IMDG, IATA	II
Environmental hazards:	
Marine pollutant:	No
Special precautions for user	Warning: Flammable liquids
Danger code (Kemler):	339
EMS Number:	F- $E$ , $S$ - $D$
Transport in bulk according to Annex MARPOL73/78 and the IBC Code	: <b>II of</b> Not applicable.
Transport/Additional information:	
ADR	
Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
IMDG	maximum nei quanuy per outer pueruging. 500 mi
IMDG Limited quantities (LQ)	IL
Linuca quantines (LV)	16

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## Trade name: SR Ivocap High Impact Monomer

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· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN ''Model Regulation'':	UN1247, Methyl methacrylate monomer, stabilized, 3, II

## 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):

80-62-6 methyl methacrylate

· 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)

80-62-6 methyl methacrylate

NL

· TLV (Threshold Limit Value established by ACGIH)

80-62-6 methyl methacrylate

A4

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

None of the ingredients is listed.

· GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms





GHS02

GHS07

- · Signal word Danger
- · Hazard-determining components of labeling:

methyl methacrylate

ethylene glycol dimethacrylate

· Hazard statements

Highly flammable liquid and vapor.

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## Trade name: SR Ivocap High Impact Monomer

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Causes skin irritation.

May cause an allergic skin reaction.

May cause respiratory irritation.

#### · Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

Avoid breathing dust/fume/gas/mist/vapors/spray

Do not get in eyes, on skin, or on clothing.

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

If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

Dispose of contents/container in accordance with local/regional/national/international regulations.

#### · 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 05/21/2015 / 3

#### · 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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Flam. Liq. 2: Flammable liquids, Hazard Category 2

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

\* \* Data compared to the previous version altered.



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### 1 Identification

- · Product identifier
- · Trade name: SR Ivocap High Impact Polymer
- · Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture Denture base material
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Ivoclar Vivadent Inc.

175 Pineview Drive, Amherst, N.Y. 14228

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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

Skin Sens. 1 H317 May cause an allergic skin reaction.

- · Label elements
- · GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms



GHS07

- · Signal word Warning
- · Hazard-determining components of labeling:

dibenzoyl peroxide

· Hazard statements

May cause an allergic skin reaction.

· Precautionary statements

Avoid breathing dust/fume/gas/mist/vapors/spray

Do not get in eyes, on skin, or on clothing.

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

Dispose of contents/container in accordance with local/regional/national/international regulations.

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



Health = 0Fire = 1Reactivity = 0

· HMIS-ratings (scale 0 - 4)



1 Health = 1 Fire = 1

· 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: Mixtures
- · Description: Mixture of the substances listed below with nonhazardous additions.
- · Dangerous components:

94-36-0 dibenzoyl peroxide

0.1-<1%

#### 4 First-aid measures

- · Description of first aid measures
- · General information: No special measures required.
- · After inhalation:

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

· After skin contact:

Rinse with water.

If skin irritation continues, consult a doctor.

· After eye contact:

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

 $\cdot$  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.

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## Trade name: SR Ivocap High Impact Polymer

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### 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

Avoid formation of dust.

Particular danger of slipping on leaked/spilled product.

· Environmental precautions:

Do not allow product to reach sewage system or any water course.

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: Protect from heat and direct sunlight.
- $\cdot$  *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:

### 94-36-0 dibenzoyl peroxide

PEL Long-term value: 5 mg/m³
REL Long-term value: 5 mg/m³

TLV Long-term value: 5 mg/m<sup>3</sup>

· Additional information: The lists that were valid during the creation were used as basis.

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## Trade name: SR Ivocap High Impact Polymer

(Contd. of page 3)

- · 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 skin.

- · Breathing equipment: Use respiratory protective device against the effects of dust.
- · Protection of hands:



Protective gloves

After use of gloves apply skin-cleaning agents and skin cosmetics.

· Material of gloves

Butyl rubber, BR

Chloroprene rubber, CR

Natural rubber, NR

Nitrile rubber, NBR

Fluorocarbon rubber (Viton)

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

· 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	l and chemica	l properties
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· General Information

 $\cdot Appearance:$ 

· Flash point:

Form: Powder

Color: According to product specification

Odor: CharacteristicOdour threshold: Not determined.

· pH-value: Not applicable.

· Change in condition

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

· Flammability (solid, gaseous): Not determined.

• Auto igniting: Product is not selfigniting.

• Danger of explosion: Product does not present an explosion hazard.

Not applicable.

· Explosion limits:

Lower: Not determined.
Upper: Not determined.

· Vapor pressure: Not applicable.

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## Trade name: SR Ivocap High Impact Polymer

(Contd. of page 4) · 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.
- · 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

8	8	
· IARC (Inte	ernational Agency for Research on Cancer)	
9011-14-7	polymethylmethacrylate	3
94-36-0	dibenzoyl peroxide	3
· NTP (Natio	onal Toxicology Program)	
None of the	e ingredients is listed.	
· OSHA-Ca (Occupational Safety & Health Administration)		
None of the	e 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.

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## Trade name: SR Ivocap High Impact Polymer

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- · Mobility in soil No further relevant information available.
- · 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.

- · 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.

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
Special precautions for user	Not applicable.
Transport in bulk according to Annex MARPOL73/78 and the IBC Code	<b>II of</b> 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):

None of the ingredients is listed.

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## Trade name: SR Ivocap High Impact Polymer

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#### · Section 313 (Specific toxic chemical listings):

94-36-0 dibenzoyl peroxide

#### · TSCA (Toxic Substances Control Act):

9011-14-7 polymethylmethacrylate

94-36-0 dibenzoyl peroxide

#### · 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)

94-36-0 dibenzoyl peroxide

*A4* 

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

None of the ingredients is listed.

#### · GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms



### · Signal word Warning

### · Hazard-determining components of labeling:

dibenzoyl peroxide

#### · Hazard statements

May cause an allergic skin reaction.

#### · Precautionary statements

Avoid breathing dust/fume/gas/mist/vapors/spray

Do not get in eyes, on skin, or on clothing.

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

Dispose of contents/container in accordance with local/regional/national/international regulations.

#### · 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.

Printing date 05/21/2015

Version number 4

Reviewed on 03/12/2015

## Trade name: SR Ivocap High Impact Polymer

(Contd. of page 7)

## 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 05/21/2015 / 3
- · 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) Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

\* \* Data compared to the previous version altered.

HS



Printing date 08/05/2015 Version number 10 Reviewed on 08/03/2015

### 1 Identification

- · Product identifier
- · Trade name: SR Ivolen Monomer
- · Application of the substance / the mixture Custom tray 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 SDS Assistance: US: 1-800-533-6825 Canada: 1-800-263-8182

### 2 Hazard(s) identification

· Classification of the substance or mixture

Flam. Liq. 2 H225 Highly flammable liquid and vapor.

Skin Irrit. 2 H315 Causes skin irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

STOT SE 3 H335 May cause respiratory irritation.

- · Label elements
- · GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms





GHS02

GHS07

- · Signal word Danger
- · Hazard-determining components of labeling:

methyl methacrylate

· Hazard statements

Highly flammable liquid and vapor.

Causes skin irritation.

(Contd. on page 2)

Printing date 08/05/2015 Version number 10 Reviewed on 08/03/2015

## Trade name: SR Ivolen Monomer

(Contd. of page 1)

May cause an allergic skin reaction.

May cause respiratory irritation.

· Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

Avoid breathing dust/fume/gas/mist/vapors/spray

Do not get in eyes, on skin, or on clothing.

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

If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

Dispose of contents/container in accordance with local/regional/national/international regulations.

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



Health = 2Fire = 3Reactivity = 2

· HMIS-ratings (scale 0 - 4)



2 Health = 2 Fire = 3

- · 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 comp	ponents:	
	CAS: 80-62-6	methyl methacrylate	50-100%
I	CAS: 8002-74-2	Paraffin waxes and Hydrocarbon waxes	≤10%

### 4 First-aid measures

- · Description of first aid measures
- · General information: Immediately remove any clothing soiled by the product.
- · 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:

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:

Rinse out mouth and then drink plenty of water.

Do not induce vomiting; immediately call for medical help.

- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.

(Contd. on page 3)

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Trade name: SR Ivolen Monomer

(Contd. of page 2)

· 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.

- · For safety reasons unsuitable extinguishing agents: Water with full jet
- · Special hazards arising from the substance or mixture No further relevant information available.
- · Advice for firefighters
- · Protective equipment: No special measures required.
- · Additional information Cool endangered receptacles with water spray.

### 6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

- · Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

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.

*Ensure good ventilation/exhaustion at the workplace.* 

For use in dentistry only.

· Information about protection against explosions and fires:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

- · Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles:

Store only in the original receptacle.

Store in a cool location.

- Information about storage in one common storage facility: Store away from oxidizing agents.
- · Further information about storage conditions:

Keep receptacle tightly sealed.

Store receptacle in a well ventilated area.

Protect from heat and direct sunlight.

 $\cdot$  *Specific end use*(s) *No further relevant information available.* 

US ·

(Contd. on page 4)

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Trade name: SR Ivolen Monomer

(Contd. of page 3)

### 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:

#### CAS: 80-62-6 methyl methacrylate

PEL Long-term value: 410 mg/m³, 100 ppm REL Long-term value: 410 mg/m³, 100 ppm

TLV Short-term value: 410 mg/m³, 100 ppm Long-term value: 205 mg/m³, 50 ppm (SEN) NIC-DSEN

#### CAS: 8002-74-2 Paraffin waxes and Hydrocarbon waxes

REL Long-term value: 2 mg/m<sup>3</sup> TLV Long-term value: 2 mg/m<sup>3</sup>

- · 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.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

Do not inhale gases / fumes / aerosols.

· 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 A1

Filter A2

Filter A3

· Protection of hands:



Protective gloves

After use of gloves apply skin-cleaning agents and skin cosmetics.

· Material of gloves

Butyl rubber, BR

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

· 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.

· Not suitable are gloves made of the following materials:

Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

(Contd. on page 5)

- US

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Trade name: SR Ivolen Monomer

(Contd. of page 4)

· Eye protection:



Tightly sealed goggles

## 9 Physical and chemical properties

· Information on	hasic	nhysical	and	chemical	nronorties
· mjormanon on	vusic	pnysicai	unu	cnemicai	properties

· General Information

· Appearance:

Form: Fluid
Color: Colorless

Odor: Pungent

Odour threshold: Not determined.

pH-value: Not determined.

· Change in condition

Melting point/Melting range: -48 °C (-54 °F)
Boiling point/Boiling range: 101 °C (214 °F)

• Flash point: 10 °C (50 °F)

· Ignition temperature: 430 °C (806 °F)

· Auto igniting: Product is not selfigniting.

• Danger of explosion: Product is not explosive. However, formation of explosive air/vapor

mixtures are possible.

· Explosion limits:

 Lower:
 2.1 Vol %

 Upper:
 12.5 Vol %

• Vapor pressure at 20 °C (68 °F): 47 hPa (35 mm Hg)

• Density at 20 °C (68 °F): 0.943 g/cm³ (7.869 lbs/gal) • Relative density Not determined.

Vapour density
 Evaporation rate
 Not determined.
 Not determined.

 $\cdot \textit{ Solubility in / Miscibility with }$ 

Water at 20 °C (68 °F): 1.6 g/l

· 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.

(Contd. on page 6)

- US

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## Trade name: SR Ivolen Monomer

(Contd. of page 5)

#### · Possibility of hazardous reactions

Forms explosive gas mixture with air.

Reacts with strong oxidizing agents.

Exothermic polymerization.

- · 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:
- · LD/LC50 values that are relevant for classification:

CAS: 80-62-6 methyl methacrylate

Oral LD50 7872 mg/kg (rat)

- · Primary irritant effect:
- · on the skin: Irritant to skin and mucous membranes.
- · on the eye: No irritating effect.
- · Sensitization: Sensitization possible through skin contact.
- · Additional toxicological information: No further relevant information available.
- · Carcinogenic categories
- · IARC (International Agency for Research on Cancer)

CAS: 80-62-6 methyl methacrylate

3

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

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:

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.

- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

US

(Contd. on page 7)

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Trade name: SR Ivolen Monomer

(Contd. of page 6)

## 13 Disposal considerations

- · Waste treatment methods
- · Recommendation:

Must not be disposed of together with household garbage. Do not allow product to reach sewage system. 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	UN1247
ADR,RID,ADN, IMDG, IATA	1247
	1217
UN proper shipping name	12.47 METHYL METHACHYLATE MONOMER OTARILITA
ADR/RID/ADN	1247 METHYL METHACRYLATE MONOMER, STABILIZE
IMDG, IATA	METHYL METHACRYLATE MONOMER, STABILIZED
Transport hazard class(es)	
DOT	
A	
Class	3 Flammable liquids
Label	3
ADR/RID/ADN	
A	
3/	
Class	3 (F1) Flammable liquids
Label	3
IMDC IATA	
IMDG, IATA	
Class	3 Flammable liquids
Label	3 Flammable liquids 3
Packing group	***
DOT, ADR,RID,ADN, IMDG, IATA	II
Environmental hazards:	
Marine pollutant:	No
Special precautions for user	Warning: Flammable liquids
Danger code (Kemler):	33
EMS Number:	F- $E$ , $S$ - $E$

Printing date 08/05/2015 Version number 10 Reviewed on 08/03/2015

Trade name: SR Ivolen Monomer

(Contd. of page 7)

· Transport in bulk according to Annex II of

MARPOL73/78 and the IBC Code Not applicable.

· UN ''Model Regulation'': UN1247, METHYL METHACRYLATE MONOMER,

STABILIZED, 3, II

## 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):

CAS: 80-62-6 methyl methacrylate

· 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)

CAS: 80-62-6 methyl methacrylate

NL

· TLV (Threshold Limit Value established by ACGIH)

CAS: 80-62-6 methyl methacrylate

A4

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

None of the ingredients is listed.

· GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms





GHS02

GHS07

- · Signal word Danger
- $\cdot \textit{Hazard-determining components of labeling:}$
- methyl methacrylate
  · Hazard statements

Highly flammable liquid and vapor.

(Contd. on page 9)

Printing date 08/05/2015 Version number 10 Reviewed on 08/03/2015

## Trade name: SR Ivolen Monomer

(Contd. of page 8)

Causes skin irritation.

May cause an allergic skin reaction.

May cause respiratory irritation.

#### · Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

Avoid breathing dust/fume/gas/mist/vapors/spray

Do not get in eyes, on skin, or on clothing.

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

If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

Dispose of contents/container in accordance with local/regional/national/international regulations.

#### · 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 08/05/2015 / 9

#### · 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)

 ${\it HMIS: Hazardous\ Materials\ Identification\ System\ (USA)}$ 

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

 $vPvB:\ very\ Persistent\ and\ very\ Bioaccumulative$ 

Flam. Liq. 2: Flammable liquids, Hazard Category 2

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

\* Data compared to the previous version altered.

ZII