

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Oil of caraway natural

article number: **7050**
Version: **1.0 en**

date of compilation: 02.08.2021

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

1.1 Product identifier

Identification of the substance	Oil of caraway natural
Article number	7050
Registration number (REACH)	It is not required to list the identified uses because the substance is not subject to registration according to REACH (< 1 t/a).
EC number	616-773-8
CAS number	8000-42-8

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

Relevant identified uses:	Laboratory chemical Laboratory and analytical use
Uses advised against:	Do not use for products which come into contact with foodstuffs. Do not use for private purposes (household).

1.3 Details of the supplier of the safety data sheet

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Competent person responsible for the safety data sheet: :Department Health, Safety and Environment

e-mail (competent person): sicherheit@carlroth.de

1.4 Emergency telephone number

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
2.6	Flammable liquid	3	Flam. Liq. 3	H226
3.1D	Acute toxicity (dermal)	4	Acute Tox. 4	H312
3.2	Skin corrosion/irritation	2	Skin Irrit. 2	H315
3.4S	Skin sensitisation	1	Skin Sens. 1	H317
3.10	Aspiration hazard	1	Asp. Tox. 1	H304
4.1A	Hazardous to the aquatic environment - acute hazard	1	Aquatic Acute 1	H400

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Section	Hazard class	Cat-egory	Hazard class and category	Hazard statement
4.1C	Hazardous to the aquatic environment - chronic hazard	1	Aquatic Chronic 1	H410

For full text of abbreviations: see SECTION 16

The most important adverse physicochemical, human health and environmental effects

The product is combustible and can be ignited by potential ignition sources. Spillage and fire water can cause pollution of watercourses.

2.2 Label elements

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

Signal word

Danger

Pictograms

GHS02, GHS07,
GHS08, GHS09



Hazard statements

H226	Flammable liquid and vapour
H304	May be fatal if swallowed and enters airways
H312	Harmful in contact with skin
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H410	Very toxic to aquatic life with long lasting effects

Precautionary statements

Precautionary statements - prevention

P210	Keep away from heat. No smoking
P233	Keep container tightly closed
P273	Avoid release to the environment

Precautionary statements - response

P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor
P302+P352	IF ON SKIN: Wash with plenty of water
P331	Do NOT induce vomiting

Labelling of packages where the contents do not exceed 125 ml

Signal word: **Danger**

Symbol(s)



H304	May be fatal if swallowed and enters airways.
H317	May cause an allergic skin reaction.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P302+P352	IF ON SKIN: Wash with plenty of water.
P331	Do NOT induce vomiting.

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2.3 Other hazards

Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

SECTION 3: Composition/information on ingredients

3.1 Substances

Name of substance	Oil of caraway
CAS No	8000-42-8
EC No	616-773-8

Impurities and additives, classification acc. to GHS				
Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms
(+)-Carvone	CAS No 2244-16-8 EC No 218-827-2 Index No 606-148-00-8	50 – < 75	Skin Sens. 1 / H317	
D-(+)-Limonene	CAS No 5989-27-5 EC No 227-813-5 Index No 601-029-00-7	25 – < 50	Flam. Liq. 3 / H226 Skin Irrit. 2 / H315 Skin Sens. 1 / H317 Aquatic Acute 1 / H400 Aquatic Chronic 1 / H410	
Myrcene	CAS No 123-35-3 EC No 204-622-5	< 1	Flam. Liq. 3 / H226 Skin Irrit. 2 / H315 Eye Irrit. 2 / H319 Asp. Tox. 1 / H304 Aquatic Acute 1 / H400 Aquatic Chronic 2 / H411	

Substance, Specific Conc. Limits, M-factors, ATE			
Specific Conc. Limits	M-Factors	ATE	Exposure route
-	-	1.780 mg/kg	dermal

For full text of abbreviations: see SECTION 16

SECTION 4: First aid measures

4.1 Description of first aid measures



General notes

Take off contaminated clothing.

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Following inhalation

Provide fresh air. In all cases of doubt, or when symptoms persist, seek medical advice.

Following skin contact

Rinse skin with water/shower. After contact with skin, wash immediately with plenty of water. In case of skin reactions, consult a physician. In case of skin irritation, consult a physician.

Following eye contact

Rinse cautiously with water for several minutes. In all cases of doubt, or when symptoms persist, seek medical advice.

Following ingestion

Call a physician immediately. Observe aspiration hazard if vomiting occurs.

4.2 Most important symptoms and effects, both acute and delayed

Aspiration hazard, Irritation, Allergic reactions

4.3 Indication of any immediate medical attention and special treatment needed

none

SECTION 5: Firefighting measures

5.1 Extinguishing media



Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings
water spray, dry extinguishing powder, BC-powder, carbon dioxide (CO₂)

Unsuitable extinguishing media

water jet

5.2 Special hazards arising from the substance or mixture

Combustible. In case of insufficient ventilation and/or in use, may form flammable/explosive vapour-air mixture. Solvent vapours are heavier than air and may spread along floors. Places which are not ventilated, e.g. unventilated below ground level areas such as trenches, conduits and shafts, are particularly prone to the presence of flammable substances or mixtures.

Hazardous combustion products

Carbon monoxide (CO), Carbon dioxide (CO₂)

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Do not allow firefighting water to enter drains or water courses. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus.

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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures



For non-emergency personnel

Do not breathe vapour/spray. Avoid contact with skin and eyes. Avoidance of ignition sources. Provide adequate ventilation.

6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it. Danger of explosion.

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

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

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

Provision of sufficient ventilation. When not in use, keep containers tightly closed.

Measures to prevent fire as well as aerosol and dust generation



Keep away from sources of ignition - No smoking.

Take precautionary measures against static discharge.

Measures to protect the environment

Avoid release to the environment.

Advice on general occupational hygiene

Wash hands before breaks and after work. Keep away from food, drink and animal feedingstuffs. When using do not smoke.

7.2 Conditions for safe storage, including any incompatibilities

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

Incompatible substances or mixtures

Observe hints for combined storage.

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Consideration of other advice:

Keep container tightly closed.

Ventilation requirements

Use local and general ventilation.

Specific designs for storage rooms or vessels

Recommended storage temperature: 15 – 25 °C

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

National limit values

Occupational exposure limit values (Workplace Exposure Limits)

Data are not available.

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
(+)-Carvone	2244-16-8	DNEL	47.500 mg/m ³	human, inhalatory	worker (industry)	chronic - systemic effects
(+)-Carvone	2244-16-8	DNEL	12 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
D-(+)-Limonene	5989-27-5	DNEL	66,7 mg/m ³	human, inhalatory	worker (industry)	chronic - systemic effects
D-(+)-Limonene	5989-27-5	DNEL	9,5 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects

Relevant PNECs of components of the mixture						
Name of substance	CAS No	End-point	Threshold level	Organism	Environmental compartment	Exposure time
(+)-Carvone	2244-16-8	PNEC	50 µg/l	aquatic organisms	freshwater	short-term (single instance)
(+)-Carvone	2244-16-8	PNEC	5 µg/l	aquatic organisms	marine water	short-term (single instance)
(+)-Carvone	2244-16-8	PNEC	20,2 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
(+)-Carvone	2244-16-8	PNEC	0,861 mg/kg	aquatic organisms	freshwater sediment	short-term (single instance)
(+)-Carvone	2244-16-8	PNEC	86,1 µg/kg	aquatic organisms	marine sediment	short-term (single instance)
(+)-Carvone	2244-16-8	PNEC	0,143 mg/kg	terrestrial organisms	soil	short-term (single instance)
D-(+)-Limonene	5989-27-5	PNEC	14 µg/l	aquatic organisms	freshwater	short-term (single instance)

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Relevant PNECs of components of the mixture						
Name of substance	CAS No	End-point	Threshold level	Organism	Environmental compartment	Exposure time
D-(+)-Limonene	5989-27-5	PNEC	1,4 µg/l	aquatic organisms	marine water	short-term (single instance)
D-(+)-Limonene	5989-27-5	PNEC	1,8 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
D-(+)-Limonene	5989-27-5	PNEC	3,85 mg/kg	aquatic organisms	freshwater sediment	short-term (single instance)
D-(+)-Limonene	5989-27-5	PNEC	0,385 mg/kg	aquatic organisms	marine sediment	short-term (single instance)
D-(+)-Limonene	5989-27-5	PNEC	0,763 mg/kg	terrestrial organisms	soil	short-term (single instance)

8.2 Exposure controls

Individual protection measures (personal protective equipment)

Eye/face protection



Use safety goggle with side protection.

Skin protection



• hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. The times are approximate values from measurements at 22 ° C and permanent contact. Increased temperatures due to heated substances, body heat etc. and a reduction of the effective layer thickness by stretching can lead to a considerable reduction of the breakthrough time. If in doubt, contact manufacturer. At an approx. 1.5 times larger / smaller layer thickness, the respective breakthrough time is doubled / halved. The data apply only to the pure substance. When transferred to substance mixtures, they may only be considered as a guide.

• type of material

NBR (Nitrile rubber)

• material thickness

0,4 mm

• breakthrough times 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.

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Respiratory protection



Respiratory protection necessary at: Aerosol or mist formation.

Environmental exposure controls

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	liquid
Colour	light yellow
Odour	characteristic
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	not determined
Flammability	flammable liquid in accordance with GHS criteria
Lower and upper explosion limit	not determined
Flash point	60 °C
Auto-ignition temperature	not determined
Decomposition temperature	not relevant
pH (value)	not determined
Kinematic viscosity	not determined
<u>Solubility(ies)</u>	
Water solubility	not determined
<u>Partition coefficient</u>	
Partition coefficient n-octanol/water (log value):	this information is not available
Vapour pressure	not determined
Density	0,91 g/cm ³ at 20 °C
Relative vapour density	information on this property is not available
Particle characteristics	not relevant (liquid)
<u>Other safety parameters</u>	
Oxidising properties	none

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9.2 Other information

Information with regard to physical hazard classes:

There is no additional information.

Other safety characteristics:

Refractive index

1,484 – 1,49

SECTION 10: Stability and reactivity

10.1 Reactivity

It's a reactive substance. Risk of ignition.

If heated

Risk of ignition. Vapours may form explosive mixtures with air.

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

Violent reaction with: strong oxidiser

10.4 Conditions to avoid

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

10.5 Incompatible materials

There is no additional information.

10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

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

Classification according to GHS (1272/2008/EC, CLP)

Acute toxicity

Harmful in contact with skin.

Acute toxicity					
Exposure route	Endpoint	Value	Species	Method	Source
dermal	LD50	1.780 mg/kg	rabbit		

Acute toxicity of components of the mixture					
Name of substance	CAS No	Exposure route	Endpoint	Value	Species
(+)-Carvone	2244-16-8	oral	LD50	3.561 mg/kg	rat
(+)-Carvone	2244-16-8	dermal	LD50	3.840 mg/kg	rabbit
D-(+)-Limonene	5989-27-5	oral	LD50	>2.000 mg/kg	rat
Myrcene	123-35-3	oral	LD50	>3.380 mg/kg	mouse

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Acute toxicity of components of the mixture					
Name of substance	CAS No	Exposure route	Endpoint	Value	Species
Myrcene	123-35-3	dermal	LD50	>5.000 mg/kg	rabbit

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

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

May be fatal if swallowed and enters airways.

Symptoms related to the physical, chemical and toxicological characteristics

• If swallowed

aspiration hazard

• If in eyes

Data are not available.

• If inhaled

Data are not available.

• If on skin

causes skin irritation, May produce an allergic reaction, pruritis, localised redness

• Other information

none

11.2 Endocrine disrupting properties

Not listed.

11.3 Information on other hazards

There is no additional information.

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SECTION 12: Ecological information

12.1 Toxicity

Very toxic to aquatic life with long lasting effects.

Aquatic toxicity (acute)				
Endpoint	Value	Species	Source	Exposure time
LC50	0,5 mg/l	fish		96 h

Aquatic toxicity (acute) of components of the mixture					
Name of substance	CAS No	Endpoint	Value	Species	Exposure time
(+)-Carvone	2244-16-8	LC50	50 mg/l	fish	96 h
D-(+)-Limonene	5989-27-5	LC50	0,46 mg/l	fish	96 h
D-(+)-Limonene	5989-27-5	EC50	0,307 mg/l	aquatic invertebrates	48 h
D-(+)-Limonene	5989-27-5	ErC50	0,32 mg/l	algae	72 h
Myrcene	123-35-3	EC50	1,47 mg/l	aquatic invertebrates	48 h
Myrcene	123-35-3	EC50	0,31 mg/l	algae	72 h
Myrcene	123-35-3	ErC50	0,342 mg/l	algae	72 h

Aquatic toxicity (chronic) of components of the mixture					
Name of substance	CAS No	Endpoint	Value	Species	Exposure time
D-(+)-Limonene	5989-27-5	EC50	<0,67 mg/l	fish	8 d
D-(+)-Limonene	5989-27-5	EC50	188 µg/l	aquatic invertebrates	21 d

Biodegradation

Data are not available.

12.2 Process of degradability

Degradability of components of the mixture						
Name of substance	CAS No	Process	Degradation rate	Time	Method	Source
D-(+)-Limonene	5989-27-5	carbon dioxide generation	58,8 %	14 d		ECHA
D-(+)-Limonene	5989-27-5	oxygen depletion	80 %	28 d		ECHA
Myrcene	123-35-3	oxygen depletion	76 %	28 d		ECHA

12.3 Bioaccumulative potential

Data are not available.

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Bioaccumulative potential of components of the mixture

Name of substance	CAS No	BCF	Log KOW	BOD5/COD
(+)-Carvone	2244-16-8		3,07 (25 °C)	
D-(+)-Limonene	5989-27-5		4,38 (pH value: 7,2, 37 °C)	
Myrcene	123-35-3		4,82 (pH value: ~6,5, 30 °C)	

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

Data are not available.

12.6 Endocrine disrupting properties

Not listed.

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods



This material and its container must be disposed of as hazardous waste. Dispose of contents/container in accordance with local/regional/national/international regulations.

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.

Waste treatment of containers/packagings

It is a dangerous waste; only packagings which are approved (e.g. acc. to ADR) may be used.

13.2 Relevant provisions relating to waste

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process. Waste catalogue ordinance (Germany).

13.3 Remarks

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

SECTION 14: Transport information

14.1 UN number or ID number

ADR/RID/ADN	UN 3082
IMDG-Code	UN 3082
ICAO-TI	UN 3082

14.2 UN proper shipping name


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ADR/RID/ADN	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
IMDG-Code	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
ICAO-TI	Environmentally hazardous substance, liquid, n.o.s.
Technical name	Oil of caraway
14.3 Transport hazard class(es)	
ADR/RID/ADN	9
IMDG-Code	9
ICAO-TI	9
14.4 Packing group	
ADR/RID/ADN	III
IMDG-Code	III
ICAO-TI	III
14.5 Environmental hazards	hazardous to the aquatic environment
14.6 Special precautions for user	
Provisions for dangerous goods (ADR) should be complied within the premises.	
14.7 Maritime transport in bulk according to IMO instruments	
The cargo is not intended to be carried in bulk.	
14.8 Information for each of the UN Model Regulations	
Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - Additional information	
Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
Particulars in the transport document	UN3082, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S., (Oil of caraway), 9, III, (-)
Classification code	M6
Danger label(s)	9, "Fish and tree"
	
Environmental hazards	yes (hazardous to the aquatic environment)
Special provisions (SP)	274, 335, 375, 601
Excepted quantities (EQ)	E1
Limited quantities (LQ)	5 L
Transport category (TC)	3
Tunnel restriction code (TRC)	-
Hazard identification No	90

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International Maritime Dangerous Goods Code (IMDG) - Additional information

Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
Particulars in the shipper's declaration	UN3082, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S., (Oil of caraway), 9, III, 60°C c.c.
Marine pollutant	yes (hazardous to the aquatic environment), (Oil of caraway)
Danger label(s)	9, "Fish and tree"
Special provisions (SP)	274, 335, 969
Excepted quantities (EQ)	E1
Limited quantities (LQ)	5 L
EmS	F-A, S-F
Stowage category	A

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

Proper shipping name	Environmentally hazardous substance, liquid, n.o.s.
Particulars in the shipper's declaration	UN3082, Environmentally hazardous substance, liquid, n.o.s., (Oil of caraway), 9, III
Environmental hazards	yes (hazardous to the aquatic environment)
Danger label(s)	9, "Fish and tree"
Special provisions (SP)	A97, A158, A197, A215
Excepted quantities (EQ)	E1
Limited quantities (LQ)	30 kg

SECTION 15: Regulatory information

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

Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII

Dangerous substances with restrictions (REACH, Annex XVII)				
Name of substance	Name acc. to inventory	CAS No	Restriction	No
Oil of caraway	this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC		R3	3
Oil of caraway	flammable / pyrophoric		R40	40
Oil of caraway	substances in tattoo inks and permanent make-up		R75	75

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Legend

- R3
1. 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 ashtrays,
 - tricks and jokes,
 - games for one or more participants, or any article intended to be used as such, even with ornamental aspects,
 2. Articles not complying with paragraph 1 shall not be placed on the market.
 3. 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.
 4. 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).
 5. 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:
 - (a) 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";
 - (b) 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';
 - (c) 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.;
- R40
1. Shall not be used, as substance or as mixtures in aerosol dispensers where these aerosol dispensers are intended for supply to the general public for entertainment and decorative purposes such as the following:
 - metallic glitter intended mainly for decoration,
 - artificial snow and frost,
 - 'whoopie' cushions,
 - silly string aerosols,
 - imitation excrement,
 - horns for parties,
 - decorative flakes and foams,
 - artificial cobwebs,
 - stink bombs.
 2. Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances, suppliers shall ensure before the placing on the market that the packaging of aerosol dispensers referred to above is marked visibly, legibly and indelibly with:
'For professional users only'.
 3. By way of derogation, paragraphs 1 and 2 shall not apply to the aerosol dispensers referred to Article 8 (1a) of Council Directive 75/324/EEC (2).
 4. The aerosol dispensers referred to in paragraphs 1 and 2 shall not be placed on the market unless they conform to the requirements indicated.

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- R75 1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be 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.

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Legend

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.

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

Not 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
E1	environmental hazards (hazardous to the aquatic environment, cat. 1)	100 200	56)

Notation

56) Hazardous to the Aquatic Environment in category Acute 1 or Chronic 1

Deco-Paint Directive

VOC content	100 % 910 g/l
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Industrial Emissions Directive (IED)

VOC content	100 %
VOC content	910 g/l

Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

not listed

Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

not listed

Water Framework Directive (WFD)

not listed

Regulation on the marketing and use of explosives precursors

not listed

Regulation on drug precursors

not listed

Regulation on substances that deplete the ozone layer (ODS)

not listed

Regulation concerning the export and import of hazardous chemicals (PIC)

not listed

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Regulation on persistent organic pollutants (POP)

not listed

National inventories

Country	Inventory	Status
AU	AICS	substance is listed
CA	DSL	substance is listed
CN	IECSC	substance is listed
KR	KECI	substance is listed
NZ	NZIoC	substance is listed
PH	PICCS	substance is listed
TW	TCSI	substance is listed
US	TSCA	substance is listed

Legend

AICS	Australian Inventory of Chemical Substances
DSL	Domestic Substances List (DSL)
IECSC	Inventory of Existing Chemical Substances Produced or Imported in China
KECI	Korea Existing Chemicals Inventory
NZIoC	New Zealand Inventory of Chemicals
PICCS	Philippine Inventory of Chemicals and Chemical Substances (PICCS)
TCSI	Taiwan Chemical Substance Inventory
TSCA	Toxic Substance Control Act

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance.

SECTION 16: Other information

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
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
Asp. Tox.	Aspiration 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)
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
COD	Chemical oxygen demand

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Abbr.	Descriptions of used abbreviations
DGR	Dangerous Goods Regulations (see IATA/DGR)
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)
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
Flam. Liq.	Flammable liquid
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
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
log KOW	n-Octanol/water
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
Skin Sens.	Skin sensitisation
SVHC	Substance of Very High Concern

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Abbr.	Descriptions of used abbreviations
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.

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

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

Code	Text
H226	Flammable liquid and vapour.
H304	May be fatal if swallowed and enters airways.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	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.