

Spiritus saponatus

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Date of issue: 02/05/2013 Revision date: 08/03/2017

262447

Version: 2.0

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

1.1. Product identifier

Product form : Mixtures
Product name : Spiritus saponatus
Product code : 262447
Product group : Raw material

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

1.2.1. Relevant identified uses

Main use category : Pharmaceutical industry

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
A. Hofmanweg 71
2031BH Haarlem - Nederland
T +31(0)23-5319093
farma@duchefa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
+31(0)23-5319093 (M-F 09:00-17:00)
+31(0)6-30109355 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Centre Hospitalier Universitaire de Constantine	Avonley Road SE14 5ER London	0870 243 2241	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Flammable liquids, Category 2

H225

Full text of hazard classes and H-statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)

:



GHS02

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H225 - Highly flammable liquid and vapour

Precautionary statements (CLP)

: P210 - Keep away from heat, hot surfaces, open flames, sparks. - No smoking
P233 - Keep container tightly closed

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ethanol 96% V/V	(CAS No) 64-17-5 (EC No) 200-578-6 (EC Index No) 603-002-00-5 (REACH-no) 01-2119457610-43	35	F; R11	Flam. Liq. 2, H225

Full text of R- and H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Assure fresh air breathing.

First-aid measures after skin contact : Wash with plenty of soap and water.

First-aid measures after eye contact : Immediately flush eyes thoroughly with water for at least 15 minutes.

First-aid measures after ingestion : Drink plenty of water. Induce vomiting. Seek medical advice.

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

No additional information available

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Fire-fighting measures**5.1. Extinguishing media**

Suitable extinguishing media : All extinguishing agents can be used.

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

No additional information available

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

General measures : Avoid contact with substance.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions**6.3. Methods and material for containment and cleaning up**

Methods for cleaning up : Absorb with liquid binding material: Sand, silica, acid binder, saw dust.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Precautions for safe handling : Keep away from sources of ignition - No smoking. Take precautionary measures against static discharge.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed. Store in a dry place. Store at room temperature.

Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

No additional information available

8.2. Exposure controls**Hand protection:**

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Respiratory protection:

None necessary

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Clear.
Colour	: Colourless.
Odour	: alcohol odour.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: 75 - 80 °C
Flash point	: > 23
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: completely miscible with water.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

None known.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

None.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Ethanol 96% V/V (64-17-5)	
LD50 oral rat	6200 mg/kg
LD50 oral	6300 mg/kg bodyweight rabbit

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Not classified

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

Potential adverse human health effects and symptoms : No data available.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : No data available.

Ethanol 96% V/V (64-17-5)	
LC50 fish 1	11200 mg/l 24h (Oncorhynchus mykiss, US EPA E03-05)
LC50 fish 2	13000 mg/l 96h (Oncorhynchus mykiss, OECD 203)
LC50 other aquatic organisms 1	275 mg/l 72h (Chlorella vulgaris, OECD 201)
EC50 Daphnia 1	12340 mg/l 48 h.
EC10	12 mg/l/72h (Chlorella vulgaris, OECD 201)
bacteria (Pseudomonas putida)	toxic limit concentration: 6500 mg/l
Activated sludge	Damage from 15 g / l
Behaviour in sewage treatment plants	EC50 > 1000 mg/l

12.2. Persistence and degradability

Ethanol 96% V/V (64-17-5)	
Persistence and degradability	readily degradable in water.
Biochemical oxygen demand (BOD)	0.93 - 1.67 g O ₂ /g substance
Chemical oxygen demand (COD)	1.99 g O ₂ /g substance
ThOD	2.1 g O ₂ /g substance

Spiritus saponatus

262447

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Ethanol 96% V/V (64-17-5)	
BOD (% of ThOD)	90 % ThOD

12.3. Bioaccumulative potential

Ethanol 96% V/V (64-17-5)	
Log Pow	- 0.31
Bioaccumulative potential	Slightly or not bioaccumulative.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
14.1. UN number	
1293	Not applicable
14.2. UN proper shipping name	
Tinctures, medical	Not applicable
14.3. Transport hazard class(es)	
3	3
Not applicable	Not applicable
14.4. Packing group	
Not applicable	Not applicable
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

14.6. Special precautions for user

- Overland transport

Classification code (ADR) : F1

- Air transport

No data available

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes:

1.4	Emergency telephone	Modified	Added additional information
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves

Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

Data sources : Ph.Ned.VI. Supplier.

Full text of R-, H- and EUH-statements:

Flam. Liq. 2	Flammable liquids, Category 2
H225	Highly flammable liquid and vapour

SDS EU (REACH Annex II) Version 2017

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product