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IODUM

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name: Iodine

Iodum Jodium Iode Iod

N° CAS: 7553-56-2 N° EC: 231-442-4

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

Identified uses: Active Pharmaceutical Ingredient or Excipient.

1.3 Details of the supplier of the safety data sheet

Company: FAC SECUNDUM ARTEM NV

Oostmalsebaan 1c (unit 5)

2960 Sint-Lenaarts

Belgium

Telephone: (+32) (0)3 457 11 76
Email: info@magis-pharma.be
Web page: www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation: Belgisch Antigifcentrum Centre Antipoisons Belge

Telephone: (+32) (0)70 245 245 (Service 24/7)

Web page: www.antigifcentrum.be www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Acute Toxicity category 4 H302
Acute Toxicity category 4 H312
Acute Toxicity category 4 H332
Specific target organ toxicity – H372

repeated exposure, category 1

Eye irritation category 2 H319
Skin irritation category 2 H315
Specific target organ toxicity – H335

single exposure, category 3

Hazardous to the aquatic H400

encironment, acute toxicity,

category 1

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2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):







Signal word(s):

Hazard statements:

H302+H312+H332 Harmful if swallowed, in contact with skin or if inhaled.

H372 Causes damage to organs through prolonged or repeated exposure.

H319 Causes serious eye irritation

H315 Causes skin irritation

H335 May cause respiratory irritation

H400 Very toxic to aquatic life.

Precautionary statements:

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 IF ON SKIN: Wash with plenty of water.

P304+P340 IF INHALED: Remove person to fresh air and keep 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.

P312 Call a POISON CENTER/doctor/... if you feel unwell.

P403+P233 Store in a well-ventilated place. Keep container tightly closed. P501 Dispose of contents/container to in conformity with local laws.

Additional applicable label

elements:



2.3 Other hazards

None.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Iodine

IUPAC name: Molecular iodine

Synonyms: Diiodine

Iode

N° CAS: 7553-56-2 231-442-4 N° EC:

Molecular Formule: I_2

Content: 99.5 per cent to 100.5 per cent of I.

3.2 Mixtures

Not applicable.

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SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: Consult a doctor. Show the safety data sheet to the doctor on duty.

After inhalation: Remove to fresh air. If breathing is irregular, call a doctor immediately. Only give

artificial respiration if breathing stops or under medical supervision.

After skin contact: Wash immediately with plenty of soap and water for at least 15 minutes. Remove all

contaminated clothing immediately. Get medical attention if irritation develops and

persists.

Remove contact lenses and rinse immediately with plenty of water, including under After eye contact:

eyelids, for at least 15 minutes. Get medical attention.

If conscious, give victim plenty of water to drink. Never give anything by mouth to an After ingestion:

unconscious person. Call a doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed

There are no known acute or delayed effects from exposure to the product.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Foam, dry powder, carbon dioxide, sand, water mist.

Neighbouring fires (containers exposed to fire): Water spray or fog.

Direct water jet. Unsuitable extinguishing media:

5.2 Special hazards arising from the substance/mixture

Non-combustible. Possibility of formation of dangerous vapours in the surroundings due to fire. In case of fire, nitrogen oxides may be produced.

5.3 Advice for firefighters

Surrounding fires: Cool containers with water to prevent decomposition of product and

> development of health hazards. Always use full fire protection. Collect water from which must not enter sewage system. Dispose of contaminated water used for extinguishing and residues in

accordance with current regulations.

Protection against fire: Helmet with visor, flame retardant clothing (jacket and trousers with

> straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the whole face of the operator or the car (self protective) in the case of large quantities

of smoke, a self-contained breathing apparatus (EN 137).

Not available. Hazardous combustion products:

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Avoid dust formation. Do not inhale dust.

For emergency responders

Avoid dust formation. Do not inhale dust.

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6.2 Environmental precautions

Avoid ingress of products into sewers, surface water, groundwater and groundwater

6.3 Methods and material for containment and cleaning up

Soffocate with soil or inert material. Collect most of the material and remove the residue with water jets, follow the recommendations in section 13.

6.4 Reference to other sections

For exposure control and personal protective measures, see section 8.

For waste disposal, follow the recommendations in section 13

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Avoid dispersal of the product in the environment. Smoking, eating

and drinking must be prohibited in the application area. Comply with occupational health and safety legislation. Keep the product in

containers made of material identical to the original one.

Personal protection: Not available.

Technical protective measures: Not available.

Handling: Comply with occupational health and safety legislation.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Not available.

Conditions for safe storage, including any

incompatibilities:

The product does not require special storage measures. Store

containers in a cool, dry place.

Storage – away from: Not available.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation at the workplace by effective local suction. When choosing personal protective equipment, ask your chemical suppliers if this is necessary. Personal protective equipment must be CE-marked for compliance with applicable regulations. Provide an emergency shower with a visco-elastic tray.

Hygiene measures: Handle with appropriate industrial hygiene precautions, and observe safety practices. Wash hands before breaks and after finishing work.

Individual protection measures

Eye/face protection: Protective face shields and safety goggles according to EN166.

Skin protection: Choose body protection according to the quantity and concentration of the

hazardous substance in the workplace.

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Hand protection: Handle with gloves. The selected protective gloves must comply with the

specifications of EU Directive 89/686/EEC and the derived EN 374 standard.

Respiratory protection: Where risk assessment shows that air-purifying respirators are appropriate, use dust

mask type N95 (USA) or type P1 (EN 143). Use respirators and components tested and approved under appropriate governmental standards such as NIOSH (US) or CEN (EU).

Thermal hazards: Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Greyish-violet, brittle plates or fine crystals with a metallic sheen.

Odour: Pungent

Odour threshold: Not available. pH: Not available.

Melting/freezing point: 113 °C Initial boiling point: 184 °C

Boiling range:

Flash point:

Evaporation rate:

Flammability (solid/gas):

Upper/lower flammability or

Not available.

Not available.

Not available.

explosive limits:

Vapour pressure: 0.233 mmHg
Vapour density: Not available.
Relative density: 4.93 at 20°C

Solubility: Very soluble in concentrated solutions of iodides, soluble in ethanol (96%), slightly

soluble in glycerol.

Solubility in water: Very slightly soluble in water.

0.30 g/L (20 °C)

Partition coefficient

Not available.

(n-octanol/water):

Auto-ignition temperature: Not available.

Decomposition temperature: Not available.

Viscosity: Not available.

Explosive properties: Not available.

Oxidising properties: Not available.

9.2 Other information

Molecular weight: 253.81 g/mol

Dry residue: 100.00 %.

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VOC (Directive 2010/75/EC): 0 VOC (Volatile carbon): 0

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No special conditions.

10.2 Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions

The product does not present the possibility of dangerous reactions.

10.4 Conditions to avoid

None in particular.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Acute Oral Toxicity (LD50, rat): 14 g/kg

Skin corrosion/irritation: Not available.

Serious eye damage/irritation: May cause irritation of eyes..

Respiratory/skin sensitisation: May cause irritation of mucous membranes and upper respiratory tract.

Germ cell mutagenicity: Not available. Carcinogenicity: Not available. Reproductive toxicity: Not available. Summary of evaluation of the Not available.

CMR properties:

STOT-single exposure: Not available. STOT-repeated exposure: Not available. Not available. Aspiration Hazard:

Other: There are no known health related events due to exposure to the product. In any

case, it is recommended to comply with the rules of good industrial hygiene.

Potential health effects

Symptoms of exposure may include: burning and irritation of the eyes, mouth, nose and throat, coughing, difficulty breathing, dizziness, headache, nausea and vomiting. In severe cases, inhalation of the product may cause inflammation and oedema of the larynx and bronchi, chemical pneumonia and pulmonary oedema. The product may cause irritation of the site of contact, usually accompanied by increased skin temperature, swelling, itching. Even small amounts ingested may cause significant health problems (abdominal pain, nausea, vomiting, diarrhoea).

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The product may cause functional alterations or morphological changes due to repeated or prolonged exposure and/or is of concern for the possibility of accumulation in the human body.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact: Acute effects: Contact with eyes causes irritation; symptoms may include: redness,

oedema, pain and tearing.

Skin contact: Acute effects: The product is harmful if absorbed through te skin. Skin contact causes

irritation with erythema, oedema, dryness and cracking. Ingestion may cause health

disturbances, including burning abdominal pain, nausea and vomiting.

Inhalation: Acute effects: The product is harmful if ihaled. Inhalation of the product causes

irritation of the upper and lower respiratory tract with coughing and shortness of

breath; at higher concentrations may also cause pulmonary oedema.

Ingestion: Acute effects: The product is harmful if swallowed. Ingestion may cause health

disturbances including burning abdominal pain, nausea and vomiting.

Aspiration: Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

LC₅₀ (fish): > 0.01 mg/L/96 h (Oncorhynchus mykiss)

EC₅₀ (algae, aquatic plants): 0.016 mg/L/72h (Daphnia magna)

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

According to available data, the product does not contain PBT or vPvB substances in concentrations above 0.10 %.

12.6 Other adverse effects

Use in accordance with good laboratory practice, avoid dispersal into the environment. Inform the competent authorities if the product contaminates ground water, sewage, soil or vegetation.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service for disposal of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated packaging

Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

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14.1 UN Number

ADR/RID(Land),IMDG(Sea),

IATA/ICAO (Air):

3495

14.2 UN proper shipping name

ADR/RID(Land),IMDG(Sea),

IATA/ICAO (Air):

ADR/RID: IODINE IMDG: IODINE

IATA: IODINE

14.3 Transport hazard class(es)

ADR/RID(Land),IMDG(Sea),

Class: 8 Label: 6.1

IATA/ICAO (Air):

14.4 Packing group

ADR/RID(Land),IMDG(Sea),

IATA/ICAO (Air):

Ш

14.5 Environmental hazards

ADR/RID(Land),IMDG(Sea),

ADR/RID: Dangerous for the Environment

IATA/ICAO (Air):

IMDG: Marine Pollutant

IATA: Dangerous for the environment

14.6 Special precautions for user

ADR/RID: HIN - Kemler: 86 Quantity Limit: 5 kg

Restriction code: (E)

Special provisions: -

IMDG:

EMS: F-A, S-B

Quantity Limit: 5 kg

IATA: Cargo: Maximum Quantity: 100 kg

Packaging instructions: 864

Pass.:

Maximum Quantity: 25 kg

Packaging instructions: 860

Particular instructions: A113, A803

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

Not available.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:





Attention

Risk phrases: R20/21 Harmful by inhalation and in contact with skin.

R50 Very toxic to aquatic organisms.

Safety phrases: S28 After contact with skin, wash immediately with plenty of water.

> S36/37/39 Wear suitable protective clothing, gloves and eye/face protection. S45 In case of accident or if you feel unwell seek medical advice immediately

(show the label where possible). S51 Use only in well-ventilated areas.

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S61 Avoid release to the environment. Refer to special instructions/safety data

Revision:

sheet.

S63 In case of accident by inhalation: remove casualty to fresh air and keep at rest.

15.2 Chemical safety assessment

A chemical safety assessment of the product has not been carried out.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR: European Agreement concerning the International Carriage of Dangerous Goods by

CAS: Chemical Abstracts Service (division of the American Chemical Society)

EC (number): European Community (number)

IATA: **International Air Transport Association** ICAO: International Civil Aviation Organization

IMDG: International Maritime Code for Dangerous Goods IUPAC: International Union of Pure and Applied Chemistry PBT: Persistent, Bioaccumulative and Toxic substance

Regulations Concerning the International Transport of Dangerous Goods by Rail RID:

STOT: **Specific Target Organ Toxicity** UN (number): United Nations (number)

vPvB: very Persistent and very Bioaccumalative

16.3 Key literature references/sources for data

European Chemicals Agency.

https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the FSA NV's

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16.8 Department issuing MSDS

Quality Department FAC SECUNDUM ARTEM NV info@magis-pharma.be