according to Regulation (EC) No. 1907/2006 (REACH)



Trade name : Pharmakas® Iodine Soap Acute

 Revision date:
 03.01.2023
 Version:
 1.0.0

 Print date:
 30.01.2024

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

1.1 Product identifier

Pharmakas® Iodine Soap Acute

Unique Formula Identifier (UFI): CD10-80TR-P00U-E0J4

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

Disinfectant

1.3 Details of the supplier of the safety data sheet

Supplier

Pharmaka GmbH

Street: Westring 24

Postal code/City: 48356 Nordwalde

Country: Deutschland

Telephone: +49 2573 920900 **Telefax:** +49 2573 9209050

Information contact: info@pharmakas.de

www.pharmakas.de

1.4 Emergency telephone number

Germany: Poisons Information Centre Berlin Charité – Universitätsmedizin Berlin Campus Benjamin Franklin Haus VIII, UG Hindenburgdamm 30 D-12203 Berlin

+49(0)30/30686 700, Internat. INFOTRAC +1 3523233500

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

Skin Irrit. 2 ; H315 - Skin corrosion/irritation : Category 2 ; Causes skin irritation.

Eye Dam. 1; H318 - Serious eye damage/eye irritation: Category 1; Causes serious eye damage.

Aquatic Chronic 3; H412 - Hazardous to the aquatic environment: Chronic 3; Harmful to aquatic life with long lasting effects.

2.2 Label elements

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

Hazard pictograms



Corrosion (GHS05)

Signal word

Danger

Hazard components for labelling

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SODIUM DODECYL SULPHATE; CAS No.: 151-21-3

2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. with iodine; CAS No.: 25655-41-8

Amides, C8-18 (even numbered) and C18-unsatd., N, N-bis(hydroxyethyl); CAS No.: 68155-07-7

Hazard statements

H318 Causes serious eye damage. H315 Causes skin irritation.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P102 Keep out of the reach of children.

P101 If medical advice is needed, have product container or label at hand.

P273 Avoid release to the environment.

P280 Wear protective gloves and eye protection.

P332+P313 If skin irritation occurs: Get medical advice/attention.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present

and easy to do. Continue rinsing.

P501 Dispose of contents/container to to hazardous or special waste collection point

2.3 Other hazards

None

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Hazardous ingredients

SODIUM DODECYL SULPHATE; REACH No.: 01-2119489461-32-0000; EC No.: 205-788-1; CAS No.: 151-21-3

Weight fraction : \geq 15 - < 20 %

Classification 1272/2008 [CLP]: Flam. Sol. 2; H228 Eye Dam. 1; H318 Acute Tox. 4; H302 Acute Tox. 4; H332

Skin Irrit. 2; H315 STOT SE 3; H335 Aquatic Chronic 3; H412

2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. with iodine; EC No.: 607-771-8; CAS No.: 25655-41-8

Weight fraction : \geq 5 - < 10 %

Classification 1272/2008 [CLP]: Eye Dam. 1; H318 Skin Irrit. 2; H315 Aquatic Chronic 2; H411

Amides, C8-18 (even numbered) and C18-unsatd., N, N-bis(hydroxyethyl); REACH No.: 01-2119490100-53; EC No.: 931-

329-6; CAS No.: 68155-07-7

Weight fraction : \geq 3 - < 5 %

 $\hbox{Classification 1272/2008 [CLP]:} \qquad \hbox{Eye Dam. 1 ; H318 Skin Irrit. 2 ; H315 Aquatic Chronic 2 ; H411 }$

Additional information

For full text of Hazard- and EU Hazard-statements: see SECTION 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information

When in doubt or if symptoms are observed, get medical advice.

Following inhalation

In case of respiratory tract irritation, consult a physician. Remove casualty to fresh air and keep warm and at rest.

In case of skin contact

In case of skin reactions, consult a physician. Wash immediately with: Water and soap

After eye contact

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart

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and consult an ophthalmologist.

Following ingestion

Rinse mouth immediately and drink plenty of water. Do NOT induce vomiting. Seek medical advice immediately (poison centre).

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

Important or further important known symptoms and effects are described in the GHS labelling of the product (see section 2) and in section 11 (Toxicological information). (Further) symptoms and/or effects are not yet known. In our experience, no special hazards are to be expected if the product is handled properly and is used as intended.

4.3 Indication of any immediate medical attention and special treatment needed

treatment: Symptoms (decontamination, vital functions), no known specific antidote.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Foam , Carbon dioxide (CO2) , Dry extinguishing powder , Sand , Co-ordinate fire-fighting measures to the fire surroundings.

Unsuitable extinguishing media

Full water jet, Strong water jet

5.2 Special hazards arising from the substance or mixture

Thermal decomposition can lead to the escape of irritating gases and vapours.

5.3 Advice for firefighters

Special protective equipment for firefighters

Full protection suit , Use suitable breathing apparatus.

5.4 Additional information

Move undamaged containers from immediate hazard area if it can be done safely.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. See protective measures under point 7 and 8. Special danger of slipping by leaking/spilling product.

6.2 Environmental precautions

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Clear contaminated areas thoroughly. Treat the recovered material as prescribed in the section on waste disposal.

6.4 Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

It is recommended to design all work processes always so that the following is excluded: Inhalation of vapours or spray/mists

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Handle and open container with care. Use only in well-ventilated areas.

Protective measures

Measures to prevent fire

Usual measures for fire prevention. Always close containers tightly after the removal of product.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed.

Protect against UV-radiation/sunlight, Heat.

Requirements for storage rooms and vessels

Floors should be impervious, resistant to liquids and easy to clean. Keep/Store only in original container. Keep container tightly closed.

Hints on joint storage

Storage class (TRGS 510): 12

7.3 Specific end use(s)

Observe instructions for use. see section 1.2

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values

GLYCEROL; CAS No.: 56-81-5

Limit value type (country of origin): TRGS 900 (D)
Parameter: E: inhalable fraction

 $\begin{array}{lll} \mbox{Limit value}: & 200 \mbox{ mg/m}^3 \\ \mbox{Peak limitation}: & 2(I) \\ \mbox{Version}: & 27.10.2020 \end{array}$

DNEL-/PNEC-values

DNEL/DMEL

Amides, C8-18 (even numbered) and C18-unsatd., N, N-bis(hydroxyethyl); CAS No.: 68155-07-7

Limit value type : DNEL Consumer (local)

Exposure route: Dermal
Exposure frequency: Long-term
Limit value: 0,0562 mg/cm²

Limit value type : DNEL Consumer (systemic)

 $\begin{array}{lll} \mbox{Exposure route}: & \mbox{Inhalation} \\ \mbox{Exposure frequency}: & \mbox{Long-term} \\ \mbox{Limit value}: & 21,73 \ \mbox{mg/m}^3 \\ \end{array}$

Limit value type : DNEL Consumer (systemic)

Exposure route: Dermal
Exposure frequency: Long-term
Limit value: 2,5 mg/kg bw/day

Limit value type : DNEL Consumer (systemic)

Exposure route:

Exposure frequency:

Limit value:

Coral

Long-term

6,25 mg/kg bw/day

DNEL worker (local)

Exposure route : Dermal
Exposure frequency : Long-term
Limit value : 0,0936 mg/cm²

Limit value type : DNEL worker (systemic)

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Exposure route: Inhalation
Exposure frequency: Long-term
Limit value: 73,4 mg/m³

Limit value type : DNEL worker (systemic)

Exposure route : Dermal
Exposure frequency : Long-term
Limit value : 4,16 mg/kg bw/day

PNEC

Amides, C8-18 (even numbered) and C18-unsatd., N, N-bis(hydroxyethyl); CAS No.: 68155-07-7

Limit value type : PNEC (Aquatic, freshwater)

Limit value : 0,007 mg/l

Limit value type : PNEC (Aquatic, marine water)

Limit value : 0,0007 mg/l

Limit value type: PNEC (Sediment, freshwater)

Limit value: 0,195 mg/kg dw

Limit value type : PNEC (Sediment, marine water)

Limit value : 0,0195 mg/kg dw
Limit value type : PNEC (Soil)
Limit value : mg/kg dw

Limit value type : PNEC (Sewage treatment plant)

Limit value: 830 mg/l

8.2 Exposure controls

Personal protection equipment

Use personal protection equipment.

Eye/face protection



Eye glasses with side protection EN 166

Skin protection Hand protection



By short-term hand contact: Suitable gloves type Disposable gloves. NBR (Nitrile rubber)

By long-term hand contact: Check leak tightness/impermeability prior to use.

Suitable material CR (polychloroprene, chloroprene rubber), NBR (Nitrile rubber), Butyl caoutchouc (butyl rubber), NR (natural rubber, Natural latex)

Breakthrough time 480 min

Thickness of the glove material Polychloroprene - CR (0.5 mm) Nitrile rubber/nitrile latex - NBR (0.35 mm) Butyl rubber - Butyl (0.5 mm)

Required properties: When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. EN ISO 374

Remark: Check leak tightness/impermeability prior to use. Breakthrough times and swelling properties of the material must be taken into consideration.

Body protection

Wear anti-static footwear and clothing

Protective clothing. EN 13034 Natural fibres (e.g. cotton), heat-resistant synthetic fibres

Chemical resistant safety shoes DIN EN 13832-2

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Respiratory protection

Usually no personal respirative protection necessary.

General information

When using do not eat, drink, smoke, sniff. Wash hands before breaks and after work.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: Liquid
Colour: brown
Odour: characteristics
Safety characteristics

 Physical state :
 Liquid

 Melting point/freezing point :
 not applicable

 Initial boiling point and boiling range :
 (1013 hPa)
 approx.
 100

 Decomposition temperature :
 not determined

 Flash point :
 not applicable

 Auto-ignition temperature :
 not applicable

 Lower explosion limit :
 not applicable

 Upper explosion limit :
 not applicable

Upper explosion limit: not applicable
Vapour pressure: (50 °C) not applicable
Density: (20 °C) 1,05 - 1,056

pH: 2,8 - 3,2
log P O/W: not determined
Viscosity: (20 °C) not determined
Cinematic viscosity: (40 °C) not relevant

Cinematic viscosity: (40 °C) not relevant
Odour threshold: not determined
Relative vapour density: (20 °C) not determined
Vapourisation rate: not determined

Maximum VOC content (EC): 0,5 Weight-%

Flammable solids: Not applicable.
Flammable gases: Not applicable.
Oxidising liquids: Not relevant.
Explosive properties: Not applicable.
Corrosive to metals: No data available.

9.2 Other information

None

SECTION 10: Stability and reactivity

10.1 Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2 Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3 Possibility of hazardous reactions

No known hazardous reactions.

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10.4 Conditions to avoid

See section 7 of the safety data sheet.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

Does not decompose when used for intended uses.

SECTION 11: Toxicological information

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

Based on available data, the classification criteria are not met.

Corrosion

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/eye irritation

Causes serious eye damage.

Respiratory or skin sensitisation

Based on available data, the classification criteria are not met.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity

Based on available data, the classification criteria are not met.

Germ cell mutagenicity

Based on available data, the classification criteria are not met.

Reproductive toxicity

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

11.2 Information on other hazards

Endocrine disrupting potential:

The product does not contain any substance above the legal limits that is included in the list established under Article 59(1) of Regulation (EC) No 1907/2006 on the basis of endocrine disrupting properties or that has endocrine disrupting or endocrine damaging properties according to Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

Other indications of toxicity

The product has not been tested. The statements on toxicology were derived from the properties of the individual components.

SECTION 12: Ecological information

12.1 Toxicity

The product has not been tested. The statement is derived from the properties of the single components.

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Aquatic toxicity

Harmful to aquatic life with long lasting effects.

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

This product does not contain components in concentrations of 0.1% or higher which are classified as either persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB).

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6 Endocrine disrupting properties

The product does not contain any substance above the legal limits that is included in the list established under Article 59(1) of Regulation (EC) No 1907/2006 on the basis of endocrine disrupting properties or that has endocrine disrupting or endocrine damaging properties according to Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

12.7 Other adverse effects

The product does not contain any substances listed in Regulation (EC) 1005/2009 on substances that deplete the ozone layer.

12.8 Additional ecotoxicological information

Additional information

Discharge into the environment must be avoided.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Dispose according to legislation.

13.2 Additional information

Non-contaminated packages may be recycled.

SECTION 14: Transport information

14.1 UN number or ID number

No dangerous good in sense of these transport regulations.

14.2 UN proper shipping name

No dangerous good in sense of these transport regulations.

14.3 Transport hazard class(es)

No dangerous good in sense of these transport regulations.

14.4 Packing group

No dangerous good in sense of these transport regulations.

14.5 Environmental hazards

No dangerous good in sense of these transport regulations.

14.6 Special precautions for user

None

14.7 Maritime transport in bulk according to IMO instruments

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No transport as bulk according to IBC Code.

SECTION 15: Regulatory information

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

EU legislation

Biocide directive ((EU) No. 528/2012)

Authorisations and/or restrictions on use

Restrictions on use

Regulation (EC) No. 1907/2006 (REACH), Annex XVII (restrictions)

Use restriction according to REACH annex XVII, no.: 3, 40, 75

National regulations

Water hazard class

Classification according to AwSV - Class: 2 (Obviously hazardous to water)

15.2 Chemical Safety Assessment

A chemical safety assessment has not been carried out for this preparation. For the following substances of this mixture a chemical safety assessment has been carried out:

SODIUM DODECYL SULPHATE; REACH No.: 01-2119489461-32-0000; EC No.: 205-788-1; CAS No.: 151-21-3

Amides, C8-18 (even numbered) and C18-unsatd., N, N-bis(hydroxyethyl); REACH No. : 01-2119490100-53; EC No. : 931-329-6; CAS No. : 68155-07-7

SECTION 16: Other information

16.1 Indication of changes

None

16.2 Abbreviations and acronyms

 $\label{eq:ADR} \mbox{ADR} = \mbox{European Agreement concerning the carriage of Dangerous goods by Road}$

ADN = European Agreement concerning the Carriage of Dangerous Goods by Inland Waterways

ATE = Estimated values for acute toxicity

AwSV = Ordinance on Installations for Handling Substances Hazardous to Water

CAS = Chemical Abstract Service Number

CE = European Community

CLP = EC Regulation 1272/2008

CMR = cancerogen mutagen reprotoxic

DIN = German Institute for Standardisation

DNEL = Derived No Effect Level

DMEL = Derived Minimum Effect Level

EC50 = Mean effective concentration that induces a defined effect other than death in a test population

EG = European Community

EN = European standards

IATA = International Air Transport Association Dangerous Goods Regulation

IBC-Code = International Code for the construction and equipment of ships carrying dangerous chemicals in large quantities

. IMDG = International Maritime Code for dangerous goods

ISO = International Organization for Standardization

LC50 = Lethal Concentration 50%

LD50 = Lethal dose 50%

MAK = Maximum workplace concentration

MARPOL = International Convention for the Protection of the Marine Environment from Ship-generated Litter

NOEC = No Observed Effect Concentration

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OECD = Organisation for Economic Cooperation and Development

PBT = Persistent, bioaccumulative and toxic

pH = potential of hydrogen

PNEC = Predicted no effect concentration

PPM = parts per million

REACH = Registration, Evaluation, Authorisation and Restriction of Chemicals (EC Regulation 1907/2006)

RID = Regulation concerning the international transport of dangerous goods by train

TRGS = Technical rules for hazardous substances (german rules)

TWA = Time-weighted average exposure limit

UN-Number = UN number for the transport of dangerous goods

vPvB = Very Persistent and very Bioaccumulative as for REACH Regulation

VOC = Volatile organic Compounds

16.3 Key literature references and sources for data

None

^{16.4} Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

16.5 Relevant H- and EUH-phrases (Number and full text)

H228 Flammable solid.
H302 Harmful if swallowed.
H315 Causes skin irritation.
H318 Causes serious eye damage.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

H411 Toxic to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting effects.

16.6 Training advice

None

16.7 Additional information

None

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

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