

Trade name: Iodi solutio ethanolica/Lohnherst

Substance number: 215805

Version: 7 / CH

Date revised: 10.01.2023

Replaces Version: 6 / CH

Print date: 10.01.23

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

1.1. Product identifier

Iodi solutio ethanolica/Lohnherst

Item No. 21580500

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

Use of the substance/preparation

Medicinal product

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. 2 H225

STOT RE 2 H373

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

H225

Highly flammable liquid and vapour.

H373

May cause damage to organs through prolonged or repeated exposure.

Thyroid

Route of exposure: oral

Precautionary statements

P210

Keep away from heat, hot surfaces, sparks, open flames and other ignition

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P260 sources. No smoking.
 Do not breathe dust/fume/gas/mist/vapours/spray.
 P280 Wear protective gloves/protective clothing/eye protection/face protection.
 P314 Get medical advice/attention if you feel unwell.
 P403+P233 Store in a well-ventilated place. Keep container tightly closed.
 P501.3 Disposal in compliance with local and national regulations.

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

contains *** Potassium iodide; iodine

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**

Alcoholic solution
 Medicinal products

Hazardous ingredients *****Potassium iodide**

CAS No.	7681-11-0			
EINECS no.	231-659-4			
Registration no.	01-2119906339-35-XXXX			
Concentration	>= 1	<	10	%
Classification (Regulation (EC) No. 1272/2008)	STOT RE 1	H372		Thyroid; Route of exposure: oral

iodine

CAS No.	7553-56-2			
EINECS no.	231-442-4			
Registration no.	01-2119485285-30-XXXX			
Concentration	>= 1	<	10	%
Classification (Regulation (EC) No. 1272/2008)	Acute Tox. 4	H312		
	Acute Tox. 4	H332		
	Skin Irrit. 2	H315		
	Eye Irrit. 2	H319		
	STOT SE 3	H335		Respiratory tract
	STOT RE 1	H372		Thyroid; Route of exposure: oral
	Aquatic Acute 1	H400		

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

M = 1

ATE	oral	315	mg/kg
ATE	dermal	1'425	mg/kg
ATE	inhalative, Dust/Mist	4.588	mg/l

Further ingredients *****ethanol**

CAS No.	64-17-5			
EINECS no.	200-578-6			
Concentration		>=	50	%

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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]

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. In the event of symptoms take medical treatment.

After skin contact

Wash immediately with plenty of water for several minutes. Consult a doctor if skin irritation persists.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). Summon a doctor immediately.

After ingestion

Rinse mouth thoroughly with water. Summon a doctor immediately.

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

Water spray jet, Carbon dioxide, Foam, Dry powder

Non suitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

In the event of fire the following can be released: Carbon monoxide (CO)

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

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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 allow to enter drains or waterways. Advise water authority if spillage has entered water course or drainage system.

6.3. Methods and material for containment and cleaning up

Take up with absorbent material (eg sand, kieselguhr, universal binder). Dispose of absorbed material in accordance with the regulations. 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. No special measures necessary if used correctly.

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and vessels**

Keep tightly closed in a dry and cool place.

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				

iodine

List	SUVA			
Type	MAK			
Value	1	mg/m ³	0,1	ppm(V)
Short term exposure limit	1	mg/m ³	0,1	ppm(V)
Skin resorption / sensibilisation: H; Remarks: H; OAW & Auge; OSHA				

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)
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Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	oral	
Mode of action	Systemic effects	
Concentration	434	mg/kg/d

iodine

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Acute	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	1	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	Systemic effects	
Concentration	0.07	mg/m ³

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Acute	
Route of exposure	dermal	
Mode of action	Systemic effects	
Concentration	0.01	mg/kg

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	dermal	
Mode of action	Systemic effects	
Concentration	0.01	mg/kg

Predicted No Effect Concentration (PNEC)

iodine

Type of value	PNEC	
Type	Freshwater	
Concentration	0.01813	mg/l

Type of value	PNEC	
Type	Saltwater	
Concentration	0.006001	mg/l

Type of value	PNEC	
Type	Sewage treatment plant (STP)	
Concentration	11	mg/l

Type of value	PNEC	
Type	Marine sediment	
Concentration	20.22	mg/kg

Type of value	PNEC	
Type	Soil	
Concentration	5.95	mg/kg

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8.2. Exposure controls

General protective and hygiene measures

Keep away from food-stuffs, beverages and feed-stocks. Avoid contact with eyes. Observe the usual precautions for handling chemicals.

Respiratory protection

necessary; Do not breathe vapours, dust or aerosol. Provide adequate ventilation.

Hand protection

Nitrile gloves.

Eye protection

Tightly fitting safety glasses

Body protection

Light protective clothing; Fire-resistant protective clothing

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state liquid, clear

Colour red-brown

Odour of ethanol

Boiling point or initial boiling point and boiling range

Value > 78 °C

Source GESTIS-Stoffdatenbank

Flash point

Value < 22 °C

Source GESTIS-Stoffdatenbank

pH value

Remarks not determined

Vapour pressure

Value < 58 hPa

Temperature 20 °C

Source GESTIS-Stoffdatenbank

Density and/or relative density

Value 0.928 to 0.933 g/cm³

Remarks Relative Density according specification

9.2. Other information

Efflux time

Value < 10 s

Method DIN 53211 4 mm

Source Estimated value

Other information

The physical data is that of the main component.

SECTION 10: Stability and reactivity

10.1. Reactivity

Risk of ignition or formation of inflammable gases or vapours with: Air

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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, peroxides, Ammonia, Oxidising agents, Reactions with metals in powder form.

10.6. Hazardous decomposition products

Hazardous determin decomposition products: Carbon monoxide, Carbon dioxide, Flammable 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)**Potassium iodide**

Species	rat		
LD50		2779	mg/kg

ethanol

Species	rat		
LD50		7060	mg/kg
Source	Toxicology and Applied Pharmacology. Vol. 16, Pg. 718, 1970.		

ethanol

Species	rat		
LD50		10470	mg/kg

iodine

Species	rat		
LD50		315	mg/kg
Method	EPA		

Acute dermal toxicity

ATE	>	10'000	mg/kg
Method	calculated value (Regulation (EC) No. 1272/2008)		

Acute dermal toxicity (Components)**Potassium iodide**

Species	rat		
LD50	>	2000	mg/kg
Method	OECD 402		

ethanol

Species	rabbit		
LD50		15800	mg/kg

iodine

Species	rabbit		
LD50		1425	mg/g
Source	US-EPA		

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Acute inhalational toxicity

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

Acute inhalative toxicity (Components)**Potassium iodide**

Remarks	No data available		
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ethanol

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

iodine

Species	rat		
	>	4.588	mg/l
Duration of exposure	4	h	
Administration/Form	Dust/Mist		
Method	OECD 403		

Skin corrosion/irritation (Components)**Potassium iodide**

Species	rabbit		
evaluation	non-irritant		
Method	OECD 404		

ethanol

evaluation	non-irritant		
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iodine

evaluation	irritant		
Method	OECD 439		
Remarks	Longer or repeated exposure with the product may cause dermatitis		

iodine

evaluation	non-corrosive		
Method	OECD 439		

iodine

evaluation	Moderately irritating		
Method	Regulation (EC) 440/2008, B.46		

Serious eye damage/irritation

Remarks	Eye contact with the product may lead to irritation.		
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Serious eye damage/irritation (Components)**Potassium iodide**

Species	rabbit		
Method	OECD 405		
Remarks	None		

ethanol

evaluation	irritant		
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iodine

evaluation	strongly irritant		
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Sensitization (Components)**Potassium iodide**

Species	Human		
Remarks	negative		

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Source Patch-Test

iodine

Species mouse
 evaluation non-sensitizing
 Method OECD 429

Subacute, subchronic, chronic toxicity (Components)**Potassium iodide**

Remarks No data available

Mutagenicity (Components)**Potassium iodide**

Species Salmonella typhimurium
 evaluation No mutagenicity in the Ames-test.
 Source ECHA

ethanol

evaluation No mutagenicity in the Ames-test.

iodine

Species mouse
 evaluation No mutagenicity according to various in vitro tests.
 Method OECD 476

Reproduction toxicity (Components)**Potassium iodide**

Remarks No data available.

iodine

Remarks No data available

Carcinogenicity (Components)**Potassium iodide**

Remarks No data available.

iodine

Remarks No data available.

Specific Target Organ Toxicity (STOT) (Components)**Potassium iodide****Repeated exposure**

evaluation Causes damage to organs through prolonged or repeated exposure
 Route of exposure oral
 Organs: Thyroid

Potassium iodide**Single exposure**

Remarks No data available

iodine**Repeated exposure**

evaluation Causes damage to organs.
 Route of exposure oral
 Organs: Thyroid

iodine**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.

SECTION 12: Ecological information ***

12.1. Toxicity

Fish toxicity (Components)

Potassium iodide

Species	zebra fish (<i>Brachydanio rerio</i>)		
LC50	> 100		mg/l
Duration of exposure	96	h	
Method	OECD 203		

iodine

Species	rainbow trout (<i>Oncorhynchus mykiss</i>)		
LC50	1.67		mg/l
Duration of exposure	96	h	
Source	ECHA		

Daphnia toxicity (Components)

Potassium iodide

Remarks	No data available.		
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iodine

Species	Daphnia magna		
EC50	0.55		mg/l
Duration of exposure	48	h	
Method	static test		
Source	ECHA		

iodine

Species	Daphnia magna		
EC50	0.2		mg/l
Duration of exposure	48	h	

Algae toxicity (Components)

Potassium iodide

Remarks	No data available.		
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iodine

Species	Desmodesmus subspicatus		
ErC50	0.13		mg/l
Duration of exposure	72	h	
Method	OECD 201		

iodine

Species	Desmodesmus subspicatus		
NOEC	0.025		mg/l
Duration of exposure	72	h	

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Method OECD 201

Bacteria toxicity (Components)**Potassium iodide**

Remarks No data available.

iodine

Species	activated sludge		
EC50	280		mg/l
Duration of exposure	3	h	
Method	OECD 209		

12.2. Persistence and degradability**Physico-chemical eliminability (Components)****iodine**

Remarks No data available.

Biodegradability (Components)**Potassium iodide**

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

ethanol

evaluation Readily biodegradable

iodine

Remarks Not applicable

Ready degradability (Components)**iodine**

Remarks Not applicable.

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

Value 0.93 to 1.67 mg/g

12.3. Bioaccumulative potential**Octanol/water partition coefficient (log Pow) (Components)****iodine**

log Pow	2.49
Method	experimental

Bioconcentration factor (BCF) (Components)**ethanol**

BCF 0.66

12.5. Results of PBT and vPvB assessment**General information**

There is no data available on the product apart from the information given in this subsection.

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

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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**

Toxic for aquatic organisms. Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.




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 ***

	Land transport ADR/RID ***	Marine transport IMDG/GGVSee ***	Air transport ICAO/IATA ***
Tunnel restriction code	D/E		
14.1. UN number	1293	1293	1293
14.2. UN proper shipping name	TINCTURES, MEDICINAL (ethanol)	TINCTURES, MEDICINAL (ethanol)	TINCTURES, MEDICINAL (ethanol)
14.3. Transport hazard class(es)	3	3	3
Label			
14.4. Packing group	II	II	II
Limited Quantity	1 I		
Transport category	2		

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 WGK 2

(Germany)

Remarks

Derivation of WGK according to Annex 1 No. 5.2 AwSV

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SECTION 16: Other information**Hazard statements listed in Chapter 3**

H225	Highly flammable liquid and vapour.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H372	Causes damage to organs through prolonged or repeated exposure.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.

CLP categories listed in Chapter 3

Acute Tox. 4	Acute toxicity, Category 4
Aquatic Acute 1	Hazardous to the aquatic environment, acute, Category 1
Eye Irrit. 2	Eye irritation, Category 2
Flam. Liq. 2	Flammable liquid, Category 2
Skin Irrit. 2	Skin irritation, Category 2
STOT RE 1	Specific target organ toxicity - repeated exposure, Category 1
STOT RE 2	Specific target organ toxicity - repeated exposure, Category 2
STOT SE 3	Specific target organ toxicity - single exposure, Category 3

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.