

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Version 8.11 Revision Date 02.07.2024 Print Date 06.07.2024

GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

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

1.1 Product identifiers

Product name : Potassium iodide EMPROVE® API Ph

Eur, BP, ChP, JP, USP

Product Number : 1.05040 Catalogue No. : 105040 Brand : Millipore

REACH No. : A registration number is not available for this substance as the

substance or its uses are exempted from registration or the

annual tonnage does not require a registration.

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

Identified uses : Pharmaceutical production and analysis

1.3 Details of the supplier of the safety data sheet

Company : Merck KGaA

Frankfurter Str. 250 D-64271 DARMSTADT

Telephone : +49 (0)6151 72-0 Fax : +49 6151 727780

E-mail address : TechnicalService@merckgroup.com

1.4 Emergency telephone

Emergency Phone #: +(44)-870-8200418 (CHEMTREC (GB))

+(353)-19014670 (CHEMTREC Ireland) 001-803-017-9114 (CHEMTREC India)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Specific target organ toxicity - H372: Causes damage to organs through repeated exposure, (Category 1), prolonged or repeated exposure if

Thyroid swallowed.

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2.2 Label elements

Labelling according Regulation (EC) No 1272/2008

Pictogram

Signal Word Danger

Hazard Statements

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. P314 Get medical advice/ attention if you feel unwell.

P501 Dispose of contents/ container to an approved waste disposal

plant.

Supplemental Hazard

Statements

none

Reduced Labeling (<= 125 ml)

Pictogram

Signal Word Danger

Hazard Statements

H372 Causes damage to organs 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. P314 Get medical advice/ attention if you feel unwell.

P501 Dispose of contents/ container to an approved waste disposal

plant.

Supplemental Hazard

Statements

none

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information:

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher. Toxicological information:

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The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.1 Substances

Molecular weight : 166,01 g/mol

Component		Classification	Concentration
potassium iodide			
CAS-No. EC-No.	7681-11-0 231-659-4	STOT RE 1; H372	<= 100 %

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

SECTION 4: First aid measures

4.1 Description of first-aid measures

General advice

Show this material safety data sheet to the doctor in attendance.

If inhaled

After inhalation: fresh air. Call in physician.

In case of skin contact

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

In case of eye contact

After eye contact: rinse out with plenty of water. Remove contact lenses.

If swallowed

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

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

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

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Unsuitable extinguishing media

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

5.2 Special hazards arising from the substance or mixture

Hydrogen iodide

Potassium oxides

Not combustible.

Fire may cause evolution of:

hydrogen iodide

Ambient fire may liberate hazardous vapours.

5.3 Advice for firefighters

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

5.4 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

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Avoid generation and inhalation of dusts in all circumstances. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert. For personal protection see section 8.

6.2 Environmental precautions

Do not let product enter drains.

6.3 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.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

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

Storage class

Storage class (TRGS 510): 6.1D: Non-combustible, acute toxic Cat.3 / toxic hazardous materials or hazardous materials causing chronic effects

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with workplace control parameters

8.2 Exposure controls

Personal protective equipment

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Safety glasses

Skin protection

This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN 16523-1 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).

Full contact

ili Contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: 480 min

Material tested: KCL 741 Dermatril® L

This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN 16523-1 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell,

Internet: www.kcl.de).

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm Break through time: 480 min

Material tested: KCL 741 Dermatril® L

Body Protection

protective clothing

Respiratory protection

required when dusts are generated.

Our recommendations on filtering respiratory protection are based on the following standards: DIN EN 143, DIN 14387 and other accompanying standards relating to the used respiratory protection system.

Recommended Filter type: Filter type P2

The entrepeneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer.

These measures have to be properly documented.

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Control of environmental exposure

Do not let product enter drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a) Physical state solid

b) Color off-whitec) Odor odorless

d) Melting Melting point: 680 °C

point/freezing point

e) Initial boiling point 1.330 °C and boiling range

f) Flammability (solid, The product is not flammable. gas)

g) Upper/lower No data available flammability or explosive limits

h) Flash point No data availablei) Autoignition No data available temperature

j) Decomposition No data available temperature

k) pH ca.6,9 at 50 g/l at 20 °C

I) Viscosity Viscosity, kinematic: No data available Viscosity, dynamic: No data available

m) Water solubility ca.1.430 g/l at 25 °C - completely solublen) Partition coefficient: Not applicable for inorganic substances

o) Vapor pressure ca.1 hPa at 745 °C

p) Density 3,13 g/cm3

n-octanol/water

q) Relative density No data available q) Relative vapor No data available density

r) Particle No data available characteristics

s) Explosive properties No data available

t) Oxidizing properties none

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9.2 Other safety information

Bulk density ca.1.500 kg/m3 Solubility in other Alcohol at 20 °C

solvents - soluble

Acetone at 20 °C

Ether at 20 °C

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature) .

10.3 Possibility of hazardous reactions

Risk of explosion with:

Alkali metals Ammonia

halogen-halogen compounds

hydrogen peroxide perchloryl fluoride

Exothermic reaction with:

Oxidizing agents

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

Fluorine

10.4 Conditions to avoid

no information available

10.5 Incompatible materials

No data available

10.6 Hazardous decomposition products

In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Oral: No data available Inhalation: No data available

LD50 Dermal - Rat - male and female - > 2.000 mg/kg

(OECD Test Guideline 402)

Skin corrosion/irritation

Skin - Rabbit

Canada

Result: No skin irritation - 4 h

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(OECD Test Guideline 404)

Serious eye damage/eye irritation

Remarks: No data available

Respiratory or skin sensitization

Patch test: - In vitro study

Result: negative Remarks: (ECHA)

Prolonged or repeated exposure may cause allergic reactions in certain sensitive

individuals.

Germ cell mutagenicity

No data available

Test Type: In vitro mammalian cell gene mutation test

Test system: mouse lymphoma cells

Metabolic activation: without metabolic activation

Method: OECD Test Guideline 476

Result: negative

Carcinogenicity

No data available

Reproductive toxicity

Exposure to excessive amounts of iodine during pregnancy is capable of producing fetal hypothyroidism. Iodine-containing drugs have been associated with fetal goiter. No data available

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

Ingestion - Causes damage to organs through prolonged or repeated exposure.
- Thyroid

Aspiration hazard

No data available

11.2 Additional Information

Endocrine disrupting properties

Product:

Assessment The substance/mixture does not contain

components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Prolonged exposure to iodides may produce iodism in sensitive individuals. Symptoms of exposure include: skin rash, running nose, headache and irritation of the mucous membrane. For severe cases the skin may show pimples, boils, hives, blisters and black and blue spots. Iodides are readily diffused across the placenta. Neonatal deaths from respiratory distress secondary to goiter have been reported. Iodides have been known to cause drug-induced fevers, which are usually of short duration.

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

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After absorption of toxic quantities:

drop in blood pressure paralysis symptoms agitation Vomiting

The following applies to iodides in general: Sensitisation possible in predisposed persons.

Other dangerous properties can not be excluded.

Handle in accordance with good industrial hygiene and safety practice.

Liver - Irregularities - Based on Human Evidence

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish static test LC50 - Oncorhynchus mykiss (rainbow trout) - 3.780 mg/l

static test EC50 - Daphnia magna (Water flea) - 7,5 mg/l - 48 h

- 96 h

(OECD Test Guideline 203)

Toxicity to daphnia and other aquatic

(OECD Test Guideline 202)

invertebrates

12.2 Persistence and degradability

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

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components

considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

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SECTION 13: Disposal considerations

13.1 Waste treatment methods

No data available

SECTION 14: Transport information

14.1 UN number

IMDG: -ADR/RID: -IATA: -

14.2 UN proper shipping name

ADR/RID: Not dangerous goods IMDG: Not dangerous goods IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: -IMDG: -IATA: -

14.4 Packaging group

ADR/RID: -IMDG: -IATA: -

14.5 Environmental hazards

IMDG Marine pollutant: no IATA: no ADR/RID: no

14.6 Special precautions for user

No data available

Further information

Not classified as dangerous in the meaning of transport regulations.

SECTION 15: Regulatory information

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

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

Other regulations

Take note of Dir 94/33/EC on the protection of young people at work.

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out

SECTION 16: Other information

Canada

Full text of H-Statements

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Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM -American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS -Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx -Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. -Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS -Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

The information is believed to be correct but is not exhaustive and will be used solely as a guideline, which is based on current knowledge of the chemical substance or mixture and is applicable to appropriate safety precautions for the product. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

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