

Safety Data Sheet

Bensan iPrep

SECTION 1: IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

- 1.1 Product Identifier
Product name : Bensan iPrep
- 1.2 Relevant identified uses of the substance or mixture and uses advised against
- Relevant identified uses
Main use category : Professional use
Function or use category : Povidone Iodine based surgical skin prep solution for Professional Use
Uses advised against : No additional information available
- 1.3 : Details of the supplier of the safety data sheet
Supplier
Safecare Medical Industries
KIZAD KHIA 8-18
P.O. Box 133685, Abu Dhabi
United Arab Emirates
Telephone: +971 2 506 7333
- Contact person: Regulatory Affairs – tel. +971 2 506 7333

SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture
- Classification according to Regulation (EC) No. 1272/2008 (CLP)
- | | |
|-----------------------------|------------|
| Eye Irrit. | Category 1 |
| Skin corrosion / Irritation | Category 2 |
| Chronic Aquatic Toxicity | Category 2 |
- Full test of hazard classes and H-statements: see section 16
- 2.2 Label elements
Labelling according to Regulation (EC) No. 1272/2008 (CLP)
Hazard Pictograms



GHS05



GHS09

- Signal word (CLP) : Warning
- Hazard statements (CLP) : H315 Causes skin irritation.
: H318 Causes serious eye damage.
: H411 Toxic to aquatic life with long lasting effects.
- Precautionary statements (CLP) P102 – Keep out of Reach of Children
P273 – Avoid release to the environment

P280 – Wear protective gloves/protective clothing/eye protection/face protection/hearing protection...
 P301 + 330 + 331 – IF SWALLOWED: Rinse mouth. Do not induce vomiting.
 P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several
 P310 – Immediately call POISON CENTER/doctor
 P391 – Collect Spillage
 P501 – Dispose of contents/container to industrial combustion plant

2.3 Other Hazards

Other hazards not contributing to the classification : None under normal conditions.

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII
 This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

SECTION 3 : COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable

3.2 Mixtures – Hazardous Ingredients

Name	Product Identifier	%	CLP Classification
Povidone Iodine	CAS Nbr 25655-41-8	=<10%	Acute Tox. 4 (Oral), H302

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

First-aid measures general : No particular / specific measures required.
 First-aid measures after inhalation : If symptoms develop move victim to fresh air. Get medical attention if irritation or other symptoms persists.
 First-aid measures after skin contact: Gently wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.
 First-aid measures after eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get immediate medical advice / attention.
 First-aid measure after ingestion : If swallowed, rinse mouth with water (only if the person is conscious). Call a POISON CENTER or doctor/physician if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed symptoms/effects
 : In all cases of doubt, or when symptoms persist, seek medical attention.
 Symptoms/effects after skin contact: Causes skin irritation
 Symptoms/effects after eye contact: Causes serious eye irritation.

4.3 Indication of any immediate medical attention and special treatment needed
 Treat symptomatically. In all cases of doubt, or when symptoms persist, seek medical attention.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media : Use extinguishing media appropriate for surrounding fire. Water fog, Foam, carbon dioxide (CO₂) and powder.
 Unsuitable extinguishing media : Do not use a heavy water stream

5.2 Special hazards arising from the substance or mixture
 Hazardous decomposition products
 in case of fire : Carbon monoxide. Carbon dioxide.

5.3 Advice for firefighters
 Firefighting instructions : Use water spray or fog for cooling exposed containers
 Protection during firefighting

: Do not enter fire area without proper personal protective equipment, including respirator protection

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

General measures : Wear appropriate personal protective equipment - see Section 8. Avoid contact with skin and eyes. No open flames. No smoking. Use special care to avoid static electric charges. No flames, no sparks. Eliminate all sources of ignition.

For non-emergency personnel
No additional information available

For emergency responders
No additional information available

6.2. Environmental precautions
Discharging into rivers and drains is forbidden.

6.3. Methods and material for containment and cleaning up
For containment : Collect all waste in suitable and labelled containers and dispose according to local legislation.

Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible.

6.4. Reference to other sections
For further information refer to section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling
Precautions for safe handling : Keep container tightly closed. Avoid contact with skin and eyes. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Hygiene measures : Do not eat, drink or smoke when using this product. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities
Storage conditions : Keep container tightly closed. Keep only in original container. Keep cool. Store in a well-ventilated place.

Incompatible materials : N/A

7.3. Specific end use(s)
Consult the supplier for further information.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Control parameters

Povidone Iodine 25655-41-8		
United Kingdom	WEL TWA (mg/m3)	10

8.2 Exposure Controls

PERSONAL PROTECTION
None expected to be required under normal usage conditions.

EYE/FACE PROTECTION

None expected to be required under normal usage conditions.

SKIN PROTECTION

None expected to be required under normal usage conditions.

RESPIRATORY PROTECTION

None expected to be required under normal usage conditions.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**9.1 Information on basic physical and chemical properties**

Physical state	: Liquid
Colour	: red brown
Odor	: Iodine Odor
Odor threshold	: Not determined
pH	: 4-7
Relative evaporation rate	: Not determined
Melting point	: Not determined
Freezing point	: Not determined
Boiling point	: Not determined
Flash point	: Product not flammable
Auto-ignition temperature	: Product not flammable
Decomposition temperature	: Not determined
Flammability (solid, gas)	: Not applicable
Vapour pressure	: Not determined
Relative vapour density at 20°C	: Not determined
Relative density	: 1.04
Solubility	: In water, material soluble.
Log Pow	: Not determined
Viscosity, kinematic	: 500-1500 mPa-s
Viscosity, dynamic	: Not determined
Explosive properties	: Product is not explosive.

9.2 Other Information

Addition Information : None to our knowledge

SECTION 10: STABILITY AND REACTIVITY**10.1. Reactivity**

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No polymerization.

10.4. Conditions to avoid

No flames, no sparks. Eliminate all sources of ignition.

10.5. Incompatible materials

Oxidizing agent. Acids. reducing materials.

10.6. Hazardous decomposition products

No decomposition if stored and used normally. Thermal decomposition generates : Carbon dioxide. Carbon monoxide. Nitrogen oxides. Amines. Chlorine. Hydrogen chloride.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Causes skin irritation
Serious eye damage/irritation	: Causes serious eye irritation
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Ecology – general : Toxic to aquatic life with long lasting effects.

12.2 persistence and degradability

Bensan iPrep	
Persistence and degradability	No data available

12.3 Bioaccumulative potential

Bensan iPrep	
Log Pow	Not determined

12.4 Mobility in Soil

Bensan iPrep	
Ecology – soil	Soluble in water

12.5 Results of PBT and vPvB assessment

Bensan iPrep	
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII	
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII	

12.6 Other adverse effects

Other adverse effects : None to our knowledge
 Additional Information : No other effects known

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Regional legislation (waste) : Dispose as hazardous waste.
 Waste treatment methods : Recover the product with absorbent material. Dispose of contents/container in accordance with licensed collector's sorting instructions.
 Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.
 Ecology - waste materials : Avoid release to the environment.
 European List of Waste (LoW) code : 19 02 08* - liquid combustible wastes containing dangerous substances

SECTION 14 : TRANSPORT INFORMATION

Marine Pollutant : NO

Land transport (UN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS Air transport

(ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport

(IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Transport in bulk according to Annex II of MARPOL 73 / 78 and the IBC code

SECTION 15: REGULATORY INFORMATION

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

EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

National regulations

EC-regulation 2015/830 /EC, 1907/2006/EC (REACH), 1272/2008/EC (CLP), 790/2009/EC. Transport of dangerous goods (ADR/RID, IMDG, IATA/ICAO). Workplace exposure limits.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out for the substance or the mixture by the supplier

SECTION 16: OTHER INFORMATION

Indication of changes: Identification of the substance/mixture and of the company/undertaking. Relevant identified uses.

3.2	Composition / Information on Ingredients	Modified
-----	--	----------

Date of issue	9.01.2024
Revision date	9.01.2024
Supersedes	NA
Date of total revision	26.08.2023
Version	2.0
Signature	Regulatory Affairs

Full test of H- and EUH-statements

Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Inhalation: vapour)	Acute toxicity (inhalation: vapor) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 2	Flammable liquids, Category 2
Flam. Liq. 3	Flammable liquids, Category 3
Skin Corr. 1A	Skin corrosion/irritation, Category 1A
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Narcosis
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H225	Highly flammable liquid and vapour
H226	Flammable liquid and vapour
H301	Toxic if swallowed
H302	Harmful if swallowed
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H319	Causes serious eye irritation
H332	Harmful if inhaled
H335	May cause respiratory irritation
H336	May cause drowsiness or dizziness
H411	Toxic to aquatic life with long lasting effects

The information in this safety data sheet is based on information from the manufacturer/supplier, present European and national legislation, and presupposes that the product is used within the specified area of application.