

Printing date 02/09/2011 Version number 3 Reviewed on 02/09/2011

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

- · Product identifier
- · Trade name: Telio Activator
- · Relevant identified uses of the substance or mixture and uses advised against
- · Application of the substance / the preparation Crowns- and bridges material
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

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USA

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Ivoclar Vivadent Inc.

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- · Information department: Quality Assurance / Regulatory Affairs
- $\cdot \textit{Emergency telephone number:}$

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 Composition/information on ingredients

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

· Dangerous components:				
80-62-6	methyl methacrylate	♠ H225; ♠ H315; H317; H335	50-100%	
97-90-5	ethylene dimethacrylate	<b>♦</b> <i>H317; H335</i>	2.5-10%	
109-16-0	triethyleneglycol dimethacrylate	<b>♦</b> Н315; Н319; Н317; Н335	2.5-10%	

### 3 Hazards identification

- · Classification of the substance or mixture
- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC



Irritant

Irritating to respiratory system and skin. May cause sensitisation by skin contact.



Highly flammable

Highly flammable.

· Information concerning particular hazards for human and environment:

The product has to be labelled due to the calculation procedure of international guidelines.

· Classification system:

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

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- · Label elements
- · Labelling according to EU guidelines:

The product has been classified and marked in accordance with directives on hazardous materials.

· Code letter and hazard designation of product:





Irritant Highly flammable

#### · Hazard-determining components of labelling:

methyl methacrylate ethylene dimethacrylate triethyleneglycol dimethacrylate

#### · Risk phrases:

Highly flammable.

Irritating to respiratory system and skin.

May cause sensitisation by skin contact.

#### · Safety phrases:

Keep container in a well-ventilated place.

Keep away from sources of ignition - No smoking.

Do not breathe fumes/aerosol.

Avoid contact with skin.

Wear suitable gloves.

This material and its container must be disposed of as hazardous waste.

- · 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.

### 4 First aid measures

- · Description of first aid measures
- · 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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· Indication of any immediate medical attention and special treatment needed No further relevant information available.

### 5 Firefighting measures

- · Extinguishing media
- · Suitable extinguishing agents:

CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- · 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.

· 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.

· 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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· Control parameters

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

#### 80-62-6 methyl methacrylate

PEL 410 mg/m³, 100 ppm

REL 410 mg/m<sup>3</sup>, 100 ppm

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

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· 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.

Do not inhale gases / fumes / aerosols.

Avoid contact with the skin.

· Breathing equipment:

Use suitable respiratory protective device in case of insufficient ventilation.

Filter A

· 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

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:

Butyl rubber, BR

· 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

- USA

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Information on basic physical and ch	nemical properties	
General Information		
Appearance:	77	
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/vapor mixtures are possible.	
Explosion limits:		
Lower:	2.1 Vol %	
Upper:	12.5 Vol %	
Vapor pressure at $20^{\circ}C$ (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	Not determined.	
Evaporation rate	Not determined.	
Solubility in / Miscibility with		
<i>Water at 20°C (68°F):</i>	1.6 g/l	
Segregation coefficient (n-octonol/we	ater): Not determined.	
Viscosity:		
Dynamic:	Not determined.	
Kinematic:	Not determined.	
Other information	No further relevant information available.	

## 10 Stability and reactivity

- · Reactivity No further relevant information available.
- · Chemical stability Stable under normal handling and storage conditions.
- · Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions

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.

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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:

The product shows the following dangers according to internally approved calculation methods for preparations:

Irritant

### 12 Ecological information

- · Toxicity
- · Acquatic 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.

### 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.

### 14 Transport information

· DOT regulations:



· Hazard class: 3

· Identification number: UN1247

· Packing group:

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- · Proper shipping name (technical name): METHYL METHACRYLATE MONOMER, STABILIZED
  - Label
- · Land transport ADR/RID (cross-border):



· ADR/RID class: 3 (F1) Flammable liquids

Danger code (Kemler): 339
UN-Number: 1247
Packaging group: II
Label: 3

· UN proper shipping name: 1247 METHYL METHACRYLATE MONOMER, STABILIZED

· Maritime transport IMDG:



IMDG Class: 3
UN Number: 1247
Label 3
Packaging group: II
EMS Number: F-E,S-D
Marine pollutant: No

· Propper shipping name: METHYL METHACRYLATE MONOMER, STABILIZED

· Air transport ICAO-TI and IATA-DGR:



· ICAO/IATA Class: 3
 · UN/ID Number: 1247
 · Label 3
 · Packaging group: II

· Proper shipping name: METHYL METHACRYLATE MONOMER, STABILIZED

- · Special precautions for user Warning: Flammable liquids
- · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable.

## 15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Sara
- · Section 355 (extremely hazardous substances):

None of the ingredients is listed.

· Section 313 (Specific toxic chemical listings):

80-62-6 methyl methacrylate

· TSCA (Toxic Substances Control Act):

All ingredients are listed.

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· 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

· IARC (International Agency for Research on Cancer)

80-62-6 methyl methacrylate

3

· NTP (National Toxicology Program)

None of the ingredients is listed.

· 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.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

#### · Product related hazard informations:

The product has been classified and marked in accordance with directives on hazardous materials.

· Hazard symbols:





Irritant Highly flammable

## · Hazard-determining components of labelling:

methyl methacrylate ethylene dimethacrylate triethyleneglycol dimethacrylate

#### · Risk phrases:

Highly flammable.

Irritating to respiratory system and skin.

May cause sensitisation by skin contact.

#### · Safety phrases:

Keep container in a well-ventilated place.

Keep away from sources of ignition - No smoking.

Do not breathe fumes/aerosol.

Avoid contact with skin.

Wear suitable gloves.

This material and its container must be disposed of as hazardous waste.

## · National regulations:

#### · Other regulations, limitations and prohibitive regulations

The product is a medical device according to the EC-directive 93/42/EEC.

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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.

USA