

Trade name: Kalii guaiacolsulfonatis sirup

Substance number: 145051

Version: 1 / CH

Date revised: 16.06.2022

Replaces Version: - / CH

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

1.1. Product identifier

Kalii guaiacolsulfonatis sirup

Item No. 14505100

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

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.

Supplemental information

EUH210

Safety data sheet available on request.

2.3. Other hazards

No special hazards have to be mentioned.

SECTION 3: Composition/information on ingredients

Chemical characterization

Extract of herbal drugs

Hazardous ingredients

sulfogaiacol

CAS No. 1321-14-8

EINECS no. 215-314-5

Concentration ≥ 1 < 10 %

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

Acute Tox. 4 H302

Acute Tox. 4 H332

Skin Irrit. 2 H315

Eye Irrit. 2 H319

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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]					

ethanol

CAS No.	64-17-5				
EINECS no.	200-578-6				
Concentration		>=	1	<	10 %
Advice: [4]					
Classification (Regulation (EC) No. 1272/2008)					
Flam. Liq. 2				H225	

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 2				H411	

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.

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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

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

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Exposure limit values**ethanol**

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; OAW, FormalKT HU; INRS, NIOSH				

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 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, clear
Colour	brownish yellow
Odour	characteristic
Odour	phenolic

Odour threshold

Remarks not determined

pH value

Remarks not determined

Melting point

Remarks Not applicable

Freezing point

Remarks not determined

Initial boiling point and boiling range

Remarks not determined

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

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Remarks not determined

Vapour pressure

Remarks Not applicable

Vapour density

Remarks not determined

Density

Value 1.26 to 1.29 g/ml

Remarks Relative Density according specification

Solubility in water

Remarks not determined

Solubility(ies)

Remarks not determined

Partition coefficient: n-octanol/water

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 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**

ATE

8'333.33

mg/kg

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Method 33
calculated value (Regulation (EC) No. 1272/2008)

Acute oral toxicity (Components)**methyl 4-hydroxybenzoate**

Species rat
LD50 2100 mg/kg
Method OECD 401

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

Remarks not determined

Acute dermal toxicity (Components)**ethanol**

Species rabbit
LD50 15800 mg/kg

Acute inhalational toxicity

ATE > 20 mg/l
Administration/Form Dust/Mist
Method calculated value (Regulation (EC) No. 1272/2008)

Acute inhalative toxicity (Components)**ethanol**

Species rat
LC50 30000 mg/m³
Duration of exposure 4 h
Administration/Form Vapors

Skin corrosion/irritation

Remarks not determined

Skin corrosion/irritation (Components)**methyl 4-hydroxybenzoate**

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

ethanol

evaluation non-irritant

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

ethanol

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evaluation irritant

Sensitization

Remarks not determined

Sensitization (Components)**methyl 4-hydroxybenzoate**

Species guinea pig
 evaluation non-sensitizing
 Method OECD 406

Subacute, subchronic, chronic toxicity

Remarks not determined

Subacute, subchronic, chronic toxicity (Components)**methyl 4-hydroxybenzoate**

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

Mutagenicity

Remarks not determined

Mutagenicity (Components)**methyl 4-hydroxybenzoate**

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

ethanol

evaluation No mutagenicity in the Ames-test.

Reproductive toxicity

Remarks not determined

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)**methyl 4-hydroxybenzoate**

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

methyl 4-hydroxybenzoate

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

Daphnia toxicity (Components)**methyl 4-hydroxybenzoate**Species *Daphnia magna*

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NOEC	0.2		mg/l
Duration of exposure	21	d	
Method	OECD 211		

methyl 4-hydroxybenzoate

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

Algae toxicity (Components)**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)**methyl 4-hydroxybenzoate**

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

methyl 4-hydroxybenzoate

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

ethanol

evaluation Readily biodegradable

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

Value	0.93	to	1.67	mg/g
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12.3. Bioaccumulative potential**General information**

not determined

Partition coefficient: n-octanol/water

Remarks not determined

Octanol/water partition coefficient (log Pow) (Components)**methyl 4-hydroxybenzoate**

log Pow	1.98
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Bioconcentration factor (BCF) (Components)**ethanol**

BCF	0.66
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12.4. Mobility in soil

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General information

not determined

Mobility in soil (Components)**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 (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**Hazard statements listed in Chapter 3**

H302 Harmful if swallowed.

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H315	Causes skin irritation.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.

CLP categories listed in Chapter 3

Acute Tox. 4	Acute toxicity, Category 4
Eye Irrit. 2	Eye irritation, Category 2
Skin Irrit. 2	Skin irritation, Category 2

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.