

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Enilconazole Liquid Formulation

Version 6.1 Revision Date: 30.09.2023 SDS Number: 906842-00020 Date of last issue: 04.04.2023
Date of first issue: 22.09.2016

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

1.1 Product identifier

Trade name : Enilconazole Liquid Formulation

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

Use of the Sub-stance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Flammable liquids, Category 3	H226: Flammable liquid and vapour.
Acute toxicity, Category 3	H301: Toxic if swallowed.
Acute toxicity, Category 4	H332: Harmful if inhaled.
Eye irritation, Category 2	H319: Causes serious eye irritation.
Carcinogenicity, Category 2	H351: Suspected of causing cancer.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	H226 Flammable liquid and vapour. H301 Toxic if swallowed. H319 Causes serious eye irritation. H332 Harmful if inhaled. H351 Suspected of causing cancer. H373 May cause damage to organs through prolonged or repeated exposure. H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements	:	Prevention: P201 Obtain special instructions before use. P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. Response: P301 + P310 + P330 IF SWALLOWED: Immediately call a POISON CENTER/ doctor. Rinse mouth. P391 Collect spillage.

Hazardous components which must be listed on the label:

1-[2-(allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole
Benzyl alcohol

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Vapours may form explosive mixture with air.

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SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Sodium bis(2-ethylhexyl)sulfosuccinate	577-11-7 209-406-4	Skin Irrit. 2; H315 Eye Dam. 1; H318	>= 30 - < 50
1-[2-(allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole	35554-44-0 252-615-0 613-042-00-5	Acute Tox. 3; H301 Acute Tox. 4; H332 Eye Dam. 1; H318 Carc. 2; H351 STOT RE 2; H373 (Liver) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity): 10	>= 10 - < 20
Benzyl alcohol	100-51-6 202-859-9 603-057-00-5	Acute Tox. 4; H302 Acute Tox. 4; H332 Eye Irrit. 2; H319 Acute toxicity estimate Acute oral toxicity: 1.620 mg/kg	>= 1 - < 10
Ethanol#	64-17-5 200-578-6 603-002-00-5	Flam. Liq. 2; H225 Eye Irrit. 2; H319 specific concentration limit Eye Irrit. 2; H319 >= 50 %	>= 1 - < 10

For explanation of abbreviations see section 16.
#: Voluntarily-disclosed substance

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SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- If inhaled : If inhaled, remove to fresh air.
If not breathing, give artificial respiration.
If breathing is difficult, give oxygen.
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
- In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.
- If swallowed : If swallowed, DO NOT induce vomiting.
Call a physician or poison control centre immediately.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

- Symptoms : Gastrointestinal disturbance
- Risks : Toxic if swallowed.
Causes serious eye irritation.
Harmful if inhaled.
Suspected of causing cancer.
May cause damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.

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SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Do not use a solid water stream as it may scatter and spread fire.
Flash back possible over considerable distance.
Vapours may form explosive mixtures with air.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Sulphur oxides
Metal oxides

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Remove all sources of ignition.
Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

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6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Non-sparking tools should be used.
Soak up with inert absorbent material.
Suppress (knock down) gases/vapours/mists with a water spray jet.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
Use explosion-proof electrical, ventilating and lighting equipment.

Advice on safe handling : Do not breathe mist or vapours.
Do not swallow.
Do not get in eyes.
Avoid prolonged or repeated contact with skin.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Non-sparking tools should be used.
Keep container tightly closed.
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Take precautionary measures against static discharges.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.
The effective operation of a facility should include review of

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engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. Keep away from heat and sources of ignition.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Flammable solids
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Substances and mixtures, which in contact with water, emit flammable gases
Explosives
Gases
Very acutely toxic substances and mixtures

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
1-[2-(allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole	35554-44-0	TWA	0.3 mg/m ³ (OEB 2)	Internal
Further information: Skin				
Ethanol	64-17-5	TWA	500 ppm 950 mg/m ³	FOR-2011-12-06-1358

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
Sodium bis(2-ethylhexyl)sulfosuccinate	Workers	Inhalation	Long-term systemic effects	1416,82 mg/m ³

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	Workers	Skin contact	Long-term systemic effects	200,89 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	419,25 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	120,54 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	13,39 mg/kg bw/day
Polyethylene glycol castor oil	Workers	Inhalation	Long-term systemic effects	16,4 mg/m ³
	Workers	Skin contact	Long-term systemic effects	4,67 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	2,9 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	1,67 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	1,67 mg/kg bw/day
Benzyl alcohol	Workers	Inhalation	Long-term systemic effects	22 mg/m ³
	Workers	Inhalation	Acute systemic effects	110 mg/m ³
	Workers	Skin contact	Long-term systemic effects	8 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	40 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	5,4 mg/m ³
	Consumers	Inhalation	Acute systemic effects	27 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	20 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	20 mg/kg bw/day
Ethanol	Workers	Inhalation	Long-term systemic effects	950 mg/m ³
	Workers	Skin contact	Long-term systemic effects	343 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	114 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	206 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	87 mg/kg bw/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
Sodium bis(2-	Fresh water	0,18 mg/l

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ethylhexyl)sulfosuccinate	Intermittent use/release	0,152 mg/l
	Marine water	0,018 mg/l
	Sewage treatment plant	12,2 mg/l
	Fresh water sediment	17,789 mg/kg dry weight (d.w.)
	Marine sediment	1,779 mg/kg dry weight (d.w.)
	Soil	1,04 mg/kg dry weight (d.w.)
Polyethylene glycol castor oil	Fresh water	0,000 mg/l
	Freshwater - intermittent	0,0661 mg/l
	Marine water	0,000 mg/l
	Marine water - intermittent	0,00661 mg/l
	Fresh water sediment	0,0129 mg/kg dry weight (d.w.)
	Marine sediment	0,00129 mg/kg dry weight (d.w.)
Benzyl alcohol	Soil	0,00258 mg/kg dry weight (d.w.)
	Fresh water	1 mg/l
	Marine water	0,1 mg/l
	Intermittent use/release	2,3 mg/l
	Sewage treatment plant	39 mg/l
	Fresh water sediment	5,27 mg/kg
Ethanol	Marine sediment	0,527 mg/kg
	Soil	0,456 mg/kg
	Fresh water	0,96 mg/l
	Freshwater - intermittent	2,75 mg/l
	Marine water	0,79 mg/l
	Sewage treatment plant	580 mg/l
Oral (Secondary Poisoning)	Fresh water sediment	3,6 mg/kg dry weight (d.w.)
	Marine sediment	2,9 mg/kg dry weight (d.w.)
	Soil	0,63 mg/kg dry weight (d.w.)
	Oral (Secondary Poisoning)	380 mg/kg food

8.2 Exposure controls

Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Laboratory operations do not require special containment.

Use explosion-proof electrical, ventilating and lighting equipment.

Personal protective equipment

Eye/face protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.

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Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection

Material : Chemical-resistant gloves

Remarks : Take note that the product is flammable, which may impact the selection of hand protection.

Skin and body protection : Work uniform or laboratory coat.

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS EN 14387

Filter type : Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : liquid

Colour : light yellow

Odour : musty

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : Not applicable

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : 45 °C

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 9,5

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Viscosity
Viscosity, kinematic : No data available

Solubility(ies)
Water solubility : soluble

Partition coefficient: n-
octanol/water : No data available

Vapour pressure : No data available

Relative density : 1,094

Relative vapour density : No data available

Particle characteristics
Particle size : No data available

9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : No data available

Molecular weight : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Flammable liquid and vapour.
Vapours may form explosive mixture with air.
Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents
Acids

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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SECTION 11: Toxicological information

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

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Toxic if swallowed.
Harmful if inhaled.

Product:

Acute oral toxicity : LD50 (Rat): 192 - 309 mg/kg

Acute inhalation toxicity : LC50 (Rat): 3,1 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 900 mg/kg

Components:

Sodium bis(2-ethylhexyl)sulfosuccinate:

Acute oral toxicity : LD50 (Rat): 3.080 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 5.000 mg/kg

1-[2-(allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:

Acute oral toxicity : LD50 (Rat): 227 mg/kg
Remarks: Based on harmonised classification in EU regulation
1272/2008, Annex VI

LD50 (Mouse): 390 - 620 mg/kg

LD50 (Dog): > 640 mg/kg

Acute inhalation toxicity : LC50 (Rat): 1,84 - 2,88 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Remarks: Based on harmonised classification in EU regulation
1272/2008, Annex VI

Acute dermal toxicity : LD50 (Rat): 4.200 - 4.800 mg/kg

LD50 (Rabbit): 4.200 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 155 mg/kg
Application Route: Intraperitoneal

Benzyl alcohol:

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Acute oral toxicity : LD50 (Rat): 1.620 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 4,178 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Ethanol:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): 124,7 mg/l
Exposure time: 4 h
Test atmosphere: vapour

Skin corrosion/irritation

Not classified based on available information.

Product:

Species : Rabbit
Result : Mild skin irritation

Components:

Sodium bis(2-ethylhexyl)sulfosuccinate:

Species : Rabbit
Method : OECD Test Guideline 404
Result : Skin irritation

1-[2-(allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:

Species : Rabbit
Result : Mild skin irritation

Benzyl alcohol:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Ethanol:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Product:

Species : Rabbit

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Result : Moderate eye irritation

Components:

Sodium bis(2-ethylhexyl)sulfosuccinate:

Species : Rabbit
Method : OECD Test Guideline 405
Result : Irreversible effects on the eye

1-[2-(allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:

Species : Rabbit
Result : Irreversible effects on the eye
Remarks : Based on harmonised classification in EU regulation
1272/2008, Annex VI

Species : Rabbit
Result : Moderate eye irritation
Remarks : Based on harmonised classification in EU regulation
1272/2008, Annex VI

Benzyl alcohol:

Species : Rabbit
Method : OECD Test Guideline 405
Result : Irritation to eyes, reversing within 21 days

Ethanol:

Species : Rabbit
Method : OECD Test Guideline 405
Result : Irritation to eyes, reversing within 21 days

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Product:

Species : Guinea pig
Result : Not a skin sensitizer.

Components:

Sodium bis(2-ethylhexyl)sulfosuccinate:

Test Type : Human repeat insult patch test (HRIPT)
Exposure routes : Skin contact
Species : Humans
Result : negative

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1-[2-(allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:

Test Type : Maximisation Test
Exposure routes : Dermal
Species : Guinea pig
Result : equivocal

Exposure routes : Dermal
Species : Humans
Result : Not a skin sensitizer.

Benzyl alcohol:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

Ethanol:

Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse
Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Sodium bis(2-ethylhexyl)sulfosuccinate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: equivocal

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

1-[2-(allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosomal aberration
Test system: Human lymphocytes
Result: negative

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Test Type: gene mutation test
Test system: Chinese hamster fibroblasts
Result: negative

Test Type: unscheduled DNA synthesis assay
Test system: rat hepatocytes
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Rat
Application Route: Oral
Result: negative

Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Mouse
Result: negative

Benzyl alcohol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo
cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Ethanol:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Mouse
Application Route: Ingestion
Result: equivocal

Carcinogenicity

Suspected of causing cancer.

Components:

1-[2-(allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:

Species : Rat

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Application Route : Oral
Exposure time : 2 Years
NOAEL : 40 mg/kg body weight
Result : negative

Species : Mouse
Application Route : Oral
Exposure time : 2 Years
LOAEL : 33 mg/kg body weight
Result : positive
Target Organs : Liver

Species : Mouse
Application Route : oral (feed)
Exposure time : 23 Months
NOAEL : 8 mg/kg body weight
LOAEL : 105 mg/kg body weight
Result : positive
Target Organs : Liver
Remarks : Based on harmonised classification in EU regulation
1272/2008, Annex VI

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in animal studies

Benzyl alcohol:

Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks
Method : OECD Test Guideline 451
Result : negative

Reproductive toxicity

Not classified based on available information.

Components:

Sodium bis(2-ethylhexyl)sulfosuccinate:

Effects on fertility : Test Type: Three-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

1-[2-(allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:

Effects on fertility : Test Type: Multi-generation study
Species: Rat
Application Route: Oral

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General Toxicity - Parent: NOAEL: 20 mg/kg body weight
Result: Maternal toxicity observed., Embryotoxic effects and adverse effects on the offspring were detected.
Remarks: Not classified due to data which are conclusive although insufficient for classification.

Effects on foetal development : Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 80 mg/kg body weight
Result: Reduced foetal weight, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses
Remarks: The effects were seen only at maternally toxic doses.

Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 10 mg/kg body weight
Result: Maternal toxicity observed., No teratogenic effects, Postimplantation loss.
Remarks: The effects were seen only at maternally toxic doses.

Benzyl alcohol:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development
Species: Mouse
Application Route: Ingestion
Result: negative

Ethanol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

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Components:

1-[2-(allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:

Target Organs : Liver
Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Product:

Species : Rabbit
NOAEL : 1 mg/kg
Application Route : Dermal
Exposure time : 21 d
Symptoms : No adverse effects

Components:

Sodium bis(2-ethylhexyl)sulfosuccinate:

Species : Rat
NOAEL : 750 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

1-[2-(allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:

Species : Rat
NOAEL : 5 mg/kg
LOAEL : 20 mg/kg
Application Route : Oral
Exposure time : 3 - 24 Months
Target Organs : Liver
Symptoms : decrease in appetite

Species : Dog
NOAEL : 2,5 mg/kg
LOAEL : 20 mg/kg
Application Route : Oral
Exposure time : 12 Months
Symptoms : Salivation, Vomiting

Species : Mouse
NOAEL : 12 mg/kg
LOAEL : 140 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : Liver

Benzyl alcohol:

Species : Rat
NOAEL : 1,072 mg/l

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Application Route : inhalation (dust/mist/fume)
Exposure time : 28 Days
Method : OECD Test Guideline 412

Ethanol:

Species : Rat
NOAEL : 1.280 mg/kg
LOAEL : 3.156 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Experience with human exposure

Product:

Inhalation : Remarks: May cause respiratory tract irritation.
Skin contact : Remarks: May irritate skin.
Eye contact : Remarks: May irritate eyes.
Ingestion : Symptoms: Gastrointestinal disturbance, central nervous system effects

Components:

1-[2-(allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:

Skin contact : Symptoms: pruritis, skin rash, Skin irritation
Eye contact : Symptoms: Eye irritation
Ingestion : Symptoms: Nausea

SECTION 12: Ecological information

12.1 Toxicity

Components:

Sodium bis(2-ethylhexyl)sulfosuccinate:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): 49 mg/l
Exposure time: 96 h
Method: Directive 67/548/EEC, Annex V, C.1.

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- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 6,6 mg/l
Exposure time: 48 h
- Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 82,5 mg/l
Exposure time: 72 h
- EC10 (Desmodesmus subspicatus (green algae)): 22 mg/l
Exposure time: 72 h
- Toxicity to microorganisms : EC50 (Pseudomonas putida): 164 mg/l
Exposure time: 16 h
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : EC10: 9 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

1-[2-(allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 1,48 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
- LC50 (Lepomis macrochirus (Bluegill sunfish)): 3,99 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 3,54 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 1,2 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
- NOEC (Pseudokirchneriella subcapitata (green algae)): 0,457 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: < 0,007 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211
- M-Factor (Chronic aquatic toxicity) : 10

Ecotoxicology Assessment

- Acute aquatic toxicity : Very toxic to aquatic life.
Remarks: Based on the harmonised classification in Turkish regulation SEA No 28848

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Benzyl alcohol:

- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 230 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
- NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 51 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

Ethanol:

- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1.000 mg/l
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia (water flea)): > 1.000 mg/l
Exposure time: 48 h
- Toxicity to algae/aquatic plants : ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l
Exposure time: 72 h
- EC10 (Chlorella vulgaris (Fresh water algae)): 11,5 mg/l
Exposure time: 72 h
- Toxicity to microorganisms : EC50 (Pseudomonas putida): 6.500 mg/l
Exposure time: 16 h
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 9,6 mg/l
Exposure time: 9 d
Species: Daphnia magna (Water flea)

12.2 Persistence and degradability

Components:

Sodium bis(2-ethylhexyl)sulfosuccinate:

- Biodegradability : Result: Readily biodegradable.
Biodegradation: 91,2 %
Exposure time: 28 d

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1-[2-(allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:

Biodegradability : Result: not rapidly degradable
Biodegradation: 50 %
Exposure time: 166 d

Benzyl alcohol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 92 - 96 %
Exposure time: 14 d

Ethanol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 84 %
Exposure time: 20 d

12.3 Bioaccumulative potential

Components:

Sodium bis(2-ethylhexyl)sulfosuccinate:

Partition coefficient: n- : log Pow: 1,998
octanol/water Remarks: Calculation

1-[2-(allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:

Partition coefficient: n- : log Pow: 3,82
octanol/water

Benzyl alcohol:

Partition coefficient: n- : log Pow: 1,05
octanol/water

Ethanol:

Partition coefficient: n- : log Pow: -0,35
octanol/water

12.4 Mobility in soil

Components:

1-[2-(allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole:

Distribution among environ- : log Koc: 3,82
mental compartments

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal. Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

ADN : UN 1992
ADR : UN 1992
RID : UN 1992
IMDG : UN 1992
IATA : UN 1992

14.2 UN proper shipping name

ADN : FLAMMABLE LIQUID, TOXIC, N.O.S.
(Ethanol, 1-[2-(allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole)

ADR : FLAMMABLE LIQUID, TOXIC, N.O.S.
(Ethanol, 1-[2-(allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole)

RID : FLAMMABLE LIQUID, TOXIC, N.O.S.

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IMDG : (Ethanol, 1-[2-(allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole)
: FLAMMABLE LIQUID, TOXIC, N.O.S.
(Ethanol, 1-[2-(allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole)

IATA : Flammable liquid, toxic, n.o.s.
(Ethanol, 1-[2-(allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole)

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	: 3	6.1
ADR	: 3	6.1
RID	: 3	6.1
IMDG	: 3	6.1
IATA	: 3	6.1

14.4 Packing group

ADN
Packing group : III
Classification Code : FT1
Hazard Identification Number : 36
Labels : 3 (6.1)

ADR
Packing group : III
Classification Code : FT1
Hazard Identification Number : 36
Labels : 3 (6.1)
Tunnel restriction code : (D/E)

RID
Packing group : III
Classification Code : FT1
Hazard Identification Number : 36
Labels : 3 (6.1)

IMDG
Packing group : III
Labels : 3 (6.1)
EmS Code : F-E, S-D

IATA (Cargo)
Packing instruction (cargo aircraft) : 366
Packing instruction (LQ) : Y343
Packing group : III
Labels : Flammable Liquids, Toxic

IATA (Passenger)
Packing instruction (passen- : 355

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ger aircraft)
Packing instruction (LQ) : Y343
Packing group : III
Labels : Flammable Liquids, Toxic

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:
Number on list 75, 3

If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

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Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

		Quantity 1	Quantity 2
E1	ENVIRONMENTAL HAZARDS	100 t	200 t
P5c	FLAMMABLE LIQUIDS	5.000 t	50.000 t

Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

The components of this product are reported in the following inventories:

AICS : not determined
DSL : not determined
IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

H225 : Highly flammable liquid and vapour.
H301 : Toxic if swallowed.
H302 : Harmful if swallowed.
H315 : Causes skin irritation.
H318 : Causes serious eye damage.
H319 : Causes serious eye irritation.
H332 : Harmful if inhaled.
H351 : Suspected of causing cancer.
H373 : May cause damage to organs through prolonged or repeated exposure.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

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Acute Tox.	: Acute toxicity
Aquatic Acute	: Short-term (acute) aquatic hazard
Aquatic Chronic	: Long-term (chronic) aquatic hazard
Carc.	: Carcinogenicity
Eye Dam.	: Serious eye damage
Eye Irrit.	: Eye irritation
Flam. Liq.	: Flammable liquids
Skin Irrit.	: Skin irritation
STOT RE	: Specific target organ toxicity - repeated exposure
FOR-2011-12-06-1358	: Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / TWA	: Long term exposure limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Classification of the mixture:

Classification procedure:

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Flam. Liq. 3	H226		Based on product data or assessment
Acute Tox. 3	H301		Based on product data or assessment
Acute Tox. 4	H332		Based on product data or assessment
Eye Irrit. 2	H319		Based on product data or assessment
Carc. 2	H351		Calculation method
STOT RE 2	H373		Calculation method
Aquatic Chronic 1	H410		Calculation method

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

NO / EN