
SAFETY DATA SHEET

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

A safety data sheet is not required for this product under Article 31 of REACH. This safety data sheet has been created on a voluntary basis to communicate relevant information under Article 32.

1.1 Product identifier

- Product Name: Peri-Prep Sensitive Protective Film Foam Applicator/Salts Barrier Film Foam Applicator
- Product Part Number: PPS2
- Product Description: Foam applicator containing solvent (1 mL isopropanol) sealed in aluminium foil sachets

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

- Use of the substance/mixture: As a topical barrier between the skin and adhesive device to protect the skin
- Use advised against: No information available

1.3 Details of the supplier of the safety data sheet

- Name of Supplier: Salts Healthcare
- Address of Supplier: Richard St,
Aston,
Birmingham
United Kingdom
B7 4AA
- Telephone: +44 (0) 121 333 2000
- Fax: +44 (0) 146 324 0950
- Email: hello@salts.co.uk

1.4 Emergency telephone number

- +44 (0) 121 333 2000

SECTION 2: Hazards identification

Exempt from the requirements of CLP as product is regulated as a medical device or an accessory to a medical device. Information is provided to inform users of the hazards associated with the use of the product.

2.1 Classification of the substance or mixture

- Classification (REGULATION (EC) No 1272/2008) [CLP/GHS]: Flam. Liq. 3, H226; Eye Irrit. 2, H319
- Additional information: For full text of Hazard- and EU Hazard-statements: see section 16

2.2 Label elements

- Exempt from labelling requirements under CLP
- This product is covered by the Medical Devices Regulation (EU) 2017/745 (MDR)

2.3 Other hazards

- Inhalation of solvent vapours may give rise to nausea, headaches and dizziness
- Not a PBT according to REACH Annex XIII
- Not a vPvB according to REACH Annex XIII
- Does not contain any substances with endocrine disrupting properties

SECTION 3: Composition/information on ingredients**3.1 Substances**

SECTION 3: Composition/information on ingredients (....)

- Not applicable

3.2 Mixtures

- Contains the following hazardous ingredients or ingredients with a workplace exposure limit:

Chemical Name	Conc.	CAS No.	EC No.	Classification (REGULATION (EC) No 1272/2008) [CLP/GHS]	SCL/ M-Factor/ ATE	REACH Registration Number	WEL/ OEL
Propan-2-ol; isopropyl alcohol; isopropanol	1-10%	67-63-0	200-661-7	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336	-	01-2119457558-25 -XXXX	Yes

SECTION 4: First aid measures

4.1 Description of first aid measures

- Rescuers should put on approved personal protective equipment (PPE) before administering first aid

Contact with eyes

If substance has got into eyes, immediately wash out with plenty of water for several minutes
Irrigate eyes thoroughly whilst lifting eyelids
Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.

Contact with skin

No hazard expected under normal conditions of use
If skin irritation or rash occurs: wash with plenty of soap and water

Ingestion

Give plenty of water to drink
Do not induce vomiting because of risk of aspiration into the lungs. If aspiration is suspected obtain immediate medical attention
Get immediate medical advice/attention.

Inhalation

If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
Keep warm and at rest, in a half upright position. Loosen clothing
If exposed or concerned: Get medical advice/attention.

4.2 Most important symptoms and effects, both acute and delayed

Contact with eyes

May cause redness and irritation
May cause blurred vision

Contact with skin

No hazard expected under normal conditions of use
Prolonged skin contact will result in defatting of the skin, leading to irritation, and in some cases, dermatitis
Repeated exposure may cause skin dryness or cracking

Ingestion

May result in feeling of intoxication and can cause visual disturbance
May cause dizziness, confusion, headache or stupor
May cause gastro-intestinal disturbances
May cause nausea/vomiting

SECTION 4: First aid measures (....)

Inhalation

- Vapours may cause drowsiness and dizziness
- May cause respiratory irritation
- May cause shortness of breath

4.3 Indication of any immediate medical attention and special treatment needed

- Treat symptomatically
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SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media: Sand/earth; alcohol resistant foam; water spray; water fog; carbon dioxide; dry powder
- Unsuitable extinguishing media: High volume water jet

5.2 Special hazards arising from the substance or mixture

- Flammable liquid and vapour.
- Vapours may ignite
- In confined spaces, sewers, etc., the vapours may collect to form explosive mixtures with air
- Vapours are heavier than air and may travel considerable distances to a source of ignition and flashback
- Gives off irritating or toxic fumes (or gases) in a fire.
- Decomposition products may include carbon oxides

5.3 Advice for firefighters

- In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion.
 - Shut off all ignition sources
 - Collect contaminated fire extinguishing water separately. This MUST not be discharged into drains. Prevent fire extinguishing water from contaminating surface or ground water.
 - Wear chemical protection suit and positive-pressure breathing apparatus
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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- Personal precautions for non-emergency personnel: Avoid contact with eyes ; Avoid breathing vapours, mist or gas; Wear protective clothing as per section 8; Ventilate the area and wash spill site after material pick-up is complete; Wash thoroughly after dealing with spillage
- Personal precautions for emergency responders: Wear chemical protection suit; Wear self-contained breathing apparatus (SCBA)

6.2 Environmental precautions

- Do not allow to enter public sewers and watercourses
- If contamination of drainage systems or water courses is unavoidable, immediately inform appropriate authorities
- Contain the spillage using bunding
- Prevent run off water from entering drains if possible

6.3 Methods and material for containment and cleaning up

- Small spills
 - Wipe up spillage with damp absorbent cloth or towel
 - Large spills
 - Ground and bond container and receiving equipment.
 - Use non-sparking tools.
 - Absorb spillage in earth or sand
 - Place in appropriate container
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SECTION 6: Accidental release measures (....)

Remove contaminated material to safe location for subsequent disposal
Ventilate the area and wash spill site after material pick-up is complete
Seek expert advice for removal and disposal of all contaminated materials and wastes

6.4 Reference to other sections

- See section(s): 7, 8 & 13

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

- Ensure adequate ventilation
- Avoid breathing vapours, mist or gas
- Avoid contact with eyes
- Keep away from oxidisers, heat, flames or ignition sources
- Do not eat, drink or smoke when using this product.

7.2 Conditions for safe storage, including any incompatibilities

- Keep locked up and out of reach of children
- Keep only in original packaging.
- Keep in a cool, dry, well ventilated place
- Store at 5 - 25 °C
- Keep container tightly closed.
- Take action to prevent static discharges.
- Incompatible with strong oxidising agents, strong acids, strong bases, reducing agents, amines and halogenated substances

7.3 Specific end use(s)

- As a topical barrier between the skin and adhesive device to protect the skin

SECTION 8: Exposure controls/personal protection**8.1 Control parameters**

- If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment.
Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace exposure - Measurement of exposure by inhalation to chemical agents - Strategy for testing compliance with occupational exposure limit values). European Standard EN 14042 (Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents). European Standard EN 482 (Workplace exposure. General requirements for the performance of procedures for the measurement of chemical agents). Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

Propan-2-ol; isopropyl alcohol; isopropanol

WEL (long term) 400 ppm 999 mg/m³ (UK)
WEL (short term limit value) 500 ppm 1250 mg/m³ (UK)
DNEL (inhalational) 500 mg/m³ Industry, Long Term, Systemic Effects
DNEL (dermal) 888 mg/kg bw/day Industry, Long Term, Systemic Effects
DNEL (inhalational) 89 mg/m³ Consumer, Long Term, Systemic Effects
DNEL (dermal) 319 mg/kg bw/day Consumer, Long Term, Systemic Effects
DNEL (oral) 26 mg/kg bw/day Consumer, Long Term, Systemic Effects
PNEC aqua (freshwater) 140.9 mg/L
PNEC aqua (intermittent releases, freshwater) 140.9 mg/L
PNEC aqua (marine water) 140.9 mg/L
PNEC (STP) 2.251 g/L
PNEC sediment (freshwater) 552 mg/kg
PNEC sediment (marine water) 552 mg/kg

SECTION 8: Exposure controls/personal protection (....)

PNEC terrestrial (soil) 28 mg/kg
PNEC secondary poisoning (food) 160 mg/kg

8.2 Exposure controls

- Selection and use of personal protective equipment should be based on a risk assessment of exposure potential
- Engineering controls
 - Ensure adequate ventilation
- Respiratory protection
 - No respiratory protection is needed during normal handling
 - Respiratory protection may be required under exceptional circumstances when excessive air contamination exists and the OEL/WEL limits are exceeded
- Skin protection
 - No special clothing/skin protection is required under normal conditions of use
- Eye/face protection
 - None required for normal handling of product
 - If there is a risk of product getting into eyes, wear safety glasses approved to standard EN 166.
- Thermal hazards
 - Not applicable
- Hygiene measures
 - Do not eat, drink or smoke when using this product.
 - Contaminated clothing should be laundered before reuse
 - Use good personal hygiene practices
 - Wash thoroughly after handling.
 - Eyewash bottles should be available
- Environmental exposure controls
 - Avoid release to the environment.
 - Do not allow to penetrate the ground/soil.
 - Do not empty into drains



SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

- Physical state: Foam applicator containing solvent sealed in aluminium foil sachets
- Colour: No information available
- Odour: Alcohol odour
- Melting point/freezing point: -89.5 to -88.5°C (isopropanol)
- Boiling point or initial boiling point and boiling range: 82.3 - 82.5 °C (isopropanol)
- Flammability: Flammable liquid and vapour.
- Lower and upper explosion limit: Lower explosive limit: (isopropanol) 2 %% (in air); Upper explosive limit: (isopropanol) 13.4 %% (in air)
- Flash point: 34.8°C (supplier)
- Auto-ignition temperature: 399 - 455.6°C (isopropanol)
- Decomposition temperature: No data available
- pH: Approx. 7
- Kinematic viscosity: Dynamic viscosity 0.576 - 4.619 mPa s (isopropanol)

SECTION 9: Physical and chemical properties (....)

- Solubility: No data available
- Partition coefficient n-octanol/water (log value): Log Pow 0.05 @ 25 °C (isopropanol)
- Vapour pressure: 44 - 60.2 hPa @ 20 - 25 °C ((isopropanol)
- Density and/or relative density: 0.79 g/cm³ @ 20 °C (isopropanol)
- Relative vapour density: No information available
- Particle characteristics: No information available

9.2 Other information

- Volatile Organic Compounds (VOC): No information available

SECTION 10: Stability and reactivity

10.1 Reactivity

- No information available

10.2 Chemical stability

- Considered stable under normal conditions

10.3 Possibility of hazardous reactions

- May form explosive vapour/air mixtures

10.4 Conditions to avoid

- Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

10.5 Incompatible materials

- Incompatible with strong oxidising agents, strong acids, strong bases, reducing agents, amines and halogenated substances

10.6 Hazardous decomposition products

- Decomposition products may include carbon oxides

SECTION 11: Toxicological information

Reviewed in accordance with ISO 10993-1:2018 Biological Evaluation of Medical Devices

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

- Acute Toxicity

Based on available data, the classification criteria are not met

Substances

Chemical Name	LD ₅₀ (oral, rat)	LC50 (inhalation, rat)	LD ₅₀ (dermal, rabbit)
Propan-2-ol; isopropyl alcohol; isopropanol	5 840 mg/kg	(6 h) 10 000 ppm	16.4 mL/kg

- Skin corrosion/irritation

Based on available data, the classification criteria are not met

Substances

Chemical Name	Irritation/corrosion
Propan-2-ol; isopropyl alcohol; isopropanol	No adverse effect observed (not irritating)

SECTION 11: Toxicological information (....)

- Serious eye damage/irritation
Causes serious eye irritation.
Classification based on calculation and concentration thresholds

Substances

Chemical Name	Irritation/corrosion
Propan-2-ol; isopropyl alcohol; isopropanol	Adverse effect observed (irritating)

- Respiratory or skin sensitisation
Based on available data, the classification criteria are not met

Substances

Chemical Name	Skin sensitisation	Respiratory sensitisation
Propan-2-ol; isopropyl alcohol; isopropanol	No adverse effect observed (not sensitising)	No study available

- Germ cell mutagenicity
No evidence of mutagenic effects

Substances

Chemical Name	Toxicity - In Vitro	Toxicity - In Vivo
Propan-2-ol; isopropyl alcohol; isopropanol	No adverse effect observed (negative)	No study available

- Carcinogenicity
No evidence of carcinogenic effects

Substances

Chemical Name	NOAEL (oral, rat)	NOAEC (inhalation, rat)	NOAEL (dermal, rat)
Propan-2-ol; isopropyl alcohol; isopropanol	No data available	No data available	No data available

- Reproductive toxicity
Based on available data, the classification criteria are not met

Substances

Chemical Name	NOAEL (oral, rat)	NOAEC (inhalation, rat)	NOAEL (dermal, rat)
Propan-2-ol; isopropyl alcohol; isopropanol	No data available	No data available	No data available

- Specific target organ toxicity (STOT) - single exposure
Based on available data, the classification criteria are not met

Substances

Chemical Name	Route	Remarks
Propan-2-ol; isopropyl alcohol; isopropanol	Respiratory	No data available

- Specific target organ toxicity (STOT) - repeated exposure
Based on available data, the classification criteria are not met

SECTION 11: Toxicological information (....)

Substances

Chemical Name	NOAEL (oral, rat)	NOAEC (inhalation, rat)	NOAEL (dermal, rat)
Propan-2-ol	No data available	5 000 ppm	No data available

- Aspiration hazard
No information available
- Contact with eyes
May cause redness and irritation
May cause blurred vision
- Contact with skin
No hazard expected under normal conditions of use
Prolonged skin contact will result in defatting of the skin, leading to irritation, and in some cases, dermatitis
Repeated exposure may cause skin dryness or cracking.
- Ingestion
May result in feeling of intoxication and can cause visual disturbance
May cause dizziness, confusion, headache or stupor
May cause gastro-intestinal disturbances
May cause nausea/vomiting
- Inhalation
Vapours may cause drowsiness and dizziness
May cause respiratory irritation.
May cause shortness of breath

11.2 Information on other hazards

- Does not contain any substances with endocrine disrupting properties

SECTION 12: Ecological information

12.1 Toxicity

- No experimental test data available for the mixture
- Based on available data, the classification criteria are not met

Substances

Chemical Name	LC ₅₀ (fish)	EL ₅₀ (aquatic invertebrates)	EC ₅₀ (aquatic algae)
Propan-2-ol; isopropyl alcohol; isopropanol	(4 days) 9.64 - 10 g/L	(24 h) 10 g/L	9.17 g/L

12.2 Persistence and degradability

- Some ingredients are biodegradable

Substances

Chemical Name	Biodegradation
Propan-2-ol; isopropyl alcohol; isopropanol	Readily biodegradable in water (100%)

12.3 Bioaccumulative potential

- Low bioaccumulation potential

SECTION 12: Ecological information (....)

Substances

Chemical Name	Bioconcentration Factor (BCF)	Log Kow
Propan-2-ol; isopropyl alcohol; isopropanol	Low potential for bioaccumulation (Log Pow < 3)	Log Pow 0.05 @ 25 °C

12.4 Mobility in soil

- Insoluble in water

Substances

Chemical Name	Adsorption/desorption
Propan-2-ol; isopropyl alcohol; isopropanol	Low potential for adsorption

12.5 Results of PBT and vPvB assessment

- Not a PBT according to REACH Annex XIII
- Not a vPvB according to REACH Annex XIII

12.6 Endocrine disrupting properties

- Does not contain any substances with endocrine disrupting properties

12.7 Other adverse effects

- No information available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

- Avoid release to the environment.
- Disposal should be in accordance with local, state or national legislation
- Dispose of contents/container to an authorised waste collection point

13.2 Classification

- The waste must be identified according to the List of Wastes (2000/532/EC)
- Hazardous Property Code(s): HP 3 Flammable; HP 4 Irritant

SECTION 14: Transport information

Sealed packets and articles containing less than 10 ml of a packing group II or III flammable liquid absorbed into a solid material are not subject to ADR/IMDG/IATA provided there is no free liquid in the packet or article.



14.1 UN number or ID number

- UN No.: 3175
- Special Provision(s): 216; A46

14.2 UN proper shipping name

- Proper Shipping Name: SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (isopropanol)

14.3 Transport hazard class(es)

- Hazard Class: 4.1

14.4 Packing group

SECTION 14: Transport information (....)

- Packing Group: II

14.5 Environmental hazards

- Presents little or no hazard to the environment

14.6 Special precautions for user

- Protect from heat

14.7 Maritime transport in bulk according to IMO instruments

- Not applicable

14.8 Road/Rail (ADR/RID)

- Proper Shipping Name: SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (isopropanol)
- ADR UN No.: 3175
- ADR Hazard Class: 4.1
- ADR Packing Group: II
- Tunnel Code: (E)
- Special Provision(s): 216; Sealed packets and articles containing less than 10 ml of a packing group II or III flammable liquid absorbed into a solid material are not subject to ADR/IMDG/IATA provided there is no free liquid in the packet or article.

14.9 Sea (IMDG)

- Proper Shipping Name: SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (isopropanol)
- IMDG UN No.: 3175
- IMDG Hazard Class: 4.1
- IMDG Packing Group: II
- Special Provision(s): 216; Sealed packets and articles containing less than 10 ml of a packing group II or III flammable liquid absorbed into a solid material are not subject to ADR/IMDG/IATA provided there is no free liquid in the packet or article.

14.10 Air (ICAO/IATA)

- Proper Shipping Name: SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (isopropanol)
- ICAO UN No.: 3175
- ICAO Hazard Class: 4.1
- ICAO Packing Group: II
- Special Provision(s): A46; Sealed packets and articles containing less than 10 ml of a packing group II or III flammable liquid absorbed into a solid material are not subject to ADR/IMDG/IATA provided there is no free liquid in the packet or article.

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

- A safety data sheet is not required for this product under Article 31 of REACH. This safety data sheet has been created on a voluntary basis to communicate relevant information under Article 32.
- This safety data sheet is provided in compliance with REACH Regulation (EC) No 1907/2006 (as amended by Regulation (EU) 2020/878) and UK REACH
- Exempt from the requirements of CLP as product is regulated as a medical device or an accessory to a medical device. Information is provided to inform users of the hazards associated with the use of the product.
- The GB Classification, Labelling and Packaging Regulation (GB CLP) applies in Great Britain
- Regulation (EC) No. 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation) applies in Europe
- This product is covered by the Medical Devices Regulation (EU) 2017/745 (MDR)
- Reviewed in accordance with ISO 10993-1:2018 Biological Evaluation of Medical Devices

15.2 Chemical safety assessment

SECTION 15: Regulatory information (....)

- A REACH chemical safety assessment has not been carried out
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SECTION 16: Other information

This information is intended to cover potential hazards at the place of work and does not detail medical uses, indications, contra-indications and precautions for the treatment of patients.

Created by ChemRegs (UK) Ltd June 2017

Revision No. 2.0.0. Revised October 2022.

Changes made: Updated to conform to the latest version of REACH Annex II and the Medical Devices Regulation (EU) 2017/745 (MDR)

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

- Flam. Liq. 3, H226: Classification based on bridging principles of similar tested mixtures
- Eye Irrit. 2, H319: Classification based on calculation and concentration thresholds

Text not given with phrase codes where they are used elsewhere in this safety data sheet:

- H225: Highly flammable liquid and vapour.
- H226: Flammable liquid and vapour
- H319: Causes serious eye irritation.
- H336: May cause drowsiness or dizziness

Acronyms

- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstracts Service
- DNEL: Derived No-Effect Level
- EC: European Community
- EC₅₀: Effective Concentration, 50%
- EL₅₀: Effective Loading Rate resulting in 50% effect.
- GHS: Globally Harmonised System
- LC₅₀: Lethal Concentration, 50%
- LD₅₀: Lethal Dose, 50%
- LOAEC: Lowest Observed Adverse Effect Concentration
- LOAEL: Lowest Observed Adverse Effect Level
- NOAEC: No Observed Adverse Effect Concentration
- NOAEL: No Observed Adverse Effect Level
- OEL: Occupational Exposure Limit
- PBT: Persistent, Bioaccumulative and Toxic
- PNEC: Predicted No-Effect Concentration
- REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
- SCL: Specific Concentration Limit
- STOT RE: Specific Target Organ Toxicity Repeated Exposure
- STOT SE: Specific Target Organ Toxicity Single Exposure
- SVHC: Substances of Very High Concern
- vPvB: very Persistent and very Bioaccumulative
- WEL: Workplace Exposure Limit

--- end of safety datasheet ---
