

Trade name: Althaeae extr pro sir 10/100

Substance number: 125641

Version: 1 / CH

Date revised: 25.05.2021

Replaces Version: - / CH

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

1.1. Product identifier

Althaeae extr pro sir 10/100

Item No. 12564100

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

Use of the substance/preparation

Active pharmaceutical substance, 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

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

3.2. Mixtures

Further ingredients

Sucrose

CAS No. 57-50-1

EINECS no. 200-334-9

Concentration >= 50 %

Advice: [4]

water

CAS No. 7732-18-5

EINECS no. 231-791-2

Concentration >= 25 < 50 %

Advice: [4]

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Maltodextrin

CAS No.	9050-36-6				
EINECS no.	232-940-4				
Concentration	>=	1	<	10	%
Advice:	[4]				

methyl 4-hydroxybenzoate

CAS No.	99-76-3				
EINECS no.	202-785-7				
Registration no.	01-2119463264-40				
Concentration			<	1	%
Advice:	[4]				
Classification (Regulation (EC) No. 1272/2008)	Aquatic Chronic 3		H412		

4-hydroxybenzoic acid propyl ester

CAS No.	94-13-3				
EINECS no.	202-307-7				
Registration no.	01-2119969462-29				
Concentration			<	1	%
Advice:	[4]				

Note

[4] Voluntary information

SECTION 4: First aid measures**4.1. Description of first aid measures****General information**

In case of persistent symptoms consult doctor.

After inhalation

Ensure supply of fresh air. In the event of symptoms take medical treatment.

After skin contact

In case of contact with skin wash off with warm water. 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 ingestion

Rinse out mouth and give plenty of water to drink.

Adhere to personal protective measures when giving first aid

First aider: Pay attention to self-protection!

4.2. Most important symptoms and effects, both acute and delayed

Until now no symptoms known so far.

4.3. Indication of any immediate medical attention and special treatment needed**Hints for the physician / hazards**

In the case of swallowing with subsequent vomiting, aspiration of the lungs can occur which can lead to chemical pneumonia or asphyxiation.

SECTION 5: Firefighting measures**5.1. Extinguishing media**

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Suitable extinguishing media

Foam, Carbon dioxide, Dry powder, Water spray jet

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.

Respiratory protection

Not necessary, but do not inhale vapours. If workplace limits are exceeded, a respiratory protection

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approved for this particular job must be worn.

Hand protection

Appropriate Material neoprene

Eye protection

Safety glasses

Body protection

Clothing as usual in the chemical industry.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Form	liquid	
Colour	yellowish brown to reddish brown	
Odour	weak	
Odour threshold		
Remarks	not determined	
pH value		
Remarks	not determined	
Melting point		
Remarks	not determined	
Freezing point		
Remarks	not determined	
Initial boiling point and boiling range		
Value	appr. 100	°C
Flash point		
Value		°C
Remarks	Not applicable	
Evaporation rate (ether = 1) :		
Remarks	not determined	
Flammability (solid, gas)		
not determined		
Upper/lower flammability or explosive limits		
Remarks	not determined	
Vapour pressure		
Remarks	Not applicable	
Vapour density		
Remarks	not determined	
Density		
Remarks	not determined	
Solubility in water		
Remarks	not determined	
Solubility(ies)		
Remarks	not determined	
Partition coefficient: n-octanol/water		
Remarks	not determined	
Ignition temperature		

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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 known.

10.2. Chemical stability

No decomposition if stored and applied as directed.

10.3. Possibility of hazardous reactions

No hazardous reactions known.

10.4. Conditions to avoid

No hazardous reactions known.

10.5. Incompatible materials

None known

SECTION 11: Toxicological information**11.1. Information on toxicological effects****Acute oral toxicity**

Remarks not determined

Acute oral toxicity (Components)**4-hydroxybenzoic acid propyl ester**

Species	rat		
LD50	>	5000	mg/kg

methyl 4-hydroxybenzoate

Species	rat		
LD50		2100	mg/kg
Method	OECD 401		

Acute dermal toxicity

Remarks not determined

Acute inhalational toxicity

Remarks not determined

Skin corrosion/irritation

Remarks not determined

Skin corrosion/irritation (Components)

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methyl 4-hydroxybenzoate

Species	rabbit		
Duration of exposure	24		h
Observation Period	72		h
evaluation	Moderately irritating		
Method	Draize method		

Serious eye damage/irritation

Remarks not determined

Serious eye damage/irritation (Components)**methyl 4-hydroxybenzoate**

Species	rabbit		
Observation Period	48		h
evaluation	Moderately irritating		
Method	Draize method		

Sensitization

Remarks not determined

Sensitization (Components)**4-hydroxybenzoic acid propyl ester**

Route of exposure	dermal		
Species	mouse		
evaluation	non-sensitizing		
Method	OECD 429		

methyl 4-hydroxybenzoate

Species	guinea pig		
evaluation	non-sensitizing		
Method	OECD 406		

Subacute, subchronic, chronic toxicity

Remarks not determined

Subacute, subchronic, chronic toxicity (Components)**4-hydroxybenzoic acid propyl ester**

Sub-chronic toxicity			
Route of exposure	oral		
Species	rat		
NOAEL	980		mg/kg
Duration of exposure	4	Weeks	

methyl 4-hydroxybenzoate

Species	rat		
NOAEL	>=	250	mg/kg
Duration of exposure	28	d	

Mutagenicity

Remarks not determined

Mutagenicity (Components)**4-hydroxybenzoic acid propyl ester**

evaluation	No mutagenicity according to various in vitro tests.		
Method	OECD 471		

methyl 4-hydroxybenzoate

evaluation	No mutagenicity according to various in vitro tests.		
Method	OECD 471		

Reproductive toxicity

Remarks not determined

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Carcinogenicity

Remarks not determined

Other information

No toxicological data are available.

SECTION 12: Ecological information**12.1. Toxicity****General information**

not determined

Fish toxicity (Components)**4-hydroxybenzoic acid propyl ester**

Species	zebra fish (<i>Brachydanio rerio</i>)		
LC50	6.4		mg/l
Duration of exposure	96	h	

methyl 4-hydroxybenzoate

Species	golden orfe (<i>Leuciscus idus</i>)		
NOEC	50		mg/l
Duration of exposure	48	h	

methyl 4-hydroxybenzoate

Species	<i>Oryzias latipes</i>		
LC50	59.5		mg/l
Duration of exposure	96	h	
Method	OECD 203		

Daphnia toxicity (Components)**4-hydroxybenzoic acid propyl ester**

Species	<i>Daphnia magna</i>		
EC50	15.4		mg/l
Duration of exposure	48	h	
Method	ISO 6341		

methyl 4-hydroxybenzoate

Species	<i>Daphnia magna</i>		
NOEC	0.2		mg/l
Duration of exposure	21	d	
Method	OECD 211		

methyl 4-hydroxybenzoate

Species	<i>Daphnia magna</i>		
EC50	11.2		mg/l
Duration of exposure	48	h	

Algae toxicity (Components)**4-hydroxybenzoic acid propyl ester**

Species	<i>Pseudokirchneriella subcapitata</i>		
EC50	15		mg/l
Duration of exposure	72	h	
Method	ISO 8692		

4-hydroxybenzoic acid propyl ester

Species	<i>Pseudokirchneriella subcapitata</i>		
NOEC	2.1		mg/l
Duration of exposure	72	h	
Method	OECD 201		

4-hydroxybenzoic acid propyl ester

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Species	Pseudokirchneriella subcapitata		
EC50	16		mg/l
Duration of exposure	72	h	
Method	OECD 201		

methyl 4-hydroxybenzoate

Species	Desmodesmus subspicatus		
EC50	91		mg/l
Duration of exposure	72	h	

methyl 4-hydroxybenzoate

NOEC	17		mg/l
Duration of exposure	72	h	
Method	OECD 201		

12.2. Persistence and degradability**General information**

not determined

Biodegradability (Components)**4-hydroxybenzoic acid propyl ester**

Value	91.5		%
Duration of test evaluation	28	d	
Method	Readily biodegradable		
	OECD 301F		

methyl 4-hydroxybenzoate

Value	92.2		%
Duration of test evaluation	28	d	
Method	Readily biodegradable		
	OECD 301F		

methyl 4-hydroxybenzoate

Value	89		%
Duration of test evaluation	28	d	
Method	Readily biodegradable		
	OECD 301 B		

12.3. Bioaccumulative potential**General information**

not determined

Partition coefficient: n-octanol/water

Remarks not determined

Octanol/water partition coefficient (log Pow) (Components)**4-hydroxybenzoic acid propyl ester**

log Pow 2.8

methyl 4-hydroxybenzoate

log Pow 1.98

12.4. Mobility in soil**General information**

not determined

Mobility in soil (Components)**4-hydroxybenzoic acid propyl ester**

Highly mobile in soils

methyl 4-hydroxybenzoate

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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 (Germany) WGK 3

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**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.