

according to Article 31 of Regulation No 1907/2006/EC (REACH)

Printing date: 19.10.2022 Version number: 14.0 Revision date: 19.10.2022

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

· 1.1 Product identifier

· Trade name: ESSENCE DE PIN

· UFI (Unique Formula Identifier): M623-40RH-9004-S3UK

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

Relevant identified uses: formulation and distribution of the mixture, formulation and use of coatings and varnishes, inks, solvents, lubricants, agrochemicals and fragrance products

· 1.3 Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

LES DERIVES RESINIQUES & TERPENIQUES (DRT)

30 rue Gambetta BP 90206

40105 DAX CEDEX

FRANCE

Tel: 33-(0)5 58 56 62 00 Fax: 33-(0)5 58 56 62 40

Email: fds@drt.fr

· 1.4 Emergency telephone numbers

NCEC (24/24 - 7/7)

Europe: +44 1235 239670

Global / English speaking countries: +44 1865 407333

Other countries: see section 16

SECTION 2: Hazards identification

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



GHS02 flame

Flam. Liq. 3 H226 Flammable liquid and vapour.



GHS08 health hazard

Asp. Tox. 1 H304 May be fatal if swallowed and enters airways.



GHS09 environment

Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.



GHS07 exclamation mark

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

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

· Information concerning particular hazards for human and environment:

Effects on human health:

if swallowed accidentally, the product may enter the lungs due to its low viscosity and lead to the rapid development of very serious pulmonary lesions (medical survey for 48 hours minimum).

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· 2.2 Label elements

· Labelling according to Regulation (EC) No 1272/2008:

The product is classified and labelled according to the CLP regulation.

· Hazard pictograms:









GHS02 GHS07 GHS08 GHS09

· Signal word: Danger

Hazard statements:

H226 Flammable liquid and vapour.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H304 May be fatal if swallowed and enters airways. H411 Toxic to aquatic life with long lasting effects.

Precautionary statements:

P273 Avoid release to the environment.

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

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

P331 Do NOT induce vomiting.

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

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present

and easy to do. Continue rinsing.

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

P501 Dispose of contents and container in accordance with local/regional/national/international

regulations.

· 2.3 Other hazards

· Results of PBT and vPvB assessment

· PBT

According to Annex XIII of REACH Regulation, the components of the mixture are not considered to be Persistent, Bioaccumulative and Toxic.

· vPvB:

According to Annex XIII of REACH Regulation, the components of the mixture are not considered to be very Persistent and very Bioaccumulative.

Determination of endocrine-disrupting properties

The components of the mixture are not included in the list established in accordance with Article 59(1) of REACH regulation for having endocrine disrupting properties, and are not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/210056 or Commission Regulation (EU) 2018/605.

SECTION 3: Composition/information on ingredients

· 3.2 Mixtures

· Description:

Mixture of terpinolene multiconstituent and terpineol multiconstituent:

terpinolene multiconstituent (EU list No. 938-945-4)

According to REACH identification rules, this product is a multiconstituent substance, consisting of the following constituents (> 10%):

- terpinolene (4-isopropylidene-1-methylcyclohexene CAS No. 586-62-9)
- 1,4-cineole (1-isopropyl-4-methyl-7-oxabicyclo[2.2.1]heptane CAS No. 470-67-7)
- 1,8-cineole (1,3,3-trimethyl-2-oxabicyclo[2.2.2]octane CAS No. 470-82-6)

According to REACH, components present at less than 10% are considered as impurities.

Main impurities:

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- d-limonene [(4R)isopropenyl1methylcyclohexene - CAS No. 5989-27-5]

- I-limonene [(4S)isopropenyl1methylcyclohexene - CAS No. 5989-54-8]

- alpha-terpineol (α,α,4-trimethyl-3-cyclohexene-1-methanol CAS No. 98-55-5)
- gamma-terpinene (1-isopropyl-4-methylcyclohexa-1,4-diene CAS No. 99-85-4)
- alpha-terpinene (1-isopropyl-4-methylcyclohexa-1,3-diene CAS No. 99-86-5)
- camphene (2,2-dimethyl-3-methylenebicyclo[2.2.1]heptane CAS No. 79-92-5)
- alpha-pinene (2,6,6-trimethylbicyclo[3.1.1]hept-2-ene CAS No. 80-56-8)

- p-cymene (1-isopropyl-4-methylbenzene - CAS No. 99-87-6)

terpineol multiconstituent (EC No. 701-188-3)

According to REACH identification rules, this product is a multiconstituent substance, consisting of the following constituents (> 10%):

- (-)-alpha-terpineol [α,α,4-trimethyl-(1S)-3-cyclohexene-1-methanol CAS No. 10482-56-1]
- (+)-alpha-terpineol [α,α,4-trimethyl-(1R)-3-cyclohexene-1-methanol CAS No. 7785-53-7]
- gamma-terpineol [1-methyl-4-(1-methylethylidene)-cyclohexanol CAS No. 586-81-2]

According to REACH, components present at less than 10% are considered as impurities. Main impurities:

- cis-beta-terpineol [cis-1-methyl-4-(1-methylethenyl)-cyclohexanol CAS No. 7299-41-4]
- trans-beta-terpineol [trans-1-methyl-4-(1-methylethenyl)-cyclohexanol CAS No. 7299-40-3]
- 3-terpinen-1-ol [4-isopropyl-1-methylcyclohex-3-en-1-ol CAS No. 586-82-3]
- delta-terpineol [α,α-dimethyl-4-methylene cyclohexanemethanol CAS No. 7299-42-5]
- terpinen-1-ol-4 [1-isopropyl-4-methylcyclohex-3-en-1-ol CAS No. 562-74-3]
- "Substance terpineol multiconstituent" (constituents + impurities) forms according to the definition of a substance under REACH 100% of the product.

· Hazardous components:				
	terpinolene multiconstituent	90,0%		
Reg.nr.: 01-2119982324-34-0000	 ♠ Flam. Liq. 3, H226; ♠ Asp. Tox. 1, H304; ♠ Aquatic Chronic 2, H411; ♠ Eye Irrit. 2, H319; Skin Sens. 1B, H317 			
	terpineol multiconstituent			
	① Skin Irrit. 2, H315; Eye Irrit. 2, H319			

[·] Additional information: For the wording of the listed hazard statements refer to section 16.

SECTION 4: First aid measures

· 4.1 Description of first aid measures

· After inhalation:

Supply fresh air. If symptoms are experienced, get medical attention.

In case of unconsciousness place patient stably in side position for transportation.

· After skin contact:

Immediately rinse with plenty of water.

Remove contaminated clothing and shoes. Wash clothing before reuse. Clean shoes thoroughly before reuse. Get medical attention if irritation or skin rash occurs.

· After eye contact:

Immediately rinse with plenty of water. Remove contact lenses, if present and easy to do. Hold eyelids apart and flush eyes with plenty of cool low-pressure water for 15 minutes. Consult an ophthalmologist.

· After swallowing:

Do NOT induce vomiting.

If the person is conscious, rinse out mouth with water.

Call for a doctor immediately.

- · 4.2 Most important symptoms and effects, both acute and delayed Pulmonary effects if swallowed accidentally.
- 4.3 Indication of any immediate medical attention and special treatment needed

If swallowed accidentally, medical survey for 48 hours minimum.

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SECTION 5: Firefighting measures

· 5.1 Suitable extinguishing agents

Foam

Fire-extinguishing powder

Carbon dioxide (CO₂)

- · 5.2 Special hazards arising from the substance or mixture In case of fire, may release irritant and toxic fumes.
- · 5.3 Advice for firefighters
- · Protective equipment:

Firefighters should wear appropriate protective equipment and self-contained breathing apparatus.

· Additional information: Cool endangered receptacles with water spray.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Wear appropriate personal protective equipment. Keep unprotected persons away.

Provide adequate ventilation.

Keep away from sources of ignition.

· 6.2 Environmental precautions

Do not allow product to reach soil, waterways, drains and sewers.

Inform the relevant authorities if the product has caused environmental pollution (soil, waterways, drains or sewers).

- 6.3 Methods and material for containment and cleaning up

Small spills:

Absorb spilled liquid with inert absorbent. Collect in an appropriate container properly labelled. Close it for disposal. Large spills:

Stop spill if it can be done without danger. Dike. Pump as much liquid as possible with an explosion-proof pump or a hand pump. Absorb the remaining liquid with inert absorbent. Collect in an appropriate container properly labelled. Close it for disposal. Use only non-sparking tools.

· 6.4 Reference to other sections

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Wear appropriate personal protective equipment. Provide adequate ventilation in the workplace.

· Information about fire - and explosion protection:

Protect against electrostatic charges.

Use only non-sparking tools.

Protect from heat.

Keep ignition sources away.

· 7.2 Conditions for safe storage

If possible, store the drums or ecobulk under shelter in a cool and well ventilated place.

Keep container type drums or ecobulk tightly closed.

All equipments including ventilation systems must be equipotential and earthed.

Keep away from sources of ignition.

Protect drums or ecobulk from high heat and direct sunlight.

· 7.3 Specific end use(s) Only identified uses listed in section 1 are covered by exposure scenarios.

SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- · Components with limit values that require monitoring at the workplace:

terpenes

Austria: limit value - 8 hours = 560 mg/m³ (100 ppm)

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Austria: limit value - short term = 560 mg/m³ (100 ppm)

Denmark: limit value - 8 hours = 25 ppm Denmark: limit value - short term = 50 ppm

Sweden: limit value - 8 hours = 150 mg/m³ (25 ppm) Sweden: limit value - short term = 300 mg/m³ (50 ppm) Switzerland: limit value - 8 hours = 112 mg/m³ (20 ppm) Switzerland: limit value - short term = 224 mg/m³ (40 ppm)

Impurities of terpinolene multiconstituent: dipentene (dl-limonene - CAS 138-86-3)

Norway: limit value - 8 hours = 140 mg/m³ (25 ppm) Sweden: limit value - 8 hours = 150 mg/m³ (25 ppm) Sweden: limit value - short term = 300 mg/m³ (50 ppm)

d-Limonene (CAS 5989-27-5) - one of the two isomers of dipentene (CAS 138-86-3)

Finland: limit value - 8 hours = 140 mg/m³ (25 ppm)
Finland: limit value - short term = 280 mg/m³ (50 ppm)
Germany (AGS): limit value - 8 hours = 28 mg/m³ (5 ppm)
Germany (AGS): limit value - short term = 110 mg/m³ (20 ppm)
Germany (DFG): limit value - 8 hours = 28 mg/m³ (5 ppm)
Germany (DFG): limit value - short term = 112 mg/m³ (20 ppm)
Norway: limit value - 8 hours = 140 mg/m³ (25 ppm)

Norway: limit value - 8 hours = 140 mg/m³ (25 ppm) Switzerland: limit value - 8 hours = 40 mg/m³ (7 ppm) Switzerland: limit value - short term = 80 mg/m³ (14 ppm) Spain: limit value - 8 hours = 168 mg/m³ (30 ppm)

alpha-pinene multiconstituent (common CAS 80-56-8)

Belgium: limit value - 8 hours = 20 ppm

Norway: limit value - 8 hours = 140 mg/m³ (25 ppm) Sweden: limit value - 8 hours = 150 mg/m³ (25 ppm) Sweden: limit value - short term = 300 mg/m³ (50 ppm) Switzerland: limit value - 8 hours = 112 mg/m³ (20 ppm) Switzerland: limit value - short term = 224 mg/m³ (40 ppm)

paracymene (CAS 99-87-6)

Belgium: limit value - 8 hours = 100 mg/m³ (20 ppm)
Denmark: limit value - 8 hours = 135 mg/m³ (25 ppm)
Denmark: limit value - short term = 270 mg/m³ (50 ppm)
Sweden: limit value - 8 hours = 140 mg/m³ (25 ppm)
Sweden: limit value - short term = 190 mg/m³ (35 ppm)

· DNELs

· DNEL (Derived No-Effect Level): Workers - Long-term exposure

terpinolene multiconstituent (EU list No. 938-945-4)

Systemic effects - inhalation: 5.12 mg/m³

Systemic effects - dermal: 1.45 mg/kg body weight/day

Local effects - dermal: 133.3 µg/cm² terpineol multiconstituent (EC 701-188-3) Systemic effects - inhalation: 44.8 mg/m³

Systemic effects - dermal: 6.36 mg/kg body weight/day

· DNEL (Derived No-Effect Level): General population - Long-term exposure

terpinolene multiconstituent (EU list No. 938-945-4)

Systemic effects - inhalation: 1.26 mg/m³

Systemic effects - dermal: 0.73 mg/kg body weight/day Systemic effects - oral: 0.73 mg/kg body weight/day

terpineol multiconstituent (EC 701-188-3) Systemic effects - inhalation: 7.96 mg/m³

Systemic effects - dermal: 2.69 mg/kg body weight/day Systemic effects - oral: 2.69 mg/kg body weight/day

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· PNECs

· PNEC (Predicted No-Effect Concentration) aqua (freshwater):

terpinolene multiconstituent (EU list No. 938-945-4) 5.2 μg/L

terpineol multiconstituent (EC 701-188-3) 12 µg/L

PNEC (Predicted No-Effect Concentration) aqua (marine water):

terpinolene multiconstituent (EU list No. 938-945-4) 0.52 μg/L

terpineol multiconstituent (EC 701-188-3) 1.2 µg/L

PNEC (Predicted No-Effect Concentration) Sewage Treatment Plant:

terpinolene multiconstituent (EU list No. 938-945-4) 3 mg/L terpineol multiconstituent (EC 701-188-3) 2.57 mg/L

PNEC (Predicted No-Effect Concentration) sediment (freshwater):

terpinolene multiconstituent (EU list No. 938-945-4) 0.581 mg/kg sediment dry weight terpineol multiconstituent (EC 701-188-3) 0.263 mg/kg sediment dry weight

PNEC (Predicted No-Effect Concentration) sediment (marine water):

terpinolene multiconstituent (EU list No. 938-945-4) 58.1 µg/kg sediment dry weight terpineol multiconstituent (EC 701-188-3) 0.026 mg/kg sediment dry weight

· PNEC (Predicted No-Effect Concentration) soil:

terpinolene multiconstituent (EU list No. 938-945-4) 113 μ g/kg soil dry weight terpineol multiconstituent (EC 701-188-3) 0.045 mg/kg soil dry weight

PNEC (Predicted No-Effect Concentration) oral:

terpinolene multiconstituent (EU list No. 938-945-4) 15 mg/kg food

terpineol multiconstituent (EC 701-188-3) 16.6 mg/kg food

· PNEC (Predicted No-Effect Concentration) aqua (intermittent releases):

terpinolene multiconstituent (EU list No. 938-945-4) 52 μ g/L terpineol multiconstituent (EC 701-188-3) 120 μ g/L

· Additional information:

This sheet is based on the current valid lists for occupational exposure limit values at the time of its preparation. The DNELs and PNECs values are derived from the chemical safety assessment conducted for REACH.

Occupational exposure limits and DNELs are health-based but they are not necessarily set in the same way. The primary duty is to comply with risk management measures which enable to limit exposures as much as possible and to be in line with exposure reference levels.

· 8.2 Exposure controls

· General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

Immediately remove all soiled and contaminated clothing.

Avoid contact with eyes and skin.

· Personal protective equipment

· Respiratory protection:

If ventilation is insufficient, use a breathing apparatus (filtering device with type A cartridge or insulating device with a source of fresh air independent of the ambient air).

· Hand protection

Protective gloves resistant to chemicals (standard EN 374-1). They should be replaced regularly and if there is any indication of degradation.

· Eye/face protection

Safety glasses (standard EN 166).

For qualifying operations with increased risk (eg: connection/disconnection of hoses, purges, sampling, etc.) wear safety glasses (standard EN 166) AND a face shield.

· Body protection: Protective work clothing.

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SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

Physical state: LiquidColour: Yellow

Odour: Pine and citrusOdour threshold: Not determined

· Change in condition

• Melting/freezing point: Not determined

• Boiling point or boiling range: 150-200°C [Differential Scanning Calorimetry method (DSC)]

• Flammability: The mixture is ignitable

• Flash point: 53°C (setaflash method - closed cup)

Auto-ignition temperature:
 Decomposition temperature:
 pH value:
 Not determined
 Not applicable

· Viscosity

• **Kinematic viscosity:** < 7 mm²/s (40°C) [OECD 114 / capillary rotational viscometer method]

Solubility
in water:

Partition coefficient (n-octanol/water):
Vapour pressure:
Not determined
Not determined

· Density and/or relative density

• Relative density: 0,873 - 0,883 (method: oscillating densimeter method at 20 °C)

Vapour density: Not determinedAuto-ignition temperature: Not determined

• Explosive properties: The components of the mixture do not contain any chemical groups

associated with explosive properties

• Oxidising properties: The components of the mixture do not contain any chemical groups

associated with oxidizing properties

• Evaporation rate: Not determined• 9.2 Other information No other data

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No data from specific reactivity tests are available for this product or this class of product.
- · 10.2 Chemical stability

Product stable under storage and handling conditions according to specifications (see section 7).

· 10.3 Possibility of hazardous reactions

No hazardous reactions known except those with incompatible products listed in point 10.5.

- 10.4 Conditions to avoid Keep away from any flame or source of sparks.
- · 10.5 Incompatible materials

Strong acids

Strong bases

Strong oxidising agents

Materials that react with oxygenated terpenes

• 10.6 Hazardous decomposition products No dangerous decomposition products known.

SECTION 11: Toxicological information

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

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· LD ₅₀ /LC ₅₀	· LD ₅₀ /LC ₅₀ values relevant for classification:			
terpinoler	ne multiconstituent			
Oral	LD ₅₀ > 2 000 mg/kg (rat) (OECD 423)			
Dermal	$ LD_{50} > 2\ 000\ mg/kg\ (rat)\ (OECD\ 402)$			
terpineol	terpineol multiconstituent			
Oral	LD ₅₀ > 2 000 mg/kg (rat) (OECD 401)			
Dermal	$ LD_{50} > 2\ 000\ mg/kg\ (rabbit)\ (OECD\ 402)$			
Inhalation	$ LC_{50} > 4,76 \text{ mg/L (rat) (OECD 403)}$			

Terpineol multiconstituent (EC 701-188-3)

No toxicity (local or systemic) was observed at the highest dose tested by inhalation (4.76 mg/L). DL₅₀ by oral route and dermal route of terpineol multiconstituent are higher than 2 000 mg/kg and no acute toxicity is expected by inhalation, at concentrations taken into account in the classification.

· Skin corrosion/irritation:

The mixture is classified as skin irritant (category 2) due to the presence of terpineol multiconstituent. terpineol multiconstituent (EC No. 701-188-3)

Terpineol multiconstituent and alpha-terpineol (main constituent) were found to be skin irritating (category 2), in several studies conducted on rabbits according to OECD 404 Guideline.

· Serious eye damage/irritation:

The mixture is classified as eye irritant (category 2) due to the following results.

terpinolene multiconstituent (EU list No. 938-945-4)

A recent BCOP study (Bovine Corneal Opacity and Permeability assay for identifying ocular corrosives and severe irritants - OECD 437) showed however that the substance has no corrosive or highly eye irritating properties. However, the substance was found irritant in an <u>in vitro</u> eye irritation study on human reconstructed corneal epithelium model and is therefore classified in category 2 - effects on the eye. terpineol multiconstituent (EC No. 701-188-3)

The substance was found to be eye irritating (category 2), in a study conducted on rabbit according to OECD 405 Guideline.

· Skin sensitisation:

The mixture is classified as skin sensitiser (category 1B) due to the presence of terpinolene multiconstituent. terpinolene multiconstituent (EU list No. 938-945-4)

The substance is classified as skin sensitiser 1B because skin sensitisation effects were observed in a murine Local Lymph Node Assay (LLNA - OECD 429).

· Mutagenicity/genotoxicity:

The components of the mixture did not show any genotoxic potential.

terpinolene multiconstituent (EU list No. 938-945-4)

Based on the results of the tests conducted with the substance, no genotoxic potential is expected:

- the substance has no mutagenic effects in an Ames test (OECD 471);
- no genotoxic effects were observed with the substance in a chromosome aberration test in human lymphocytes (OECD 473). However, an equivocal result had been obtained after exposing cells for 20 hours without metabolic activation S9. The toxicological significance of this observation was considered questionable. Therefore, an <u>in vitro</u> micronucleus test (OECD 487) was performed under similar experimental conditions (24-h exposure without metabolic activation, human lymphocytes). No biologically relevant increases in micronuclei were observed, supporting the absence of genotoxic potential;
- the substance did not induce mutagenic effects in a gene mutation test in chinese hamster cells (OECD 476). terpineol multiconstituent (EC No. 701-188-3)

Based on the results of the tests conducted with this substance and one of its main constituents, no genotoxic potential is expected:

- terpineol multiconstituent and alpha-terpineol were not mutagenic in several Ames tests (OECD 471);
- no genotoxic effects were observed with this substance in an in vitro chromosome aberration test in human lymphocytes (OECD 473);
- alpha-terpineol was not mutagenic in a gene mutation test on mouse lymphoma L5178Y cells (OECD 476).

· Carcinogenicity:

This mixture is not expected to be carcinogenic: no mutagenic effects were observed with the components of the mixture and the repeated dose toxicity study doesn't bring to light any hyperplasia or pre-neoplastic lesions.

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· Reproductive toxicity:

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No toxic effects for reproduction are expected from this mixture based on the following result. terpinolene multiconstituent (EU list No. 938-945-4)

No toxic effects for reproduction are expected.

In a combined repeated dose and reproduction/developmental screening test conducted on rats according to OECD Guideline No 422, no effects were observed on reproductive performance, gestation parameters, pup survival and development.

NOAEL (No Observed Adverse Effect Level) - systemic toxicity for males and females (P) = 435.8 mg/kg body weight/day (higher dose tested)

NOAEL - reproduction and developmental toxicity = 435.8 mg/kg body weight/day (higher dose tested) terpineol multiconstituent (EC No. 701-188-3)

Based on findings from three studies conducted on rats, there is strong evidence that no reproductive effects are likely to occur by the possible routes of human exposure.

A prenatal developmental toxicity study was conducted according to OECD 414 Guideline. Administration of the substance by gavage to pregnant female rats at doses up to 600 mg/kg body weight/day did not induce effects considered as adverse on pup survival and development.

NOAEL (maternal toxicity) = 600 mg/kg body weight/day

NOAEL (enbryo-foetal toxicity) = 600 mg/kg body weight/day

A prenatal developmental toxicity study was conducted according to OECD Guideline 414. Administration of the substance by gavage to pregnant female rabbits at doses up to 500 mg/kg body weight/day did not induce effects considered as adverse on pup survival and development.

NOAEL (maternal toxicity) = 500 mg/kg body weight/day

NOAEL (enbryo-foetal toxicity) = 500 mg/kg body weight/day

No effects were observed on the reproductive organs in two 90-day repeated toxicity studies conducted on rat: by inhalation according to OECD Guideline No. 413 and by oral route.

· Specific target organ toxicity - single exposure:

No specific target organ toxicity leading to classification was observed in the LD₅₀ determination studies carried out with the tested components of this product.

· Specific target organ toxicity - repeated exposure:

Available data on the components of the mixture do not lead to any classification.

terpinolene multiconstituent (EU list No. 938-945-4)

The substance is not classified based on the following available results.

A combined repeated dose and reproduction/developmental screening test was conducted on rats according to OECD Guideline No 422. Daily administration of the substance by diet for 42 days to male and unmated female rats was well tolerated at dose levels up to 438.5 mg/kg body weight/day. Only effects considered as adaptative or specific to male rats were observed.

NOAEL = 435.8 mg/kg body weight/day (higher dose tested)

terpineol multiconstituent (EC No. 701-188-3)

Available data presented below do not lead to any classification of the substance.

In a repeated dose toxicity study, daily administration of terpineol multiconstituent by gavage for 5 weeks to male and female rats was generally well tolerated at dose levels up to 750 mg/kg body weight/day.

NOAEL = 250 mg/kg (testicles)

There is strong evidence that no effects will occur when animals are exposed through a route relevant for human exposure (diet) rather than gavage.

A 90-day repeated dose toxicity study was carried out by inhalation on rat, according to OECD 413 Guideline. Administration of the substance to male and unmated female rats, at dose levels up to 2.23 mg/L, was well tolerated and no effects were observed on the reproductive organes. NOAEL= 2,23 mg/L

- · Aspiration hazard: If swallowed accidentally, the product may enter the respiratory tract due to its low viscosity.
- · Additional toxicological information:
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction):

According to Regulation (EC) No 1272/2008 criteria, the components of the mixture are not considered to be CMR.

- · 11.2 Information on other hazards
- · Endocrine disrupting properties

The components of the mixture are not included in the list established in accordance with Article 59(1) of REACH regulation for having endocrine disrupting properties, and are not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/210056 or Commission Regulation (EU) 2018/605.

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SECTION 12: Ecological information

· 12.1 Aquatic toxicity

The mixture is classified toxic to the aquatic life (long term, category 2) due to the presence of terpinolene multiconstituent.

terpinolene multiconstituent (EU list No. 938-945-4)

The substance is classified toxic to aquatic life based on the results below.

EC₅₀ (48 h), daphnia (Daphnia magna): 5.184 mg/L (nominal concentration - OECD 202)

LC₅₀ (96 h), fish (Danio rerio): 6.104 mg/L (nominal concentration - OECD 203)

EC₅₀ (72 h), algae (Pseudokirchneriella subcapitata): 5.40 mg/L (based on growth rate - measured concentration - OECD 201)

 EC_{50} (72 h), algae (Pseudokirchneriella subcapitata): 2.82 mg/L (based on yield - measured concentration - OECD 201)

· Toxicity to aquatic microorganisms:

Sewage containing the mixture can be treated by a municipal sewage treatment plant (taking into account the 2 PNECs sewage treatment plant given in section 8).

terpinolene multiconstituent (EU list No. 938-945-4)

EC₅₀ (3 h): 178 mg/L (respiration rate - nominal concentration - activated sludge - OECD 209)

terpineol multiconstituent (EC No. 701-188-3)

No toxic effects were observed with this substance on activated sludge from a predominant domestic sewage, in a ready biodegradability study.

Terrestrial toxicity:

Assays were conducted only on terpineol multiconstituent.

terpineol multiconstituent (EC No. 701-188-3)

LC₅₀ (14 days), earthworm (Eisenia fetida): 499 - 799 mg/kg soil dry weight (based on mortality - nominal concentration - OECD 207 Guideline)

NOEC (14 days), earthworm (Eisenia fetida): 311 mg/kg soil dry weight (based on mortality - nominal concentration - OECD 207 Guideline)

NOEC (14 days), earthworm (Eisenia fetida): 311 mg/kg soil dry weight (based on growth - nominal concentration - OECD 207 Guideline)

12.2 Persistence and degradability

The mixture consists of 2 substances readily biodegradable.

terpinolene multiconstituent (EU list No. 938-945-4)

The substance is readily biodegradable.

Degradation after 28 days: 72% (oxygen consumption - OECD 301 D test - activated sludge from a domestic waste water - non adapted).

terpineol multiconstituent (EC No. 701-188-3)

The substance is readily biodegradable.

Degradation after 28 days: 80% (inorganic carbon concentration - OECD 310 Guideline - activated sludge from a domestic waste water - non adapted - 60% being surpassed within 10 days after reaching 10%).

· 12.3 Bioaccumulative potential

No accumulation in organisms is expected based on the results below.

terpinolene multiconstituent (EU list No. 938-945-4)

No measured data are available for the substance. Based on estimations using 3 different QSARs (Quantitative Structure-Activity Relationship methods) and on the value of the substance partition coefficient n-octanol/water (< 3), an accumulation in organisms is not expected.

terpineol multiconstituent (EC No. 701-188-3)

No measured data are available for the substance. Based on estimations using 3 different QSARs (Quantitative Structure-Activity Relationship methods) and on the value of the substance partition coefficient n-octanol/water (< 3), an accumulation in organisms is not expected.

· 12.4 Mobility in soil

terpinolene multiconstituent (EU list No. 938-945-4)

No measured data available.

terpineol multiconstituent (EC No. 701-188-3)

The adsorption coefficient of the substance was determined in a study conducted according to OECD 106 Guideline: $28.8 \le \text{Koc} \le 50.9$

Taken with the high water solubility, this value is low enough to suggest that terpineol multiconstituent will show limited adsorption to soil or sediment particulates, and with a partition mainly to water (in the surface or ground water

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compartments).

· 12.5 Results of PBT and vPvB assessment

· PBT:

According to Annex XIII of REACH Regulation, the components of the mixture are not considered to be Persistent, Bioaccumulating and Toxic.

· vPvB:

According to Annex XIII of REACH Regulation, the components of the mixture are not considered to be very Persistent and very Bioaccumulating.

12.6 Endocrine disrupting properties

The components of the mixture are not included in the list established in accordance with Article 59(1) of REACH regulation for having endocrine disrupting properties, and are not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/210056 or Commission Regulation (EU) 2018/605.

· 12.7 Other adverse effects No data available.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods National and regional regulations have to be adhered to.
- · Recommendation: The product has to be disposed of in an authorised incinerator, according to regulation.
- · Uncleaned packaging
- · Recommendation: Packaging has to be sent to an authorised waste treatment facility, for recycling or disposal.

SECTION 14: Transport information		
· 14.1 UN number or ID number · ADR, IMDG, IATA	UN 1993	
· 14.2 UN proper shipping name · ADR	1993 FLAMMABLE LIQUID, N.O.S. (1,4-cineole, terpinolene), ENVIRONMENTALLY HAZARDOUS	
· IMDG	FLAMMABLE LIQUID, N.O.S. (1,4-cineole, terpinolene), MARINE POLLUTANT	
·IATA	FLAMMABLE LIQUID, N.O.S. (1,4-cineole, terpinolene)	
· 14.3 Transport hazard class(es)		
· ADR, IMDG		
1 1 1 1 1 1 1 1 1 1		
· Class	3 Flammable liquids.	
· Label · IATA	3	
· Class	3 Flammable liquids.	
· Label	3	

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· 14.4 Packing group · ADR, IMDG, IATA	III
14.5 Environmental hazards Marine pollutant:	Environmentally hazardous substance, liquid; Marine Pollutant Product contains environmentally hazardous substances: terpinolene multiconstituent Symbol (fish and tree)
Special marking (ADR): 14.6 Special precautions for user	Symbol (fish and tree) Warning: Flammable liquids
Danger code:EMS Number:	30 F-E, <u>S-E</u>
· 14.7 Maritime transport in bulk according to IMO instruments Not applicable	
· Transport/Additional information:	
ADRTunnel restriction codeClassification code (letter/figure)	D/E F1
· UN "Model Regulation"	UN 1993, FLAMMABLE LIQUID, N.O.S. (1,4-cineole, terpinolene), ENVIRONMENTALLY HAZARDOUS, 3, III

SECTION 15: Regulatory information

· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture Regulation (EC) No 1907/2006 (REACH):

The product does not contain any of the substances included in the following lists

- Annex XIV (authorisation) / substances of very high concern (SVHC)
- Annex XVII (restrictions)

Directive 2012/18/EU:

Product fulfilling the criteria of hazard categories:

- P5c "Flammable liquids, category 3 (H226)",
- E2 "Hazardous to the Aquatic Environment in Category Chronic 2 (H411)".
- · 15.2 Chemical safety assessment

A chemical safety assessment has been carried out for terpinolene multiconstituent (EU list No 938-945-4) and for terpineol multiconstituent (EC No. 701-188-3).

SECTION 16: Other information

Information provided in this safety data sheet is based on our experience and present knowledge. It is a description of safety requirements and data given on the product and cannot be considered as specifications. They shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- · Version 14.0
- · Previous version: 13.0 of 12/10/2021
- · Emergency telephone numbers (other countries):

NCEC - In-Country Numbers (24/24 - 7/7) Australia: +61 2 8014 4558 / 18000 74234

Bangladesh: +65 3158 1200

China: 400 120 6011

China (Mainland): +86 532 8388 9090 Czech Republic: +420 228 882 830

Denmark: +45 8988 2286 Finland: +358 9 7479 0199 Greece: +30 21 1198 3182

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India: +65 3158 1198 India: 000 800 100 7479 Indonesia: 007 803 011 0293 Japan: +81 3 4578 9341 Malaysia: +60 3 6207 4347

New Zealand: +64 9 929 1483 / 0800 446 881

Norway: +47 2103 4452 Pakistan: +65 3158 1329 Philippines: +63 2 8231 2149 Singapore: +65 3165 2217 South Africa: +27 21 300 2732 South Korea: +82 2 3479 8401 Sri Lanka: +65 3158 1195 Sweden: +46 8 566 42573 Taiwan: +886 2 8793 3212 Thailand: 001 800 120 666 751 Turkey: +90 212 375 5231 Vietnam: +84 28 4458 2388

· Full text of H and EUH mentions indicated in sections 2 and 3:

H226: Flammable liquid and vapour

H315: Causes skin irritation

H319: Causes serious eye irritation

H317: May cause an allergic skin reaction

H304: May be fatal if swallowed and enters airways H411: Toxic to aquatic life with long lasting effects

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.

H319 Causes serious eye irritation.

H411 Toxic to aquatic life with long lasting effects.

· Abbreviations and acronyms:

CLP: Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging

EC_{so}: Concentration which leads to a 50% reduction in treated organism responses compared to untreated organism responses (algae) or concentration which causes effects to 50% of the tested organisms (daphnids)

 LC_{50} : Lethal concentration for 50% of exposed animals

LD₅₀: Lethal dose for 50% of animals exposed by oral or dermal route

Koc. Organic carbon/water partition coefficient. It represents the potential of retention of the substance on soil organic matter

LLNA: Local Lymph Node Assay

NOAEL: No Observed Adverse Effect Level NOEC: No Observed Effect Concentration

OECD: Guidelines from the Organisation for Economic Co-operation and Development

SVHC: Substances of Very High Concern

PBT: Persistent, Bioaccumulative and Toxic substance vPvB: very Persistent and very Bioaccumulative substance

Flam. Liq. 3: Flammable liquids, Category 3 Skin Irrit. 2: Skin corrosion/irritation, Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1B: Skin sensitisation, Category 1B Asp. Tox. 1: Aspiration hazard, Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

· Sources:

Literature and company data

REACH registration dossiers of the components of the mixture

Modified data compared to the previous version:

Change of emergency response service: National Chemical Emergency Centre (NCEC) (sections 1 and 16)

· Annex:

on request at the following address, fds@drt.fr

End of the safety data sheet