

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.

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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 SDS Assistance: US: 1-800-533-6825 Canada: 1-800-263-8182

2 Hazard(s) identification

· Classification of the substance or mixture

Flammable Liquids - Category 2 H225 Highly flammable liquid and vapour.

Skin Irritation - Category 2 H315 Causes skin irritation.

Skin Sensitizer - Category 1 H317 May cause an allergic skin reaction.

Specific Target Organ Toxicity - Single Exposure -H335 May cause respiratory irritation.

Category 3

- · 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 vapour.

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Causes skin irritation.

May cause an allergic skin reaction.

May cause respiratory irritation.

· Precautionary statements

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Avoid breathing dust/fume/gas/mist/vapours/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 [or shower]. Dispose of contents/container in accordance with local/regional/national/international regulations.

- · Hazard description:
- · WHMIS-symbols:

B2 - Flammable liquid

D2B - Toxic material causing other toxic effects



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



Health = 2 Fire = 3Reactivity = 2

· HMIS-ratings (scale 0 - 4)



2 Health = 23 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
- · Description: Mixture of the substances listed below with nonhazardous additions.

ſ	· Dangerous components:				
Ī	CAS: 80-62-6	methyl methacrylate	60-100%		
	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.

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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.
- · 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.

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Store receptacle in a well ventilated area.

Protect from heat and direct sunlight.

· 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:

CAS: 80-62-6 methyl methacrylate

EL Short-term value: 100 ppm

Long-term value: 50 ppm

S

EV Short-term value: 100 ppm Long-term value: 50 ppm

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

EL Long-term value: 2 mg/m³

EV Long-term value: 2 mg/m³

fume

- · 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.

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· Eye protection:



Tightly sealed goggles

9 Physical and chemical properties

· Information on basic physical and chemical 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
Boiling point/Boiling range: 101 °C

Flash point: 10 °C

· Ignition temperature: 430 °C

· 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: 47 hPa

Density at 20 °C: 0.943 g/cm³
 Relative density Not determined.
 Vapour density Not determined.
 Evaporation rate Not determined.

· Solubility in / Miscibility with

Water at 20 °C: 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.

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· 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.

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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.

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· UN-Number	
$\cdot DOT$	UN1247
· TDG, IMDG, IATA	1247

· UN proper shipping name

• DOT, IMDG, IATA METHYL METHACRYLATE MONOMER, STABILIZED
• ADR/RID/ADN 1247 METHYL METHACRYLATE MONOMER, STABILIZED

- · Transport hazard class(es)
- $\cdot DOT$



· Class 3 Flammable liquids

· Label 3

· TDG (Transport dangerous goods):



· Class 3 (F1) Flammable liquids

· Label

· IMDG, IATA



· Class 3 Flammable liquids

· Label

· Packing group

· DOT, TDG, IMDG, IATA

· Environmental hazards:

· Marine pollutant:

· Special precautions for user Warning: Flammable liquids

Danger code (Kemler): 33EMS Number: F-E,S-E

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· 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
- · Hazard-determining components of labeling: methyl methacrylate
- · Hazard statements

Highly flammable liquid and vapour.

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Trade name: SR Ivolen Monomer

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Causes skin irritation.

May cause an allergic skin reaction.

May cause respiratory irritation.

· Precautionary statements

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

 $A void\ breathing\ dust/fume/gas/mist/vapours/spray.$

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 [or 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:

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)

WHMIS: Workplace Hazardous Materials Information System (Canada)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

 $Flammable \ Liquids \ - \ Category \ 2: \ Flammable \ liquids, \ Hazard \ Category \ 2$

Skin Irritation - Category 2: Skin corrosion/irritation, Hazard Category 2

Skin Sensitizer - Category 1: Sensitisation - Skin, Hazard Category 1

Specific Target Organ Toxicity - Single Exposure - Category 3: Specific target organ toxicity - Single exposure, Hazard Category 3

* * Data compared to the previous version altered.

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