SAFETY DATA SHEET

Enilconazole Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 07.06.2024
9.0	28.09.2024	906768-00022	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 Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
20 Spartan Road
1619 Spartan, South Africa

Telephone : +27119239300

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)

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

Additional Labelling

EUH208 Contains Benzyl alcohol. May produce an allergic reaction.

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.
Vapours may form explosive mixture with air.

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	>= 10 - < 20

		(Liver) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 ——————— M-Factor (Chronic aquatic toxicity): 10	
Benzyl alcohol	100-51-6 202-859-9 603-057-00-5	Acute Tox. 4; H302 Eye Irrit. 2; H319 Skin Sens. 1B; H317	>= 1 - < 10
Ethanol#	64-17-5 200-578-6 603-002-00-5	Flam. Liq. 2; H225 Eye Irrit. 2; H319	>= 1 - < 10

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

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.

May produce an allergic reaction.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

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.

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 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-	35554-44-0	TWA	0.3 mg/m3 (OEB 2)	Internal

dichloro-phenyl)ethyl]-1H-imidazole				
	Further information: Skin			
Ethanol	64-17-5	OEL- RL STEL/C	2.000 ppm	ZA OEL
	Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents			

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-ethylhex-yl)sulfosuccinate	Workers	Inhalation	Long-term systemic effects	1416,82 mg/m3
	Workers	Skin contact	Long-term systemic effects	200,89 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	419,25 mg/m3
	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/m3
	Workers	Skin contact	Long-term systemic effects	4,67 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	2,9 mg/m3
	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/m3
	Workers	Inhalation	Acute systemic effects	110 mg/m3
	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/m3
	Consumers	Inhalation	Acute systemic effects	27 mg/m3
	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	380 mg/m3

			effects	
	Workers	Skin contact	Long-term systemic effects	267 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	114 mg/m3

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

Substance name	Environmental Compartment	Value
Sodium bis(2-ethylhexyl)sulfosuccinate	Fresh water	0,18 mg/l
	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.)
	Soil	0,00258 mg/kg dry weight (d.w.)
Benzyl alcohol	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
	Marine sediment	0,527 mg/kg
	Soil	0,456 mg/kg
Ethanol	Fresh water	0,96 mg/l
	Freshwater - intermittent	2,75 mg/l
	Marine water	0,79 mg/l
	Sewage treatment plant	580 mg/l
	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. 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.
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

Appearance	:	liquid
Colour	:	light yellow
Odour	:	musty
Odour Threshold	:	No data available
pH	:	9,5
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	45 °C
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	1,094

Solubility(ies)		
Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

9.2 Other information

Flammability (liquids)	:	Not applicable
Molecular weight	:	No data available
Particle size	:	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.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of	:	Inhalation

exposure

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:

Acute oral toxicity	:	LD50 (Rat): 1.200 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 5,4 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403

Assessment: The substance or mixture has no acute inhalation toxicity

Ethanol:

Acute oral toxicity	:	LD50 (Rat): 10.470 mg/kg Method: OECD Test Guideline 401
Acute inhalation toxicity	:	LC50 (Rat, male): 116,9 mg/l Exposure time: 4 h Test atmosphere: vapour
Acute dermal toxicity	:	LD50 (Rabbit): > 15.800 mg/kg

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
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

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

Assessment	:	Probability or evidence of low to moderate skin sensitisation rate in humans

Ethanol:

Test Type	:	Mouse ear swelling test (MEST)
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 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: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Rat
Application Route: Ingestion
Result: negative

Carcinogenicity

Suspected of causing cancer.

Components:

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

Species	:	Rat
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 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.

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
Application Route	:	inhalation (dust/mist/fume)
Exposure time	:	28 Days

Method	:	OECD Test Guideline 412

Ethanol:

Species	:	Rat
NOAEL	:	1.730 mg/kg
LOAEL	:	3.200 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days

Aspiration toxicity

Not classified based on available information.

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.
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 (Chron-	:	EC10: 9 mg/l Exposure time: 21 d

ic toxicity)		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

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)): 14.200 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Ceriodaphnia dubia (water flea)): 5.012 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 (Protozoa): 5.800 mg/l Exposure time: 4 h
Toxicity to fish (Chronic toxicity)	:	NOEC: >= 79 mg/l Exposure time: 100 d Species: Oryzias latipes (Japanese medaka)
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

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

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

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

Benzyl alcohol:

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

Ethanol:

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

12.4 Mobility in soil

Components:

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

Distribution among environmental compartments	:	log Koc: 3,82

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.

12.6 Other adverse effects

Product:

Endocrine disrupting potential	:	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.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	:	Dispose of in accordance with local regulations.

Contaminated packaging	:	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. 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

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. (Ethanol, 1-[2-(allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole)
IMDG	:	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 (passenger aircraft)	:	355
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 Transport in bulk according to Annex II of Marpol and the IBC Code

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

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.
H317 : May cause an allergic skin reaction.
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

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
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure
ZA OEL : South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits
ZA OEL / OEL- RL STEL/C : Occupational Exposure Limit Restricted limit - Short term oc-

cupational exposure limits / ceiling limits

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:**
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

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

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.

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