

Trade name: Polygalae extr p sir 1/10

Substance number: 126400 Version: 2 / CH Date revised: 17.12.2018

Replaces Version: 1 / CH Print date: 01.10.19

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

1.1. Product identifier

Polygalae extr p sir 1/10

Item No. 12640000

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. E-mail address of 0041 (0)71 353 58 58 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. Lig. 3 H226

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.

P233 Keep container tightly closed.

P243 Take action to prevent static discharges.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P370+P378.1 In case of fire: Use water sprayjet, carbon dioxide, alcohol-resistant foam or dry

powder for extinction.



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P403+P235 Store in a well-ventilated place. Keep cool.

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

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.

After indestion

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



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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.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limit values

Ammonia, anhydrous

List SUVA Type MAK

Value 14 mg/m^3 20 ppm(V)Short term exposure limit 28 mg/m^3 40 ppm(V)

Pregnancy group: S; Status: 2017; Remarks: SSc; AugeKT HU & OAWKT HU; NIOSH, OSHA

Ethanol

List SUVA Type MAK

Value 960 mg/m³ 500 ppm(V)
Short term exposure limit 1920 mg/m³ 1000 ppm(V)
Pregnancy group: S; Status: 2017; Remarks: SSc; OAW, FormalKT HU; INRS, NIOSH

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



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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

Form liquid, clear Colour dark brown

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

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 toxicological effects

Acute oral toxicity (Components)

Ethanol

Species rat

LD50 7060 mg/kg

Source Toxicology and Applied Pharmacology. Vol. 16, Pg. 718, 1970.

Ethanol



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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/m³

Duration of exposure 4 h

Administration/Form Vapors

Skin corrosion/irritation (Components)

Ethanol

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.

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

12.5. Results of PBT and vPvB assessment

Evaluation of persistance and bioaccumulation potential

The product contains no PBT or vPvB substances.

Evaluation of persistance and bioaccumulation potential (Components)

Ethanol

The Substance doesn't meets PBT/vPvB-criterions

12.6. Other adverse effects

General information / ecology

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



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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
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	***	***	3
14.4. Packing group	III	III	III
Special provision	640E		
Limited Quantity	5 I		
Transport category	3		

SECTION 15: Regulatory information

SECTION 16: Other information

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.