

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

1.1. Product identifier

Product form : Mixture
Product name : OPTIBOND SOLO PLUS

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

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. Not classified
Skin Irrit. 2 H315
Eye Irrit. 2 H319
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

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2.2. Label elements

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

Hazard pictograms (CLP)



GHS07

Signal word (CLP)

: Warning

Contains

: 2-hydroxyethyl methacrylate

Hazard statements (CLP)

: H315 - Causes skin irritation.

H317 - May cause an allergic skin reaction.

H319 - Causes serious eye irritation.

Precautionary statements (CLP)

: P261 - Avoid breathing vapours, mist, spray.

P264 - Wash hands, forearms and face thoroughly after handling.

P272 - Contaminated work clothing should not be allowed out of the workplace.

P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

P302+P352 - IF ON SKIN: Wash with plenty of water.

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P321 - Specific treatment (see supplemental first aid instruction on this label).

P332+P313 - If skin irritation occurs: Get medical advice/attention.

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

P337+P313 - If eye irritation persists: Get medical advice/attention.

P362+P364 - Take off contaminated clothing and wash it before reuse.

P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

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	20 – 25	Flam. Liq. 2, H225
2-hydroxyethyl methacrylate (Note D)	(CAS-No.) 868-77-9 (EC-No.) 212-782-2 (EC Index-No.) 607-124-00-X (REACH-no) 01-2119490169-29	15 – 20	Eye Irrit. 2, H319 Skin Irrit. 2, H315 Skin Sens. 1, H317

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alkali fluorosilicates(Na) (Note A)	(CAS-No.) 16893-85-9 (EC-No.) 240-934-8 (EC Index-No.) 009-012-00-0 (REACH-no) 01-2119519245-43	0.8 – 1.2	Acute Tox. 3 (Oral), H301 (ATE=125 mg/kg bodyweight) Acute Tox. 3 (Dermal), H311 (ATE=300 mg/kg bodyweight) Acute Tox. 3 (Inhalation:dust,mist), H331 (ATE=0.5 mg/l/4h) Eye Dam. 1, H318
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Note A : Without prejudice to Article 17(2), the name of the substance must appear on the label in the form of one of the designations given in Part 3. In Part 3, use is sometimes made of a general description such as '... compounds' or '... salts'. In this case, the supplier is required to state on the label the correct name, due account being taken of section 1.1.1.4.

Note D : Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in Part 3. However, such substances are sometimes placed on the market in a non-stabilised form. In this case, the supplier must state on the label the name of the substance followed by the words 'non-stabilised'.

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	: No particular/specific measures required.
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. If skin irritation occurs: Get medical advice/attention.
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 after skin contact	: Causes skin irritation. May cause an allergic skin reaction.
Symptoms/effects after eye contact	: Causes serious eye 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 (CO2) and powder.
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5.2. Special hazards arising from the substance or mixture

Explosion hazard	: Product is not explosive.
Hazardous decomposition products in case of fire	: Carbon dioxide. Carbon monoxide. Fluoride, as F.

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. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking. Ensure adequate ventilation, especially in confined areas.
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6.1.1. For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel.
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6.1.2. For emergency responders

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

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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 : Large spills: scoop solid spill into closing containers. Take up liquid spill into absorbent material. Notify authorities if product enters sewers or public waters.

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 : Do not eat, drink or smoke when using this product. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

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

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 ³
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

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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:

Chemical goggles or face shield. 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:

Respiratory protection not applicable. In case of insufficient ventilation, wear suitable respiratory equipment. Wear a respirator conforming to EN140 with Type A/P2 filter or better

8.2.2.4. Thermal hazards

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.
Appearance	: Paste.
Odour	: Fruity.
Odour threshold	: Not available
Melting point	: Not determined.
Freezing point	: Not determined.
Boiling point	: 35 °C
Flammability	: Highly flammable liquid and vapour.
Explosive properties	: Not determined.
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	: In water, material is partially soluble.
Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water (Log Pow)	: Not determined.

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Vapour pressure	: Not determined.
Vapour pressure at 50 °C	: Not available
Density	: Not available
Relative density	: 1.25 g/cm³
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 of use.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

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

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-hydroxyethyl methacrylate (868-77-9)

LD50 oral rat	5050 mg/kg
LD50 dermal rabbit	> 3000 mg/kg

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alkali fluorosilicates(Na) (16893-85-9)	
LD50 oral rat	125 mg/kg

Skin corrosion/irritation	: Causes skin irritation. pH: Not determined.
Serious eye damage/irritation	: Causes serious eye irritation. pH: Not determined.
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

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Viscosity, kinematic	Not determined.

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 %
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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

2-hydroxyethyl methacrylate (868-77-9)	
LC50 - Fish [1]	227 mg/l (96 hours - Pimephales promelas)
EC50 - Crustacea [1]	> 280 mg/l Daphnia magna, 48 hours

alkali fluorosilicates(Na) (16893-85-9)	
LC50 - Fish [1]	49 mg/l (96 hours - Lepomis macrochirus)

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12.2. Persistence and degradability

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Persistence and degradability	No data available.
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Ethanol; ethyl alcohol (64-17-5)

BOD (% of ThOD)	≥ 0.4 % ThOD BOD5/COD
Biodegradation	85 % (OECD 301D method)

2-hydroxyethyl methacrylate (868-77-9)

Biodegradation	84 % (OECD 301D method)
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12.3. Bioaccumulative potential

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

2-hydroxyethyl methacrylate (868-77-9)

Bioconcentration factor (BCF REACH)	1,3 - 1,5
Partition coefficient n-octanol/water (Log Pow)	0.47

12.4. Mobility in soil

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Ecology - soil	Slightly soluble.
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12.5. Results of PBT and vPvB assessment

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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.
Ecology - waste materials	: Avoid release to the environment.
European List of Waste (LoW) code	: 18 01 06* - chemicals consisting of or containing dangerous substances

SECTION 14: Transport information






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

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
UN 3082	UN 3082	UN 3082	UN 3082	UN 3082

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14.2. UN proper shipping name				
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (2-hydroxyethyl methacrylate)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (2-hydroxyethyl methacrylate)	Environmentally hazardous substance, liquid, n.o.s. (2-hydroxyethyl methacrylate)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (2-hydroxyethyl methacrylate)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (2-hydroxyethyl methacrylate)
Transport document description				
UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (2-hydroxyethyl methacrylate), 9, III, (-)	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (2-hydroxyethyl methacrylate), 9, III	UN 3082 Environmentally hazardous substance, liquid, n.o.s. (2-hydroxyethyl methacrylate), 9, III	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (2-hydroxyethyl methacrylate), 9, III	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (2-hydroxyethyl methacrylate), 9, III
14.3. Transport hazard class(es)				
9	9	9	9	9
				
14.4. Packing group				
III	III	III	III	III
14.5. Environmental hazards				
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) : M6
Special provisions (ADR) : 274, 335, 375, 601
Limited quantities (ADR) : 5I
Excepted quantities (ADR) : E1
Orange plates :



EAC code : •3Z

Transport by sea

Special provisions (IMDG) : 274, 335, 969
Limited quantities (IMDG) : 5 L
Excepted quantities (IMDG) : E1
EmS-No. (Fire) : F-A
EmS-No. (Spillage) : S-F

Air transport

PCA Excepted quantities (IATA) : E1
PCA Limited quantities (IATA) : Y964
Special provisions (IATA) : A97, A158, A197, A215

Inland waterway transport

Classification code (ADN) : M6
Special provisions (ADN) : 274, 335, 375, 601
Limited quantities (ADN) : 5 L
Excepted quantities (ADN) : E1

Rail transport

Special provisions (RID) : 274, 335, 375, 601
Limited quantities (RID) : 5L
Excepted quantities (RID) : E1
Hazard identification number (RID) : 90

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

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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

SECTION 16: Other information

Indication of changes:			
Section	Changed item	Change	Comments
2.2	Precautionary statements (CLP)	Modified	

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.

Other information : None.

Full text of H- and EUH-statements:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 2	Flammable liquids, Category 2
Flam. Liq. Not classified	Flammable liquids Not classified
H225	Highly flammable liquid and vapour.
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
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.