

Page 1/9

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 10.03.2023 Version number 2.00 (replaces version 1.00) Revision: 10.03.2023

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

· Product identifier

Trade name: Povidone, iodinated, API

· Article number: 2546

• CAS Number: 25655-41-8 • EC number: 607-771-8

- · Registration number The substance is exempt from REACH-registration.
- Relevant identified uses of the substance or mixture and uses advised against
- · Application of the substance / the mixture

Ingredient for pharmaceutical drugs or active pharmaceutical ingredient.

- · Uses advised against No relevant information available.
- · Details of the supplier of the safety data sheet
- Manufacturer/Supplier:

CAELO

Caesar & Loretz GmbH

Herderstr. 31

D-40721 Hilden

GERMANY

· Further information obtainable from:

E-mail: info@caelo.de

Tel.: +49210349940 (during regular opening hours)

Emergency telephone number:

Poison Information Center Bonn Venusberg-Campus 1, 53127 Bonn

Tel: +49 (0) 228-192400

2 Hazards identification

- · Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

Skin Irrit. 2 H315 Causes skin irritation.

Eye Dam. 1 H318 Causes serious eye damage.

Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.

- · Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The substance is classified and labelled according to the CLP regulation.

(Contd. on page 2)



Page 2/9

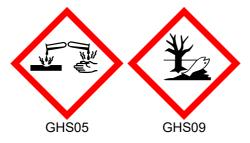
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Printing date 10.03.2023 Version number 2.00 (replaces version 1.00) Revision: 10.03.2023

Trade name: Povidone, iodinated, API

(Contd. of page 1)

· Hazard pictograms



· Signal word Danger

· Hazard statements

H315 Causes skin irritation.

H318 Causes serious eye damage.

H411 Toxic to aquatic life with long lasting effects.

· Precautionary statements

P280 Wear eye protection / face protection.

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

present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor.

P321 Specific treatment (see on this label).

P362+P364 Take off contaminated clothing and wash it before reuse.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

· Other hazards

· Results of PBT and vPvB assessment

- · PBT: Not applicable.
- · vPvB: Not applicable.
- Determination of endocrine-disrupting properties Not applicable.

3 Composition/information on ingredients

- · Substances
- · CAS No. Description

CAS: 25655-41-8 Polyvinylpyrrolidone iodine

- · Identification number(s)
- EC number: 607-771-8

4 First aid measures

- Description of first aid measures
- · After inhalation: Fresh air. If irritation of respiratory ways continues seek medical advice.
- After skin contact:

Take off contaminated clothes and shoes, wash immediately with plenty of water and soap.

· After eye contact:

Rinse opened eye for several minutes under running water.

Seek medical advice, even if no immediate symptoms are observed.

(Contd. on page 3)



Page 3/9

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 10.03.2023 Version number 2.00 (replaces version 1.00) Revision: 10.03.2023

Trade name: Povidone, iodinated, API

(Contd. of page 2)

· After swallowing:

Drink plenty of water.

Call a doctor immediately.

· Most important symptoms and effects, both acute and delayed

No further relevant information available.

Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Firefighting measures

- · Extinguishing media
- Suitable extinguishing agents:

All regular extinguishing media can be used.

Use fire extinguishing methods suitable to surrounding conditions.

Special hazards arising from the substance or mixture

In case of fire, the following can be released:

Rauchgas, loddampf

- Advice for firefighters
- · Protective equipment: In case of fire wear suitable protective clothes and respiratory protection.
- **Additional information**

Prevent from entering into drains. Fire residues must be disposed in accordance with official regulations.

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

Avoid formation of dust.

Avoid contact with the substance.

· Environmental precautions:

Inform respective authorities in case of seepage into water course or sewage system.

Do not allow to enter sewers/ surface or ground water.

· Methods and material for containment and cleaning up:

Use neutralising agent.

Dispose contaminated material as waste according to item 13.

· Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and storage

· Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Thorough dedusting.

- · Information about fire and explosion protection: No special measures required.
- · Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles:

Tightly closed. Store at a dry place. At room temperature (+15°C to +25°C).

(Contd. on page 4)



Page 4/9

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 10.03.2023 Version number 2.00 (replaces version 1.00) Revision: 10.03.2023

Trade name: Povidone, iodinated, API

(Contd. of page 3)

- · Information about storage in one common storage facility: Not required.
- Further information about storage conditions: No further information
- · Storage class: TRHS 510: 8A Combustible corrosive substances
- · Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- · Control parameters
- · Ingredients with limit values that require monitoring at the workplace: Not required.
- · Additional information: The lists valid during the making were used as basis.
- · Exposure controls
- · Appropriate engineering controls No further data; see item 7.
- · Individual protection measures, such as personal protective equipment
- · General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the skin.

Avoid contact with the eyes and skin.

- · Respiratory protection: Dust protection mask.
- · Hand protection Protective gloves
- Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye/face protection Tightly sealed goggles

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

Physical state
Colour:
Odour:
Odour threshold:
Solid
Brown
Characteristic
Not determined.

· Melting point/freezing point: 350 °C

· Boiling point or initial boiling point and boiling

range Undetermined.

• **Flammability** Product is not flammable.

· Lower and upper explosion limit

Lower: Not determined.
 Upper: Not determined.
 Flash point: Not applicable.
 Decomposition temperature: Not determined.

· pH (100 g/l) at 20 °C 1.5–2.5

(Contd. on page 5)



Page 5/9

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 10.03.2023 Version number 2.00 (replaces version 1.00) Revision: 10.03.2023

Trade name: Povidone, iodinated, API

(Contd. of page 4)

· Viscosity:

Kinematic viscosityDynamic:Not applicable.Not applicable.

· Solubility

· water at 20 °C: 200 g/l

Partition coefficient n-octanol/water (log value)
 Vapour pressure:
 Not determined.
 Not applicable.

Vapour pressure: Density and/or relative density

Density: Not determined.
 Relative density Not determined.
 Bulk density: 450 kg/m³
 Vapour density Not applicable.
 Particle characteristics Not determined

· Other information

· Appearance:

· Form: Solid

Important information on protection of health and environment, and on safety.

• Auto-ignition temperature: Not determined.

• Explosive properties: Product does not present an explosion hazard.

Change in condition

· **Evaporation rate** Not applicable.

· Information with regard to physical hazard

classes

· Explosives Void Void

· Flammable gases Void

Void

· Aerosols Void

Void

· Oxidising gases Void

· Gases under pressure Void

Void

· Flammable liquids Void

Void
• Flammable solids

Void

Void

· Self-reactive substances and mixtures Void Void

· Pyrophoric liquids Void

Void • Pyrophoric solids Void

Pyropnoric solids Void Void

(Contd. on page 6)



Page 6/9

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 10.03.2023 Version number 2.00 (replaces version 1.00) Revision: 10.03.2023

Trade name: Povidone, iodinated, API

		(Contd. of page 5)
Self-heating substances and mixtures	Void	` · · · · ·
-	Void	
· Substances and mixtures, which emit flamma	able	
gases in contact with water	Void	
	Void	
· Oxidising liquids	Void	
	Void	
· Oxidising solids	Void	
	Void	
· Organic peroxides	Void	
	Void	
· Corrosive to metals	Void	

Void

Void Void

10 Stability and reactivity

Desensitised explosives

- · Reactivity No further relevant information available.
- · Chemical stability
- · Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

Processing temperature over 5 °C.

Possibility of hazardous reactions

Reacts with metals.

Reaction with reducing agents.

- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: Corrosive gases/vapours

11 Toxicological information

- · Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Based on available data, the classification criteria are not met.
- LD/LC50 values relevant for classification:

Oral LD50 >4,640 mg/kg (rat)

Dermal LD50 >2,500 mg/kg (rat)

- · Skin corrosion/irritation Causes skin irritation.
- · Serious eye damage/irritation Causes serious eye damage.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity 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.

(Contd. on page 7)



Page 7/9

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 10.03.2023 Version number 2.00 (replaces version 1.00) Revision: 10.03.2023

Trade name: Povidone, iodinated, API

(Contd. of page 6)

- · Information on other hazards
- Endocrine disrupting properties

On the basis of the available data, the substance does not meet the criteria for the identification of substances having properties of interference with the endocrine system, in accordance with Article 59, paragraph 1 of the REACH Regulation and the criteria established in the Delegated Regulation (EU) 2017 / 2100 of the Commission or in Commission Regulation (EU) 2018/605.

12 Ecological information

- · Toxicity
- · Aquatic toxicity:

LC50 (static) >4.6–10 mg/L /96h (fish: leuciscus idus)

EC50 (static) 2.79 mg/L /48h (Daphnia magna)

4.91 mg/L /72h (Algae: desmodesmus subspicatus)

EC10 270 mg/L /17h (bacteria: pseudomonas putida)

Persistence and degradability

Heavily biodegradable

Heavily eliminable from water.

- Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · Endocrine disrupting properties

Based on the available data, the substance does not meet the criteria for the identification of substances with properties affecting the endocrine system according to Article 59(1) of the REACH Regulation and the criteria of the Commission Delegated Regulation (EU) 2017/2100 or in the Commission Regulation (EU) 2018/605.

The product does not contain substances with endocrine disrupting properties.

- · Other adverse effects
- · Remark: Toxic for fish
- · Additional ecological information:
- · General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

Must not reach sewage water or drainage ditch undiluted or unneutralised. Danger to drinking water if even small quantities leak into the ground.

Also poisonous for fish and plankton in water bodies.

Toxic for aquatic organisms

Rinse off of bigger amounts into drains or the aquatic environment may lead to decreased pH-values. A low pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably increased, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

(Contd. on page 8)



Page 8/9

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 10.03.2023 Version number 2.00 (replaces version 1.00) Revision: 10.03.2023

Trade name: Povidone, iodinated, API

(Contd. of page 7)

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to local regulations.

14 Transport information

· UN number or ID number

· ADR, IMDG, IATA UN3077

· UN proper shipping name

· **ADR** 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE,

SOLID, N.O.S. (Polyvinylpyrrolidone iodine)

· IMDG ENVIRONMENTALLY HAZARDOUS SUBSTANCE,

SOLID, N.O.S. (Polyvinylpyrrolidone iodine)

· IATA Environmentally hazardous substance, solid, n.o.s.

(Polyvinylpyrrolidone iodine)

· Transport hazard class(es)

· ADR, IMDG, IATA

• Class 9 Miscellaneous dangerous substances and articles.

· Label 9

· Packing group

· ADR, IMDG, IATA

· Environmental hazards:

Marine pollutant:
 Special marking (ADR):
 Special marking (IATA):
 Symbol (fish and tree)
 Symbol (fish and tree)

Special precautions for user Warning: Miscellaneous dangerous substances and

articles.

· Hazard identification number (Kemler code): 90 · EMS Number: F-A.S-F

· Maritime transport in bulk according to IMO

instruments Not applicable.

· Transport/Additional information:

· ADR

Limited quantities (LQ)
 Transport category
 Tunnel restriction code

IMDG

Limited quantities (LQ) 5 kg

(Contd. on page 9)



Page 9/9

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 10.03.2023 Version number 2.00 (replaces version 1.00) Revision: 10.03.2023

Trade name: Povidone, iodinated, API

(Contd. of page 8)

UN "Model Regulation": UN 3077 ENVIRONMENTALLY HAZARDOUS

SUBSTANCE, SOLID, N.O.S.

(POLYVINYLPYRROLIDONE IODINE), 9, III

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (ANNEX XIV) Not listed
- · REGULATION (EC) No 1907/2006 ANNEX XVII Not listed
- DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment Annex II

Substance is not listed.

- · National regulations:
- Storage of hazardous substances in in nonstationary vessels (TRGS 510) (Germany)

TRHS 510: 8A Combustible corrosive substances

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

The information provided is based on our current level of knowledge. This MSDS has been compiled and is exclusively for this product intended.

- · Reasons for alterations This version replaces all old versions.
- · Version number of previous version: 1.00
- · Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

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

MAL-Code: Måleteknisk Arbejdshygiejnisk Luftbehov (Regulation for the labeling concerning inhalation hazards, Denmark)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard - Category 2