

Safety Data Sheet

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

DC Orange

Version number: 2.0 Revision: 03.04.2023
Replaces version of: 14.12.2021 (1) First version: 14.12.2021

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

1.1 Product identifier

Trade name DC Orange

Registration number (REACH)Not relevant (mixture)

CAS number Not relevant (mixture)

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

Relevant identified uses Special cleaners

1.3 Details of the supplier of the safety data sheet

DC DentalCentral GmbH Telephone: +49 40 280054 0
Owiedenfeldstraße 6 Telefax: +49 40 280054 170
30559 Hannover e-mail: order@dental-central.de
Germany Website: www.dental-central.de

e-mail (competent person) sdb@csb-compliance.com

Please do not use this e-mail address to ask for the latest safety data sheet. For this purpose contact DC DentalCentral GmbH.

1.4 Emergency telephone number

Emergency information +49 5661 7317 0

This number is only available during the follow-

ing office hours:

Mon - Thu 09:00 - 15:00

Fri 09:00 - 12:00

As above or nearest toxicological information centre.

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

Classification									
Section	Hazard class	Category	Hazard class and category	Hazard state- ment					
2.6	flammable liquid	3	Flam. Liq. 3	H226					
3.2	skin corrosion/irritation	2	Skin Irrit. 2	H315					

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Classification **Section Hazard class** Category **Hazard class and Hazard state**category ment 3.45 1 H317 skin sensitisation Skin Sens. 1 1 3.10 aspiration hazard Asp. Tox. 1 H304 H400 4.1A hazardous to the aquatic environment - acute 1 Aquatic Acute 1 hazard 4.1C hazardous to the aquatic environment -3 Aquatic Chronic 3 H412 chronic hazard

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.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

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.

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

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.

P331 Do NOT induce vomiting.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P370+P378 In case of fire: Use for extinction: Special powder for metal fires.

P403+P235 Store in a well-ventilated place. Keep cool.

P501 Dispose of contents/container in accordance with local/regional/national/interna-

tional regulations.

Hazardous ingredients for labelling orange, sweet, extr.

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Additional labelling requirements

see section 15 of the safety data sheet

2.3 Other hazards

Results of PBT and vPvB assessment

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

Endocrine disrupting properties

Does not contain an endocrine disruptor (EDC) in a concentration of $\geq 0.1\%$.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not relevant (mixture).

3.2 Mixtures

Description of the mixture

Essential oil.

Contains surfactant.

Hazardous	ingredients
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Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
(R)-p-mentha-1,8- diene	CAS No 5989-27-5 EC No 227-813-5 Index No 601-029-00-7	≥ 90	Flam. Liq. 3 / H226 Skin Irrit. 2 / H315 Skin Sens. 1B / H317 Asp. Tox. 1 / H304 Aquatic Acute 1 / H400 Aquatic Chronic 3 / H412		GHS-HC

Notes

GHS- Harmonised classification (the classification of the substance corresponds to the entry in the list according to

HC: 1272/2008/EC, Annex VI)

Name of substance	Specific Conc. Limits	M-Factors	ATE	Exposure route
(R)-p-mentha-1,8-diene	-	M-factor (acute) = 1	-	-

For full text of H-phrases: see SECTION 16

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SECTION 4: First aid measures

4.1 Description of first aid measures

General notes

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.

Following skin contact

After contact with skin, take off immediately all contaminated clothing, and wash immediately with plenty of water and soap.

If skin irritation or rash occurs: Get medical advice/attention.

Following eye contact

Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.

Following ingestion

Rinse mouth. Do not induce vomiting.

Call a physician in any case.

Notes for the doctor

None.

4.2 Most important symptoms and effects, both acute and delayed

Death following aspiration.

4.3 Indication of any immediate medical attention and special treatment needed

None.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

water spray, alcohol resistant foam, fire extinguishing powder, carbon dioxide (CO2)

Unsuitable extinguishing media

water jet

5.2 Special hazards arising from the substance or mixture

Hazardous decomposition products: Section 10.

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.

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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.

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 (EN 133)

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.

Prevent skin contact.

Do not breathe vapour/spray.

Special danger of slipping by leaking/spilling product.

Wearing of suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

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 clean up a spill

Collect spillage.

Absorbent material (e.g. sand, diatomaceous earth, acid binder, universal binder, sawdust, etc.).

Appropriate containment techniques

Use of adsorbent materials.

Other information relating to spills and releases

Place in appropriate containers for disposal.

Ventilate affected area.

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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

Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation.

Keep away from sources of ignition - No smoking.

Take precautionary measures against static discharge.

Due to danger of explosion, prevent leakage of vapours into cellars, flues and ditches.

Use explosion-proof electrical/ventilating/lighting/equipment.

Use only non-sparking tools.

Specific notes/details

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.

Vapours are heavier than air, spread along floors and form explosive mixtures with air.

Measures to protect the environment

Avoid release to the environment.

Advice on general occupational hygiene

Do not eat, drink and smoke in work areas.

Wash hands after use.

Preventive skin protection (barrier creams/ointments) is recommended.

Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities

Explosive atmospheres

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

Use local and general ventilation.

Keep cool.

Protect from sunlight.

Flammability hazards

Keep away from sources of ignition - No smoking.

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

Take precautionary measures against static discharge.

Protect from sunlight.

Incompatible substances or mixtures

Incompatible materials: see section 10.

Protect against external exposure, such as

heat

Consideration of other advice

Keep away from food, drink and animal feeding stuffs.

Ventilation requirements

Provision of sufficient ventilation.

Packaging compatibilities

Only packagings which are approved (e.g. acc. to ADR) may be used.

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occup	Occupational exposure limit values (Workplace Exposure Limits)											
Coun- try	Name of agent	CAS No	Identi- fier	TWA [ppm]	TWA [mg/m³]	STEL [ppm]	STEL [mg/m³]	Nota- tion	Source			
DE	(R)-p-mentha-1,8- diene	5989-27- 5	AGW	5	28	20	112	H, Sh, Y	TRGS 900			

Notation

H absorbed through the skinSh skin-sensitising substances

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)

Y a risk of developmental toxicity does not need to be expected if the occupational exposure limit value and the

biological limit value (BGW) are adhered to

Relevant DNELs of components of the mixture **CAS No** Name of sub-End-Threshol **Protection Used** in **Exposure time** stance point d level goal, route of exposure (R)-p-mentha-1,8-5989-27-5 DNEL 66,7 mg/ human, inhalatworker (industry) chronic - systemic effects diene m³ ory (R)-p-mentha-1,8-5989-27-5 DNEL 9,5 mg/kg human, dermal worker (industry) chronic - systemdiene bw/day ic effects

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Relevant PNECs of components of the mixture

Name of substance	CAS No	Endpoint	Threshold level	Environmental compartment
(R)-p-mentha-1,8-diene	5989-27-5	PNEC	14 ^{µg} / _l	freshwater
(R)-p-mentha-1,8-diene	5989-27-5	PNEC	1,4 ^{µg} / _l	marine water
(R)-p-mentha-1,8-diene	5989-27-5	PNEC	1,8 ^{mg} / _l	sewage treatment plant (STP)
(R)-p-mentha-1,8-diene	5989-27-5	PNEC	3,85 ^{mg} / _{kg}	freshwater sediment
(R)-p-mentha-1,8-diene	5989-27-5	PNEC	0,385 ^{mg} / _{kg}	marine sediment
(R)-p-mentha-1,8-diene	5989-27-5	PNEC	0,763 ^{mg} / _{kg}	soil

8.2 Exposure controls

Appropriate engineering controls

Use local and general ventilation.

Individual protection measures (personal protective equipment)

Eye/face protection

Wear eye/face protection. (EN 166).

Hand protection

Protective gloves

Material	Material thickness	Breakthrough times of the glove material
IIR: isobutene-isoprene (butyl) rubber	≥ 0,7 mm	>480 minutes (permeation: level 6)
NBR: acrylonitrile-butadiene rubber	≥ 0,4 mm	>480 minutes (permeation: level 6)
FKM: fluoro-elastomer	≥ 0,5 mm	>480 minutes (permeation: level 6)

Wear suitable gloves.

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

Check leak-tightness/impermeability prior to use.

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.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

Type: A-P2 (combined filters against particles and organic gases and vapours, colour code: Brown/ White).

Environmental exposure controls

Use appropriate container to avoid environmental contamination.

Keep away from drains, surface and ground water.

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state liquid

Colour clear - light yellow

Odour characteristic

orange fragrance

Melting point/freezing point -89 °C

Boiling point or initial boiling point and boiling

range

160 °C at 1.026 hPa

Flammability flammable liquid in accordance with GHS criteria

Lower and upper explosion limit ~0,7 vol% - ~6,1 vol%

Flash point ~53 °C

Auto-ignition temperature 230 – 250 °C

Decomposition temperature not relevant

pH (value) not determined

Kinematic viscosity not determined

Dynamic viscosity not determined

Solubility(ies)

Water solubility 1.767 ^{mg}/_l at 25 °C

not miscible in any proportion

Partition coefficient n-octanol/water (log value) not determined

Vapour pressure 186,4 Pa at 25 °C

Density and/or relative density

Density 0,825 – 0,855 ^g/_{cm³} at 20 °C

Relative vapour density this information is not available

Particle characteristics not relevant

(liquid)

9.2 Other information

Information with regard to physical hazard

classes

there is no additional information

Other safety characteristics

Temperature class (EU, acc. to ATEX)

T3

(maximum permissible surface temperature on the equipment: 200°C)

SECTION 10: Stability and reactivity

10.1 Reactivity

This material is not reactive under normal ambient conditions.

10.2 Chemical stability

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

See below "Conditions to avoid".

10.3 Possibility of hazardous reactions

In case of insufficient ventilation and/or in use, may form flammable/explosive vapour-air mixture.

10.4 Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharge.

Use explosion-proof electrical/ventilating/lighting/equipment.

Use only non-sparking tools.

10.5 Incompatible materials

acids, bases, oxidisers

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

Classification procedure

If not otherwise specified the classification is based on:

Ingredients of the mixture (additivity formula).

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

Acute toxicity

Test data are not available for the complete mixture.

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Acute toxicity of components of the mixture

Name of substance	CAS No	Expos- ure route	End- point	Value	Species	Method	Source
(R)-p-mentha-1,8-diene	5989-27-5	oral	LD50	>2.000 ^{mg} / _{kg}	rat, fe- male	OECD Guideline 423	ЕСНА
(R)-p-mentha-1,8-diene	5989-27-5	dermal	LD50	>5.000 ^{mg} / _{kg}	rabbit	OECD Guideline 402	ЕСНА

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 Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Based on available data, the classification criteria are not met.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Shall not be classified as carcinogenic.

Reproductive toxicity

Based on available data, the classification criteria are not met.

Specific target organ toxicity - single exposure

Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

May be fatal if swallowed and enters airways.

11.2 Information on other hazards

Endocrine disrupting properties

Does not contain an endocrine disruptor (EDC) in a concentration of $\geq 0.1\%$.

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SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity (acute)

Very toxic to aquatic organisms.

Test data are not available for the complete mixture.

Aquatic toxicity (acute) of components of the mixture

Name of sub- stance	CAS No	Endpoint	Expos- ure time	Value	Species	Method	Source
(R)-p-mentha- 1,8-diene	5989-27-5	LC50	96 h	702 ^{µg} / _l	fathead min- now (Pimephales promelas)	OECD Guideline 203	ECHA
(R)-p-mentha- 1,8-diene	5989-27-5	ErC50	72 h	0,32 ^{mg} / _l	algae (pseudokirch- neriella subcap- itata)	OECD Guideline 201	ECHA
(R)-p-mentha- 1,8-diene	5989-27-5	EC50	72 h	0,214 ^{mg} / _l	algae (pseudokirch- neriella subcap- itata)	OECD Guideline 201	ECHA
(R)-p-mentha- 1,8-diene	5989-27-5	EC50	48 h	0,307 ^{mg} / _l	daphnia magna	OECD Guideline 202	ECHA
(R)-p-mentha- 1,8-diene	5989-27-5	EC50	96 h	688 ^{µg} / _l	fathead min- now (Pimephales promelas)	OECD Guideline 203	ECHA

Aquatic toxicity (chronic)

Harmful to aquatic life with long lasting effects.

Test data are not available for the complete mixture.

Aquatic toxicity (chronic) of components of the mixture

Name of sub- stance	CAS No	Endpoint	Expos- ure time	Value	Species	Method	Source
(R)-p-mentha- 1,8-diene	5989-27-5	EC50	21 d	188 ^{µg} / _I	daphnia magna	OECD Guideline 211	ECHA
(R)-p-mentha- 1,8-diene	5989-27-5	EC50	8 d	>0,37 - <0,6 7 ^{mg} / _l	fathead min- now (Pimephales promelas)	OECD Guideline 212	ECHA

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Name of sub- stance	CAS No	Endpoint	Expos- ure time	Value	Species	Method	Source
(R)-p-mentha- 1,8-diene	5989-27-5	EC50	3 h	209 ^{mg} / _l	activated sludge of a pre- dominantly do- mestic sewage	OECD Guideline 209	ECHA
(R)-p-mentha- 1,8-diene	5989-27-5	LC50	8 d	0,41 ^{mg} / _l	fathead min- now (Pimephales promelas)	OECD Guideline 212	ECHA
(R)-p-mentha- 1,8-diene	5989-27-5	NOEC	8 d	0,19 ^{mg} / _l	fathead min- now (Pimephales promelas)	OECD Guideline 212	ECHA
(R)-p-mentha- 1,8-diene	5989-27-5	LOEC	8 d	0,19 ^{mg} / _l	fathead min- now (Pimephales promelas)	OECD Guideline 212	ECHA
(R)-p-mentha- 1,8-diene	5989-27-5	LOEC	21 d	173 ^{µg} / _l	daphnia magna	OECD Guideline 211	ECHA
(R)-p-mentha- 1,8-diene	5989-27-5	growth (Eb- Cx) 10%	8 d	>0,37 - <0,6 7 ^{mg} / _I	fathead min- now (Pimephales promelas)	OECD Guideline 212	ECHA
(R)-p-mentha- 1,8-diene	5989-27-5	growth (Eb- Cx) 10%	72 h	0,149 ^{mg} / _l	algae (pseudokirch- neriella subcap- itata)	OECD Guideline 201	ECHA
(R)-p-mentha- 1,8-diene	5989-27-5	growth (Eb- Cx) 10%	21 d	153 ^{µg} / _l	daphnia magna	OECD Guideline 211	ЕСНА
(R)-p-mentha- 1,8-diene	5989-27-5	growth (Eb- Cx) 10%	3 h	18 ^{mg} / _l	activated sludge of a pre- dominantly do- mestic sewage	OECD Guideline 209	ECHA
(R)-p-mentha- 1,8-diene	5989-27-5	growth rate (ErCx) 10%	72 h	0,174 ^{mg} / _l	algae (pseudokirch- neriella subcap- itata)	OECD Guideline 201	ECHA
(R)-p-mentha- 1,8-diene	5989-27-5	growth rate (ErCx) 20%	48 h	0,17 ^{mg} / _l	algae (pseudokirch- neriella subcap- itata)	OECD Guideline 201	ECHA

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12.2 Persistence and degradability

Biodegradation

The surfactant contained in this preparation complies with the biodegradability criteria as laid down in Regulation (EC) No 648/2004 on detergents.

Degradability of components of the mixture

Name of substance	CAS No	Process	Degradation rate	Time	Method	Source
(R)-p-mentha- 1,8-diene	5989-27-5	carbon diox- ide generation	71,4 %	28 d	OECD Guideline 301 B	ECHA
(R)-p-mentha- 1,8-diene	5989-27-5	oxygen deple- tion	80 %	28 d	OECD Guideline 301 D	ECHA

Persistence

No data available.

12.3 Bioaccumulative potential

Test data are not available for the complete mixture.

Bioaccumulative potential of components of the mixture

Name of substance	CAS No	BCF	Log KOW
(R)-p-mentha-1,8-diene	5989-27-5	-	4,57

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

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

12.6 Endocrine disrupting properties

Does not contain an endocrine disruptor (EDC) in a concentration of \geq 0,1%.

12.7 Other adverse effects

Data are not available.

Remarks

Wassergefährdungsklasse, WGK (water hazard class): 2

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SECTION 13: Disposal considerations

13.1 Waste treatment methods

This material and its container must be disposed of as hazardous waste.

Sewage disposal-relevant information

Do not empty into drains.

Waste treatment of containers/packagings

Completely emptied packages can be recycled.

Handle contaminated packages in the same way as the substance itself.

Remarks

Please consider the relevant national or regional provisions.

SECTION 14: Transport information

14.1 UN number or ID number

ADR/RID/ADN UN2319
IMDG-Code UN2319
ICAO-TI UN2319

14.2 UN proper shipping name

ADR/RID/ADN TERPENE HYDROCARBONS, N.O.S.

IMDG-Code TERPENE HYDROCARBONS, N.O.S.

ICAO-TI Terpene hydrocarbons, n.o.s.

14.3 Transport hazard class(es)

ADR/RID/ADN 3
IMDG-Code 3

ICAO-TI 3

14.4 Packing group

ADR/RID/ADN III

IMDG-Code III

ICAO-TI III

14.5 Environmental hazards hazardous to the aquatic environment

Environmentally hazardous substance (aquatic dipentene **environment)**

14.6 Special precautions for user

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14.7 Maritime transport in bulk according to IMO - instruments

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

Particulars in the transport document UN2319, TERPENE HYDROCARBONS, N.O.S., 3, III,

(D/E), environmentally hazardous

Classification code F1

Danger label(s) 3, fish and tree



Environmental hazards yes

(hazardous to the aquatic environment)

Excepted quantities (EQ) E1

Limited quantities (LQ) 5 L

Transport category (TC) 3

Tunnel restriction code (TRC) D/E

Hazard identification No 30

European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN) Additional information

Number of cones/blue lights 0

International Maritime Dangerous Goods Code (IMDG) Additional information

Marine pollutant yes

(hazardous to the aquatic environment)

Danger label(s) 3, fish and tree



Special provisions (SP)

Excepted quantities (EQ) E1

Limited quantities (LQ) 5 L

EmS F-E, S-D

Stowage category A

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

Environmental hazards yes

(hazardous to the aquatic environment)

Danger label(s) 3

Excepted quantities (EQ) E1

Limited quantities (LQ) 10 L

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

Name	Name acc. to inventory	CAS No	Restriction
orange, sweet, extr.	this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC	-	R3
(R)-p-mentha-1,8-diene	flammable / pyrophoric	-	R40
(R)-p-mentha-1,8-diene	substances in tattoo inks and perman- ent make-up	-	R75

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
- $\boldsymbol{-}$ 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.';

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Legend

- 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,
- 'whoopee' 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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Legend

- 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";

Legend

(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.

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

None of the ingredients are listed.

Seveso Directive

2012/	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)	
P5c	flammable liquids (cat. 2, 3)	5.000	50.000	51)	

Notation

- 51) flammable liquids, categories 2 or 3 not covered by P5a and P5b
- 56) hazardous to the Aquatic Environment in category Acute 1 or Chronic 1

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

None of the ingredients are listed.

Regulation 648/2004/EC on detergents

Labelling of contents	
Wt%	Constituents
-	perfumes (D-LIMONENE, LINALOOL)

Regulation on the marketing and use of explosives precursors

None of the ingredients are listed.

Regulation on drug precursors

None of the ingredients are listed.

Regulation on substances that deplete the ozone layer (ODS)

None of the ingredients are listed.

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

None of the ingredients are listed.

Regulation on persistent organic pollutants (POP)

None of the ingredients are listed.

National regulations (Germany)

Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (Ordinance on facilities for handling substances hazardous to water) (AwSV)

Wassergefährdungsklasse, WGK 2

(water hazard class) - classification acc. to annex 1 (AwSV)

Technical instructions on air quality control (Germany)

Number	Group of substances	Class	Conc.	Mass flow	Mass con- centration	Nota- tion
5.2.5	organic substances	-	≥ 25 wt%	0,5 ^{kg} / _h	50 ^{mg} / _{m³}	3)

Notation

Storage of hazardous substances in non-stationary containers (TRGS 510) (Germany)

3

Storage class (LGK)

(flammable and desensitizing explosive liquids)

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³⁾ a total mass flow of 0.50 kg/h or a total mass concentration of 50 mg/m³, each of which to be indicated as total carbon, shall not be exceeded (except organic particulate matter)

Other information

Observe employment restrictions for young people according to § 22 JArbSchG. Observe occupational restrictions for mothers acc. to § 11 MuSchG!

15.2 Chemical Safety Assessment

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

SECTION 16: Other information

Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)
1.3	e-mail (competent person): sdb@csb-online.de	e-mail (competent person): sdb@csb-compliance.com
	Please do not use this e-mail address to ask for the latest safety data sheet. For this purpose contact DC DentalCentral GmbH.	Please do not use this e-mail address to ask for the latest safety data sheet. For this purpose contact DC DentalCentral GmbH.
1.4	Emergency information service: +49 5661 7317 0 Monday-Friday 07:00 - 16:00.	Emergency information: +49 5661 7317 0 This number is only available during the following office hours: Mon - Thu 09:00 - 15:00 Fri 09:00 - 12:00
2.1	-	Classification: change in the listing (table)
2.2	-	Hazard statements: change in the listing (table)
2.3	Results of PBT and vPvB assessment: This mixture does not contain any substances that are assessed to be a PBT or a vPvB.	Results of PBT and vPvB assessment: Does not contain a PBT-/vPvB-substance in a con- centration of ≥ 0,1%.
3.2	-	Hazardous ingredients: change in the listing (table)
3.2	-	Hazardous ingredients: change in the listing (table)
8.1	-	Relevant PNECs of components of the mixture: change in the listing (table)
8.2	Eye/face protection: Wear eye/face protection.	Eye/face protection: Wear eye/face protection. (EN 166).
14.5	-	Environmentally hazardous substance (aquatic environment): dipentene
14.8	-	European Agreement concerning the Internation- al Carriage of Dangerous Goods by Inland Water- ways (ADN) Additional information
14.8	<u>-</u>	Number of cones/blue lights: 0

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Section	Former entry (text/value)	Actual entry (text/value)
15.1	Restrictions according to REACH, Annex XVII: None of the ingredients are listed.	Restrictions according to REACH, Annex XVII
15.1	-	Restrictions according to REACH, Annex XVII: change in the listing (table)
15.1	-	2012/18/EU (Seveso III): change in the listing (table)
15.1	Wassergefährdungsklasse, WGK (water hazard class): 3 - classification acc. to annex 1 (AwSV)	Wassergefährdungsklasse, WGK (water hazard class): 2 - classification acc. to annex 1 (AwSV)

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
ADDI.	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 con- cerning 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)
AGW	Workplace exposure limit
Aquatic Acute	Hazardous to the aquatic environment - acute hazard
Aquatic Chron- ic	Hazardous to the aquatic environment - chronic hazard
Asp. Tox.	Aspiration hazard
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
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
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

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Abbr.	Descriptions of used abbreviations	
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	
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 dur- ing a specified time interval	
LGK	Lagerklasse (storage class according to TRGS 510, Germany)	
LOEC	Lowest Observed Effect Concentration	
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	
PBT	Persistent, Bioaccumulative and Toxic	
PNEC	Predicted No-Effect Concentration	
ppm	Parts per million	
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals	
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regula- tions concerning the International carriage of Dangerous goods by Rail)	
Skin Corr.	Corrosive to skin	
Skin Irrit.	Irritant to skin	
Skin Sens.	Skin sensitisation	

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Abbr.	Descriptions of used abbreviations	
STEL	Short-term exposure limit	
SVHC	Substance of Very High Concern	
TRGS	Technische Regeln für Gefahrstoffe (technical rules for hazardous substances, Germany)	
TRGS 900	Arbeitsplatzgrenzwerte (TRGS 900)	
TWA	Time-weighted average	
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).

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).

Classification procedure

Physical and chemical properties.

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
H226	Flammable liquid and vapour.
H304	May be fatal if swallowed and enters airways.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life.
H412	Harmful to aquatic life with long lasting effects.

Responsible for the safety data sheet

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Disclaimer

This information is based upon the present state of our knowledge.

This SDS has been compiled and is solely intended for this product.

This safety data sheet is for information only and does not comply with the official language requirements of article 31 (5) of REACH.

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