

Solutio Iodi Spirituosa

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Date of issue: 09/09/2014 Revision date: 06/03/2017

897558

Version: 2.0

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

1.1. Product identifier

Product form : Mixtures
Product name : Solutio Iodi Spirituosa
Product code : 897558
Synonyms : Tinctura Jodi; tincture of iodine

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : Industrial
For professional use only

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 3

H226

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

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Not classified

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)

: Warning

Hazard statements (CLP)

: H226 - Flammable liquid and vapour

Precautionary statements (CLP)

: P211 - Do not spray on an open flame or other ignition source

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	~ 66	F; R11	Flam. Liq. 2, H225
Iodine	(CAS No) 7553-56-2 (EC No) 231-442-4 (EC Index No) 053-001-00-3	2.4 - 2.7	Xn; R20/21 N; R50	Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation:dust,mist), H332 Aquatic Acute 1, H400

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 general

: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation	: Assure fresh air breathing. Allow the victim to rest.
First-aid measures after skin contact	: Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
First-aid measures after eye contact	: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists. Ensure adequate flushing of eyes by separating eyelids with the fingers.
First-aid measures after ingestion	: Rinse mouth. Drink plenty of water. Obtain emergency medical attention. Induce vomiting if person is conscious.

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

Symptoms/injuries	: Not expected to present a significant hazard under anticipated conditions of normal use.
-------------------	--

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	: Foam. Dry powder. Carbon dioxide. Water spray. Sand. For large fire: Water.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Flammable liquid and vapour.
Explosion hazard	: May form flammable/explosive vapour-air mixture.

5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking.
------------------	---

6.1.1. For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel.
----------------------	-----------------------------------

6.1.2. For emergency responders

Protective equipment	: Equip cleanup crew with proper protection.
Emergency procedures	: Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Store away from other materials.
-------------------------	------------------------------------

6.4. Reference to other sections

Reference to other sections (8, 13).

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Additional hazards when processed : Handle empty containers with care because residual vapours are flammable.
- Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. No open flames. No smoking. Take precautionary measures against static discharge. Use only non-sparking tools.

7.2. Conditions for safe storage, including any incompatibilities

- Technical measures : Proper grounding procedures to avoid static electricity should be followed. Ground/bond container and receiving equipment. Use spark-/explosionproof appliances and lighting system.
- Storage conditions : Keep container tightly closed. Store in a dry place. Keep only in the original container in a cool, well-ventilated place.
- Incompatible products : Strong bases. Strong acids.
- Incompatible materials : Sources of ignition. Direct sunlight. Heat sources.
- Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

Pharmaceutical industry.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Personal protective equipment:

Avoid all unnecessary exposure.

Hand protection:

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

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Respiratory protection:

No special respiratory protection equipment is recommended under normal conditions of use with adequate ventilation

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

- Physical state : Liquid
- Colour : brown.

Safety Data Sheet

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

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	: No data available
Flash point	: > 23 °C
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Flammable liquid and vapour
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 0.894 - 0.923 g/cm ³
Solubility	: Completely miscibility 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

Flammable liquid and vapour. May form flammable/explosive vapour-air mixture.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures. Open flame. Overheating. Heat. Sparks.

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

May release flammable gases.

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

Iodine (7553-56-2)	
LD50 oral rat	14000 mg/kg

Skin corrosion/irritation : Not classified
Additional information : Based on available data, the classification criteria are not met
Serious eye damage/irritation : Not classified
Additional information : Based on available data, the classification criteria are not met
Respiratory or skin sensitisation : Not classified
Additional information : Based on available data, the classification criteria are not met
Germ cell mutagenicity : Not classified
Based on available data, the classification criteria are not met
Carcinogenicity : Not classified
Additional information : Based on available data, the classification criteria are not met

Reproductive toxicity : Not classified
Additional information : Based on available data, the classification criteria are not met
STOT-single exposure : Not classified
Additional information : Based on available data, the classification criteria are not met
STOT-repeated exposure : Not classified
Additional information : Based on available data, the classification criteria are not met

Aspiration hazard : Not classified
Additional information : Based on available data, the classification criteria are not met
Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met.

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

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

Iodine (7553-56-2)	
LC50 fish 1	0.53 mg/l Oncorhynchus mykiss, 96h
EC50 Daphnia 1	0.33 mg/l 48h

12.2. Persistence and degradability

Solutio Iodi Spirituosa	
Persistence and degradability	Not established.
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
BOD (% of ThOD)	90 % ThOD

12.3. Bioaccumulative potential

Solutio Iodi Spirituosa	
Bioaccumulative potential	Not established.

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

Iodine (7553-56-2)	
Log Pow	2.49
Bioaccumulative potential	None.

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

Additional information : Avoid release to the environment

SECTION 13: Disposal considerations**13.1. Waste treatment methods**


Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of this material and its container at hazardous or special waste collection point.

Additional information : Handle empty containers with care because residual vapours are flammable.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

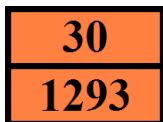
In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
14.1. UN number	
1293	1293
14.2. UN proper shipping name	
TINCTURES, MEDICINAL	Not applicable
14.3. Transport hazard class(es)	
3	3
	Not applicable

ADR	IATA
14.4. Packing group	
III	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
Special provisions (ADR) : 601
Limited quantities (ADR) : 5I
Excepted quantities (ADR) : E1
Vehicle for tank carriage : FL
Transport category (ADR) : 3
Hazard identification number (Kemler No.) : 30
Orange plates :



Tunnel restriction code (ADR) : D/E
EAC code : •2YE

- 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 chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

1.4	Emergency telephone	Modified	Added additional information
2	Classification (DSD/DPD)	Removed	Obsolete
8.2	Hand protection	Modified	Specified material, thickness, et

Safety Data Sheet

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

			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 : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : REACH Disclaimer:
This information is based on current knowledge. Consistency of data in the SDS with CSR is considered, as far as the information is available at the time of compilation (cfr Revision date and Version number). **DISCLAIMER OF LIABILITY** The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness.

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

Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Flam. Liq. 2	Flammable liquids, Category 2
Flam. Liq. 3	Flammable liquids, Category 3
H225	Highly flammable liquid and vapour
H226	Flammable liquid and vapour
H312	Harmful in contact with skin
H332	Harmful if inhaled
H400	Very toxic to aquatic life

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