Safety data sheet
according to UK REACH

Printing date 28.02.2025 Version number 1 Revision: 28.02.2025

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

· **Product identifier**

· **Trade name: Peak™ SE Primer (Part 1 of 2)**

· **Article number:** SDS 69-001.12R01, 15076, 35016
· **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Ultradent Products Inc.
505 W. Ultradent Drive (10200 S)
South Jordan, UT 84095-3942
USA
onlineordersupport@ultradent.com
Ultradent Products Inc.
505 W. Ultradent Drive (10200 S)
South Jordan, UT 84095-3942
USA
onlineordersupport@ultradent.com

EC Responsible Person
Ultradent Products GmbH
Am Westhover Berg 30
51149 Cologne Germany
Email: infoDE@ultradent.com
Emergency Phone: +49(0)2203-35-92-0

· **Further information obtainable from:** Customer Service
· **Emergency telephone number:**
CHEMTREC (NORTH AMERICA) :(800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazards identification

· **Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**

flame

Flam. Liq. 3 H226 Flammable liquid and vapour.

health hazard

Repr. 1B H360 May damage fertility or the unborn child.

corrosion

Skin Corr. 1A H314 Causes severe skin burns and eye damage.
Eye Dam. 1 H318 Causes serious eye damage.

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

· **Label elements**
· **Labelling according to Regulation (EC) No 1272/2008** Void
· **Hazard pictograms** GHS02, GHS05, GHS07, GHS08
· **Signal word** Danger

· **Hazard-determining components of labelling:**
Trade Secret
2-Hydroxyethyl Methacrylate
Ethyl-4-Dimethylamino Benzoate
Irgacure 819
· **Hazard statements**
H226 Flammable liquid and vapour.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H360 May damage fertility or the unborn child.
· **Precautionary statements**

P101	If medical advice is needed, have product container or label at hand.
P102	Keep out of reach of children.
P103	Read carefully and follow all instructions.
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor.
P321	Specific treatment (see on this label).
P362+P364	Take off contaminated clothing and wash it before reuse.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

3 Composition/information on ingredients

· **Mixtures**
· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**		
CAS: 64-17-5 EINECS: 200-578-6	Ethyl Alcohol Flam. Liq. 2, H225	≥0-<40%
CAS: 868-77-9 EINECS: 212-782-2	2-Hydroxyethyl Methacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	>10-≤25%
	Trade Secret Skin Corr. 1A, H314; Eye Dam. 1, H318	≥5-≤10%
	Trade Secret Skin Corr. 1A, H314	≥5-≤10%

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CAS: 10287-53-3 EINECS: 233-634-3	Ethyl-4-Dimethylamino Benzoate Repr. 1B, H360; Aquatic Chronic 2, H411	≥0.3-<2.5%
	Irgacure 819 Skin Sens. 1A, H317; Aquatic Chronic 4, H413	≥0.1-<1%

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

· **Description of first aid measures**
· **General information:** Immediately remove any clothing soiled by the product.
· **After inhalation:**
Seek medical treatment in case of complaints.
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:**
If skin irritation continues, consult a doctor.
Immediately wash with water and soap and rinse thoroughly.
· **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
· **After swallowing:**
Do NOT induce vomiting.
Rinse mouth with water.
Drink plenty of water and provide fresh air. Call for a doctor immediately.
· **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 Firefighting measures

· **Extinguishing media**
· **Suitable extinguishing agents:**
Carbon dioxide
Dry Chemical
Foam
· **Special hazards arising from the substance or mixture**
During heating or in case of fire poisonous gases are produced.
· **Advice for firefighters:**
General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.
· **Protective equipment:**
Wear fully protective suit.
Mouth respiratory protective device.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Mount respiratory protective device.
Wear protective equipment. Keep unprotected persons away.
· **Environmental precautions:**
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.

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· **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Use neutralising agent.
Dispose contaminated material as waste according to section 13.
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

· **Precautions for safe handling:**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
· **Information about fire - and explosion protection:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
Keep respiratory protective device available.

· **Conditions for safe storage, including any incompatibilities**
· **Storage:**
· **Requirements to be met by storerooms and receptacles:** No special requirements.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** Keep container tightly sealed.
· **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· **Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**	
64-17-5 Ethyl Alcohol	
WEL	Long-term value: 1920 mg/m³, 1000 ppm

· **Additional information:** The lists valid during the making were used as basis.

· **Exposure controls**
· **Appropriate engineering controls** No further data; see section 7.
· **Individual protection measures, such as personal protective equipment**
· **General protective and hygienic measures:**
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.
Avoid contact with the eyes and skin.
· **Respiratory protection:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
· **Hand protection**

Protective gloves

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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 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 breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye/face protection**

Tightly sealed goggles

· **Body protection:** *Protective work clothing*

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Physical state**	*Fluid*
· **Colour:**	*Yellow*
· **Odour:**	*Methacrylate*
· **Odour threshold:**	*Not determined.*
· **Melting point/freezing point:**	*Undetermined.*
· **Boiling point or initial boiling point and boiling range**	*Undetermined.*
· **Flammability**	*Flammable.*
· **Lower and upper explosion limit**	
· **Lower:**	*Not determined.*
· **Upper:**	*Not determined.*
· **Flash point:**	*<27 °C (64-17-5 Ethyl Alcohol)*
· **Decomposition temperature:**	*Not determined.*
· **pH at 20 °C**	*0.9-1.5*
· **Viscosity:**	
· **Kinematic viscosity**	*Not determined.*
· **Dynamic:**	*Not determined.*
· **Solubility**	
· **water:**	*Fully miscible.*
· **Partition coefficient n-octanol/water (log value)**	*Not determined.*
· **Vapour pressure at 20 °C:**	*552 hPa (64-17-5 Ethyl Alcohol)*
· **Density and/or relative density**	
· **Density at 20 °C:**	*1.015 g/cm³*
· **Relative density**	*Not determined.*
· **Vapour density**	*Not determined.*

· **Other information**	
· **Appearance:**	
· **Form:**	*Liquid*

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· **Important information on protection of health and environment, and on safety.**	
· **Ignition temperature:**	Product is not selfigniting.
· **Explosive properties:**	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· **Change in condition**	
· **Evaporation rate**	Not determined.

· **Information with regard to physical hazard classes**	
· **Explosives**	Void
· **Flammable gases**	Void
· **Aerosols**	Void
· **Oxidising gases**	Void
· **Gases under pressure**	Void
· **Flammable liquids**	Flammable liquid and vapour.
· **Flammable solids**	Void
· **Self-reactive substances and mixtures**	Void
· **Pyrophoric liquids**	Void
· **Pyrophoric solids**	Void
· **Self-heating substances and mixtures**	Void
· **Substances and mixtures, which emit flammable gases in contact with water**	Void
· **Oxidising liquids**	Void
· **Oxidising solids**	Void
· **Organic peroxides**	Void
· **Corrosive to metals**	Void
· **Desensitised explosives**	Void

10 Stability and reactivity

· **Reactivity** Polymerization occurs when exposed to visible light, ultraviolet light or extreme heat.
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:** Stable under recommended storage conditions
· **Possibility of hazardous reactions:** No dangerous reactions known.
· **Conditions to avoid:**
Direct Light
Heat
Flames
Void
Not applicable
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

· **Information on hazard classes as defined in Regulation (EC) No 1272/2008**
· **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values relevant for classification:**		
64-17-5 Ethyl Alcohol		
Oral	LD50	5,600 mg/kg (guinea pig)

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		3,400 mg/kg (mouse)
		7,060 mg/kg (rat)
	LC50 Fish	>10,000 mg/l (Fish)
Inhalative	LC50/4 h	39 mg/l (mouse)
		20,000 mg/l (rat)
868-77-9 2-Hydroxyethyl Methacrylate		
Oral	LD50	3,275 mg/kg (mouse)
		>5,000 mg/kg (rat)
	LC50 Fish	>100 mg/l (Fish)
Dermal	LD50	>3,000 mg/kg (rabbit)
	LC50(Daphnia magna)	24.1 mg/l (daphnia)
Irgacure 819		
Oral	LD50	>2,000 mg/kg (rat)
	LC50 Fish	>0.09 mg/l (Fish) (Toxicity to fish)
Dermal	LD50	>2,000 mg/kg (rat)

· **Primary irritant effect:**
· **Skin corrosion/irritation** Causes severe skin burns and eye damage.
· **Serious eye damage/irritation** Causes serious eye damage.
· **Respiratory or skin sensitisation** May cause an allergic skin reaction.
· **Reproductive toxicity** May damage fertility or the unborn child.
· **Information on other hazards**

· **Endocrine disrupting properties**
None of the ingredients is listed.

12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**	
64-17-5 Ethyl Alcohol	
Algae Toxicity	1,000 mg/l (Algae)
868-77-9 2-Hydroxyethyl Methacrylate	
EC50	345 mg/kg (Algae)
Irgacure 819	
EC50 (static)	>1.175 mg/kg (daphnia) (Toxicity to aquatic invertebrates)
Aqua toxicity	≥0.008 mg/l (daphnia) (Daphnia Magna Reproduction Test)
Toxicity to Aquatic Plants (static)	>0.26 mg/l (Plant) (Toxicity to algae)

· **Persistence and degradability** No further relevant information available.
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Endocrine disrupting properties** The product does not contain substances with endocrine disrupting properties.

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· **Other adverse effects**
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (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.
Must not reach sewage water or drainage ditch undiluted or unneutralised.
Rinse off of bigger amounts into drains or the aquatic environment may lead to decreased pH-values. A low pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably increased, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Dispose of contents/container in accordance with international, federal, state, and local regulations.

· **Uncleaned packaging:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

· **UN number or ID number**	
· **ADR, IMDG, IATA**	UN2920
· **UN proper shipping name**	
· **ADR**	2920 CORROSIVE LIQUID, FLAMMABLE, N.O.S. (PHOSPHORUS PENTOXIDE, Ethyl Alcohol)
· **IMDG, IATA**	CORROSIVE LIQUID, FLAMMABLE, N.O.S. (PHOSPHORUS PENTOXIDE, Ethyl Alcohol)
· **Transport hazard class(es)**	
· **ADR**	

· **Class**	8 Corrosive substances.
· **Label**	8+3
· **IMDG**	

· **Class**	8 Corrosive substances.
· **Label**	8/3

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· **IATA**

· **Class**	8 Corrosive substances.
· **Label**	8 (3)
· **Packing group**	
· **ADR, IMDG, IATA**	II
· **Environmental hazards:**	Not applicable.
· **Special precautions for user**	Warning: Corrosive substances.
· **Hazard identification number (Kemler code):**	83
· **EMS Number:**	F-E,S-C
· **Segregation groups**	(SGG1) Acids
· **Stowage Category**	C
· **Stowage Code**	SW1 Protected from sources of heat. SW2 Clear of living quarters.
· **Maritime transport in bulk according to IMO instruments**	Not applicable.
· **Transport/Additional information:**	
· **ADR**	
· **Limited quantities (LQ)**	1L
· **Excepted quantities (EQ)**	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· **Transport category**	2
· **Tunnel restriction code**	D/E
· **IMDG**	
· **Limited quantities (LQ)**	1L
· **Excepted quantities (EQ)**	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· **UN "Model Regulation":**	UN 2920 CORROSIVE LIQUID, FLAMMABLE, N.O.S. (PHOSPHORUS PENTOXIDE, ETHYL ALCOHOL), 8 (3), II

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

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

None of the ingredients is listed.

· **Poisons Act**

· **Regulated explosives precursors**

None of the ingredients is listed.

· **Regulated poisons**

None of the ingredients is listed.

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· **Reportable explosives precursors**
None of the ingredients is listed.

· **Reportable poisons**
None of the ingredients is listed.

· **Directive 2012/18/EU**
· **Named dangerous substances - ANNEX I** None of the ingredients is listed.
· **Seveso category** P5c FLAMMABLE LIQUIDS
· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5,000 t
· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50,000 t
· **Chemical safety assessment:**
Device is biocompatible when used as directed by dental professionals per ISO 10993-1

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.

· **Relevant phrases from Section 3**
H225 Highly flammable liquid and vapour.
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H360 May damage fertility or the unborn child.
H411 Toxic to aquatic life with long lasting effects.
H413 May cause long lasting harmful effects to aquatic life.

· **Department issuing SDS:** Environmental, Health, and Safety
· **Contact:** Customer Service
· **Abbreviations and acronyms:**
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
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)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
ATE: Acute toxicity estimate values
Flam. Liq. 2: Flammable liquids – Category 2
Flam. Liq. 3: Flammable liquids – Category 3
Skin Corr. 1A: Skin corrosion/irritation – Category 1A
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
Skin Sens. 1A: Skin sensitisation – Category 1A
Repr. 1B: Reproductive toxicity – Category 1B
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4