



SAFETY DATA SHEET

Revision date: 22-Feb-2018

Version: 3.0

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Povidone-Iodine Solution (Alcoholic)

Trade Name: Povidone-Iodine, Ethanol
Synonyms: Alcoholic Povidone-Iodine Solution; Alcoholic Povidone-Iodine 10% Solution
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as antiseptic, disinfectant

Details of the Supplier of the Safety Data Sheet

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2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Flammable liquids- Category 2

Label Elements

Signal Word: Danger
Hazard Statements: H225 - Highly flammable liquid and vapor

Precautionary Statements: P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
P233 - Keep container tightly closed
P370 + P378 - In case of fire: Use dry chemical, carbon dioxide (CO₂), alcohol-resistant foam for extinction
P403 + P235 - Store in a well-ventilated place. Keep cool
P501 - Dispose of contents/container in accordance with all local and national regulations



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Other Hazards An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
ETHANOL	64-17-5	200-578-6	Flam. Liq. 2 (H225)	60-100
Povidone-Iodine	25655-41-8	Not Listed	Acute Tox 4 (H312, H332)Acute 1 (H400)	9-10

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Water	7732-18-5	231-791-2	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

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5. FIRE FIGHTING MEASURES

Extinguishing Media: Dry chemical, carbon dioxide, water spray or alcohol-resistant foam .

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire. May include oxides of carbon and products of iodine.

Fire / Explosion Hazards: Flammable liquid and vapor. Vapors are heavier than air and may travel along surfaces to remote ignition sources and flash back.

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. Eliminate all sources of ignition and ventilate area using explosion-proof equipment.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Use only in a well-ventilated area. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Keep away from heat, sparks, flame and all other sources of ignition. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store in a cool, dry, well-ventilated area. Keep away from heat, sparks, flame, and other sources of ignition. Keep container tightly closed when not in use.

Incompatible Materials: Strong oxidizing agents and strong inorganic acids

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

ETHANOL

ACGIH Threshold Limit Value (STEL)	1000 ppm
Australia TWA	1000 ppm
	1880 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Austria OEL - MAKs	1000 ppm 1900 mg/m ³
Belgium OEL - TWA	1000 ppm 1907 mg/m ³
Bulgaria OEL - TWA	1000 mg/m ³
Czech Republic OEL - TWA	1000 mg/m ³
Denmark OEL - TWA	1000 ppm 1900 mg/m ³
Estonia OEL - TWA	500 ppm 1000 mg/m ³
Finland OEL - TWA	1000 ppm 1900 mg/m ³
France OEL - TWA	1000 ppm 1900 mg/m ³
Germany - TRGS 900 - TWAs	500 ppm 960 mg/m ³
Germany (DFG) - MAK	500 ppm 960 mg/m ³
Greece OEL - TWA	1000 ppm 1900 mg/m ³
Hungary OEL - TWA	1900 mg/m ³
Latvia OEL - TWA	1000 mg/m ³
Lithuania OEL - TWA	500 ppm 1000 mg/m ³
Netherlands OEL - TWA	260 mg/m ³
OSHA - Final PELs - TWAs:	1000 ppm 1900 mg/m ³
Poland OEL - TWA	1900 mg/m ³
Portugal OEL - TWA	1000 ppm
Romania OEL - TWA	1000 ppm 1900 mg/m ³
Russia OEL - TWA	1000 mg/m ³
Slovakia OEL - TWA	500 ppm 960 mg/m ³
Slovenia OEL - TWA	1000 ppm 1900 mg/m ³
Sweden OEL - TWAs	500 ppm 1000 mg/m ³
Switzerland OEL - TWAs	500 ppm 960 mg/m ³
Vietnam OEL - TWAs	1000 mg/m ³

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Povidone-Iodine

Pfizer Occupational Exposure Band (OEB): OEB 2 (control exposure to the range of 100ug/m³ to < 1000ug/m³)

Exposure Controls

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
Hands:	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
Eyes:	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)
Respiratory protection:	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid	Color:	Brown
Odor:	Alcohol	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Solvent Solubility:	No data available
Water Solubility:	Soluble
pH:	No data available.
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	78.5 based on major component Ethanol
Partition Coefficient: (Method, pH, Endpoint, Value)	

ETHANOL

No data available

Water

No data available

Povidone-Iodine

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s):	No data available
Vapor Pressure (kPa):	7.91 (Ethanol)
Vapor Density (g/ml):	1.59 (Ethanol)
Relative Density:	No data available
Viscosity:	No data available

Flammability:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	12.8 Closed cup based on major component (Ethanol)
Upper Explosive Limits (Liquid) (% by Vol.):	19
Lower Explosive Limits (Liquid) (% by Vol.):	3.3

Polymerization: Will not occur

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10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: None
Conditions to Avoid: Keep away from heat, spark, flames and all other sources of ignition.
Incompatible Materials: Strong oxidizing agents and strong inorganic acids
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.

Short Term: May cause eye irritation. May cause mild skin irritation (based on animal data). Exposure to high concentrations of gas, vapor, or mist may cause irritation. Exposure to high concentrations may cause irritation, headache, drowsiness, and symptoms of alcohol intoxication.

Long Term: Chronic ingestion of ethanol has been associated with an increased incidence of cancer, liver cirrhosis, and, if ingested during pregnancy, congenital malformations.

Acute Toxicity: (Species, Route, End Point, Dose)

ETHANOL

Rat Oral LD 50 7060 mg/kg
Mouse Oral LD 50 3450mg/kg
Rat Inhalation LC 50 20000ppm/10H
Mouse Inhalation LC 50 39gm/m³/4h

Povidone-Iodine

Rat Oral LD50 > 8000 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

ETHANOL

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Povidone-Iodine

Skin Irritation Rabbit Mild

Carcinogen Status:

Carcinogenicity of the mixture has not been determined. Alcohol is listed as a carcinogen by IARC. The IARC monograph examining the carcinogenic potential of ethanol examined only alcoholic beverages. No other components are listed as carcinogens by IARC, US OSHA or NTP.

ETHANOL

IARC: Group 1 (Carcinogenic to Humans)

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12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

Toxicity: No data available

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

ETHANOL

<i>Oncorhynchus mykiss</i> (Rainbow Trout)	NPDES	LC-50	96 Hours	12900 mg/L
Fingerling Trout	NPDES	LC-50	24 Hours	11200 mg/L
Fathead Minnow	NPDES	LC-50	96 Hours	14200 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

This material is regulated for transport under DOT, ADR, IMDG, and IATA regulations.

UN number:	UN 1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II

Flash Point (°C): 12.8

Flash Point (°C): 12.8

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

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15. REGULATORY INFORMATION

ETHANOL

CERCLA/SARA 313 Emission reporting California Proposition 65	Not Listed carcinogen 4/29/2011 in alcoholic beverages developmental toxicity 10/1/1987 in alcoholic beverages
Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS/ELINCS List	Present Present 200-578-6

Water

CERCLA/SARA 313 Emission reporting California Proposition 65	Not Listed Not Listed
Inventory - United States TSCA - Sect. 8(b) Australia (AICS): REACH - Annex IV - Exemptions from the obligations of Register: EU EINECS/ELINCS List	Present Present Present Present 231-791-2

Povidone-Iodine

CERCLA/SARA 313 Emission reporting California Proposition 65	Not Listed Not Listed
Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS/ELINCS List	Present Present Not Listed

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor
Acute toxicity, dermal-Cat.4; H312 - Harmful in contact with skin
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life

Data Sources:	Publicly available toxicity information.
Reasons for Revision:	Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Revision date:	22-Feb-2018 Product Stewardship Hazard Communication
Prepared by:	Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet