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

1.1. Product identifier

Hyoscyami oleum / Permamed AG
Item No. 33673000

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

Use of the substance/preparation

Active pharmacutical substance

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 person responsible for this SDS sdb@haenseler.ch

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)
Aquatic Chronic 3 H412

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 statements

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P273 Avoid release to the environment.
P501.3 Disposal in compliance with local and national regulations.

Reduced labeling (<= 125 ml)

Hazard statements

H412 Harmful to aquatic life with long lasting effects.

2.3. Other hazards

The Substance does not meet PBT-criteria. This substance does not meet the vPvB-criteria. This substance does not have endocrine disrupting properties with respect to humans. This substance does not have endocrine disrupting properties with respect to non-target organisms.

SECTION 3: Composition/information on ingredients

Chemical characterization

Medicinal products

Hazardous ingredients

copper, particle size <0.063 mm

CAS No.	7440-50-8				
EINECS no.	231-159-6				
Registration no.	EXCEMPT				
Concentration	>=	0.25	<	1	%

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

Flam. Sol. 1	H228
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

Further ingredients

Arachis hypogaea oil

CAS No.	8002-03-7			
EINECS no.	232-296-4			
Concentration		>=	95	%

Advice: [4]

hyoscyamine

CAS No.	101-31-5			
EINECS no.	202-933-0			
Concentration		<	1	%

Advice: [4]

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

Acute Tox. 2	H300
Acute Tox. 2	H330

hyoscine

CAS No.	51-34-3			
EINECS no.	200-090-3			
Concentration		<	1	%

Advice: [4]

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

Acute Tox. 1	H310
Acute Tox. 2	H300
Acute Tox. 2	H330

water

CAS No.	7732-18-5			
EINECS no.	231-791-2			
Concentration		<	1	%

Advice: [4]

ethanol

CAS No.	64-17-5			
EINECS no.	200-578-6			
Registration no.	01-2119457610-43-0098			
Concentration		<	1	%

Advice: [4]

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

Flam. Liq. 2	H225

ammonia

CAS No.	1336-21-6
EINECS no.	215-647-6
Registration no.	01-2119488876-14-XXXX
Concentration	< 1 %

Advice: [4]

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

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

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. Seek medical advice immediately.

After skin contact

After contact with skin, wash immediately with plenty of water. Consult a doctor if skin irritation persists.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). By continuous complaints consult a physician.

After ingestion

Rinse out mouth and give plenty of water to drink. Summon a doctor immediately.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Sand

Non suitable extinguishing media

Water

5.2. Special hazards arising from the substance or mixture

In case of combustion evolution of dangerous gases possible. The product is combustible.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. Use personal protective clothing.

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). Clean up affected area. Send in suitable containers for recovery or disposal.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

No special requirements.

7.2. Conditions for safe storage, including any incompatibilities

Recommended storage temperature

Value	15	25	°C

Storage classes

Storage class according to TRGS 510	10	Flammable liquids
Storage category (Switzerland)	10/12	Other liquid hazardous substances

Further information on storage conditions

Protect from light. Keep container tightly closed and dry.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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/m³

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/m³

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/m³

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/m³

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Local effects	
Concentration	14	mg/m³

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/m³

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/m³

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/m³

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/m³

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

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

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

General industrial hygiene practice. Avoid any contact with the body.

Respiratory protection

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

Hand protection

The glove material must be sufficient impermeable and resistant to the substance. Check the tightness before wear. Gloves should be well cleaned before being removed, then stored in a well ventilated location.

Eye protection

Tightly fitting safety glasses

Body protection

Light protective clothing

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	liquid, clear
Colour	green
Odour	peculiar

Boiling point or initial boiling point and boiling range

Remarks	Not applicable

Flash point

Remarks	Not applicable

Vapour pressure

Remarks	Not applicable

Density and/or relative density

Value	0.912	to	0.920	g/ml
Remarks	Relative Density according specification			

9.2. Other information

Solubility in water

Remarks	insoluble

SECTION 10: Stability and reactivity

10.1. Reactivity

No decomposition if stored and applied as directed.

10.2. Chemical stability

No decomposition if stored and applied as directed.

10.3. Possibility of hazardous reactions

No decomposition if stored and applied as directed.

10.4. Conditions to avoid

Protect from heat/overheating.

10.5. Incompatible materials

Oxidising agents

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

ammonia

Species	rat	
LD50	350	mg/kg
Source	GESTIS-Stoffdatenbank	

ammonia

Species	Human	
LDLo	43	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

ammonia

Remarks	No data available.

Acute inhalational toxicity

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

Acute inhalative toxicity (Components)

ethanol

Species	rat	
LC50	30000	mg/m³

Duration of exposure	4	h
Administration/Form	Vapors	

ammonia

Remarks	No data available.

Skin corrosion/irritation

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

Skin corrosion/irritation (Components)

ethanol

evaluation	non-irritant

ammonia

Species	rabbit
evaluation	strongly irritant
Method	OECD 404

Serious eye damage/irritation

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

Serious eye damage/irritation (Components)

ethanol

evaluation	irritant

ammonia

Species	rabbit
evaluation	strongly irritant
Remarks	Influence of the product with the eyes can lead to blindness.

Sensitization

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

Sensitization (Components)

ethanol

evaluation	non-sensitizing

ammonia

Species	guinea pig
evaluation	non-sensitizing

Subacute, subchronic, chronic toxicity (Components)

ammonia

Route of exposure	inhalative		
Species	rat		
NOAEL	0.035		mg/l
Duration of exposure	50	Days	

Mutagenicity

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

Mutagenicity (Components)

ethanol

evaluation	No mutagenicity in the Ames-test.

ammonia

Species	mouse
evaluation	No experimental indications on genotoxicity in vivo found.
Method	OECD 474

ammonia

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

Reproductive toxicity

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

Reproduction toxicity (Components)

ammonia

Route of exposure	oral		
Species	rat		
Dose		408	mg/kg
evaluation	No negative effects		
Method	OECD 422		

Carcinogenicity

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

Carcinogenicity (Components)

ammonia

Route of exposure	oral		
Species	rat		
Dose		67	mg/kg
Duration of exposure		104	Weeks
Method	OECD 453		
Remarks	negative		

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.

Specific Target Organ Toxicity (STOT) (Components)

ammonia

Single exposure

evaluation May cause respiratory irritation.
Route of exposure inhalative

ammonia

Repeated exposure

Source Nicht eingestuft, basierend auf der Berechnungsmethode der CLP Verordnung.

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

This substance does not have endocrine disrupting properties with respect to humans.

Other information

No toxicological data are available.

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		

ammonia

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

ammonia

Species	rainbow trout (Oncorhynchus mykiss)			
LOEC	0.022			mg/l
Duration of exposure	73	d		
Method	Flow test; FIFRA Guideline 72-1			

ammonia

Species	Ictalurus punctatus			
NOEC	0.06			mg/l
Duration of exposure	27	d		
Method	Flow test; FIFRA Guideline 72-1			

ammonia

Species	Fathead minnow (Pimephales promelas)			
LC50	0.068			mg/l
Duration of exposure	96	h		
Method	Flow test; FIFRA Guideline 72-1			

ammonia

Species	Ictalurus punctatus			
NOEC	0.048			mg/l
Duration of exposure	31	d		
Method	OECD 215			

copper, particle size <0.063 mm

Species	Fathead minnow (Pimephales promelas)			
LC50	0.0094			mg/l
Duration of exposure	96	h		
Source	ECOTOX Database			

Daphnia toxicity (Components)

ethanol

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

ammonia

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

ammonia

Species	Daphnia magna			
NOEC	0.79			mg/l
Duration of exposure	96	h		

ammonia

Species	Daphnia magna			
NOEC	0.42			mg/l
Duration of exposure	21	d		

ammonia

Species	Daphnia magna			
LC50	4.07			mg/l
Duration of exposure	96	h		
Method	US-EPA			

ammonia

Species	Daphnia magna		
NOEC	0.79		mg/l
Duration of exposure	96	h	
Method	US-EPA		

copper, particle size <0.063 mm

Species	Ceriodaphnia dubia		
EC50	0.0016		mg/l
Duration of exposure	48	h	
Source	ECOTOX Database		

Algae toxicity (Components)

ammonia

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

Bacteria toxicity (Components)

ammonia

Remarks: No data available.

12.2. Persistence and degradability

Biodegradability (Components)

ethanol

Value	94	%
evaluation	Readily biodegradable	

ammonia

evaluation: Readily biodegradable

copper, particle size <0.063 mm

Remarks: Inorganic product, cannot be eliminated from the water by biological purification processes.

Ready degradability (Components)

ammonia

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

12.4. Mobility in soil

Mobility in soil (Components)

ammonia

Adsorbs on soil.

12.5. Results of PBT and vPvB assessment

General information

not determined

Results of PBT and vPvB assessment

The Substance does not meet PBT-criteria.
This substance does not meet the vPvB-criteria.

12.6 Endocrine disrupting properties

Endocrine disrupting properties with respect to the envrionment

This substance does not have endocrine disrupting properties with respect to non-target organisms.

12.7. Other adverse effects

General information / ecology

Ecological injuries are not known or expected under normal use.

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

	Land transport ADR/RID	Marine transport IMDG/GGVSee	Air transport ICAO/IATA
14.1. UN number or ID number	The product does not constitute a hazardous substance in land transport.	The product does not constitute a hazardous substance in sea transport.	The product does not constitute a hazardous substance in air transport.

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 >= 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)

Aquatic Chronic 3	H412	Calculation method

Hazard statements listed in Chapter 2/3

H228	Flammable solid.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

H412	Harmful to aquatic life with long lasting effects.

CLP categories listed in Chapter 2/3

Aquatic Acute 1	Hazardous to the aquatic environment, acute, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment, chronic, Category 1
Aquatic Chronic 3	Hazardous to the aquatic environment, chronic, Category 3
Flam. Sol. 1	Flammable solid, Category 1

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.