



Safety Data Sheet

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This Safety Data Sheet has been prepared in accordance with the GHS guidelines & India Hazardous substances (Classification, Labeling & Packaging) Draft Rules 2011.

SECTION 1: Identification

1.1. Product identifier

3M Skin Prep Povidone Iodine Solution IP 10% w/v

Product Identification Numbers

IA-4201-0025-6 IA-4201-0028-0 IA-4201-0081-9 IA-4201-0086-8

1.2. Recommended use and restrictions on use

Recommended use

Skin antiseptic for patient before surgery, Sanitizer

1.3. Supplier's details

Address: 3M India Limited, plot-48-51, Electronic city, Hosur road, Bangalore-560100
Telephone: 080-45543000, contact Product EHS team
E Mail: productehs.in@mmm.com
Website: <http://solutions.3mindia.co.in>

1.4. Emergency telephone number

080-45543000 (Contact hours: 8:00 AM to 5:00 PM)

SECTION 2: Hazard identification

Under MSIHC Rules, information is noted below on flammability, acute toxicity and explosivity relevant to this product. In line with international standards, information on other hazard classes and associated precautionary statements relevant to this product are included as well.

2.1. Classification of the substance or mixture

Skin Corrosion/Irritation: Category 2.
Serious Eye Damage/Irritation: Category 1.
Acute Aquatic Toxicity: Category 3.
Chronic Aquatic Toxicity: Category 3.

2.2. Label elements

Signal Word

Danger

Symbols

Corrosion |

Pictograms



HAZARD STATEMENTS:

- H315 Causes skin irritation.
- H318 Causes serious eye damage.

- H412 Harmful to aquatic life with long lasting effects.

PRECAUTIONARY STATEMENTS

Prevention:

P280B Wear protective gloves and eye/face protection.

Response:

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 or doctor/physician.

2.3. Other hazards

None known.

SECTION 3: Composition/information on ingredients

This material is a mixture.

Ingredient	CAS Nbr	% by Wt
Water	7732-18-5	80 - 90
Poly(vinylpyrrolidinone)iodide	25655-41-8	5 - 15
Sodium nitrite	7632-00-0	< 1

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation

Remove person to fresh air. If you feel unwell, get medical attention.

Skin contact

Immediately wash with soap and water. Remove contaminated clothing and wash before reuse. If signs/symptoms develop, get medical attention.

Eye contact

Immediately flush with large amounts of water for at least 15 minutes. Remove contact lenses if easy to do. Continue rinsing. Immediately get medical attention.

If swallowed

Rinse mouth. If you feel unwell, get medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Serious damage to the eyes (corneal cloudiness, severe pain, tearing, ulcerations, and significantly impaired or loss of vision).

4.3. Indication of any immediate medical attention and special treatment required

Not applicable

SECTION 5: Fire-fighting measures

5.1. Suitable Extinguishing media

Use a fire fighting agent suitable for the surrounding fire.

5.2. Special hazards arising from the substance or mixture

None inherent in this product.

Hazardous Decomposition or By-Products

<u>Substance</u>	<u>Condition</u>
Carbon monoxide.	During combustion.
Carbon dioxide.	During combustion.
Irritant vapours or gases.	During combustion.

5.3. Special protective actions for fire-fighters

No special protective actions for fire-fighters are anticipated.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Evacuate area. Ventilate the area with fresh air. For large spill, or spills in confined spaces, provide mechanical ventilation to disperse or exhaust vapors, in accordance with good industrial hygiene practice. Use PPE - Exposure Assessment

Use personal protective equipment based on the results of an exposure assessment. Refer to Section 8 for PPE recommendations. If anticipated exposure resulting from an accidental release exceeds the protective capabilities of the PPE listed in Section 8, or are unknown, select PPE that offers an appropriate level of protection. Consider the physical and chemical hazards of the material when doing so. Examples of PPE ensembles for emergency response could include wearing bunker gear for a release of flammable material; wearing chemical protective clothing if the spilled material is a corrosive, a sensitizer, a significant dermal irritant, or can be absorbed through the skin; or donning a positive pressure supplied-air respirator for chemicals with inhalation hazards. For information regarding physical and health hazards, refer to sections 2 and 11 of the SDS.

6.2. Environmental precautions

Avoid release to the environment. For larger spills, cover drains and build dykes to prevent entry into sewer systems or bodies of water.

6.3. Methods and material for containment and cleaning up

Contain spill. Working from around the edges of the spill inward, cover with bentonite, vermiculite, or commercially available inorganic absorbent material. Mix in sufficient absorbent until it appears dry. Remember, adding an absorbent material does not remove a physical, health, or environmental hazard. Collect as much of the spilled material as possible. Place in a closed container approved for transportation by appropriate authorities. Clean up residue with water. Seal the container. Dispose of collected material as soon as possible in accordance with applicable local/regional/national/international regulations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

For industrial/occupational use only. Not for consumer sale or use. Avoid breathing dust/fume/gas/mist/vapours/spray. Do not get in eyes, on skin, or on clothing. Do not eat, drink or smoke when using this product. Wash thoroughly after

handling. Avoid release to the environment.

7.2. Conditions for safe storage including any incompatibilities

Store away from heat.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits

No occupational exposure limit values exist for any of the components listed in Section 3 of this Safety Data Sheet.

8.2. Exposure controls

8.2.1. Engineering controls

Use general dilution ventilation and/or local exhaust ventilation to control airborne exposures to below relevant Exposure Limits and/or control dust/fume/gas/mist/vapours/spray. If ventilation is not adequate, use respiratory protection equipment.

8.2.2. Personal protective equipment (PPE)

Eye/face protection

Eye protection not required. Select and use eye/face protection to prevent contact based on the results of an exposure assessment. The following eye/face protection(s) are recommended:

Full face shield.

Indirect vented goggles.

Skin/hand protection

Select and use gloves and/or protective clothing approved to relevant local standards to prevent skin contact based on the results of an exposure assessment. Selection should be based on use factors such as exposure levels, concentration of the substance or mixture, frequency and duration, physical challenges such as temperature extremes, and other use conditions. Consult with your glove and/or protective clothing manufacturer for selection of appropriate compatible gloves/protective clothing. No chemical protective gloves are required. Note: Nitrile gloves may be worn over polymer laminate gloves to improve dexterity.

Gloves made from the following material(s) are recommended: Polymer laminate

Respiratory protection

Respiratory protection is not required.

An exposure assessment may be needed to decide if a respirator is required. If a respirator is needed, use respirators as part of a full respiratory protection program. Based on the results of the exposure assessment, select from the following respirator type(s) to reduce inhalation exposure:

Half facepiece or full facepiece air-purifying respirator suitable for organic vapours and particulates

For questions about suitability for a specific application, consult with your respirator manufacturer.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Liquid.
Specific Physical Form:	Emulsion
Color	Brown
Odor	Iodine

Odour threshold	<i>No data available.</i>
pH	3 - 6.5
Melting point/Freezing point: NA	<i>Not applicable.</i>
Boiling point/Initial boiling point/Boiling range	<i>No data available.</i>
Flash point	No flash point
Evaporation rate	<i>No data available.</i>
Flammability	Not applicable.
Flammable Limits(LEL)	<i>No data available.</i>
Flammable Limits(UEL)	<i>No data available.</i>
Vapour pressure	<i>No data available.</i>
Relative Vapor Density	<i>No data available.</i>
Density	1.02 g/ml
Relative density	1.02 [Ref Std: WATER=1]
Water solubility	Complete
Solubility- non-water	<i>Not applicable.</i>
Partition coefficient: n-octanol/water	<i>No data available.</i>
Autoignition temperature	<i>No data available.</i>
Decomposition temperature	<i>No data available.</i>
Kinematic Viscosity	29.4 mm ² /sec
Volatile organic compounds (VOC)	<i>No data available.</i>
Percent volatile	<i>No data available.</i>
VOC less H₂O & exempt solvents	<i>No data available.</i>

Particle Characteristics	<i>Not applicable.</i>
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SECTION 10: Stability and reactivity

10.1 Reactivity

This material may be reactive with certain agents under certain conditions - see the remaining headings in this section

10.2 Chemical stability

Stable.

10.3 Possibility of hazardous reactions

Hazardous polymerisation will not occur.

10.4 Conditions to avoid

Heat.

Sparks and/or flames.

10.5 Incompatible materials

Not determined

10.6 Hazardous decomposition products

Substance

None known.

Condition

Refer to section 5.2 for hazardous decomposition products during combustion.

SECTION 11: Toxicological information

The information below may not be consistent with the material classification in Section 2 if specific ingredient

classifications are mandated by a competent authority. In addition, toxicological data on ingredients may not be reflected in the material classification and/or the signs and symptoms of exposure, because an ingredient may be present below the threshold for labelling, an ingredient may not be available for exposure, or the data may not be relevant to the material as a whole.

11.1 Information on Toxicological effects

Signs and Symptoms of Exposure

Based on test data and/or information on the components, this material may produce the following health effects:

Inhalation

Respiratory tract irritation: Signs/symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain.

Skin contact

Skin Irritation: Signs/symptoms may include localized redness, swelling, itching, dryness, cracking, blistering, and pain.
Allergic Skin Reaction (non-photo induced) in sensitive people: Signs/symptoms may include redness, swelling, blistering, and itching.

Eye contact

Corrosive (eye burns): Signs/symptoms may include cloudy appearance of the cornea, chemical burns, severe pain, tearing, ulcerations, significantly impaired vision or complete loss of vision.

Ingestion

Gastrointestinal irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhoea.

Toxicological Data

If a component is disclosed in section 3 but does not appear in a table below, either no data are available for that endpoint or the data are not sufficient for classification.

Acute Toxicity

Name	Route	Species	Value
Overall product	Ingestion		No data available; calculated ATE >5,000 mg/kg
Poly(vinylpyrrolidinone)iodide	Dermal	Rat	LD50 > 2,500 mg/kg
Poly(vinylpyrrolidinone)iodide	Ingestion	Rat	LD50 > 4,640 mg/kg
Sodium nitrite	Ingestion	Rat	LD50 180 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Poly(vinylpyrrolidinone)iodide	Rabbit	Irritant
Sodium nitrite	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Poly(vinylpyrrolidinone)iodide	Rabbit	Corrosive
Sodium nitrite	Rabbit	Severe irritant

Sensitization:

Skin Sensitisation

Name	Species	Value
Poly(vinylpyrrolidinone)iodide	Guinea	Not classified

	pig	
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Respiratory Sensitisation

For the component/components, either no data are currently available or the data are not sufficient for classification.

Germ Cell Mutagenicity

Name	Route	Value
Poly(vinylpyrrolidinone)iodide	In vivo	Not mutagenic
Poly(vinylpyrrolidinone)iodide	In Vitro	Some positive data exist, but the data are not sufficient for classification
Sodium nitrite	In Vitro	Some positive data exist, but the data are not sufficient for classification
Sodium nitrite	In vivo	Some positive data exist, but the data are not sufficient for classification

Carcinogenicity

Name	Route	Species	Value
Sodium nitrite	Ingestion	Multiple animal species	Some positive data exist, but the data are not sufficient for classification

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test result	Exposure Duration
Sodium nitrite	Ingestion	Not classified for female reproduction	Mouse	NOAEL 425 mg/kg/day	2 generation
Sodium nitrite	Ingestion	Not classified for male reproduction	Mouse	NOAEL 425 mg/kg/day	2 generation
Sodium nitrite	Ingestion	Not classified for development	Rat	NOAEL 50 mg/kg/day	gestation into lactation

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Poly(vinylpyrrolidinone)iodide	Inhalation	respiratory irritation	Some positive data exist, but the data are not sufficient for classification	similar health hazards	NOAEL Not available	
Sodium nitrite	Inhalation	respiratory irritation	Some positive data exist, but the data are not sufficient for classification	similar health hazards	NOAEL Not available	
Sodium nitrite	Ingestion	methemoglobinemia	Causes damage to organs	Human	NOAEL Not available	

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Poly(vinylpyrrolidinone)iodide	Ingestion	endocrine system	Not classified	similar compounds	NOAEL Not available	
Sodium nitrite	Ingestion	skin	Not classified	Rat	NOAEL 310 mg/kg/day	14 weeks
Sodium nitrite	Ingestion	gastrointestinal tract	Not classified	Rat	NOAEL 310 mg/kg/day	14 weeks
Sodium nitrite	Ingestion	hematopoietic system	Not classified	Rat	NOAEL 310 mg/kg/day	14 weeks
Sodium nitrite	Ingestion	eyes	Not classified	Rat	NOAEL 310 mg/kg/day	14 weeks
Sodium nitrite	Ingestion	kidney and/or	Not classified	Rat	NOAEL 310	14 weeks

		bladder			mg/kg/day	
Sodium nitrite	Ingestion	heart	Not classified	Rat	NOAEL 310 mg/kg/day	14 weeks
Sodium nitrite	Ingestion	endocrine system	Not classified	Rat	NOAEL 310 mg/kg/day	14 weeks
Sodium nitrite	Ingestion	bone, teeth, nails, and/or hair	Not classified	Rat	NOAEL 310 mg/kg/day	14 weeks
Sodium nitrite	Ingestion	liver	Not classified	Rat	NOAEL 310 mg/kg/day	14 weeks
Sodium nitrite	Ingestion	immune system	Not classified	Rat	NOAEL 310 mg/kg/day	14 weeks
Sodium nitrite	Ingestion	muscles	Not classified	Rat	NOAEL 310 mg/kg/day	14 weeks
Sodium nitrite	Ingestion	nervous system	Not classified	Rat	NOAEL 310 mg/kg/day	14 weeks
Sodium nitrite	Ingestion	respiratory system	Not classified	Rat	NOAEL 310 mg/kg/day	14 weeks

Aspiration Hazard

For the component/components, either no data are currently available or the data are not sufficient for classification.

Please contact the address or phone number listed on the first page of the SDS for additional toxicological information on this material and/or its components.

SECTION 12: Ecological information

The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. Additional information leading to material classification in Section 2 is available upon request. In addition, environmental fate and effects data on ingredients may not be reflected in this section because an ingredient is present below the threshold for labelling, an ingredient is not expected to be available for exposure, or the data is considered not relevant to the material as a whole.

12.1. Toxicity

Acute aquatic hazard:

GHS Acute 3: Harmful to aquatic life.

Chronic aquatic hazard:

GHS Chronic 3: Harmful to aquatic life with long lasting effects.

No product test data available.

Material	CAS Nbr	Organism	Type	Exposure	Test endpoint	Test result
Poly(vinylpyrrolidone)iodide	25655-41-8	Golden Orfe	Experimental	96 hours	LC50	4.6 mg/l
Poly(vinylpyrrolidone)iodide	25655-41-8	Green algae	Experimental	72 hours	ErC50	4.91 mg/l
Poly(vinylpyrrolidone)iodide	25655-41-8	Water flea	Experimental	48 hours	EC50	2.79 mg/l
Poly(vinylpyrrolidone)iodide	25655-41-8	Bacteria	Experimental	17 hours	EC10	270 mg/l
Sodium nitrite	7632-00-0	Green algae	Experimental	72 hours	EC50	>100 mg/l
Sodium nitrite	7632-00-0	Invertebrate	Experimental	48 hours	LC50	37 mg/l
Sodium nitrite	7632-00-0	Rainbow trout	Experimental	96 hours	LC50	0.9 mg/l
Sodium nitrite	7632-00-0	Fathead minnow	Estimated	32 days	NOEC	3.1 mg/l

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Poly(vinylpyrrolidone)iodide	25655-41-8	Experimental Biodegradation	28 days	CO2 evolution	<10 %CO2 evolution/THCO2 evolution	ISO 14593 Inorg C Headspace
Sodium nitrite	7632-00-0	Data not available-insufficient	N/A	N/A	N/A	N/A

12.3 : Bioaccumulative potential

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Poly(vinylpyrrolidone)iodide	25655-41-8	Unknown Bioconcentration		Log Kow	0.81	
Sodium nitrite	7632-00-0	Experimental Bioconcentration		Log Kow	-3.7	OECD 107 log Kow shke flask mtd

12.4. Mobility in soil

Please contact manufacturer for more details

12.5 Other Adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Disposal methods

Dispose of contents/ container in accordance with the local/regional/national/international regulations.

Dispose of waste product in a permitted industrial waste facility. As a disposal alternative, incinerate in a permitted waste incineration facility. Empty drums/barrels/containers used for transporting and handling hazardous chemicals (chemical substances/mixtures/preparations classified as Hazardous as per applicable regulations) shall be considered, stored, treated & disposed of as hazardous wastes unless otherwise defined by applicable waste regulations. Consult with the respective regulating authorities to determine the available treatment and disposal facilities.

SECTION 14: Transport Information

Not hazardous for transportation.

Air Transport (IATA) Regulations

UN No Not applicable

Proper Shipping Name Not applicable

Hazard Class/Division Not applicable

Subsidiary Risk Not applicable

Other Dangerous Goods Descriptions: None assigned.

Packing Group: Not applicable

Marine Transport (IMDG)

UN No Not applicable

Proper Shipping Name Not applicable

Hazard Class/Division Not applicable

Subsidiary Risk Not applicable

Other Dangerous Goods Descriptions: None assigned.

Packing Group: Not applicable

Environmental Hazards: Not applicable

SECTION 15: Regulatory information

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

Global inventory status

Contact 3M for more information.

Applicable Environmental, Health and Safety Regulations

The Manufacture, Storage and Import of Hazardous Chemical Rules, 1989

The Bio Medical Waste (Management & Handling) Rules, 1998

The following ingredients are listed as hazardous on Part II of Schedule I of the India Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) rules

None.

The following ingredients are classified as hazardous based on the criteria listed under Part I of Schedule I of the India Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) rules:

The product is classified as Non-Hazardous as per MSIHC Rules, 1989.

SECTION 16: Other information

NFPA Hazard Classification

Health: 1 **Flammability:** 1 **Instability:** 0 **Special Hazards:** None

National Fire Protection Association (NFPA) hazard ratings are designed for use by emergency response personnel to address the hazards that are presented by short-term, acute exposure to a material under conditions of fire, spill, or similar emergencies. Hazard ratings are primarily based on the inherent physical and toxic properties of the material but also include the toxic properties of combustion or decomposition products that are known to be generated in significant quantities.

Revision information:

Section 02: GHS Pictogram Not Applicable information was deleted.

Section 02: GHS Signal Word - Not applicable information was deleted.

Section 02: GHS Symbol Text - Not applicable information was deleted.

Label: GHS Classification information was added.

Label: GHS Classification information was modified.

Label: GHS Precautionary - Prevention information was added.

Label: GHS Precautionary - Response information was added.

Label: Graphic information was added.

Label: Signal Word information was added.

Label: Symbol information was added.

Section 2: Ingredient table information was modified.

Section 04: First Aid - Symptoms and Effects (GHS) information was added.

Section 4: First aid for eye contact information information was modified.

Section 4: First aid for ingestion (swallowing) information information was modified.

Section 4: First aid for inhalation information information was modified.

Section 4: First aid for skin contact information information was modified.

Section 5: Fire - Extinguishing media information information was modified.

Section 5: Hazardous combustion products table information was modified.

Section 6: Accidental release personal information information was modified.

Section 7: Precautions safe handling information information was modified.

Section 8: Eye/face protection information information was added.

Section 8: Personal Protection - Eye information information was modified.

Section 8: Personal Protection - Respiratory Information information was modified.
Section 8: Personal Protection - Skin/hand information information was modified.
Section 8: Respiratory protection - recommended respirators guide information was added.
Section 8: Respiratory protection - recommended respirators information information was added.
Section 8: Skin protection - recommended gloves information information was added.
Section 8: Skin protection - recommended gloves text information was added.
Section 9: Flammability (solid, gas) information information was deleted.
Section 09: Flammability information information was added.
Section 09: Kinematic Viscosity information information was added.
Section 09: Particle Characteristics N/A information was added.
Section 09: Vapor Density Value information was modified.
Section 09: Viscosity information was deleted.
Section 11: Acute Toxicity table information was modified.
Section 11: Carcinogenicity Table information was added.
Section 11: Carcinogenicity text information was deleted.
Section 11: Germ Cell Mutagenicity Table information was added.
Section 11: Germ Cell Mutagenicity text information was deleted.
Section 11: Health Effects - Eye information information was modified.
Section 11: Health Effects - Ingestion information information was modified.
Section 11: Health Effects - Inhalation information information was modified.
Section 11: Health Effects - Skin information information was modified.
Section 11: Reproductive and/or Developmental Effects text information was added.
Section 11: Reproductive Toxicity Table information was added.
Section 11: Serious Eye Damage/Irritation Table information was added.
Section 11: Serious Eye Damage/Irritation text information was deleted.
Section 11: Skin Corrosion/Irritation Table information was added.
Section 11: Skin Corrosion/Irritation text information was deleted.
Section 11: Skin Sensitization Table information was added.
Section 11: Skin Sensitization text information was deleted.
Section 11: Specific Target Organ Toxicity - repeated exposure text information was deleted.
Section 11: Specific Target Organ Toxicity - single exposure text information was deleted.
Section 11: Target Organs - Repeated Table information was added.
Section 11: Target Organs - Single Table information was added.
Section 12: Component ecotoxicity information information was modified.
Section 12: Persistence and Degradability information information was modified.
Section 12: Bioaccumulative potential information information was modified.
Section 13: Standard Phrase Category Waste GHS information was modified.
Section 14: Air Transport - Other Dangerous Goods Descriptions heading information was added.
Section 14: Marine Transport - Other Dangerous Goods Descriptions heading information was added.
Section 14: Other Dangerous Goods Descriptions (IATA) information was added.
Section 14: Other Dangerous Goods Descriptions (IMO) information was added.
Section 16: NFPA hazard classification for flammability information was modified.
Section 16: NFPA hazard classification for health information was modified.

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