

according to the (US) Hazard Communication Standard (29 CFR 1910.1200)

Revision Date 07/29/2015

Version 3.0

SECTION 1.Identification

Product identifier

Product number 104760

Product name Iodine purified by sublimation suitable for use as excipient

EMPROVE® exp Ph Eur, BP, USP

CAS-No. 7553-56-2

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

Identified uses Pharmaceutical production, Reagent for research and development

Details of the supplier of the safety data sheet

Company EMD Millipore Corporation | 290 Concord Road, Billerica, MA 01821,

United States of America | General Inquiries: +1-978-715-4321 | Monday to Friday, 9:00 AM to 4:00 PM Eastern Time (GMT-5)

Emergency telephone 800-424-9300 CHEMTREC (USA)

+1-703-527-3887 CHEMTREC (International)

24 Hours/day; 7 Days/week

SECTION 2. Hazards identification

GHS Classification

Acute toxicity, Category 4, Inhalation, H332

Acute toxicity, Category 4, Dermal, H312

Skin irritation, Category 2, H315

Eye irritation, Category 2A, H319

 $Specific \ target \ organ \ systemic \ toxicity \ - \ single \ exposure, \ Category \ 3, \ Respiratory \ system, \ H335$

Specific target organ systemic toxicity - repeated exposure, Category 1, Oral, thyroid, H372

For the full text of the H-Statements mentioned in this Section, see Section 16.

GHS-Labeling

Hazard pictograms





Signal Word
Danger

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Hazard Statements

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

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H372 Causes damage to organs (thyroid) through prolonged or repeated exposure if swallowed.

Precautionary Statements

P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P271 Use only outdoors or in a well-ventilated area.

P280 Wear protective gloves/ eye protection/ face protection.

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

P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position 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.

P314 Get medical advice/ attention if you feel unwell.

P322 Specific measures (see supplemental first aid instructions on this label).

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

P337 + P313 If eye irritation persists: Get medical advice/ attention.

P362 Take off contaminated clothing and wash before reuse.

P403 + P233 Store in a well-ventilated place. Keep container tightly closed.

P405 Store locked up.

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. Composition/information on ingredients

Formula I_2 (Hill) Molar mass 253.8 g/mol

Hazardous ingredients

Chemical Name (Concentration)

CAS-No.

Iodine (>= 90 % - <= 100 %)

7553-56-2

Exact percentages are being withheld as a trade secret.

SECTION 4. First aid measures

Description of first-aid measures

Inhalation

After inhalation: fresh air. If breathing stops: mouth-to-mouth breathing or artificial respiration.

Oxygen if necessary. Immediately call in physician.

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Skin contact

In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/shower. Consult a physician.

Eye contact

After eye contact: rinse out with plenty of water. Call in ophthalmologist.

Inaestion

After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed

irritant effects, conjunctivitis, Asthma, bronchitis, Dermatitis, Skin disorders, Fever, bloody diarrhea, collapse, rhinitis, metallic taste

Indication of any immediate medical attention and special treatment needed

Laxative: Sodium sulfate (1 tablespoon/1/4 I water).

SECTION 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media

For this substance/mixture no limitations of extinguishing agents are given.

Special hazards arising from the substance or mixture

Not combustible.

Ambient fire may liberate hazardous vapors.

Fire may cause evolution of:

hydrogen iodide

Advice for firefighters

Special protective equipment for fire-fighters

Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

Further information

Suppress (knock down) gases/vapors/mists with a water spray jet. Prevent fire extinguishing water from contaminating surface water or the ground water system.

SECTION 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Avoid substance contact. Avoid inhalation of dusts. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.

Advice for emergency responders: Protective equipment see section 8.

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Environmental precautions

Do not empty into drains.

Methods and materials for containment and cleaning up

Cover drains. Collect, bind, and pump off spills.

Observe possible material restrictions (see sections 7 and 10).

Take up dry. Dispose of properly. Clean up affected area. Avoid generation of dusts.

SECTION 7. Handling and storage

Precautions for safe handling

Observe label precautions.

Work under hood. Do not inhale substance/mixture.

Conditions for safe storage, including any incompatibilities

Tightly closed. Dry. Keep in a well-ventilated place. Keep locked up or in an area accessible only to qualified or authorized persons.

Store at $+5^{\circ}$ C to $+30^{\circ}$ C ($+41^{\circ}$ F to $+86^{\circ}$ F).

SECTION 8. Exposure controls/personal protection

Exposure limit(s)

Ingrea	lients
--------	--------

Basis	Value	Threshold limits	Remarks	
Iodine 7553-56-2				
NIOSH/GUIDE	Ceiling Limit Value and Time Period (if specified):	0.1 ppm 1 mg/m³		
OSHA_TRANS	Ceiling Limit Value:	0.1 ppm 1 mg/m³		
Z1A	Ceiling Limit Value:	0.1 ppm 1 mg/m³		
ACGIH	Short Term Exposure Limit (STEL):	0.1 ppm	Form of exposure: Vapor and aerosol.	
	Time Weighted Average (TWA):	0.01 ppm	Form of exposure: Inhalable fraction and vapor.	

Engineering measures

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

Individual protection measures

Protective clothing should be selected specifically for the workplace, depending on concentration and quantity of the hazardous substances handled. The chemical resistance of the protective equipment should be inquired at the respective supplier.

Hygiene measures

Immediately change contaminated clothing. Apply skin- protective barrier cream. Wash hands and face after working with substance.

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Eye/face protection Safety glasses

Hand protection

full contact:

Glove material: Nitrile rubber
Glove thickness: 0.11 mm
Break through time: > 480 min

splash contact:

Glove material: Nitrile rubber
Glove thickness: 0.11 mm
Break through time: > 480 min

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374, for example KCL 741 Dermatril® L (full contact), KCL 741 Dermatril® L (splash contact).

The breakthrough times stated above were determined by KCL in laboratory tests acc. to EN374 with samples of the recommended glove types.

This recommendation applies only to the product stated in the safety data sheet and supplied by us as well as to the purpose specified by us. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).

Other protective equipment: protective clothing

Respiratory protection

required when dusts are generated. Recommended Filter type: Filter B-(P2)

The entrepeneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are performed according to the instructions of the producer. These measures have to be properly documented.

SECTION 9. Physical and chemical properties

Physical state solid

Color dark violet

Odor stinging

Odor Threshold No information available.

pH 5.4

(saturated solution)

Melting point 114 °C

Boiling point/boiling range 185 °C (185 °C)

at 1,013 hPa

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Flash point No information available.

Evaporation rate No information available.

Flammability (solid, gas)

The product is not flammable.

Lower explosion limit Not applicable

Upper explosion limit Not applicable

Vapor pressure 0.41 hPa

at 25 °C (25 °C)

Relative vapor density 8.8

Density 4.93 g/cm3

at 20 °C (20 °C)

Relative density No information available.

Water solubility 0.3 g/l

at 20 °C (20 °C)

Partition coefficient: n-

octanol/water

log Pow: 2.49 (experimental)

Bioaccumulation is not expected. (Lit.)

Autoignition temperature No information available.

Decomposition temperature No information available.

Viscosity, dynamic 2.27 mPa.s

at 116 °C (116 °C)

Explosive properties Not classified as explosive.

Oxidizing properties none

Bulk density ca.2,100 kg/m3

Viscosity, kinematic 0.57 mm2/s

at 116 °C (116 °C)

liquid

SECTION 10. Stability and reactivity

Reactivity

See below

Chemical stability

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Eur, BP, USP

sublimable

Possibility of hazardous reactions

Risk of explosion with:

Reducing agents, Alkali metals, Acetylene, Ammonia, Potassium, copper compounds, sodium, oxyhalogenic compounds, Boron, halogen oxides, iodides, azides, ammonium compounds antimony, in powder form

mercury oxide, with, Methanol, and, ethanol

Risk of ignition or formation of inflammable gases or vapors with:

Powdered metals, Zinc, semimetals, halogen-halogen compounds, nonmetals, nonmetallic oxides, alkali salts, Iron, Fluorine, formaldehyde, hydrides, sodium phosphite, phosphorus, sulfur, Titanium, powdered aluminum, acetylidene, combustible substances, powdered magnesium, petrol, butadiene, CALCIUM HYDRIDE

Diethyl ether, with, Aluminum

Exothermic reaction with:

carbides, azides, turpentine oils and/or turpentine substitutes, alkali oxides, lithium silicide, alkaline earth compounds, nitrides, Acetaldehyde, Lithium, fluorides, Oxides of phosphorus, Chlorine

Iron, in powder form

Conditions to avoid

no information available

Incompatible materials

no information available

Hazardous decomposition products

in the event of fire: See section 5.

SECTION 11. Toxicological information

Information on toxicological effects

Likely route of exposure

Eye contact, Skin contact, Ingestion

Target Organs

Eyes

Skin

Respiratory system

Central nervous system

cardiovascular system

Acute oral toxicity

LD50 Rat: 14,000 mg/kg (RTECS)

Symptoms: metallic taste, bloody diarrhea, Circulatory collapse

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Acute inhalation toxicity

Symptoms: mucosal irritations, Cough, Shortness of breath, Possible damages:, damage of respiratory tract absorption

Acute dermal toxicity

LD50 Rabbit: 1,425 mg/kg

US-EPA

absorption

Skin irritation

In vitro study

Result: non-corrosive OECD Test Guideline 435

In vitro study Result: Irritations

OECD Test Guideline 439

Causes skin irritation.

Possible damages: Dermatitis

Eye irritation

Causes serious eye irritation.

Sensitization

In animal experiments: Mouse

Result: negative

Method: OECD Test Guideline 429

Repeated dose toxicity (as aqueous solution)

Genotoxicity in vitro

Mutagenicity (mammal cell test): MOUSE LYMPHOMA TEST

Result: negative

Method: OECD Test Guideline 476

UDS (Unscheduled DNA synthesis assay)

Result: negative

Method: OECD Test Guideline 482

Specific target organ systemic toxicity - single exposure

Inhalation

Target Organs: Respiratory system May cause respiratory irritation.

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Specific target organ systemic toxicity - repeated exposure

Ingestion

Target Organs: thyroid

Causes damage to organs through prolonged or repeated exposure.

Aspiration hazard

Regarding the available data the classification criteria are not fulfilled.

Carcinogenicity

IARC No ingredient of this product present at levels greater than or

equal to 0.1% is identified as probable, possible or confirmed

human carcinogen by IARC.

OSHA No ingredient of this product present at levels greater than or

equal to 0.1% is identified as a carcinogen or potential

carcinogen by OSHA.

NTP No ingredient of this product present at levels greater than or

equal to 0.1% is identified as a known or anticipated carcinogen

by NTP.

ACGIH No ingredient of this product present at levels greater than or

equal to 0.1% is identified as a carcinogen or potential

carcinogen by ACGIH.

Further information

Systemic effects:

After uptake:

Fever

Chronic intoxication:

Skin disorders, rhinitis, conjunctivitis, bronchitis, Asthma

Handle in accordance with good industrial hygiene and safety practice.

SECTION 12. Ecological information

Ecotoxicity

Toxicity to fish

static test LC50 Oncorhynchus mykiss (rainbow trout): 1.67 mg/l; 96 h (ECHA)

Toxicity to daphnia and other aquatic invertebrates

static test EC50 Daphnia magna (Water flea): 0.55 mg/l; 48 h (ECHA)

Toxicity to algae

Growth inhibition ErC50 Desmodesmus subspicatus (green algae): 0.13 mg/l; 72 h

OECD Test Guideline 201

Growth inhibition NOEC Desmodesmus subspicatus (green algae): 0.025 mg/l; 72 h

OECD Test Guideline 201

Toxicity to bacteria

EC50 activated sludge: 280 mg/l; 3 h

OECD Test Guideline 209

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Persistence and degradability

Biodegradability

The methods for determining the biological degradability are not applicable to inorganic substances.

Bioaccumulative potential

Partition coefficient: n-octanol/water

log Pow: 2.49 (experimental)

Bioaccumulation is not expected. (Lit.)

Mobility in soil

No information available.

SECTION 13. Disposal considerations

The information presented only applies to the material as supplied. The identification based on characteristic(s) or listing may not apply if the material has been used or otherwise contaminated. It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and disposal methods in compliance with applicable regulations. Disposal should be in accordance with applicable regional, national and local laws and regulations.

SECTION 14. Transport information

Land transport (DOT)

UN number UN 3495
Proper shipping name IODINE
Class 8 (6.1)
Packing group III
Environmentally hazardous --

Air transport (IATA)

UN number
UN 3495
Proper shipping name
IODINE
Class
8 (6.1)
Packing group
III
Environmentally hazardous
Special precautions for user
uno 1495
IODINE
8 (6.1)

Sea transport (IMDG)

UN number
UN 3495
Proper shipping name
IODINE
Class
8 (6.1)
Packing group
III
Environmentally hazardous
Special precautions for user
UN 3495
IODINE
8 (6.1)
9 (6.1)

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EmS F-A S-B

SECTION 15. Regulatory information

United States of America

SARA 313

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 302

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311,

Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311,

Table 117.3.

DEA List I

Listed Ingredients

lodine 7553-56-2

DEA List IINot listed

US State Regulations

Massachusetts Right To Know

Ingredients lodine

Pennsylvania Right To Know

Ingredients lodine

New Jersey Right To Know

Ingredients

lodine

California Prop 65 Components

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

Notification status

TSCA: All components of the product are listed in the TSCA-inventory.

DSL: All components of this product are on the Canadian DSL.

SECTION 16. Other information

according to the (US) Hazard Communication Standard (29 CFR 1910.1200)

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Training advice

Provide adequate information, instruction and training for operators.

Labeling

Hazard pictograms







Signal Word Danger

Hazard Statements

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

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H372 Causes damage to organs (thyroid) through prolonged or repeated exposure if swallowed.

H400 Very toxic to aquatic life.

Precautionary Statements

Prevention

P273 Avoid release to the environment.

Response

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

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

lenses, if present and easy to do. Continue rinsing.

P314 Get medical advice/ attention if you feel unwell.

Full text of H-Statements referred to under sections 2 and 3.

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 if swallowed.

Key or legend to abbreviations and acronyms used in the safety data sheet

Used abbreviations and acronyms can be looked up at www.wikipedia.org.

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The information contained herein is based on the present state of our knowledge. It characterizes the product with regard to appropriate safety precautions. It does not represent a warranty of any product properties and we assume no liability for any loss or injury which may result from the use of this information. Users should conduct their own investigations to determine the suitability of the information.

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