

Trade name: Ammonii anisatus spirit

Substance number: 146501

Version: 3 / CH

Date revised: 23.08.2023

Replaces Version: 2 / CH

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

### **1.1. Product identifier**

Ammonii anisatus spirit

Item No. 14650100

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

#### **Use of the substance/preparation**

Manufacture of pharmaceutical products

### **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. 2 H225

Skin Irrit. 2 H315

Eye Irrit. 2 H319

Skin Sens. 1B H317

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 \*\*\***

Danger

#### **Hazard statements \*\*\***

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

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**Precautionary statements \*\*\***

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P501.3	Disposal in compliance with local and national regulations.

**Hazardous component(s) to be indicated on label (Regulation (EC) No. 1272/2008)**

contains \*\*\* (E)-anethole; 4-Allylanisol

**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

**Hazardous ingredients \*\*\*****(E)-anethole**

CAS No.	4180-23-8
EINECS no.	224-052-0
Registration no.	01-2119979097-22-XXXX
Concentration	>= 1 < 10 %
Classification (Regulation (EC) No. 1272/2008)	Skin Sens. 1B H317

**ammonia ....%**

CAS No.	1336-21-6
EINECS no.	215-647-6
Registration no.	01-2119488876-14-XXXX
Concentration	>= 1 < 2.5 %
Classification (Regulation (EC) No. 1272/2008)	Skin Corr. 1B H314 Eye Dam. 1 H318 STOT SE 3 H335 Aquatic Acute 1 H400 Aquatic Chronic 2 H411

Concentration limits (Regulation (EC) No. 1272/2008)

STOT SE 3	H335	>= 5
Aquatic Acute 1	H400	M = 10

ATE oral 350 mg/kg

Additional remarks:

CLP Regulation (EC) No 1272/2008, Annex VI, Note B

**4-Allylanisol**

CAS No.	140-67-0
EINECS no.	205-427-8
Concentration	>= 0.1 < 1 %

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

Acute Tox. 4	H302
Skin Irrit. 2	H315
Skin Sens. 1	H317
Eye Irrit. 2	H319
Aquatic Chronic 3	H412

**Further ingredients \*\*\*****ethanol**

CAS No.	64-17-5			
EINECS no.	200-578-6			
Concentration		>=	50	%
Advice: [4]				
Classification (Regulation (EC) No. 1272/2008)				
	Flam. Liq. 2			H225

**water**

CAS No.	7732-18-5					
EINECS no.	231-791-2					
Concentration		>=	10	<	25	%
Advice: [4]						

**3,7-Dimethyl-1,6-octadien-3-ol**

CAS No.	78-70-6			
EINECS no.	201-134-4			
Concentration		<	1	%
Advice: [4]				
Classification (Regulation (EC) No. 1272/2008)				
	Skin Irrit. 2			H315
	Eye Irrit. 2			H319
	Skin Sens. 1B			H317

**dipentene**

CAS No.	138-86-3			
EINECS no.	205-341-0			
Concentration		<	1	%
Advice: [4]				
Classification (Regulation (EC) No. 1272/2008)				
	Flam. Liq. 3			H226
	Skin Irrit. 2			H315
	Skin Sens. 1			H317
	Aquatic Acute 1			H400
	Aquatic Chronic 1			H410

## Additional remarks:

CLP Regulation (EC) No 1272/2008, Annex VI, Note C

**1,8-Cineole**

CAS No.	470-82-6			
EINECS no.	207-431-5			
Concentration		<	1	%
Advice: [4]				
Classification (Regulation (EC) No. 1272/2008)				
	Flam. Liq. 3			H226
	Skin Sens. 1B			H317

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**3-Carene, not specified**

CAS No. 13466-78-9

EINECS no. 236-719-3

Concentration &lt; 1 %

Advice: [4]

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

Flam. Liq. 3 H226

Acute Tox. 4 H332

Asp. Tox. 1 H304

Skin Irrit. 2 H315

Skin Sens. 1 H317

Aquatic Chronic 2 H411

**(1S)-alpha-Pinene**

CAS No. 7785-26-4

EINECS no. 232-077-3

Concentration &lt; 1 %

Advice: [4]

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

Flam. Liq. 3 H226

Asp. Tox. 1 H304

Skin Irrit. 2 H315

Skin Sens. 1 H317

Aquatic Acute 1 H400

Aquatic Chronic 1 H410

**p-mentha-1,4(8)-diene**

CAS No. 586-62-9

EINECS no. 209-578-0

Concentration &lt; 1 %

[4]

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

Asp. Tox. 1

Flam. Liq. 3

Aquatic Chronic 2

**Note**

[4] Voluntary information

**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.

**After inhalation**

Ensure supply of fresh air. Take medical treatment.

**After skin contact**

After contact with skin, wash immediately with plenty of water. Remove contaminated, soaked clothing immediately and dispose of safely. Consult a doctor if skin irritation persists.

**After eye contact**

Separate eyelids, wash the eyes thoroughly with water (15 min.). Summon a doctor immediately.

**After ingestion**

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Never give anything by mouth to an unconscious person. Drink water in small gulps. Do not induce vomiting - aspiration hazard. Summon a doctor immediately.

## **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 (CO<sub>2</sub>)

### **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**

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

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

**Derived No/Minimal Effect Levels (DNEL/DMEL)****ethanol**

Type of value	Derived No Effect Level (DNEL)			
Reference group	Worker			
Route of exposure	inhalative			
Mode of action	Local effects			
Concentration	1900			mg/m <sup>3</sup>
Type of value	Derived No Effect Level (DNEL)			
Reference group	Worker			
Duration of exposure	Long term			
Route of exposure	oral			
Mode of action	Systemic effects			
Concentration	434			mg/kg/d

**ammonia ....%**

Type of value	Derived No Effect Level (DNEL)			
Reference group	Worker			
Duration of exposure	Acute			
Route of exposure	dermal			
Mode of action	Systemic effects			
Concentration	6.8			mg/kg
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	6.8			mg/kg
Type of value	Derived No Effect Level (DNEL)			
Reference group	Worker			
Duration of exposure	Acute			
Route of exposure	inhalative			
Mode of action	Systemic effects			
Concentration	47.6			mg/m <sup>3</sup>
Type of value	Derived No Effect Level (DNEL)			
Reference group	Worker			
Duration of exposure	Acute			
Route of exposure	inhalative			
Mode of action	Local effects			
Concentration	36			mg/m <sup>3</sup>
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	47.6			mg/m <sup>3</sup>
Type of value	Derived No Effect Level (DNEL)			

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Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Local effects	
Concentration	14	mg/m <sup>3</sup>
Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Duration of exposure	Acute	
Route of exposure	dermal	
Mode of action	Systemic effects	
Concentration	68	mg/kg
Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Duration of exposure	Long term	
Route of exposure	dermal	
Mode of action	Systemic effects	
Concentration	68	mg/kg
Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Duration of exposure	Acute	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	23.8	mg/m <sup>3</sup>
Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Duration of exposure	Acute	
Route of exposure	inhalative	
Mode of action	Local effects	
Concentration	7.2	mg/m <sup>3</sup>
Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	23.8	mg/m <sup>3</sup>
Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Local effects	
Concentration	2.8	mg/m <sup>3</sup>
Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Duration of exposure	Acute	
Route of exposure	oral	
Mode of action	Systemic effects	
Concentration	6.8	mg/kg
Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	

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Duration of exposure	Long term	
Route of exposure	oral	
Mode of action	Systemic effects	
Concentration	6.8	mg/kg

**Predicted No Effect Concentration (PNEC)****ammonia ....%**

Type of value	PNEC	
Type	Freshwater	
Concentration	0.0011	mg/l
Type of value	PNEC	
Type	Saltwater	
Concentration	0.00011	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. Hold eye wash fountain available. Hold emergency shower available. Wash thoroughly after work. Take off immediately all contaminated clothing.

**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**

<b>Physical state</b>	liquid, clear
<b>Colour</b>	colourless to slightly yellow
<b>Odour</b>	of ammonia
<b>Boiling point or initial boiling point and boiling range</b>	
Value	>= 78 °C
Source	Estimated value
<b>Flash point</b>	
Value	13 to 22 °C
Source	Estimated value
<b>Vapour pressure</b>	
Value	<= 5.8
Source	Estimated value
<b>Density and/or relative density</b>	
Value	0.864 to 0.868
Remarks	Relative Density according specification

**SECTION 10: Stability and reactivity**



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**10.1. Reactivity**

Formation of explosive gas/air mixtures.

**10.2. Chemical stability**

No decomposition if stored and applied as directed.

**10.3. Possibility of hazardous reactions**

Possible incompatibility with materials listed under section 10.5.

**10.4. Conditions to avoid**

Heat

**10.5. Incompatible materials**

Alkaline metals, Ammonia, peroxides, Oxidising agents

**10.6. Hazardous decomposition products**

In the event of fire the following can be released: Carbon monoxide, Carbon dioxide, Hazardous decomposition products: Flammable gases/vapours

**SECTION 11: Toxicological information****11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute oral toxicity**

ATE	>	10'000	mg/kg
Method	calculated value (Regulation (EC) No. 1272/2008)		

**Acute oral toxicity (Components)****1,8-Cineole**

Species	rat		
LD50		2840	mg/kg
Source	RTECS		

**4-Allylanisol**

LD50		1230	mg/kg
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**ethanol**

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

**ethanol**

Species	rat		
LD50		10470	mg/kg

**ammonia ....%**

Species	rat		
LD50		350	mg/kg
Source	GESTIS-Stoffdatenbank		

**Acute dermal toxicity (Components)****ethanol**

Species	rabbit		
LD50		15800	mg/kg

**ammonia ....%**

Remarks	No data available.		
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**Acute inhalative toxicity (Components)****ethanol**

Species	rat		
LC50		30000	mg/m <sup>3</sup>

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Duration of exposure 4 h  
Administration/Form Vapors

**ammonia ....%**

Remarks No data available.

**Skin corrosion/irritation (Components)****ethanol**

evaluation non-irritant

**ammonia ....%**

Species rabbit  
evaluation corrosive  
Method OECD 404

**Serious eye damage/irritation**

Remarks Eye contact with the product may lead to irritation.

**Serious eye damage/irritation (Components)****ethanol**

evaluation irritant

**ammonia ....%**

Species rabbit  
evaluation irritant - risk of serious damage to eyes

**Sensitization (Components)****ammonia ....%**

Species guinea pig  
evaluation non-sensitizing

**Subacute, subchronic, chronic toxicity (Components)****ammonia ....%**

Remarks No data available.

**Mutagenicity (Components)****ethanol**

evaluation No mutagenicity in the Ames-test.

**ammonia ....%**

evaluation No experimental indications on genotoxicity in vivo found.

**ammonia ....%**

evaluation No experimental information on genotoxicity in vitro available.  
Method Ames test

**Reproduction toxicity (Components)****ammonia ....%**

Remarks Indications of toxic effects are available from reproduction studies in animals.

**Carcinogenicity (Components)****ammonia ....%**

Remarks No evidence available on carcinogenicity.

**Specific Target Organ Toxicity (STOT) (Components)****ammonia ....%**

Remarks No data available

**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

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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)****1,8-Cineole**

Species	Fathead minnow ( <i>Pimephales promelas</i> )		
LC50	102		mg/l
Duration of exposure	96	h	

**ammonia ....%**

Species	rainbow trout ( <i>Oncorhynchus mykiss</i> )		
LC50	0.89		mg/l
Duration of exposure	96	h	

**Daphnia toxicity (Components)****ammonia ....%**

Species	Daphnia magna		
LC50	101		mg/l
Duration of exposure	48	h	

**Algae toxicity (Components)****ammonia ....%**

Species	Chlorella vulgaris		
EC50	2700		mg/l
Duration of exposure	18	d	

**Bacteria toxicity (Components)****ammonia ....%**

Remarks	No data available.		
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**12.2. Persistence and degradability****Biodegradability (Components)****ethanol**

evaluation	Readily biodegradable		
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**ammonia ....%**

evaluation	Readily biodegradable		
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**Ready degradability (Components)****ammonia ....%****Chemical oxygen demand (COD) (Components)****ethanol**

Value	0.93	to	1.67	mg/g
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**12.3. Bioaccumulative potential**

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**General information**

For this subsection there is no ecotoxicological data available on the product as such.

**Bioconcentration factor (BCF) (Components)****ethanol**

BCF

0.66

**12.4. Mobility in soil****General information**

For this subsection there is no ecotoxicological data available on the product as such.

**Mobility in soil (Components)****ammonia ....%**

Adsorbs on soil.

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

For this subsection there is no ecotoxicological data available on the product as such.

**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**

For this subsection there is no ecotoxicological data available on the product as such.

**General information / ecology**

Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

**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 ***
Tunnel restriction code	D/E		
14.1. UN number	1993	1993	1993
14.2. UN proper shipping name	FLAMMABLE LIQUID, N.O.S. (ethanol)	FLAMMABLE LIQUID, N.O.S. (ethanol)	FLAMMABLE LIQUID, N.O.S. (ethanol)
14.3. Transport hazard class(es)	3	3	3
Label			
14.4. Packing group	II	II	II
Special provision	640D		
Limited Quantity	1 I		
Transport category	2		

## 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 2

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

## SECTION 16: Other information

### Hazard statements listed in Chapter 3

H225	Highly flammable liquid and vapour.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

### CLP categories listed in Chapter 3

Acute Tox. 4	Acute toxicity, Category 4
Aquatic Acute 1	Hazardous to the aquatic environment, acute, Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment, chronic, Category 2

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Aquatic Chronic 3	Hazardous to the aquatic environment, chronic, Category 3
Eye Dam. 1	Serious eye damage, Category 1
Eye Irrit. 2	Eye irritation, Category 2
Flam. Liq. 2	Flammable liquid, Category 2
Skin Corr. 1B	Skin corrosion, Category 1B
Skin Irrit. 2	Skin irritation, Category 2
Skin Sens. 1	Skin sensitization, Category 1
Skin Sens. 1B	Skin sensitization, Category 1B
STOT SE 3	Specific target organ toxicity - single exposure, 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.