Revision: 5 Jan 2017

SAFETY DATA SHEET

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

1.1 Product identifier

- Product Name: Peri-Prep Sensitive Wipes / Salts Barrier Film Wipes
- Product Part Number: PPS1
- Product Description: Non-woven swab containing solvent sealed in aluminium foil sachets
- Contains 2 ml isopropanol

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

- Use of the substance/mixture: For skin cleansing and preparation prior to application of adhesive device
- 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) 121 359 0830
- Email: salt@salts.co.uk

1.4 Emergency telephone number

- +44 (0) 121 333 2000

SECTION 2: Hazards identification

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

GHS02

GHS07

- Signal Word: Warning
- Contains isopropanol
- Hazard statements
  H226 - Flammable liquid and vapour.
  H319 - Causes serious eye irritation.
- Precautionary statements

SECTION 2: Hazards identification (....)

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P370+P378 - In case of fire: Use alcohol resistant foam, dry powder or sand to extinguish.
P403+P235 - Store in a well-ventilated place. Keep cool.
P501 - Dispose of contents/container to an authorised waste collection point

- Supplemental Hazard Information (EU)
  None

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

SECTION 3: Composition/information on ingredients

3.1 Substances

3.2 Mixtures

- propan-2-ol; isopropyl alcohol; isopropanol
  Concentration: 1-10%
  CAS Number: 67-63-0
  EC Number: 200-661-7
  Classification (REGULATION (EC) No 1272/2008) [CLP/GHS]: Flam. Liq. 2, H225, Eye Irrit. 2, H319, STOT SE 3, H336
  Substance with a workplace exposure limit, see Section 8

SECTION 4: First aid measures

4.1 Description of first aid measures

- Contact with eyes
  Rinse cautiously with 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
  Obtain immediate medical attention

4.2 Most important symptoms and effects, both acute and delayed

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

- Contact with eyes
  May cause redness and irritation
  May cause blurred vision
- Contact with skin
  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

4.3 Indication of any immediate medical attention and special treatment needed

- Treat symptomatically

SECTION 5: Firefighting measures

5.1 Extinguishing media

- In case of fire: Use alcohol resistant foam, dry powder or sand to extinguish.
- In the event of an adjacent fire, cool containers with water spray
- Unsuitable extinguishing media: high volume water jet

5.2 Special hazards arising from the substance or mixture

- 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

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).

SECTION 6: Accidental release measures (....)

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

- Ground/bond container and receiving equipment.
- Use only non-sparking tools.
- Absorb spillage in earth or sand
- Place in appropriate container
- 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 7 and 8

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Ensure adequate ventilation
- Vapours are heavier than air and may travel considerable distances to a source of ignition and flashback
- In confined spaces, sewers, etc., the vapours may collect to form explosive mixtures with air
- Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- Take precautionary measures against static discharge.
- Do not eat, drink or smoke when using this product.
- Eyewash bottles should be available
- See Section 8

7.2 Conditions for safe storage, including any incompatibilities

- Keep only in original container.
- Keep in a cool, dry, well ventilated place
- Store at 0 - 30°C
- Keep container tightly closed.
- Take precautionary measures against static discharge.
- Use explosion-proof electrical equipment.
- Use explosion-proof ventilating and lighting equipment.

7.3 Specific end use(s)

- For skin cleansing and preparation prior to application of adhesive device

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

- propan-2-ol; isopropyl alcohol; isopropanol
  WEL (long term) 400 ppm (UK)
  WEL (long term) 999 mg/m3 (UK)
  WEL (short term) 500 ppm (UK)
  WEL (short term) 1250 mg/m3 (UK)

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

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 (marine water) 140.9 mg/l
PNEC aqua (intermittent releases) 140.9 mg/l
PNEC (STP) 2251 mg/l
PNEC sediment (freshwater) 55255 mg/kg
PNEC sediment (marine water) 552 mg/kg
PNEC terrestrial (soil) 28 mg/kg

8.2 Exposure controls

- Ensure adequate ventilation
- Use explosion-proof ventilating and lighting equipment.
- Eyewash bottles should be available
- No respiratory protection is needed during normal handling
- In case of insufficient ventilation, wear suitable respiratory equipment
- In case of fire:
  Wear protective gloves/protective clothing/eye protection/face protection.
  The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and standard EN 374.
  Wear safety glasses approved to standard EN 166.
  In case of inadequate ventilation wear respiratory protection.

Gloves Suit Goggles Respirator

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- Appearance: Non-woven swab containing solvent sealed in aluminium foil sachets
- Odour: Alcohol odour
- Odour threshold: No information available
- pH: approx. 7
- Melting point/freezing point: -89.5 to -88.5°C (isopropanol)
- Initial boiling point and boiling range: 82.5°C (isopropanol)
- Flashpoint: (supplier) 34.8°C
- Evaporation Rate: No information available
- Flammability (solid,gas): Not applicable
- Upper/lower flammability or explosive limits: Lower explosive limit (isopropanol) 2 % (in air), Upper explosive limit (isopropanol) 13.4 % (in air)
- Vapour Pressure: 44 hPa @20°C (isopropanol)
- Vapour Density: No information available
- Relative Density: 0.8 (isopropanol)
- Solubility(ies): Soluble in water
- Partition Coefficient (n-Octanol/Water): Log Pow 0.05 @25°C (isopropanol)

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

- Autoignition Temperature: 399 - 455.6°C (isopropanol)
- Decomposition temperature: No information available
- Viscosity: Dynamic viscosity 0.576 - 4.619 mPa s (isopropanol
- Explosive Properties: No information available
- Oxidising Properties: No information available

9.2 Other information

- 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 oxidizing substances
- Incompatible with acid
- Incompatible with reducing agents
- Incompatible with amines
- Incompatible with halogenated substances

10.6 Hazardous decomposition products

- Decomposition products may include carbon oxides

SECTION 11: Toxicological information

11.1 Information on toxicological effects

- Reviewed in accordance with ISO 10993-1:2009 Biological Evaluation of Medical Devices

- Acute Toxicity
  No experimental test data available for the mixture
  LD50 (oral,rat) (isopropanol) 5840 mg/kg
  LC50 (inhalational, rat) (isopropanol) : 10 000 ppm/6
  LD50 (dermal, rabbit) (isopropanol) 16.4 ml/kg bw
  Based on available data, the classification criteria are not met
- Skin corrosion/irritation
  Based on available data, the classification criteria are not met
- Serious eye damage/irritation
  Causes serious eye irritation.
  Classification based on calculation and concentration thresholds
- Respiratory or skin sensitisation
  Based on available data, the classification criteria are not met
- Germ cell mutagenicity
  No evidence of mutagenic effects

SECTION 11: Toxicological information (....)

- Carcinogenicity
  No evidence of carcinogenic effects
- Reproductive toxicity
  No evidence of reproductive effects
- Specific target organ toxicity (STOT) - single exposure
  Based on available data, the classification criteria are not met
- Specific target organ toxicity (STOT) - repeated exposure
  No information available
- Aspiration hazard
  No information available
- Contact with eyes
  May cause redness and irritation
  May cause blurred vision
- Contact with skin
  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

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
- propan-2-ol; isopropyl alcohol; isopropanol
  LC50 (fish) 9.64-10 g/l (4 days)
  EC50 (aquatic invertebrates) 10 g/l (24 hr)
  LC50 (aquatic invertebrates) 10 g/l (24 hr)

12.2 Persistence and degradability

- No information available

12.3 Bioaccumulative potential

- No information available

12.4 Mobility in soil

- Insoluble in water

12.5 Results of PBT and vPvB assessment

- No information available

12.6 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

13.2 Classification

- The waste must be identified according to the List of Wastes (2000/532/EC)

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.

Flammable Solid

14.1 UN 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

- 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 Transport in bulk according to Annex II of Marpol and the IBC Code

- 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)

SECTION 14: Transport information (....)

- Proper Shipping Name: SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (isopropanol)
- IMDG UN No.: 3175
- IMDG Hazard Class: 4.1
- IMDG Pack 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

- This Safety Data Sheet is provided in compliance with REACH Regulation (EC) No 1907/2006 as amended by Regulation (EU) 2015/830
- Regulation (EC) No. 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation) applies in Europe
- Reviewed in accordance with ISO 10993-1:2009 Biological Evaluation of Medical Devices

15.2 Chemical safety assessment

- A REACH chemical safety assessment has not been carried out

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.

Revision No. 3.0.0. Revised January 2017 by ChemRegs (UK) Ltd.
Changes made: Change to classification in section 2 (addition of H319); Updated sections to conform to latest version of REACH

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.

SECTION 16: Other information (....)

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

--- end of safety datasheet ---