

Hardener red

Version number: 1.0

Date of compilation: 10.06.2025

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

1.1 Product identifier

Trade name	Hardener red
Registration number (REACH)	not relevant (mixture)
Unique formula identifier (UFI)	36R9-UVUY-KN9R-3FS8

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

Relevant identified uses	Hardener Industrial use Professional use
Uses advised against	Do not use for private purposes (household)

1.3 Details of the supplier of the safety data sheet

Chemical Europe NV
Baarbeek 2
2070 Zwijndrecht
Belgium

Telephone: +32 3 234 87 80
e-mail: msds@emm.com
Website: www.finixa.com

e-mail (competent person) msds@emm.com

1.4 Emergency telephone number

Emergency information service	+31 38 4676600 This number is only available during the following office hours: Mon-Fri 09:00 - 17:00
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SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP)

Section	Hazard class	Category	Hazard class and category	Hazard statement
2.15	organic peroxide	E	Org. Perox. E	H242
3.3	serious eye damage/eye irritation	2	Eye Irrit. 2	H319
3.4S	skin sensitisation	1	Skin Sens. 1	H317
4.1A	hazardous to the aquatic environment - acute hazard	1	Aquatic Acute 1	H400
4.1C	hazardous to the aquatic environment - chronic hazard	1	Aquatic Chronic 1	H410

For full text of H-phrases: see SECTION 16

The most important adverse physicochemical, human health and environmental effects

Spillage and fire water can cause pollution of watercourses.

2.2 Label elements

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

- signal word Warning

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- pictograms

GHS02, GHS07,
GHS09



- hazard statements

H242 Heating may cause a fire.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H410 Very toxic to aquatic life with long lasting effects.

- precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P234 Keep only in original packaging.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P410 Protect from sunlight.
P411 Store at temperatures not exceeding 25 °C.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- hazardous ingredients for labelling

Contains: dibenzoyl peroxide.

2.3 Other hazards

Heating may cause a fire. Special danger of slipping by leaking/spilling product.

Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance at a concentration of $\geq 0,1\%$.

Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of $\geq 0,1\%$.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not relevant (mixture).

3.2 Mixtures

The product does not contain (other) ingredients which are classified according to present knowledge of the supplier and contribute to the classification of the product and hence require reporting in this section.

Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
dibenzoyl peroxide	CAS No 94-36-0 EC No 202-327-6 Index No 617-008-00-0 REACH Reg. No 01-2119511472- 50-xxxx	25 – 50	Org. Perox. B / H241 Eye Irrit. 2 / H319 Skin Sens. 1 / H317 Aquatic Acute 1 / H400 Aquatic Chronic 1 / H410		GHS-HC
ethanediol	CAS No 107-21-1 EC No 203-473-3	2,5 – < 10	Acute Tox. 4 / H302 STOT RE 2 / H373		GHS-HC IOELV

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Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
	Index No 603-027-00-1 REACH Reg. No 01-2119456816- 28-xxxx				

Notes

GHS-HC: Harmonised classification (the classification of the substance corresponds to the entry in the list according to 1272/2008/EC, Annex VI)
IOELV: Substance with a community indicative occupational exposure limit value

Name of substance	Identifier	Specific Conc. Limits	M-Factors	ATE	Exposure route
dibenzoyl peroxide	CAS No 94-36-0	-	M-factor (acute) = 10 M-factor (chronic) = 10	-	
ethanediol	CAS No 107-21-1	-	-	500 mg/kg	oral

Remarks

All the percentages given are percentages by weight unless stated otherwise. For full text of H-phrases: see SECTION 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General notes

Do not leave affected person unattended. Remove victim out of the danger area. In case of unconsciousness place person in the recovery position. Never give anything by mouth. Take off immediately all contaminated clothing. In all cases of doubt, or when symptoms persist, seek medical advice.

Following inhalation

Provide fresh air. If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. In case of respiratory tract irritation, consult a physician.

Following skin contact

Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention.

Following eye contact

Do not rub the eyes. Mechanical stress can cause damage to the cornea. Irrigate copiously with clean, fresh water for at least 15 minutes, holding the eyelids apart. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTER/doctor.

Following ingestion

Rinse mouth with water (only if the person is conscious). Call a POISON CENTER or doctor if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms and effects are not known to date.

4.3 Indication of any immediate medical attention and special treatment needed

For specialist advice physicians should contact the poison centre.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water; Dry extinguishing powder;
Co-ordinate firefighting measures to the fire surroundings.

Unsuitable extinguishing media

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Water jet.

5.2 Special hazards arising from the substance or mixture

Oxidising property.

Hazardous combustion products

During fire hazardous fumes/smoke could be produced. Carbon monoxide (CO). Carbon dioxide (CO₂).

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

Special protective equipment for firefighters

Self-contained breathing apparatus (SCBA). Standard protective clothing for firefighters.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove persons to safety. Ventilate affected area.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases. Use personal protective equipment as required.

6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it. If substance has entered a water course or sewer, inform the responsible authority.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains.

Advice on how to clean up a spill

Take up mechanically.

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Recommendations

- measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Use only in well-ventilated areas. Take any precaution to avoid mixing with combustibles.

- handling of incompatible substances or mixtures

- keep away from

Organic absorbing material, Pulp/paper

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Managing of associated risks

- flammability hazards

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

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from oil and grease.

- incompatible substances or mixtures

Keep/store away from clothing/combustible materials. Take any precaution to avoid mixing with combustibles. Keep away from alkalis, oxidising substances, acids.

Control of effects

Protect against external exposure, such as

High temperatures. UV-radiation/sunlight. Static discharges.

Consideration of other advice

Store in a well-ventilated place. Keep container tightly closed.

- specific designs for storage rooms or vessels

- storage temperature

Maximum storage temperature: 25 °C

- packaging compatibilities

Keep only in original container.

7.3 Specific end use(s)

See section 1.2.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

National limit values

Generic EU SDS - No country specific limit values mentioned.

Occupational exposure limit values (Workplace Exposure Limits)									
Country	Name of agent	CAS No	Identifier	TWA [ppm]	TWA [mg/m ³]	STEL [ppm]	STEL [mg/m ³]	Notation	Source
EU	ethylene glycol	107-21-1	IOELV	20	52	40	104	H	2000/39/EC

Notation

H absorbed through the skin

STEL short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified)

TWA time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours time-weighted average (unless otherwise specified)

Relevant DNELs/DMELs/PNECs and other threshold levels

Relevant DNELs of components of the mixture						
Name of substance	CAS No	End-point	Threshold level	Protection goal, route of exposure	Used in	Exposure time
dibenzoyl peroxide	94-36-0	DNEL	39 mg/m ³	human, inhalatory	worker (industry)	chronic - systemic effects
dibenzoyl peroxide	94-36-0	DNEL	13,3 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
dibenzoyl peroxide	94-36-0	DNEL	34 µg/cm ²	human, dermal	worker (industry)	chronic - local effects
dibenzoyl peroxide	94-36-0	DNEL	2 mg/kg bw/day	human, oral	consumer (private households)	chronic - systemic effects
ethanediol	107-21-1	DNEL	35 mg/m ³	human, inhalatory	worker (industry)	chronic - local effects
ethanediol	107-21-1	DNEL	106 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects

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Relevant DNELs of components of the mixture						
Name of substance	CAS No	End-point	Threshold level	Protection goal, route of exposure	Used in	Exposure time
ethanediol	107-21-1	DNEL	7 mg/m ³	human, inhalatory	consumer (private households)	chronic - local effects
ethanediol	107-21-1	DNEL	53 mg/kg bw/day	human, dermal	consumer (private households)	chronic - systemic effects

Relevant PNECs of components						
Name of substance	CAS No	End-point	Threshold level	Organism	Environmental compartment	Exposure time
dibenzoyl peroxide	94-36-0	PNEC	0,02 µg/l	aquatic organisms	freshwater	short-term (single instance)
dibenzoyl peroxide	94-36-0	PNEC	0,002 µg/l	aquatic organisms	marine water	short-term (single instance)
dibenzoyl peroxide	94-36-0	PNEC	0,35 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
dibenzoyl peroxide	94-36-0	PNEC	0,013 mg/kg	aquatic organisms	freshwater sediment	short-term (single instance)
dibenzoyl peroxide	94-36-0	PNEC	0,001 mg/kg	aquatic organisms	marine sediment	short-term (single instance)
dibenzoyl peroxide	94-36-0	PNEC	0,003 mg/kg	terrestrial organisms	soil	short-term (single instance)
ethanediol	107-21-1	PNEC	10 mg/l	aquatic organisms	water	intermittent release
ethanediol	107-21-1	PNEC	10 mg/l	aquatic organisms	freshwater	short-term (single instance)
ethanediol	107-21-1	PNEC	1 mg/l	aquatic organisms	marine water	short-term (single instance)
ethanediol	107-21-1	PNEC	199,5 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
ethanediol	107-21-1	PNEC	37 mg/kg	aquatic organisms	freshwater sediment	short-term (single instance)
ethanediol	107-21-1	PNEC	3,7 mg/kg	aquatic organisms	marine sediment	short-term (single instance)
ethanediol	107-21-1	PNEC	1,53 mg/kg	terrestrial organisms	soil	short-term (single instance)

8.2 Exposure controls

Appropriate engineering controls

General ventilation. Provide eyewash stations and safety showers at the workplace.

Individual protection measures (personal protective equipment)

Eye/face protection



Use safety goggle with side protection (EN 166).

Skin protection



Chemical protective clothing. Protective clothing (EN 340 & EN ISO 13688).

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Hand protection



Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. 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.

- type of material

Nitrile rubber

- material thickness

Use gloves with a minimum material thickness: $\geq 0,38$ mm.

- breakthrough time of the glove material

Use gloves with a minimum breakthrough time of the glove material: >480 minutes (permeation: level 6).

- other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.

Respiratory protection

In case of inadequate ventilation wear respiratory protection. Full face mask/half mask/quarter mask (EN 136/140). Type: ABEK-P2 (combined filters against gases, vapours and particles, colour code: Brown/Grey/Yellow/Green/White).

Environmental exposure controls

Take appropriate precautions to avoid uncontrolled release into the environment. Keep away from drains, surface and ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	solid
Colour	red
Odour	characteristic
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	197,4 °C at 1.013 hPa calculated value, referring to a component of the mixture
Flammability	this material is combustible, but will not ignite readily
Lower and upper explosion limit	LEL: UEL: not relevant (solid)
Flash point	not applicable
Auto-ignition temperature	
Decomposition temperature	no data available
pH (value)	not applicable
Kinematic viscosity	not relevant
Solubility	not determined

Partition coefficient n-octanol/water (log value)	this information is not available
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Safety Data Sheet

acc. to Regulation (EC) No. 1907/2006 (REACH)
 GENERIC EU SDS - NO COUNTRY SPECIFIC DATA

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Vapour pressure	0,123 hPa at 25 °C calculated value, referring to a component of the mixture
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Density and/or relative density

Density	1,262 g/cm ³ at 20 °C (DIN EN ISO 2811-1)
Relative vapour density	information on this property is not available

Particle characteristics	no data available
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9.2 Other information

Information with regard to physical hazard classes	there is no additional information
Other safety characteristics	there is no additional information

SECTION 10: Stability and reactivity

10.1 Reactivity

The mixture contains reactive substance(s). Oxidising property.

10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

10.3 Possibility of hazardous reactions

No known hazardous reactions.

10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

10.5 Incompatible materials

Oxidisers. Combustible materials.

10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Test data are not available for the complete mixture.

Classification procedure

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

Classification acc. to GHS

Acute toxicity

Shall not be classified as acutely toxic.

Acute toxicity estimate (ATE) of components			
Name of substance	CAS No	Exposure route	ATE
ethanediol	107-21-1	oral	500 mg/kg

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Acute toxicity of components					
Name of substance	CAS No	Exposure route	Endpoint	Value	Species
ethanediol	107-21-1	oral	LD50	7.712 mg/kg	rat
ethanediol	107-21-1	dermal	LD50	>3.500 mg/kg	mouse

Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

Serious eye damage/eye irritation

Causes serious eye irritation.

Respiratory or skin sensitisation

May cause an allergic skin reaction.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Shall not be classified as carcinogenic.

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

11.2 Information on other hazards

Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of $\geq 0,1\%$.

Other information

There is no additional information.

SECTION 12: Ecological information

12.1 Toxicity

Very toxic to aquatic life with long lasting effects.

Aquatic toxicity (acute) of components of the mixture					
Name of substance	CAS No	Endpoint	Value	Species	Exposure time
dibenzoyl peroxide	94-36-0	LC50	0,06 mg/l	fish	96 h
dibenzoyl peroxide	94-36-0	EC50	0,11 mg/l	aquatic invertebrates	48 h
dibenzoyl peroxide	94-36-0	ErC50	0,071 mg/l	algae	72 h
dibenzoyl peroxide	94-36-0	NOEC	0,032 mg/l	fish	96 h
ethanediol	107-21-1	ErC50	<13.000 mg/l	algae	96 h
ethanediol	107-21-1	LC50	53.000 mg/l	fish	96 h
ethanediol	107-21-1	EC50	>100 mg/l	aquatic invertebrates	48 h
ethanediol	107-21-1	NOEC	>100 mg/l	algae	72 h

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Aquatic toxicity (chronic) of components of the mixture					
Name of substance	CAS No	Endpoint	Value	Species	Exposure time
dibenzoyl peroxide	94-36-0	EC50	35 mg/l	microorganisms	30 min
dibenzoyl peroxide	94-36-0	growth (EbCx) 10%	0,001 mg/l	aquatic invertebrates	21 d
ethanediol	107-21-1	EC50	>15.000 mg/l	aquatic invertebrates	21 d
ethanediol	107-21-1	LC50	>1.500 mg/l	fish	28 d
ethanediol	107-21-1	NOEC	>40 mg/l	fish	28 d
ethanediol	107-21-1	growth (EbCx) 20%	>1.995 mg/l	microorganisms	30 min

12.2 Persistence and degradability

Biodegradation

The relevant substances of the mixture are readily biodegradable.

Degradability of components					
Name of substance	CAS No	Process	Degradation rate	Time	Method
dibenzoyl peroxide	94-36-0	oxygen depletion	71 %	28 d	
ethanediol	107-21-1	DOC removal	90 – 100 %	10 d	
ethanediol	107-21-1	oxygen depletion	≥83 %	14 d	

12.3 Bioaccumulative potential

Bioaccumulative potential of components				
Name of substance	CAS No	BCF	Log KOW	BOD5/COD
dibenzoyl peroxide	94-36-0		3,2 (pH value: 7,02, 22 °C)	
ethanediol	107-21-1		-1,36	

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance at a concentration of ≥ 0,1%.

12.6 Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of ≥ 0,1%.

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment.

Waste treatment of containers/packagings

Only packagings which are approved (e.g. acc. to the Dangerous Goods Regulations) may be used. Completely emptied packages can be recycled. Handle contaminated packages in the same way as the substance itself.

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Remarks

Please consider the relevant national or regional provisions. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.

SECTION 14: Transport information

14.1 UN number or ID number

ADR/RID/ADN	UN 3108
IMDG-Code	UN 3108
ICAO-TI	UN 3108

14.2 UN proper shipping name

ADR/RID/ADN	ORGANIC PEROXIDE TYPE E, SOLID
IMDG-Code	ORGANIC PEROXIDE TYPE E, SOLID
ICAO-TI	Organic peroxide type E, solid
Technical name (Hazardous ingredients)	dibenzoyl peroxide

14.3 Transport hazard class(es)

ADR/RID/ADN	5.2
IMDG-Code	5.2
ICAO-TI	5.2

14.4 Packing group

not assigned

14.5 Environmental hazards

Environmentally hazardous substance (aquatic environment)	hazardous to the aquatic environment dibenzoyl peroxide
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14.6 Special precautions for user

There is no additional information.

14.7 Maritime transport in bulk according to IMO instruments

No data available.

Additional information for each of the UN Model Regulations

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - additional information

Classification code	P1
Danger label(s)	5.2, fish and tree
 	
Environmental hazards	yes (hazardous to the aquatic environment)
Special provisions (SP)	122, 274
Excepted quantities (EQ)	E0
Limited quantities (LQ)	500 g
Transport category (TC)	2
Tunnel restriction code (TRC)	D

International Maritime Dangerous Goods Code (IMDG) - additional information

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Marine pollutant yes (hazardous to the aquatic environment) (dibenzoyl peroxide)
Danger label(s) 5.2, fish and tree



Special provisions (SP) 122, 274
Excepted quantities (EQ) E0
Limited quantities (LQ) 500 g
EmS F-J, S-R
Stowage category D

International Civil Aviation Organization (ICAO-IATA/DGR) - additional information

Environmental hazards yes (hazardous to the aquatic environment)
Danger label(s) 5.2



Special provisions (SP) A20
Excepted quantities (EQ) E0

SECTION 15: Regulatory information

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

This Safety Data Sheet is purely informative and does comply with EU regulations, but not with country-specific regulations.

Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII

Name	Name acc. to inventory	Restriction	No
Hardener red	this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC	R3	3
dibenzoyl peroxide	substances in tattoo inks and permanent make-up	R75	75

Legend

- R3
- Shall not be used in:
 - ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ash-trays,
 - tricks and jokes,
 - games for one or more participants, or any article intended to be used as such, even with ornamental aspects,
 - Articles not complying with paragraph 1 shall not be placed on the market.
 - Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, or both, if they:
 - can be used as fuel in decorative oil lamps for supply to the general public, and
 - present an aspiration hazard and are labelled with H304.
 - Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation (CEN).
 - Without prejudice to the implementation of other Union provisions relating to the classification, labelling and packaging of substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met:
 - lamp oils, labelled with H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: "Keep lamps filled with this liquid out of the reach of children"; and, by 1 December 2010, "Just a sip of lamp oil – or even sucking the wick of lamps – may lead to life-threatening lung damage";
 - grill lighter fluids, labelled with H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: 'Just a sip of grill lighter fluid may lead to life threatening lung damage';
 - lamps oils and grill lighters, labelled with H304, intended for supply to the general public are packaged in black opaque containers not exceeding 1 litre by 1 December 2010.;
- R75
- Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be

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Legend

used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances:

(a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;

(b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;

(c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;

(d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:

(i) 0,1 % by weight, if the substance is used solely as a pH regulator;

(ii) 0,01 % by weight, in all other cases;

(e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (*1), the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;

(f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight:

(i) "Rinse-off products";

(ii) "Not to be used in products applied on mucous membranes";

(iii) "Not to be used in eye products";

(g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column;

(h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.

2. For the purposes of this entry use of a mixture "for tattooing purposes" means injection or introduction of the mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.

3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.

4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:

(a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);

(b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).

5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.

6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.

7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:

(a) the statement "Mixture for use in tattoos or permanent make-up";

(b) a reference number to uniquely identify the batch;

(c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredient does not need to be marked in accordance with this Regulation;

(d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1;

(e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Appendix 13;

(f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below the concentration limit specified in Appendix 13;

(g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008.

The information shall be clearly visible, easily legible and marked in a way that is indelible.

The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.

Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use.

Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph.

8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for tattooing purposes.

9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50 °C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).

10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.

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List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list

None of the ingredients are listed.

Seveso Directive

2012/18/EU (Seveso III)				
No	Dangerous substance/hazard categories	Qualifying quantity (tonnes) for the application of lower and upper-tier requirements		Notes
P6b	self-reactive substances and mixtures and organic peroxides (Type, C-F)	50	200	53)

Notation

53) self-reactive substances and mixtures, Type C, D, E or F or organic peroxides, Type C, D, E, or F

Directive on industrial emissions (VOCs, 2010/75/EU)

VOC content	6 %
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Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

None of the ingredients are listed.

Water Framework Directive (WFD)

None of the ingredients are listed.

Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors, amending Regulation (EC) No 1907/2006 and repealing Regulation (EU) No 98/2013

None of the ingredients are listed.

Regulation on persistent organic pollutants (POP)

None of the ingredients are listed.

15.2 Chemical safety assessment

No Chemical Safety Assessment has been carried out for this mixture by the supplier.

SECTION 16: Other information

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
2000/39/EC	Commission Directive establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC
Acute Tox.	Acute toxicity
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
ADR/RID/ADN	Agreements concerning the International Carriage of Dangerous Goods by Road/Rail/Inland Waterways (ADR/RID/ADN)
Aquatic Acute	Hazardous to the aquatic environment - acute hazard
Aquatic Chronic	Hazardous to the aquatic environment - chronic hazard
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BOD	Biochemical Oxygen Demand
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)

Safety Data Sheet

acc. to Regulation (EC) No. 1907/2006 (REACH)
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Abbr.	Descriptions of used abbreviations
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
COD	Chemical oxygen demand
DGR	Dangerous Goods Regulations (see IATA/DGR)
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
ED	Endocrine disruptor
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule
ErC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control
Eye Dam.	Seriously damaging to the eye
Eye Irrit.	Irritant to the eye
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
ICAO-TI	Technical instructions for the safe transport of dangerous goods by air
IMDG	International Maritime Dangerous Goods Code
IMDG-Code	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
IOELV	Indicative occupational exposure limit value
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
LEL	Lower explosion limit (LEL)
log KOW	n-Octanol/water
M-factor	Means a multiplying factor. It is applied to the concentration of a substance classified as hazardous to the aquatic environment acute category 1 or chronic category 1, and is used to derive by the summation method the classification of a mixture in which the substance is present
NLP	No-Longer Polymer
NOEC	No Observed Effect Concentration
Org. Perox.	Organic peroxide
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals

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acc. to Regulation (EC) No. 1907/2006 (REACH)
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Abbr.	Descriptions of used abbreviations
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
Skin Sens.	Skin sensitisation
STEL	Short-term exposure limit
STOT RE	Specific target organ toxicity - repeated exposure
SVHC	Substance of Very High Concern
TWA	Time-weighted average
UEL	Upper explosion limit (UEL)
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

UN Recommendations on the Transport of Dangerous Good. International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

Classification procedure

Physical and chemical properties: The classification is based on tested mixture.

Health hazards, Environmental hazards: The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text
H241	Heating may cause a fire or explosion.
H242	Heating may cause a fire.
H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.