

Trade name: Sulphur D12 Similasan für Swimmers Ear Relief

Substance number: 484920

Version: 1 / CH

Date revised: 02.03.2026

Replaces Version: - / CH

Print date: 02.03.26

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

1.1. Product identifier

Sulphur D12 Similasan für Swimmers Ear Relief
Item No. 48492000

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

Use of the substance/preparation

Medicinal product

1.3. Details of the supplier of the safety data sheet

Address/Manufacturer

Hänseler AG
Industriestrasse 35
9100 Herisau
Telephone no. 0041 (0)71 353 58 58
E-mail address of sdb@haenseler.ch
person responsible
for this SDS

1.4. Emergency telephone number

Switzerland :145 / Abroad +41 (0)44 251 51 51

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (Regulation (EC) No. 1272/2008)

Classification (Regulation (EC) No. 1272/2008)
Flam. Liq. 3 H226

The product is classified and labelled in accordance with Regulation (EC) No 1272/2008
For explanation of abbreviations see section 16.

2.2. Label elements

Labelling according to regulation (EC) No 1272/2008

Hazard pictograms



Signal word

Warning

Hazard statements

H226 Flammable liquid and vapour.

Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P243 Take action to prevent static discharges.
P280 Wear protective gloves/protective clothing/eye protection/face protection.

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P303+P361+P353

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P403+P233

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

P501.3

Disposal in compliance with local and national regulations.

Reduced labeling (<= 125 ml)**Hazard pictograms****Signal word**

Warning

2.3. Other hazards

The product contains no PBT substances. The product contains no vPvB substances. This product does not contain a substance that has endocrine disrupting properties with respect to human. The product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms.

SECTION 3: Composition/information on ingredients**3.2. Mixtures****Chemical characterization**

Alcoholic solution

Extract of herbal drugs

Medicinal products

Further ingredients**ethanol**

CAS No. 64-17-5

EINECS no. 200-578-6

Registration no. 01-2119457610-43-0098

Concentration >= 25 < 50 %

Advice: [3]

Classification (Regulation (EC) No. 1272/2008)

Flam. Liq. 2

H225

Note

[3] Substance with occupational exposure limits

Other information

The product is an article within the meaning of Article 3 No. 3 of the REACH Regulation and thus not to be labelled according to the CLP regulation. The compilation of the Safety Data sheet is not required according to Article 31 REACH Regulation for articles and is done on a voluntary basis.

SECTION 4: First aid measures**4.1. Description of first aid measures****General information**

If you feel unwell, seek medical advice (show the label where possible). Take off contaminated clothing and shoes immediately.

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After inhalation

Ensure supply of fresh air. In the event of symptoms take medical treatment. Irregular breathing/no breathing: artificial respiration.

After skin contact

Wash immediately with plenty of water for several minutes. Consult a doctor if skin irritation persists.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). In case of irritation consult an oculist.

After ingestion

Consult a physician if necessary. Rinse out mouth and give plenty of water to drink.

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**

Water spray jet, Carbon dioxide, Alcohol-resistant foam, Dry powder, Extinguishing measures to suit surroundings

Non suitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

In the event of a fire, toxic and combustible gases can be formed. In the event of fire the following can be released: Carbon monoxide (CO); Carbon dioxide (CO₂)

5.3. Advice for firefighters**Special protective equipment for fire-fighting**

Wear full protective suit. Use self-contained breathing apparatus.

Other information

Cool endangered containers with water spray jet.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Ensure adequate ventilation. Remove persons to safety. Keep away sources of ignition.

6.2. Environmental precautions

Do not discharge into the drains/surface waters/groundwater.

6.3. Methods and material for containment and cleaning up

Take up with absorbent material (eg sand, kieselguhr, universal binder). Send in suitable containers for recovery or disposal. Clean up affected area.

SECTION 7: Handling and storage**7.1. Precautions for safe handling****Advice on safe handling**

Keep away from heat and sources of ignition. Take action to prevent static discharges.

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and vessels**

Keep tightly closed in a dry and cool place. Storage rooms must be properly ventilated.

Storage classes

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Storage class according to TRGS 510	3	Flammable liquid
Storage category (Switzerland)	3	Flammable liquid

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limit values

ethanol

List	SUVA			
Type	MAK			
Value	960	mg/m ³	500	ppm(V)
Short term exposure limit	1920	mg/m ³	1000	ppm(V)
Pregnancy group: S Remarks: SSs; Formal; INRS NIOSH				

Derived No/Minimal Effect Levels (DNEL/DMEL)

ethanol

Type of value	Derived No Effect Level (DNEL)			
Reference group	Worker			
Duration of exposure	Long term			
Route of exposure	dermal			
Mode of action	Systemic effects			
Concentration	343			mg/kg/d

Type of value	Derived No Effect Level (DNEL)			
Reference group	Worker			
Duration of exposure	Long term			
Route of exposure	inhalative			
Mode of action	Systemic effects			
Concentration	950			mg/m ³

Predicted No Effect Concentration (PNEC)

ethanol

Type of value	PNEC			
Type	Freshwater			
Conditions	Long term			
Concentration	0.96			mg/l

Type of value	PNEC			
Type	Saltwater			
Concentration	0.79			mg/l

Type of value	PNEC			
Type	Freshwater sediment			
Concentration	3.6			mg/kg

Type of value	PNEC			
Type	Marine sediment			
Concentration	2.9			mg/kg

Type of value	PNEC			
Type	Freshwater			
Conditions	Intermittend			
Concentration	2.75			mg/l

Type of value	PNEC			
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Type	Sewage treatment plant (STP)	
Concentration	580	mg/l

8.2. Exposure controls**General protective and hygiene measures**

Avoid any contact with the body. Observe the usual precautions for handling chemicals. Keep away from food-stuffs, beverages and feed-stocks.

Respiratory protection

necessary; Do not breathe vapours, dust or aerosol. Provide adequate ventilation.

Hand protection

Appropriate Material Gloves / resistant to chemicals

Eye protection

Tightly fitting safety glasses

Body protection

Fire-resistant protective clothing

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state liquid

Colour colourless

Odour Alcohol

Boiling point or initial boiling point and boiling range

Value > 78 °C

Source GESTIS-Stoffdatenbank

Flash point

Value > 24 °C

Source GESTIS-Stoffdatenbank

Vapour pressure

Value < 5.8 kPa

Source GESTIS-Stoffdatenbank

Density and/or relative density

Value 0.916 to 0.927 g/ml

Remarks Relative Density according specification

SECTION 10: Stability and reactivity**10.1. Reactivity**

Risk of ignition or formation of inflammable gases or vapours with: Air

10.2. Chemical stability

No decomposition if stored and applied as directed.

10.3. Possibility of hazardous reactions

Keep away from sources of heat and ignition. No decomposition if stored and applied as directed.

10.4. Conditions to avoid

Heat

10.5. Incompatible materials

Alkaline metals, Ammonia, peroxides, Oxidising agents

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10.6. Hazardous decomposition products

Hazardous determin decomposition products: Carbon monoxide, Carbon dioxide, Flammable gases/vapours

SECTION 11: Toxicological information

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

Acute oral toxicity

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

Acute oral toxicity (Components)

ethanol

Species	rat		
LD50		7060	mg/kg
Source	Toxicology and Applied Pharmacology. Vol. 16, Pg. 718, 1970.		

ethanol

Species	rat		
LD50		10470	mg/kg

Acute dermal toxicity

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

Acute dermal toxicity (Components)

ethanol

Species	rabbit		
LD50		15800	mg/kg

ethanol

NOAEL		8232	mg/kg
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Acute inhalational toxicity

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

Acute inhalative toxicity (Components)

ethanol

Species	rat		
LC50		30000	mg/m ³
Duration of exposure		4	h
Administration/Form	Vapors		

Skin corrosion/irritation

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

Skin corrosion/irritation (Components)

ethanol

evaluation	non-irritant
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Serious eye damage/irritation

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

Serious eye damage/irritation (Components)

ethanol

evaluation	irritant
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Sensitization

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

Sensitization (Components)

ethanol

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evaluation non-sensitizing

Mutagenicity

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

Mutagenicity (Components)**ethanol**

evaluation No mutagenicity in the Ames-test.

Reproductive toxicity

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

Carcinogenicity

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

Specific Target Organ Toxicity (STOT)**Single exposure**

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

Repeated exposure

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

Aspiration hazard

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

11.2. Information on other hazards**Endocrine disrupting properties with respect to humans**

The product does not contain a substance that has endocrine disrupting properties with respect to humans.

Experience in practice

The solvent vapours cause an irritating effect to the respiratory organs. Causes disorders of the central nervous system and can cause headache, respiratory difficulties or unconsciousness. Causes a numb feeling. Liver damage is possible.

Other information

When handled appropriately, even after long years of experience with this product, no adverse health effects are known.

Product specific toxicological data are not known.

SECTION 12: Ecological information**12.1. Toxicity****Fish toxicity (Components)****ethanol**

Species	golden orfe (Leuciscus idus)		
LC50	8140		mg/l
Duration of exposure	96	h	

Daphnia toxicity (Components)**ethanol**

Species	Daphnia magna		
EC50	9000	to	14000 mg/l
Duration of exposure	48	h	

12.2. Persistence and degradability**Biodegradability (Components)****ethanol**

Value	94	%
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evaluation Readily biodegradable

Chemical oxygen demand (COD) (Components)

ethanol

Value 0.93 to 1.67 mg/g

12.3. Bioaccumulative potential**Octanol/water partition coefficient (log Pow) (Components)**

ethanol

log Pow -0.31

Bioconcentration factor (BCF) (Components)

ethanol

BCF 0.66

12.5. Results of PBT and vPvB assessment**Results of PBT and vPvB assessment**

The product contains no PBT substances

The product contains no vPvB substances.

Results of PBT and vPvB assessment (Ingredients)

ethanol

The Substance doesn't meets PBT/vPvB-criteria

12.6 Endocrine disrupting properties**Endocrine disrupting properties with respect to the environment**

The product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms.

12.7. Other adverse effects**General information / ecology**

Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system. For this subsection there is no ecotoxicological data available on the product as such.

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Disposal recommendations for the product**

Disposal in compliance with local and national regulations.

Disposal recommendations for packaging

Dispose of as unused product.

SECTION 14: Transport information

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	Land transport ADR/RID	Marine transport IMDG/GGVSee	Air transport ICAO/IATA
14.1. UN number or ID number	1170	1170	1170
14.2. UN proper shipping name	ETHANOL SOLUTION	ETHANOL SOLUTION	ETHANOL SOLUTION
14.3. Transport hazard class(es)	3	3	3
Label			
14.4. Packing group	III	III	III
Limited Quantity	5 l	5 l	
Transport category	3		
14.5. Environmental hazards	-		
Tunnel restriction code	D/E		

SECTION 15: Regulatory information

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

Water Hazard Class (Germany)

Water Hazard Class (Germany) WGK 1

Remarks Derivation of WGK according to Annex 1 No. 5.2 AwSV

Other information

The product does not contain substances according to Candidate List for inclusion in Annex XIV of Regulation (EC) No. 1907/2006 (REACH) with a content of $\geq 0.1\%$ w/w.

SECTION 16: Other information

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Classification (Regulation (EC) No. 1272/2008)

Flam. Liq. 3

H226

On basis of test data

Hazard statements listed in Chapter 2/3

H226

Flammable liquid and vapour.

CLP categories listed in Chapter 2/3

Flam. Liq. 3

Flammable liquid, Category 3

Supplemental information

Relevant changes compared with the previous version of the safety data sheet are marked with: ***
This information is based on our present state of knowledge. However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.

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