

Trade name: Saponatus spiritus

Substance number: 147401

Version: 2 / CH

Date revised: 23.08.2023

Replaces Version: 1 / CH

Print date: 23.08.23

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

1.1. Product identifier

Saponatus spiritus

Item No. 14740100

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

Use of the substance/preparation

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

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

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

Flam. Liq. 3 H226

Skin Corr. 1B H314

Eye Dam. 1 H318

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 ***

Danger

Hazard statements ***

H226

Flammable liquid and vapour.

H314

Causes severe skin burns and eye damage.

Precautionary statements ***

P210

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

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P280 P304+P340 Wear protective gloves/protective clothing/eye protection/face protection.
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER or doctor.

P403+P233 Store in a well-ventilated place. Keep container tightly closed.

Hazardous component(s) to be indicated on label (Regulation (EC) No. 1272/2008)

contains *** potassium hydroxide

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**

soap

Hazardous ingredients *****potassium hydroxide**

CAS No.	1310-58-3
EINECS no.	215-181-3
Registration no.	01-2119487136-33-XXXX
Concentration	>= 2 < 3 %
Classification (Regulation (EC) No. 1272/2008)	
	Acute Tox. 4 H302
	Skin Corr. 1A H314

Concentration limits (Regulation (EC) No. 1272/2008)

Eye Irrit. 2	H319	>= 0.5 < 2 %
Skin Corr. 1A	H314	>= 5 %
Skin Corr. 1B	H314	>= 2 < 5 %
Skin Irrit. 2	H315	>= 0.5 < 2 %

ATE oral 273 mg/kg

Further ingredients *****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

water

CAS No.	7732-18-5
EINECS no.	231-791-2
Concentration	>= 25 < 50 %
Advice: [4]	

Water

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CAS No. 7732-18-5
 EINECS no. 231-791-2
 Concentration < 1 %
 Advice: [4]

hydrochloric acid ... %

CAS No. 7647-01-0
 EINECS no. 231-595-7
 Registration no. 01-2119484862-27-XXXX
 Concentration < 1 %
 Advice: [4]

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

Skin Corr. 1B H314
 STOT SE 3 H335

Concentration limits (Regulation (EC) No. 1272/2008)

Eye Irrit. 2 H319 >= 10 < 25 %
 Skin Corr. 1B H314 >= 25 %
 Skin Irrit. 2 H315 >= 10 < 25 %
 STOT SE 3 H335 >= 10 %

CLP Regulation (EC) No 1272/2008, Annex VI, Note B

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. Take medical treatment.

After skin contact

After contact with skin, wash immediately with plenty of water. Remove contaminated, soaked clothing immediately and dispose of safely. Summon a doctor immediately.

After eye contact

In case of contact with the eyes, rinse immediately for at least 15 minutes with plenty of water. Summon a doctor immediately.

After ingestion

Never give anything by mouth to an unconscious person. Drink water in small gulps. Do not induce vomiting - aspiration hazard. Summon a doctor immediately. No trials on neutralisation.

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

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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**

Do not use zinc containers. Do not use aluminium containers.

Storage classes

Storage class according to TRGS 510	3	Flammable liquid
Storage category (Switzerland)	3	Flammable liquid

Further information on storage conditions

Protect from light.

SECTION 8: Exposure controls/personal protection *****8.1. Control parameters****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; Formal; INRS NIOSH				

potassium hydroxide

List	SUVA
Type	MAK

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Value 2 mg/m³

Remarks: Haut, OAWKT & AugeKT; 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

hydrochloric acid ... %

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Acute	
Route of exposure	inhalative	
Mode of action	Local effects	
Concentration	15	mg/m ³
Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Local effects	
Concentration	8	mg/m ³

Predicted No Effect Concentration (PNEC)**hydrochloric acid ... %**

Type of value	PNEC	
Type	Freshwater	
Concentration	36	µg/l
Type of value	PNEC	
Type	Saltwater	
Concentration	36	µg/l
Type of value	PNEC	
Type	Sewage treatment plant (STP)	
Concentration	45	µg/l

8.2. Exposure controls**General protective and hygiene measures**

Remove contaminated, soaked clothing immediately and dispose of safely. Preventative skin protection. Wash hands and face after work.

Respiratory protection

Breathing apparatus in the event of vapours. Breathing apparatus in the event of aerosol or mist formation.

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Hand protection

Appropriate Material nitrile rubber - NBR
 Material thickness 0.11 mm
 Breakthrough time > 480 min

Eye protection

Tightly fitting safety glasses

Body protection

Protective clothing

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties****Physical state** liquid, clear**Colour** yellow**Boiling point or initial boiling point and boiling range**

Value > 78 °C

Source Estimated value

Flash point

Value > 24 °C

Source Estimated value

pH value

Value to 13.0

Vapour pressure

Value < 5.8 kPa

Source Estimated value

Density and/or relative density

Value 0.910 to 0.925

Remarks Relative Density according specification

9.2. Other information**Efflux time**

Value 11 s

Method DIN EN ISO 2431 - 4 mm

SECTION 10: Stability and reactivity**10.1. Reactivity**

Exothermic reaction with: Water

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

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gases/vapours

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute oral toxicity

ATE	>	10'000	mg/kg
Method	calculated value (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

potassium hydroxide

Species	rat		
LD50		273	mg/kg

potassium hydroxide

Species	rat		
LD50		333	mg/kg
Method	OECD 425		

hydrochloric acid ... %

Species	rabbit		
LD50		900	mg/kg
Remarks	Ingestion causes burns of the upper digestive and respiratory tracts.		

Acute dermal toxicity (Components)

ethanol

Species	rabbit		
LD50		15800	mg/kg

potassium hydroxide

Remarks	No data available.		
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Acute inhalative toxicity (Components)

ethanol

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

potassium hydroxide

Remarks	No data available.		
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hydrochloric acid ... %

Reference substance	hydrogen chloride		
Species	rat		
LC50		31000	ppm(V)
Duration of exposure		5	min
Administration/Form	Vapors		
Source	NCBI Bookshelf 1998		

hydrochloric acid ... %

Reference substance	hydrogen chloride		
Species	mouse		
LC50		11200	ppm(V)

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Duration of exposure 5 min

Administration/Form Vapors
Source NCBI Bookshelf 1998**hydrochloric acid ... %**Reference substance hydrogen chloride
Species rat
LC50 5600 ppm(V)
Duration of exposure 30 min
Administration/Form Vapors
Source NCBI Bookshelf 1998**hydrochloric acid ... %**Reference substance hydrogen chloride
Species mouse
LC50 2100 ppm(V)
Duration of exposure 30 min
Administration/Form Vapors
Source NCBI Bookshelf 1998**hydrochloric acid ... %**Reference substance hydrogen chloride
Species guinea pig
LC50 2519 ppm(V)
Duration of exposure 30 min
Administration/Form Vapors
Source Kirsch and Drabk 1982**Skin corrosion/irritation (Components)****ethanol**

evaluation non-irritant

potassium hydroxideSpecies rabbit
Duration of exposure 24 h
evaluation corrosive
Method OECD 405**hydrochloric acid ... %**Species rabbit
Remarks Corrosive**Serious eye damage/irritation**

Remarks Eye contact with the product may lead to irritation.

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

evaluation irritant

potassium hydroxideSpecies rabbit
evaluation strongly corrosive
Method OECD 405
Remarks Influence of the product with the eyes can lead to blindness.**hydrochloric acid ... %**Species rabbit eye
evaluation strongly corrosive
Method OECD 405**Sensitization (Components)****potassium hydroxide**

Species guinea pig

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evaluation	non-sensitizing
Source	Literature value

hydrochloric acid ... %

Species	guinea pig
Remarks	No sensitisation effect known.

Subacute, subchronic, chronic toxicity (Components)**potassium hydroxide**

Remarks	No data available.
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hydrochloric acid ... %

Remarks	No data available
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Mutagenicity (Components)**ethanol**

evaluation	No mutagenicity in the Ames-test.
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potassium hydroxide

evaluation	No mutagenicity in the Ames-test.
Source	Literature value

hydrochloric acid ... %

evaluation	No experimental information on genotoxicity in vitro available.
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Reproduction toxicity (Components)**potassium hydroxide**

Remarks	not determined
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hydrochloric acid ... %

Remarks	No indications of toxic effects were observed in reproduction studies in animals.
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Carcinogenicity (Components)**potassium hydroxide**

Remarks	No evidence available on carcinogenicity.
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hydrochloric acid ... %

Remarks	negative on animals
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Specific Target Organ Toxicity (STOT) (Components)**potassium hydroxide**

Remarks	Not applicable
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hydrochloric acid ... %**Single exposure**

evaluation	May cause respiratory irritation. Route of exposure inhalative Organs: Respiratory tract
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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.

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Product specific toxicological data are not known.

SECTION 12: Ecological information *****12.1. Toxicity****Fish toxicity (Components)****potassium hydroxide**

Species	Gambusia affinis		
LC50	80		mg/l
Duration of exposure	96	h	

hydrochloric acid ... %

Species	Gambusia affinis		
LC50	282		mg/l
Duration of exposure	96	h	

hydrochloric acid ... %

Species	Bluegill (Lepomis macrochirus)		
LC50	20.5		mg/l
Duration of exposure	24	h	

Daphnia toxicity (Components)**potassium hydroxide**

Remarks	No data available.
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hydrochloric acid ... %

Species	Daphnia magna		
EC50	0.45		mg/l
Duration of exposure	48	h	
Method	OECD 201		

Algae toxicity (Components)**potassium hydroxide**

Remarks	No data available.
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hydrochloric acid ... %

Species	Chlorella vulgaris		
ErC50	0.73		mg/l
Duration of exposure	72	h	
Method	OECD 201		

Bacteria toxicity (Components)**potassium hydroxide**

Remarks	No data available.
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hydrochloric acid ... %

Remarks	No data available.
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12.2. Persistence and degradability**Biodegradability (Components)****ethanol**

evaluation	Readily biodegradable
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potassium hydroxide

Remarks	Inorganic product, cannot be eliminated from the water by biological purification processes.
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hydrochloric acid ... %

Remarks	Not applicable
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Chemical oxygen demand (COD) (Components)

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ethanol

Value

0.93

to

1.67

mg/g

12.3. Bioaccumulative potential**Bioconcentration factor (BCF) (Components)****ethanol**

BCF

0.66

12.4. Mobility in soil**Mobility in soil (Components)****potassium hydroxide**

Will not adsorb on soil.

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.

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 ***

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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			
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

H226 Flammable liquid and vapour.
 H302 Harmful if swallowed.
 H314 Causes severe skin burns and eye damage.
 H318 Causes serious eye damage.

CLP categories listed in Chapter 3

Acute Tox. 4 Acute toxicity, Category 4
 Eye Dam. 1 Serious eye damage, Category 1
 Flam. Liq. 3 Flammable liquid, Category 3
 Skin Corr. 1A Skin corrosion, Category 1A
 Skin Corr. 1B Skin corrosion, Category 1B

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.