

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

### 1.1. Product identifier

Product form : Mixture  
Product name : SILANE PRIMER

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

#### Relevant identified uses

Main use category : Professional use  
Use of the substance/mixture : Preparation intended for dental medical use  
Function or use category : Dental materials.

#### Uses advised against

No additional information available

### 1.3. Details of the supplier of the safety data sheet

#### Supplier

Kerr Italia S.r.l.  
Via Passanti, 174  
Scafati (SA) 84018 (Italy)  
T +39 081 850 3511 / Information Phone Number: 1-800-841-1428 (Customer Service)  
[safety@envistaco.com](mailto:safety@envistaco.com)

### 1.4. Emergency telephone number

Emergency number : CHEMTREC® Emergency Call Center. Emergency Telephone Number (for USA only) 001-800-424-9300  
International and Maritime Telephone Number +1 (703) 527-3887

Country	Official advisory body	Address	Emergency number	Comment
Gibraltar	GHA Call Centre Zone 2, Level3, St Bernard's Hospital	Harbour Views Road	+350 200 79700 +350 200 72266	
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	
Malta	Medicines & Poisons Info Office	Mater Dei Hospital MSD 2090 Msida	+356 2545 6508	
United Kingdom	National Poisons Information Service (Newcastle Unit)	Claremont Place Newcastle-upon-Tyne, Newcastle	+44 191 2606182 +44 191 2606180	Hours of operation: 24hrs

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

#### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Flam. Liq. 2 H225  
Skin Sens. 1 H317

Full text of hazard classes and H-statements : see section 16

#### Adverse physicochemical, human health and environmental effects

No additional information available

### 2.2. Label elements

#### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



Signal word (CLP) : Danger

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according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Contains	: (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate, 2,2'-ethylenedioxydiethyl dimethacrylate
Hazard statements (CLP)	: H225 - Highly flammable liquid and vapour. H317 - May cause an allergic skin reaction.
Precautionary statements (CLP)	: P210 - Keep away from heat/sparks/open flames/hot surfaces. – No smoking. P243 - Take precautionary measures against static discharge. P261 - Avoid breathing vapours. P272 - Contaminated work clothing should not be allowed out of the workplace. P280 - Wear protective gloves. P302+P352 - IF ON SKIN: Wash with plenty of soap and water. P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P362+P364 - Take off contaminated clothing and wash it before reuse. P403+P235 - Store in a well-ventilated place. Keep cool. P501 - Dispose of contents/container to a hazardous or special waste collection point.
Extra phrases	: The product is seen as a medical device (Directive 90/385/EEC, 93/42/EEC, 98/79/EC) and therefore not subject to labelling (EU-regulation 1272/2008, article 1, paragraph 5d). A safety data sheet is not required for this product under Article 31 of REACH. This Product Safety Information Sheet has been created on a voluntary basis. For professional users only.

### 2.3. Other hazards

Other hazards which do not result in classification : None under normal conditions.

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Name	Product identifier	Conc. (% w/w)	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ethanol; ethyl alcohol substance with national workplace exposure limit(s) (GB, IE)	(CAS-No.) 64-17-5 (EC-No.) 200-578-6 (EC Index-No.) 603-002-00-5 (REACH-no) 01-2119457610-43	70 – 85	Flam. Liq. 2, H225
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	(CAS-No.) 1565-94-2 (EC-No.) 216-367-7 (REACH-no) N/A	5 – 6.1	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317
2,2'-ethylenedioxydiethyl dimethacrylate	(CAS-No.) 109-16-0 (EC-No.) 203-652-6 (REACH-no) 01-2119969287-21	3.3 – 4.1	Skin Sens. 1, H317

Full text of H- and EUH-statements: see section 16

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures general	: If medical advice is needed, have product container or label at hand.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Get medical advice/attention if you feel unwell.
First-aid measures after skin contact	: Gently wash with plenty of soap and water.
First-aid measures after eye contact	: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical advice/attention if you feel unwell.
First-aid measures after ingestion	: If swallowed, rinse mouth with water (only if the person is conscious). Call a POISON CENTER/doctor if you feel unwell.

### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects	: In all cases of doubt, or when symptoms persist, seek medical attention.
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Symptoms/effects after skin contact	: May cause an allergic skin reaction. May cause skin irritation.
Symptoms/effects after eye contact	: Liquid splashes in the eye may cause irritation.

### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically. In all cases of doubt, or when symptoms persist, seek medical attention.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire. Foam, carbon dioxide (CO <sub>2</sub> ) and powder.
Unsuitable extinguishing media	: Do not use a heavy water stream.

### 5.2. Special hazards arising from the substance or mixture

Fire hazard	: Highly flammable liquid and vapour.
Explosion hazard	: May form flammable/explosive vapour-air mixture.
Hazardous decomposition products in case of fire	: Carbon dioxide. Carbon monoxide.

### 5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
Protection during firefighting	: Do not enter fire area without proper personal protective equipment, including respiratory protection (EN137).

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Do not eat, drink or smoke in areas where product is used. Avoid contact with skin and eyes.
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#### 6.1.1. For non-emergency personnel

Protective equipment	: See Section 8.
Emergency procedures	: Evacuate unnecessary personnel.

#### 6.1.2. For emergency responders

Protective equipment	: Equip cleanup and emergency crew with proper protection.
Emergency procedures	: Ventilate area.

### 6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

### 6.3. Methods and material for containment and cleaning up

For containment	: Collect all waste in suitable and labelled containers and dispose according to local legislation.
Methods for cleaning up	: Small quantities of liquid spill: take up in non-combustible absorbent material and shovel into container for disposal. Large spills: scoop solid spill into closing containers. This material and its container must be disposed of in a safe way, and as per local legislation. Notify authorities if product enters sewers or public waters. Wash off with plenty of water.

### 6.4. Reference to other sections

For further information refer to section 13. See Section 8. Exposure controls and personal protection.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Additional hazards when processed	: Handle empty containers with care because residual vapours are flammable.
Precautions for safe handling	: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharge. Do not eat, drink or smoke when using this product. Avoid contact with skin, eyes and clothing. Wear personal protective equipment.
Hygiene measures	: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not eat, drink or smoke when using this product.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep only in original container. Keep container tightly closed.
Incompatible materials	: Oxidizing substances.
Storage area	: Store in a well-ventilated place.

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### 7.3. Specific end use(s)

No additional data.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### 8.1.1 National occupational exposure and biological limit values

Ethanol; ethyl alcohol (64-17-5)	
Ireland - Occupational Exposure Limits	
Local name	Ethanol [Ethyl alcohol]
OEL STEL [ppm]	1000 ppm
Regulatory reference	Chemical Agents Code of Practice 2021
United Kingdom - Occupational Exposure Limits	
Local name	Ethanol
WEL TWA (OEL TWA) [1]	1920 mg/m <sup>3</sup>
WEL TWA (OEL TWA) [2]	1000 ppm
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

#### 8.1.2. Recommended monitoring procedures

No additional information available

#### 8.1.3. Air contaminants formed

No additional information available

#### 8.1.4. DNEL and PNEC

No additional information available

#### 8.1.5. Control banding

No additional information available

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

##### Appropriate engineering controls:

Ensure good ventilation of the work station.

#### 8.2.2. Personal protection equipment

##### Personal protective equipment:

Gloves. Safety glasses.



##### 8.2.2.1. Eye and face protection

###### Eye protection:

Use splash goggles when eye contact due to splashing is possible. STANDARD EN 166.

##### 8.2.2.2. Skin protection

###### Skin and body protection:

Wear suitable protective clothing

###### Hand protection:

Wear suitable gloves. Nitrile rubber gloves. Layer thickness : 0,09mm. Breakthrough time : >480 min. STANDARD EN 374.

##### 8.2.2.3. Respiratory protection

###### Respiratory protection:

No special protection required where adequate ventilation is maintained.

##### 8.2.2.4. Thermal hazards

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No additional information available

### 8.2.3. Environmental exposure controls

#### Other information:

Do not eat, drink or smoke during use. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the protective equipment.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Pale yellow.
Odour	: Fruity.
Odour threshold	: Not determined.
Melting point	: Not determined.
Freezing point	: Not determined.
Boiling point	: Not determined.
Flammability	: Flammable liquid and vapour.
Explosive properties	: Not explosive.
Oxidising properties	: Highly flammable liquid and vapour.
Explosive limits	: Not available
Lower explosive limit (LEL)	: Not available
Upper explosive limit (UEL)	: Not available
Flash point	: 18 °C
Auto-ignition temperature	: Not determined.
Decomposition temperature	: Not determined.
pH	: Not determined.
Viscosity, kinematic	: Not determined.
Viscosity, dynamic	: Not determined.
Solubility	: Soluble in water.
Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water (Log Pow)	: Not determined.
Vapour pressure	: Not determined.
Vapour pressure at 50 °C	: Not available
Density	: 0.96 g/cm <sup>3</sup>
Relative density	: Not available
Relative vapour density at 20 °C	: Not determined.
Particle size	: Not applicable
Particle size distribution	: Not applicable
Particle shape	: Not applicable
Particle aspect ratio	: Not applicable
Particle aggregation state	: Not applicable
Particle agglomeration state	: Not applicable
Particle specific surface area	: Not applicable
Particle dustiness	: Not applicable

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

Relative evaporation rate (butylacetate=1) : Not determined.

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

No polymerization.

### 10.4. Conditions to avoid

No flames, no sparks. Eliminate all sources of ignition.

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### 10.5. Incompatible materials

Oxidizing agent.

### 10.6. Hazardous decomposition products

No decomposition if stored and used normally.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified  
Acute toxicity (dermal) : Not classified  
Acute toxicity (inhalation) : Not classified  
Additional information : Based on available data, the classification criteria are not met

#### Ethanol; ethyl alcohol (64-17-5)

LD50 oral rat	7060 mg/kg
LD50 dermal rabbit	> 20000 mg/kg
LC50 Inhalation - Rat (Vapours)	124.7 mg/l/4h

#### 2,2'-ethylenedioxydiethyl dimethacrylate (109-16-0)

LD50 oral rat	10837 mg/kg
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Skin corrosion/irritation : Not classified  
pH: Not determined.  
Additional information : Based on available data, the classification criteria are not met  
Serious eye damage/irritation : Not classified  
pH: Not determined.  
Additional information : Based on available data, the classification criteria are not met  
Respiratory or skin sensitisation : May cause an allergic skin reaction.  
Germ cell mutagenicity : Not classified  
Additional information : Based on available data, the classification criteria are not met  
Carcinogenicity : Not classified  
Additional information : Based on available data, the classification criteria are not met  
Reproductive toxicity : Not classified  
Additional information : Based on available data, the classification criteria are not met  
STOT-single exposure : Not classified  
Additional information : Based on available data, the classification criteria are not met  
STOT-repeated exposure : Not classified  
Additional information : Based on available data, the classification criteria are not met  
Aspiration hazard : Not classified  
Additional information : Based on available data, the classification criteria are not met

#### SILANE PRIMER

Viscosity, kinematic	Not determined.
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### 11.2. Information on other hazards

#### 11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

#### 11.2.2 Other information

Potential adverse human health effects and symptoms : For further information see section 4

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### SECTION 12: Ecological information

#### 12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified

Hazardous to the aquatic environment, long-term (chronic) : Not classified

Ethanol; ethyl alcohol (64-17-5)	
LC50 - Fish [1]	13500 mg/l (96 hours - Pimephales promelas)
EC50 - Crustacea [1]	54000 mg/l (48 hours - Daphnia magna)
ErC50 algae	10.9 mg/l

#### 12.2. Persistence and degradability

SILANE PRIMER	
Persistence and degradability	No data available.

Ethanol; ethyl alcohol (64-17-5)	
BOD (% of ThOD)	≥ 0.4 % ThOD BOD5/COD
Biodegradation	85 % (OECD 301D method)

#### 12.3. Bioaccumulative potential

SILANE PRIMER	
Partition coefficient n-octanol/water (Log Pow)	Not determined.
Bioaccumulative potential	No data.

(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate (1565-94-2)	
Bioconcentration factor (BCF REACH)	2.46
Partition coefficient n-octanol/water (Log Pow)	4.94

#### 12.4. Mobility in soil

SILANE PRIMER	
Ecology - soil	soluble in water.

#### 12.5. Results of PBT and vPvB assessment

SILANE PRIMER	
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII	
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII	

#### 12.6. Endocrine disrupting properties

No additional information available

#### 12.7. Other adverse effects

Other adverse effects : None to our knowledge.

Additional information : No other effects known

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Waste treatment methods : Must not be disposed together with household garbage. Do not allow product to reach the sewage system.

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Empty container completely. After cleaning, recycle or dispose of at an authorised site.

European List of Waste (LoW) code : 18 01 06\* - chemicals consisting of or containing dangerous substances






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### SECTION 14: Transport information

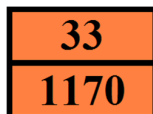
In accordance with ADR / IMDG / IATA / ADN / RID /

ADR	IMDG	IATA	ADN	RID
<b>14.1. UN number or ID number</b>				
UN 1170	UN 1170	UN 1170	UN 1170	UN 1170
<b>14.2. UN proper shipping name</b>				
ETHANOL (ETHYL ALCOHOL) / ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) (ethanol, ethyl alcohol(64-17-5))	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) (ethanol, ethyl alcohol(64-17-5))	Ethanol solution (ethanol, ethyl alcohol(64-17-5))	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) (ethanol, ethyl alcohol(64-17-5))	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) (ethanol, ethyl alcohol(64-17-5))
<b>Transport document description</b>				
UN 1170 ETHANOL (ETHYL ALCOHOL) / ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) (ethanol, ethyl alcohol(64-17-5)), 3, II, (D/E)	UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) (ethanol, ethyl alcohol(64-17-5)), 3, II	UN 1170 Ethanol solution (ethanol, ethyl alcohol(64-17-5)), 3, II	UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) (ethanol, ethyl alcohol(64-17-5)), 3, II	UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) (ethanol, ethyl alcohol(64-17-5)), 3, II
<b>14.3. Transport hazard class(es)</b>				
3	3	3	3	3
				
<b>14.4. Packing group</b>				
II	II	II	II	II
<b>14.5. Environmental hazards</b>				
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : No	Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available				

#### 14.6. Special precautions for user

##### Overland transport

Classification code (ADR) : F1  
Special provisions (ADR) : 144, 601  
Limited quantities (ADR) : 1I  
Excepted quantities (ADR) : E2  
Orange plates :



EAC code : •2YE

##### Transport by sea

Special provisions (IMDG) : 144  
Limited quantities (IMDG) : 1 L  
Excepted quantities (IMDG) : E2  
EmS-No. (Fire) : F-E  
EmS-No. (Spillage) : S-D

##### Air transport

PCA Excepted quantities (IATA) : E2  
PCA Limited quantities (IATA) : Y341  
Special provisions (IATA) : A3, A58, A180

##### Inland waterway transport

Classification code (ADN) : F1  
Special provisions (ADN) : 144, 601  
Limited quantities (ADN) : 1 L  
Excepted quantities (ADN) : E2



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### Rail transport

Special provisions (RID) : 144, 601  
Limited quantities (RID) : 1L  
Excepted quantities (RID) : E2  
Hazard identification number (RID) : 33

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### 15.1.1. EU-Regulations

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006:		
Reference code	Applicable on	Entry title or description
40.	Ethanol; ethyl alcohol	Substances classified as flammable gases category 1 or 2, flammable liquids categories 1, 2 or 3, flammable solids category 1 or 2, substances and mixtures which, in contact with water, emit flammable gases, category 1, 2 or 3, pyrophoric liquids category 1 or pyrophoric solids category 1, regardless of whether they appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 or not.

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

#### 15.1.2. National regulations

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out for the substance or the mixture by the supplier

## SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

### Full text of H- and EUH-statements:

Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 2	Flammable liquids, Category 2
H225	Highly flammable liquid and vapour.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1

The information in this safety data sheet is based on information from the manufacturer/supplier, present european and national legislation, and presupposes that the product is used within the specified area of application.