

Trade name: Polygalae extr liquidum 1/1

Substance number: 127921

Version: 3 / CH

Date revised: 08.08.2023

Replaces Version: 2 / CH

Print date: 08.08.23

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

1.1. Product identifier

Polygalae extr liquidum 1/1

Item No. 12792100

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

Use of the substance/preparation

Active pharmaceutical 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 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.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin

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P403+P233 with water [or shower].
 P501.3 Store in a well-ventilated place. Keep container tightly closed.
 Disposal in compliance with local and national regulations.

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

water

CAS No.	7732-18-5				
EINECS no.	231-791-2				
Concentration		>=	50		%
Advice: [4]					

ethanol

CAS No.	64-17-5				
EINECS no.	200-578-6				
Concentration		>=	25	<	50 %
Advice: [4]					
Classification (Regulation (EC) No. 1272/2008)					
	Flam. Liq. 2			H225	

Note

[4] Voluntary information

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.

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.

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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

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

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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: 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 ³

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

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	brown	
Odour	weak	
Odour	characteristic	
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

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Value	0.980	to	1.050	g/ml
Remarks	Relative Density according specification			

9.2. Other information**Solubility in water**

Remarks	soluble
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Efflux time

Value	11	s
Method	DIN EN ISO 2431 - 4 mm	

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

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 (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 (Components)**ethanol**

Species	rabbit	
LD50	15800	mg/kg

Acute inhalative toxicity (Components)**ethanol**

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

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

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evaluation non-irritant

Serious eye damage/irritation

Remarks Eye contact with the product may lead to irritation.

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

evaluation irritant

Mutagenicity (Components)**ethanol**

evaluation No mutagenicity in the Ames-test.

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

evaluation Readily biodegradable

Chemical oxygen demand (COD) (Components)**ethanol**

Value 0.93 to 1.67 mg/g

12.3. Bioaccumulative potential**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.

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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 ***

	Land transport ADR/RID ***	Marine transport IMDG/GGVSee ***	Air transport ICAO/IATA ***
Tunnel restriction code	D/E		
14.1. UN number	1293	1293	1293
14.2. UN proper shipping name	TINCTURES, MEDICINAL	TINCTURES, MEDICINAL	TINCTURES, MEDICINAL
14.3. Transport hazard class(es)	3	3	3
Label			
14.4. Packing group	III	III	III
Limited Quantity	5 l		
Transport category	3		

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

SECTION 16: Other information**Hazard statements listed in Chapter 3**

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CLP categories listed in Chapter 3

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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.