

Issue Date: 04/02/2021
Last Revision Date: 11/04/2024
Superseded Date: 04/02/2021
Version Number: 02

SAFETY DATA SHEET

Product Code: JJ10516

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SECTION 1 PRODUCT IDENTIFICATION

Product Name Inadine Dressing

Relevant identified uses of the substance or mixture and uses advised against Wound dressing.
This product is only supplied for professional use as a medical device.

SECTION 2 HAZARD IDENTIFICATION

Classification of the Substance or Mixture This product is not classified as hazardous in accordance with EU regulations (Dangerous Preparations Directive 1999/45/EC or CLP Regulation (EC) No 1272/2008).

Label Elements No labelling is required in accordance with EU regulations (Dangerous Preparations Directive 1999/45/EC or CLP Regulation (EC) No 1272/2008).

Other Hazards This product is not expected to be hazardous under foreseen conditions of use. However, as with all health care products, care should be taken to carefully read the instructions before use.

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

Substances Not applicable. Product is not a substance.

Mixtures INADINE® PVP-I Non-Adherent Dressing is a warp knitted fabric impregnated with an orange-brown polyethylene glycol/water ointment containing povidone-iodine and interleaved between two sheets of white polyethylene film.

Name	CAS No	Classification
Povidone-iodine	25655-41-8	Not hazardous
Polyethylene glycol		Not hazardous
Purified Water		Not hazardous

SECTION 4 FIRST AID MEASURES

Description of first aid measures

Eye Contact: Rinse eye with plenty of water.

Inhalation: Inhalation is not likely to occur.

Skin Contact: Wash skin with plenty of soap and water.

Ingestion: Ingestion is not likely to occur.

Most important symptoms and effects, both acute and delayed No effects from skin or eye contact are anticipated.

Indication of any immediate medical attention and special treatments needed Symptomatic treatment as required

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SECTION 5 FIRE FIGHTING MEASURES

- Extinguishing Media** No known adverse reactions with any extinguishing media. Use extinguisher appropriate to surrounding conditions.
- Special Hazards Arising from the Substance or Mixture** Normal combustion products are considered to be carbon dioxide, although incomplete combustion may lead to the formation of organic decomposition products.
- Advice for fire Fighters** No special precautions required. Wear normal fire-fighting kit and breathing apparatus as appropriate.

SECTION 6 ACCIDENTAL RELEASE MEASURES

- Personal Precautions, Protective Equipment and Emergency Procedures** No special precautions required for unused dressings.
- Environmental Precautions** No special precautions required.
- Methods And Materials for Containment and Clearing Up** Unused dressings should be collected and disposed of according to local and national regulations. Used dressing should be collected and disposed of as clinical waste.
- References to other Sections** None.

SECTION 7 HANDLING AND STORAGE

- Precautions for Safe Handling** Normal sterile working procedures will provide adequate protection.
- Conditions for safe storage, including any incompatibilities** Store in a cool dry place. Avoid extremes of temperature.
- Specific End Uses(s)** None.

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Substance	8 Hour Exposure Limit	15 Minute Exposure Limit	Source, Type
Iodine	-	0.1ppm (1.1mg/m3)	EH40, 2011

- Exposure Controls** Engineering controls are not required.
- Respiratory Protection** No special precautions required. Inhalation is not likely to occur.
- Hand Protection** Surgical gloves should be worn in accordance with normal working procedures.

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Eye Protection	No special precautions required.
Skin Protection	No special precautions required.
Environmental Exposure Controls	None required.

SECTION 9 PHYSICAL/CHEMICAL PROPERTIES

Information on Basic Physical and Chemical Properties

Appearance:	A warp knitted fabric impregnated with an orange-brown polyethylene glycol/water ointment containing povidone-iodine and interleaved between two sheets of white polyethylene film.
Odour:	None
Odour Threshold:	Not applicable
pH:	Not applicable
Melting Point:	Not applicable
Boiling Point:	Not applicable
Flashpoint:	Not applicable
Evaporation Rate:	Not applicable
Flammability:	Combustible
Upper/Lower Flammability Limits:	Not applicable
Vapour Pressure:	Not applicable
Vapour Density:	Not applicable
Relative Density:	Not applicable
Solubility in Water:	Ointment is soluble in water
Solubility in other Solvents:	Not applicable
Partition Coefficient (Log Kow):	Not applicable
Autoignition Temperature:	No data
Decomposition Temperature:	No data
Viscosity:	Not applicable
Explosive Properties:	Not considered explosive
Oxidising Properties:	Not considered oxidising
Other information	None

SECTION 10 STABILITY AND REACTIVITY

Reactivity	No reactive hazards known.
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Chemical Stability	Stable under normal conditions of use.
Possibility of Hazardous Reactions	No hazardous reactions expected.
Conditions to Avoid	Avoid extremes of temperature
Incompatible Materials	Avoid contact with strong oxidizing agents
Hazardous Decomposition Products	Normal combustion products.

SECTION 11 TOXICOLOGICAL INFORMATION

Information On Toxicological Effects	This product has not been tested. Judgements on the expected toxicity of this product have been made based upon consideration of its major components.
Acute Toxicity	No effects are anticipated from the product as supplied.
Skin Corrosion/Irritation	Iodine may be absorbed through the skin. May cause irritation and sensitivity in certain susceptible individuals.
Serious Eye Damage/Irritation	No effects are anticipated from the product as supplied.
Respiratory/Skin Sensitisation	May cause irritation and sensitivity in certain susceptible individuals.
Germ Cell Mutagenicity	Contains no known mutagens
Carcinogenicity	Contains no known carcinogens
Reproductive Toxicity	This product is not recommended for use in pregnant and breast feeding women due to the possibility of iodine absorption through the skin.
Stot-Single Exposure	No effects are anticipated from the product as supplied.
Stot-Repeated Exposure	No effects are anticipated from the product as supplied.
Aspiration Hazard	Not applicable to this product

SECTION 12 ECOLOGICAL INFORMATION

Toxicity	Although iodine is considered to be acutely toxic to aquatic organisms, it is only released slowly from the povidone polymer. Given the very small quantities contained in each dressing, it is unlikely that INADINE® dressings would have a significant effect upon the environment.
Persistence and Degradability	This product will biodegrade slowly in the environment.
Bioaccumulative Potential	None of the components are known to be bioaccumulative.
Mobility in Soil	Not expected to be mobile.
Results of PBT and vPvB Assessment	None of the components are known to be PBT or vPvB.

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Other Adverse Effects None known.

SECTION 13 DISPOSAL CONSIDERATIONS

Waste Treatment Methods Disposal should be in accordance with local and national regulations.
 Used dressings should be disposed of as clinical waste.

SECTION 14 TRANSPORT INFORMATION

Not regulated as hazardous for transport.

	ADR	IMDG	ICAO
UN Number	None	None	None
UN Proper shipping name	None	None	None
Transport hazard class(es)	None	None	None
Packing group	None	None	None
Environmental hazards	None	None	None
Special precautions for user	None	None	None
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	None	None	None

SECTION 15 REGULATORY INFORMATION

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

All components are listed as existing substances in Europe

Chemical Safety Assessment A Chemical Safety Assessment has not been carried out for this product.

SECTION 16 OTHER INFORMATION

Revision information: Update to CA contact details.
 Approved for use as a medical device. Refer to full Instructions For Use.

Special Training: No specialist training required with respect to chemical hazards

List of Abbreviations used in this SDS:

CAS	Chemical Abstracts Service
CLP	Classification, Labelling and Packaging Regulation (EC) no 1272/2008
DSD	Dangerous Substances Directive 67/548/EEC
DPD	Dangerous Preparations Directive 1999/45/EC
EC	European Community/Commission

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PBT Persistent, Bioaccumulative and Toxic

REACH Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) no 1907/2006
vPvB very Persistent, very Bioaccumulative

References: ECHA CHEM database
EH40, 2011

Reason for Revision: To bring to date

END OF SDS