

SAFETY DATA SHEET

HEXI PREP

According to Regulation (EU) No 2020/878 & Regulation (EC) No 1272/2008

Issue Date: 21st April 2021

Version Number: 2

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

1.1 Product Identifier

Product Name HEXI PREP

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified Use Disinfection of the skin prior to invasive medical procedures that do not require a clean air environment.

1.3 Details of the supplier of the safety data sheet

Supplier GAMA Healthcare
The Maylands Building
Maylands Avenue, Hemel Hempstead Industrial Estate
Hemel Hempstead
Hertfordshire
HP2 7TG
Tel: +44 (0) 207 993 0030
Email: info@gamahealthcare.com

1.4 Emergency telephone number

Tel: +44 20 7993 0030

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product Classified as a Medicine according to Directive 2001/83/EC

2.2 Label Elements

CAUTION: For external use only. Flammable.
Avoid exposure of the container and contents to naked flames during use, storage and disposal Keep out of the sight and reach of children. Store below 25°C. The pad is sterile unless seal is broke.

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2.3 Other hazards

Not applicable

SECTION 3: Composition/information on ingredients

3.2 Mixtures

| Declarable components | Conc. (%) | EC No. | CAS No. | Classification according to Regulation (EC) 1272/2008 |
|---------------------------|-----------|-----------|------------|--|
| Isopropyl Alcohol | 70% v/v | 200-661-7 | 67-63-0 | Flam Liq. 2: H225, Eye Irrit. 2: H319, STOT SE 3: H336. |
| Chlorhexidine Digluconate | 2% w/v | 242-354-0 | 18472-51-0 | Eye Dam. 1: H318, Aquatic Acute 1: H400, Aquatic Chronic 1: H410 |

Other components: Water

SECTION 4: First aid measures

4.1 Description of first aid measures

Inhalation

If adverse effects (e.g. irritation of the airways, drowsiness, or dizziness) occur, remove patient from exposure and give fresh air and rest. Obtain prompt medical attention.

Skin

For industrial use of the liquid, remove contaminated clothing and wash affected area with soap and water. If irritation occurs, seek medical attention. Launder contaminated clothing before re-use.

Eye

In case of contact with eyes, irrigate with water for 15 minutes, occasionally lifting eyelids. Seek prompt medical attention for signs of irritation.

Ingestion

For industrial use of the liquid, if swallowed, wash out mouth thoroughly and give water to drink. Seek medical attention if significant amounts (e.g. more than a teaspoonful) are ingested, or for any symptoms occurring after ingestion. Do not induce vomiting, unless instructed by medical personnel.

4.2 Most important symptoms and effects, both acute and delayed

May cause eye damage. Vapours may cause drowsiness or dizziness.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptoms as they occur.

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SECTION 5: Firefighting measures

5.1 Extinguishing media

Water spray, carbon dioxide, dry chemical and foam are compatible with the product. Remove containers from fire or cool them with water.

5.2 Special hazards arising from the substance of mixture

The liquid is expected to be flammable. Vapour may produce explosive mixture in air in confined space.

When heated sufficiently, product may decompose to form smoke and toxic fumes, gases or vapours, including oxides of carbon and nitrogen, hydrogen chloride, ammonia, and small amounts of p-chloroaniline.

5.3 Advice for firefighters

Fire fighters should wear an approved self-contained breathing apparatus and full protective clothing.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For industrial spills of the liquid, ensure full personal protection is worn (see Section 8). Ensure all sources of ignition are extinguished. Keep unauthorised personnel from the spillage area.

6.2 Environmental precautions

Prevent leakage of product into water-courses or drainage system by diking with sand or other absorbent material. Contact authorities, water company, and waste-water treatment plant as appropriate if significant contamination occurs.

6.3 Methods and material for containment and cleaning up

Stop the source of leak or release. Clean up spill as soon as possible using non-sparking equipment and machinery. Small spills can be mopped up with dry cloth. Collect larger spill using techniques such as sorbent materials or pumping. Place material in suitable container for disposal in accordance with local and national regulations. Wash contaminated surfaces with water, and collect washings for safe disposal. Follow prescribed procedures for responding to large spills and reporting to appropriate authorities.

6.4 Reference to other sections

For recommended personal protective equipment see Section 8.
For disposal considerations see Section 13.

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

For industrial use of the liquid, avoid contact with skin and eyes. Remove sources of ignition. Wear protective clothing as in Section 8. Good general ventilation is recommended.

7.2 Conditions for safe storage, including any incompatibilities

Store below 25°C.

7.3 Specific end use

Identified in Section 1.2

SECTION 8: Exposure controls/personal protection

8.1 Control Parameters

EU Limit: None

UK Limit: Isopropyl Alcohol: long-term exposure limit (8 h), 999 mg/m³ (400 ppm); short-term exposure limit (15 min), 1250 mg/m³ (500 ppm).

8.2 Exposure controls

Engineering controls

For industrial use of the liquid, good general ventilation is recommended. Where exposure limits may be exceeded, local exhaust ventilation may be necessary.

Personal protective equipment

For professional use of the liquid, the need for personal protective equipment should be based on a workplace risk assessment for the particular use. Prevent skin and eye contact by wearing chemical resistant gloves (eg rubber, neoprene, PVC) and safety goggles. Where more extensive contact may occur, wear suitable protective clothing (eg apron, sleeves, boots). PPE should be to European (EN) standards. Consult manufacturers concerning breakthrough times

Environmental exposure controls

Not available

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

Moist non-woven wipe

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| | |
|------------------------------|--|
| Odour | Alcohol |
| Odour threshold | Not available |
| pH | 5.0-8.0 |
| Melting/freezing point | -88 to -90°C (propan-2-ol) |
| Initial boiling point/range | 82 to 83°C (propan-2-ol) |
| Flash point | ca. 18°C (70% propan-2-ol) |
| Evaporation rate | Not available |
| Explosive limits (in air) | 1.8-12% (propan-2-ol) |
| Vapour pressure (20°C) | 4.3 kPa (propan-2-ol) |
| Solubility | Soluble in water |
| Partition coef | Not available |
| Auto-ignition temperature | Not available |
| Decomposition temperature | Not available |
| Viscosity | Not available |
| Explosive properties | Vapours may form explosive mixtures with air |
| 9.2 Other information | Not available |

SECTION 10: Stability and reactivity

10.1 Reactivity

Not available

10.2 Chemical stability

Stable under recommended handling conditions

10.3 Possibility of hazardous reactions

Not available

10.4 Conditions to avoid

Sources of ignition (e.g. heat, spark, flame).

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10.5 Incompatible materials

Oxidising agents, ammonia, and chlorine. Contact with anionic substance will reduce effectiveness of the product

10.6 Hazardous decomposition products

Not available

SECTION 11: Toxicological information

11.1 Information of toxicological effects

This preparation has not been tested for its toxicological effects.

Acute toxicity

Not expected to be toxic by ingestion, skin contact or inhalation

Skin corrosion/irritation

Not likely to cause dermal irritation.

Serious eye damage/irritation

Mild irritant to eyes

Respiratory or skin sensitisation

No data available

Germ cell mutagenicity

None of the ingredients have exhibited confirmed mutagenic characteristics in the evaluation of their toxicity to date.

Carcinogenicity

None of the ingredients have exhibited confirmed carcinogenic characteristics in the evaluation of their toxicity to date.

Reproductive toxicity

No information available regarding toxicity to reproduction.

STOT-single exposure

No data available

STOT-repeated exposure

No data available

Aspiration hazard

Not expected to be an aspiration hazard

SECTION 12: Ecological information

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12.1 Toxicity

Contains a substance (chlorhexidine digluconate) which can be toxic to aquatic organisms, but at the levels contained in this mixture it is not considered to be toxic.

12.2 Persistence and degradability

Contains a substance (Chlorhexidine digluconate) which is not readily biodegradable.

12.3 Bioaccumulative potential

Not available

12.4 Mobility soil

Not available

12.5 Results of PBT and vPvB assessment

Not available

12.6 Other adverse effects

Not available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

For large-scale industrial use, the liquid should be disposed of by incineration. Do not dispose of via the drains, or by landfill. Disposal must be in accordance with current national and local regulations. In industry, chemical residues generally count as special waste, and their disposal may be regulated in the EC member countries through corresponding laws and regulations. We recommend that you contact either the authorities or approved waste disposal companies who will advise you on how to dispose of special waste.

General EU requirements are given in the Waste Framework Directive (75/442/EEC) and the Hazardous Waste Directive (91/689/EEC).

The wipes are not flushable or maceratable.

SECTION 14: Transport Information

14.1 UN Number

3175 with special provisions: IATA A46, ADR 216 & 274, IMDG 216 & 274.

14.2 UN Proper Shipping Name

SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S (contains isopropanol)

14.3 Transport hazard class(es)

4.1

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14.4 Packing groups

II

14.5 Environmental hazards

Marine pollutant

14.6 Special precautions for user

Not available

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

Not available

SECTION 15: Regulatory information

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

Product Classified as a Medicine according to Directive 2001/83/EC

15.2 Chemical safety assessment

Not available

SECTION 16: Other Information

Revisions
Currently in the second revision.

Basis of classification
The mixture is self-classified on the basis of available information on the ingredients

List of hazard statements
H225: Highly flammable liquid and vapour
H318: Causes serious eye damage
H319: Causes serious eye irritation
H336: May cause drowsiness or dizziness
H400: Very toxic to aquatic life
H410: Very toxic to aquatic life with long lasting effects

This safety data sheet was compiled using the ECHA Guidance on the compilation of Safety Data Sheets, Version 4.0, December 2020.

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