Safety data sheet in accordance with regulation (EC) No 1907/2006

Trade name: Althaeae sirupus conservatus

Substance number: 143801

Version: 1 / CH

Replaces Version: - / CH

Date revised: 16.06.2022 Print date: 16.06.22

HANSELER

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

1.1. Product identifier

Althaeae sirupus conservatus Item No. 14380100

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 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

Voluntary product information following the Safety Data Sheet format This product is not classified hazardous in accordance with Regulation (EC) No 1272/2008.

2.2. Label elements

Labelling according to regulation (EC) No 1272/2008

The product does not require a hazard warning label in accordance with Regulation (EC) No 1272/2008.

2.3. Other hazards

No special hazards have to be mentioned.

SECTION 3: Composition/information on ingredients

Chemical characterization

Extract of herbal drugs

Further ingredients

| Sucrose CAS No. EINECS no. Concentration Advice: [4] | 57-50-1 200-334-9 | | >= | 50 | % |
|--|------------------------------|----|----|----|---|
| water CAS No. EINECS no. Concentration Advice: [4] | 7732-18-5 231-791-2 >= | 25 | < | 50 | % |

| Frade name: Althaeae sirup | | | | | | STIDSFIRM |
|---|--|--|--|-----------------------------------|--|------------------------------|
| naue name. Annaeae silup | us conservatus | | | | | |
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| | | Replace | es Versio | on: - / Cl | Н | Print date: 16.06.2 |
| | | | | | | |
| ALTHAEA OFFICINA | ALIS ROOT | | | | | |
| CAS No. EINECS no. | 73049-65-7 277-254-6 | | | | | |
| Concentration | | 1 | < | 10 | % | |
| Advice: [4] | ~= | | | 10 | 70 | |
| methyl 4-hydroxybe | nzoate | | | | | |
| CAS No. | 99-76-3 | | | | | |
| EINECS no. | 202-785-7 | | | | | |
| Registration no. | 01-211946326 | 4-40 | | | | |
| Concentration | | | < | 1 | % | |
| Advice: [4] Classification (Regu | ulation (EC) No. 12 | 72/2008) | | | | |
| | Aquatic Chroni | | H411 | | | |
| 4-hydroxybenzoic a | cid propyl ester | | | | | |
| CAS No. | 94-13-3 | | | | | |
| EINECS no. | 202-307-7 | | | | | |
| Registration no. | 01-211996946 | 2-29 | | | 0/ | |
| Concentration Advice: [4] | | | < | 1 | % | |
| | | | | | | |
| [4] Voluntary inform | ation | | | | | |
| ECTION 4: First ai | <u>d measures</u> | | | | | |
| SECTION 4: First ai | | S | | | | |
| | st aid measure | S | | | | |
| 4.1. Description of firs | st aid measure | | | | | |
| 4.1. Description of firs General information | st aid measure | | | | | |
| 4.1. Description of firs General information In case of persisten | st aid measure n t symptoms consu | lt doctor. | toms tak | e medic | al treatment. | |
| 4.1. Description of firs General information In case of persisten After inhalation | st aid measure n t symptoms consu | lt doctor. | toms tak | e medic | al treatment. | |
| 4.1. Description of firs General information In case of persisten After inhalation Ensure supply of free | St aid measure n t symptoms consu esh air. In the even | It doctor. t of symp | | | | irritation persists. |
| 4.1. Description of firs General information In case of persisten After inhalation Ensure supply of fre After skin contact | St aid measure n t symptoms consu esh air. In the even | It doctor. t of symp | | | | irritation persists. |
| 4.1. Description of firs General information In case of persisten After inhalation Ensure supply of fre After skin contact In case of contact w After eye contact | St aid measure n It symptoms consu esh air. In the even vith skin wash off w | It doctor. t of symp [:] rith warm | water. C | onsult a | doctor if skin | irritation persists. |
| 4.1. Description of firs General information In case of persisten After inhalation Ensure supply of fre After skin contact In case of contact w After eye contact | St aid measure n It symptoms consu esh air. In the even vith skin wash off w | It doctor. t of symp [:] rith warm | water. C | onsult a | doctor if skin | |
| 4.1. Description of firs General information In case of persisten After inhalation Ensure supply of fre After skin contact In case of contact w After eye contact Separate eyelids, w | at aid measures n t symptoms consu esh air. In the even vith skin wash off w vash the eyes thoro | It doctor. t of symp vith warm pughly with | water. C | onsult a | doctor if skin | |
| 4.1. Description of firs General information In case of persisten After inhalation Ensure supply of fre After skin contact In case of contact w After eye contact Separate eyelids, w After ingestion | at aid measures n t symptoms consu esh air. In the even vith skin wash off w vash the eyes thoro | It doctor. t of symp vith warm bughly with | water. C h water (hk. | onsult a (15 min.) | doctor if skin . In case of in | |
| 4.1. Description of firs General information In case of persisten After inhalation Ensure supply of fre After skin contact In case of contact w After eye contact Separate eyelids, w After ingestion Rinse out mouth an | st aid measures n t symptoms consu esh air. In the even vith skin wash off w vash the eyes thoro d give plenty of wa protective mea | It doctor. t of symp rith warm oughly with tter to drin sures wi | water. C h water (hk. | onsult a (15 min.) | doctor if skin . In case of in | |
| 4.1. Description of first General information In case of persisten After inhalation Ensure supply of free After skin contact In case of contact w After eye contact Separate eyelids, w After ingestion Rinse out mouth an Adhere to personal | st aid measures n t symptoms consu esh air. In the even vith skin wash off w vash the eyes thoro d give plenty of wa protective mea untion to self-protec ymptoms and e | It doctor. t of sympton with warm bughly with ter to drin sures wl ttion! | water. C h water (hk. h en giv | onsult a (15 min.) ing firs | doctor if skin . In case of in t aid | itation consult an oculist. |
| 4.1. Description of first General information In case of persisten After inhalation Ensure supply of free After skin contact In case of contact w After eye contact Separate eyelids, w After ingestion Rinse out mouth an Adhere to personal First aider: Pay atte | st aid measures n t symptoms consu esh air. In the even vith skin wash off w vash the eyes thoro d give plenty of wa protective mea ention to self-protect ymptoms and e poms known so far. | It doctor. t of sympton with warm bughly with ter to drin sures with ttion! effects, | water. C h water (hen giv both a | ing firs | doctor if skin . In case of in .t aid nd delayed | itation consult an oculist. |
| 4.1. Description of first General information In case of persisten After inhalation Ensure supply of free After skin contact In case of contact weight of the second second | st aid measures n t symptoms consu esh air. In the even vith skin wash off w vash the eyes thoro d give plenty of wa protective mea intion to self-protect ymptoms and e oms known so far. | It doctor. t of sympton with warm bughly with ter to drin sures with ttion! effects, | water. C h water (hen giv both a | ing firs | doctor if skin . In case of in .t aid nd delayed | itation consult an oculist. |
| 4.1. Description of first General information In case of persisten After inhalation Ensure supply of free After skin contact In case of contact we After eye contact Separate eyelids, we After ingestion Rinse out mouth an Adhere to personal First aider: Pay attended 4.2. Most important sy Until now no sympton 4.3. Indication of any ind | st aid measures n t symptoms consu esh air. In the even vith skin wash off w vash the eyes thoro d give plenty of wa protective mea ention to self-protect ymptoms and e coms known so far. immediate mea cian / hazards | It doctor. t of sympton with warm bughly with atter to drin sures with the to drin sures with the to drin sures with the to drin sures with the to drin sures with the to drin sures with the todrin sures wit | water. C h water (hen giv both a ention | ing firs cute an and s | doctor if skin In case of in It aid Ind delayed Pecial treat | ritation consult an oculist. |
| 4.1. Description of first General information In case of persisten After inhalation Ensure supply of free After skin contact In case of contact we After eye contact Separate eyelids, we After ingestion Rinse out mouth an Adhere to personal First aider: Pay attended 4.2. Most important sy Until now no sympton 4.3. Indication of any ind | st aid measures n t symptoms consu esh air. In the even vith skin wash off w vash the eyes thoro d give plenty of wa protective mea ention to self-protect ymptoms and e oms known so far. immediate mea cian / hazards owing with subseq | It doctor. t of sympton with warm bughly with atter to drin sures with the to drin sures with the to drin sures with the to drin sures with the to drin sures with the to drin sures with the todrin sures wit | water. C h water (hen giv both a ention | ing firs cute an and s | doctor if skin In case of in It aid Ind delayed Pecial treat | itation consult an oculist. |
| 4.1. Description of first General information In case of persisten After inhalation Ensure supply of free After skin contact In case of contact we After eye contact Separate eyelids, we After ingestion Rinse out mouth an Adhere to personal First aider: Pay attee 4.2. Most important sy Until now no sympto 4.3. Indication of any in Hints for the physic In the case of swalle | st aid measures n t symptoms consu esh air. In the even with skin wash off w vash the eyes thoro ad give plenty of wa protective mea ontion to self-protection ymptoms and e oms known so far. immediate mea cian / hazards owing with subseq a or asphyxiation. | It doctor. t of symp with warm wughly with ter to drin sures wl tion! effects, dical att uent vomi | water. C h water (hen giv both a ention | ing firs cute an and s | doctor if skin In case of in It aid Ind delayed Pecial treat | ritation consult an oculist. |

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5.1. Extinguishing media

Suitable extinguishing media

Product itself is non-combustible; adapt fire extinguishing measures to surrounding areas.

5.3. Advice for firefighters

Special protective equipment for fire-fighting

In case of combustion use a suitable breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures Wear protective equipment

6.2. Environmental precautions

Do not allow to enter drains or waterways.

6.3. Methods and material for containment and cleaning up Pick up with absorbent material. Clean contaminated floors and objects thoroughly, observing environmental regulations.

6.4. Reference to other sections

Information regarding Safe handling, see Section 7. Information regarding personal protective measures, see Section 8.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Observe the usual precautions for handling chemicals.

Advice on protection against fire and explosion

No special measures required.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Store product in closed containers.

Hints on storage assembly

Do not store together with foodstuffs.

Storage classes

Storage class according to TRGS 510 12

Non-combustible liquids

Further information on storage conditions

Keep container tightly closed and dry.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Other information

Contains no substances with occupational exposure limit values.

8.2. Exposure controls

General protective and hygiene measures

Observe the usual precautions for handling chemicals.

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| Respiratory protection | | |
| | inhale vapours. If workplace limits are exceeded r job must be worn. | l, a respiratory protection |
| Hand protection | | |
| Appropriate Material | neoprene | |
| Eye protection | | |
| Safety glasses | | |
| Body protection | | |
| Clothing as usual in the ch | emical industry. | |
| | | |
| SECTION 9: Physical an | d chemical properties | |
| 9.1. Information on basic p | hysical and chemical properties | |
| Form | viscous liquid | |
| Colour | yellowish, clear | |
| Odour Colour | weak | |
| Odour | cloudy fruity | |
| Odour threshold | inaky | |
| Remarks | not determined | |
| pH value | not determined | |
| Remarks | not determined | |
| | not determined | |
| Melting point Remarks | not determined | |
| | not determined | |
| Freezing point Remarks | not determined | |
| | | |
| Initial boiling point and b Remarks | not determined | |
| Flash point | not determined | |
| Value | °C | |
| Remarks | Not applicable | |
| Evaporation rate (ether = | | |
| Remarks | not determined | |
| Flammability (solid, gas) | | |
| not determined | | |
| Upper/lower flammability | or explosive limits | |
| Remarks | not determined | |
| Vapour pressure | | |
| Value | kPa | |
| Temperature | 20 °C | |
| Remarks | Not applicable | |
| Vapour density | | |
| Remarks | not determined | |
| Density | | |
| Value Remarks | 1.295 to 1.326 g/m Relative Density according specification | ป |
| | | |
| Remarks Solubility in water | Relative Density according specification | |

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| Remarks | not determined | |
| Solubility(ies) | | |
| Remarks | not determined | |
| Partition coefficient: n-octar | | |
| Remarks | not determined | |
| Ignition temperature | | |
| Remarks | not determined | |
| Decomposition temperature | | |
| Remarks | not determined | |
| Viscosity | | |
| Remarks | not determined | |
| Explosive properties | | |
| evaluation | not determined | |
| Oxidising properties | | |
| Remarks | not determined | |
| 9.2. Other information | | |
| Other information None known | | |
| SECTION 10: Stability and | reactivity | |
| 10.1. Reactivity No dangerous reactions know | | |
| 10.2. Chemical stability No decomposition if stored an | d applied as directed. | |
| 10.3. Possibility of hazardous No hazardous reactions know | | |
| 10.4. Conditions to avoid No hazardous reactions know | n. | |
| 10.5. Incompatible materials None known | | |
| SECTION 11: Toxicologica | l information | |
| 11.1. Information on toxicolog | | |
| Acute oral toxicity | | |
| - | not determined | |
| Acute oral toxicity (Compon | ents) | |
| | - | |
| | rat | |
| 4-hydroxybenzoic acid propyl Species | | ···· |
| | > 5000 | mg/kg |
| Species LD50 methyl 4-hydroxybenzoate | | mg/kg |
| Species LD50 methyl 4-hydroxybenzoate Species | rat | |
| Species LD50 methyl 4-hydroxybenzoate Species LD50 | | mg/kg |

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| Remarks | not det | ermined | | | |
| Acute inhalational toxicity | | | | | |
| Remarks | • | ermined | | | |
| Skin corrosion/irritation | | | | | |
| Remarks | not det | ermined | | | |
| Skin corrosion/irritation (| Compon | ents) | | | |
| wethyl 4-hydroxybenzoate | - | , | | | |
| Species | rabbit | | | | |
| Duration of exposure | | 24 | h | | |
| Observation Period | Madau | 72 | h | | |
| evaluation Method | | ately irritat method | ing | | |
| Serious eye damage/irrita | | methou | | | |
| Remarks | | ermined | | | |
| | | | | | |
| Serious eye damage/irrita | | mponen | (5) | | |
| methyl 4-hydroxybenzoate | rabbit | | | | |
| Species Observation Period | Taddit | 48 | h | | |
| evaluation | Modera | ately irritat | | | |
| Method | | method | 0 | | |
| Sensitization | | | | | |
| Remarks | not det | ermined | | | |
| Sensitization (Componen | ts) | | | | |
| 4-hydroxybenzoic acid pro | pyl ester | | | | |
| Route of exposure | | | | | |
| Species | mouse | | | | |
| evaluation Method | non-se OECD | nsitizing | | | |
| | | 429 | | | |
| methyl 4-hydroxybenzoate Species | guinea | nia | | | |
| evaluation | | nsitizing | | | |
| Method | OECD | 406 | | | |
| Subacute, subchronic, ch | ronic to | kicity | | | |
| Remarks | not det | ermined | | | |
| Subacute, subchronic, ch | ronic to | cicity (Co | omponents) | | |
| 4-hydroxybenzoic acid pro | pyl ester | | | | |
| Sub-chronic toxicity | امتعا | | | | |
| Route of exposure Species | oral rat | | | | |
| NOAEL | ιαι | 980 | | mg/kg | |
| Duration of exposure | | 4 | Weeks | 33 | |
| methyl 4-hydroxybenzoate | | | | | |
| Species | rat | | | | |
| NOAEL | >= | 250 | d | mg/kg | |
| Duration of exposure | | 28 | d | | |
| Mutagenicity | المحمر | o noo lio a -l | | | |
| Remarks | | ermined | | | |
| Mutagenicity (Componen | ts) | | | | |

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| evaluation Method | No mutagenicity a OECD 471 | according to v | /arious in vitro tests. | |
| methyl 4-hydroxybenzoate evaluation Method | No mutagenicity according to various in vitro tests. OECD 471 | | | |
| Reproductive toxicity Remarks | not determined | | | |
| Carcinogenicity Remarks | not determined | | | |
| Other information No toxicological data are av | ailable. | | | |
| SECTION 12: Ecological i | information | | | |
| 12.1. Toxicity | | | | |
| General information | | | | |
| not determined | | | | |
| Fish toxicity (Components |) | | | |
| 4-hydroxybenzoic acid prop | yl ester | | | |
| Species | zebra fish (Brach | ydanio rerio) | | |
| LC50 Duration of exposure | 6.4 96 | h | mg/l | |
| methyl 4-hydroxybenzoate | 90 | 11 | | |
| Species | golden orfe (Leuc | siscus idus) | | |
| NOEC | 50 | | mg/l | |
| Duration of exposure | 48 | h | | |
| methyl 4-hydroxybenzoate | | | | |
| Species | Oryzias latipes | | | |
| LC50 Duration of exposure | 59.5 96 | h | mg/l | |
| Method | OECD 203 | | | |
| Daphnia toxicity (Compon | ents) | | | |
| 4-hydroxybenzoic acid prop | | | | |
| Species | Daphnia magna | | | |
| EC50 | 15.4 | | mg/l | |
| Duration of exposure | 48 | h | | |
| Method | ISO 6341 | | | |
| methyl 4-hydroxybenzoate Species | Daphnia magna | | | |
| NOEC | 0.2 | | mg/l | |
| Duration of exposure | 21 | d | 3 | |
| Method | OECD 211 | | | |
| methyl 4-hydroxybenzoate | | | | |
| Species EC50 | Daphnia magna 11.2 | | ma/l | |
| Duration of exposure | 48 | h | mg/l | |
| Algae toxicity (Component | | | | |
| 4-hydroxybenzoic acid prop | - | | | |
| Species | Pseudokirchnerie | lla subcanitat | ta | |
| EC50 | 15 | | mg/l | |
| Duration of exposure | 72 | h | - | |

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| Method | ISO 8692 | | | |
| 4-hydroxybenzoic acid pro | | | | |
| Species | Pseudokirchne | eriella subcapit | | |
| NOEC | 2.1 | L | mg/l | |
| Duration of exposure Method | 72 OECD 201 | h | | |
| 4-hydroxybenzoic acid pro | | | | |
| Species | Pseudokirchne | eriella subcapit | ata | |
| EC50 | 16 | | mg/l | |
| Duration of exposure | 72 | h | | |
| Method | OECD 201 | | | |
| methyl 4-hydroxybenzoate | | | | |
| Species | Desmodesmus | s subspicatus | 100 m /l | |
| EC50 Duration of exposure | 91 72 | h | mg/l | |
| methyl 4-hydroxybenzoate | | | | |
| NOEC | - 17 | | mg/l | |
| Duration of exposure | 72 | h | | |
| Method | OECD 201 | | | |
| 12.2. Persistence and degr | adability | | | |
| General information | | | | |
| not determined | | | | |
| Biodegradability (Compo | (nonte) | | | |
| | - | | | |
| 4-hydroxybenzoic acid pro Value | opyl ester 91.5 | | % | |
| Duration of test | 28 | d | 70 | |
| evaluation | Readily biodeg | | | |
| Method | OECD 301F | | | |
| methyl 4-hydroxybenzoate | 9 | | | |
| Value | 92.2 | | % | |
| Duration of test | 28 | d | | |
| evaluation Method | Readily biodeg OECD 301F | gradable | | |
| Method | | | | |
| methyl 4-hydroxybenzoate Value | 9 89 | | % | |
| Duration of test | 28 | d | /0 | |
| evaluation | Readily biodeg | - | | |
| Method | OECD 301 B | | | |
| 2.3. Bioaccumulative pote | ential | | | |
| General information | | | | |
| not determined | | | | |
| Partition coefficient: n-o | stanolwatar | | | |
| Remarks | not determi | nod | | |
| | | | nonto) | |
| Octanol/water partition c 4-hydroxybenzoic acid pro | | ow) (Compo | ments) | |
| log Pow | 2.8 | | | |
| methyl 4-hydroxybenzoate log Pow | e 1.9 | 8 | | |
| IUYFUW | | | | |



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General information

not determined

Mobility in soil (Components)

4-hydroxybenzoic acid propyl ester Highly mobile in soils methyl 4-hydroxybenzoate Highly mobile in soils

12.5. Results of PBT and vPvB assessment

General information

not determined

12.6. Other adverse effects

General information

not determined

General information / ecology

Do not discharge product unmonitored into the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations for the product

Disposal in compliance with local and national regulations. Allocation of a waste code number, according to the European Waste Catalogue (EWC), should be carried out in agreement with the regional waste disposal company.

Disposal recommendations for packaging

Packaging that cannot be cleaned should be disposed off as product waste.

SECTION 14: Transport information

| | Land transport ADR/RID | Marine transport IMDG/GGVSee | Air transport ICAO/IATA |
|-----------------|--|---|---|
| 14.1. UN 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 | WGK 3 |
|--------------------|---|
| (Germany) | |
| Remarks | Derivation of WGK according to Annex 1 No. 5.2 AwSV |

15.2. Chemical safety assessment

For this preparation a chemical safety assessment has not been carried out.

SECTION 16: Other information

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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.