SAFETY DATA SHEET

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

1.1 Product identifier

- Product Name: Stoma Paste / Salts Stoma Paste
- Chemical Name: Contains ethanol, butanol and propanol

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

- Use of the substance/mixture: Application to skin as part of an adhesive device.
- Use advised against: Not for internal use.

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. Sol. 2, H228; Eye Irrit. 2, H319; STOT SE 3, H336; STOT RE 2, H373; EUH208
- Additional information: For full text of Hazard- and EU Hazard-statements: see section 16

2.2 Label elements

GHS02

GHS07

GHS08

- Signal Word: Warning
- Contains ethanol, butanol and propanol
- Hazard statements
  H228 - Flammable solid.
  H319 - Causes serious eye irritation.
  H336 - May cause drowsiness or dizziness.
  H373 - May cause damage to organs through prolonged or repeated exposure.
- Precautionary statements
  P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

SECTION 2: Hazards identification (....)

P260 - Do not breathe dust/fume/gas/mist/vapours/spray.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P312 - Call a POISON CENTRE or doctor if you feel unwell.

- Supplemental Hazard Information (EU)
  EUH208 - Contains N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]. May produce an allergic reaction.

2.3 Other hazards

- May cause skin sensitisation. Stop using product if skin sensitisation occurs.

SECTION 3: Composition/information on ingredients

3.1 Substances

3.2 Mixtures

- ethanol; ethyl alcohol
  Concentration: 10 - 20%
  CAS Number: 64-17-5
  EC Number: 200-578-6
  Classification (REGULATION (EC) No 1272/2008) [CLP/GHS]: Flam. Liq. 2, H225; Eye Irrit. 2, H319
  REACH Registration Number: 01-2119457610-43-XXXX
  Substance with a workplace exposure limit, see Section 8

- propan-2-ol; isopropyl alcohol; isopropanol
  Concentration: 10 - 20%
  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

- butan-1-ol; n-butanol
  Concentration: 1 - 5%
  CAS Number: 71-36-3
  EC Number: 200-751-6
  Classification (REGULATION (EC) No 1272/2008) [CLP/GHS]: Flam. Liq. 3, H226; Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Dam. 1, H318; STOT SE 3, H335; STOT SE 3, H336; STOT RE 1, H372

- N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]
  Concentration: <1%
  CAS Number: 39236-46-9
  EC Number: 254-372-6
  Classification (REGULATION (EC) No 1272/2008) [CLP/GHS]: Skin Sens. 1B, H317
  REACH Registration Number: 01-2119983788-11-XXXX

SECTION 4: First aid measures

4.1 Description of first aid measures

- Contact with eyes
  If substance has got into eyes, immediately wash out with plenty of water
  Remove contact lenses, if present and easy to do. Continue rinsing.
  If eye irritation persists: Get medical advice/attention.
- Contact with skin
  May cause skin sensitisation. Stop using product if skin sensitisation occurs.
  If skin irritation or rash occurs: Get medical advice/attention.
  Gently wash with plenty of soap and water.
- Ingestion
  Rinse mouth with water (do not swallow)
  Do NOT induce vomiting.
  Never give anything by mouth to an unconscious person
- Inhalation
  If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
  If experiencing respiratory symptoms: Call a POISON CENTER/doctor/

4.2 Most important symptoms and effects, both acute and delayed

- Contact with eyes
  Causes serious eye irritation.
  Causes redness and swelling
  May cause blurred vision
- Contact with skin
  May cause an allergic skin reaction.
  Prolonged skin contact will result in defatting of the skin, leading to irritation, and in some cases, dermatitis
- Ingestion
  Causes gastro-intestinal disturbances
  Causes nausea/vomiting
  Causes diarrhoea
  The ingestion of significant quantities may cause damage to central nervous system
- Inhalation
  Inhalation of solvent vapours may give rise to nausea, headaches and dizziness
  May cause respiratory tract irritation.
  May cause coughing
  In cases of severe exposure, respiratory failure may develop

4.3 Indication of any immediate medical attention and special treatment needed

- Symptoms of poisoning may occur even after several hours; therefore provide medical observation for at least 48 hours after the accident.

SECTION 5: Firefighting measures

5.1 Extinguishing media

SECTION 5: Firefighting measures (....)

- In case of fire: use water, alcohol resistant foam or dry agent to extinguish.
- Do not use halons

5.2 Special hazards arising from the substance or mixture

- Flammable solid
- In case of fire, do not breathe fumes
- Gives off irritating or toxic fumes (or gases) in a fire.
- Decomposition products may include nitrogen and carbon oxides
- Decomposition products may include hydrocarbons

5.3 Advice for firefighters

- Special protective equipment: Wear self-contained breathing apparatus (SCBA). Wear full protective clothing including chemical protection suit.
- Keep container(s) exposed to fire cool, by spraying with water
- Collect contaminated fire extinguishing water separately. This MUST not be discharged into drains. Prevent fire extinguishing water from contaminating surface or ground water.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- Personal precautions for non-emergency personnel: Evacuate the area and keep personnel upwind; Vapours are heavier than air and may travel considerable distances to a source of ignition and flashback; Avoid breathing dust/fume/gas/mist/vapours/spray; Wear protective clothing as per section 8; Wash thoroughly after dealing with spillage; Eyewash bottles should be available
- Personal precautions for emergency responders: Wear chemical protection suit; Wear self-contained breathing apparatus (SCBA).

6.2 Environmental precautions

- Avoid release to the environment.
- If contamination of drainage systems or water courses is unavoidable, immediately inform appropriate authorities

6.3 Methods and material for containment and cleaning up

- Absorb spillage in inert material and shovel up
- Place in sealable container
- Seal containers and label them
- Remove contaminated material to safe location for subsequent disposal
- Ventilate the area and wash spill site after material pick-up is complete

6.4 Reference to other sections

- See Section 7 and 8

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Do not breathe vapour/fumes
- Avoid contact with eyes
- Do not eat, drink or smoke when using this product.
- Ensure adequate ventilation
- Wash thoroughly after handling.
- Eyewash bottles should be available
- See Section 8

7.2 Conditions for safe storage, including any incompatibilities

SECTION 7: Handling and storage (....)

- Keep in a cool, dry, well ventilated place
- Keep only in original packaging.
- Opened containers should be carefully resealed and stored in an upright position
- Keep away from oxidisers, heat, flames or ignition sources
- Keep away from acid
- Keep away from alkalis (strong bases)
- Incompatible with ammonia solution
- Keep away from aluminium
- Incompatible with halogenated substances

7.3 Specific end use(s)

- Application to skin as part of an adhesive device.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

- ethanol; ethyl alcohol
  WEL (long term): 1920 mg/m3 (UK)
  WEL (long term): 1000 ppm (UK)
  DNEL (inhalational) 950 mg/m3 Industry, Long Term, Systemic Effects
  DNEL (inhalational) 1900 mg/m3 Industry, Acute/Short Term, Local Effects
  DNEL (dermal) 343 mg/kg (bw/day) Industry, Long Term, Systemic Effects
  DNEL (inhalational) 114 mg/m3 Consumer, Long Term, Systemic Effects
  DNEL (inhalational) 950 mg/m3 Consumer, Acute/Short Term, Local Effects
  DNEL (dermal) 206 mg/kg (bw/day) Consumer, Long Term, Systemic Effects
  DNEL (oral) 87 mg/kg (bw/day) Consumer, Long Term, Systemic Effects
  PNEC aqua (freshwater) 960 ug/l
  PNEC aqua (marine water) 790 ug/l
  PNEC aqua (intermittent releases) (freshwater) 2.75 mg/l
  PNEC (STP) 580 mg/l
  PNEC sediment (freshwater) 3.6 mg/kg
  PNEC sediment (marine water) 2.9 mg/kg
  PNEC terrestrial (soil) 630 ug/kg

- butan-1-ol; n-butanol
  WEL (short term): 154 mg/m3 (UK)
  WEL (short term): 50 ppm (UK)
  DNEL (inhalational) 310 mg/m3 Industry, Long Term, Local Effects
  DNEL (inhalational) 55.357 mg/m3 Consumer, Long Term, Systemic Effects
  DNEL (inhalational) 155 mg/m3 Consumer, Long Term, Local Effects
  DNEL (dermal) 3.125 mg/kg (bw/day) Consumer, Long Term, Systemic Effects
  DNEL (oral) 1.562 mg/kg (bw/day) Consumer, Long Term, Systemic Effects
  PNEC aqua (freshwater) 82 ug/l
  PNEC aqua (marine water) 8.2 ug/l
  PNEC aqua (intermittent releases) (freshwater) 2.25 mg/l
  PNEC (STP) 2476 mg/l
  PNEC sediment (freshwater) 324 ug/kg
  PNEC sediment (marine water) 32.4 ug/kg
  PNEC terrestrial (soil) 16.6 ug/kg

- propan-2-ol; isopropyl alcohol; isopropanol

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

WEL (long term): 999 mg/m3 (UK)
WEL (long term): 400 ppm (UK)
WEL (short term): 1250 mg/m3 (UK)
WEL (short term): 500 ppm (UK)
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) (freshwater) 140.9 mg/l
PNEC (STP) 2251 mg/l
PNEC sediment (freshwater) 552 mg/kg
PNEC sediment (marine water) 552 mg/kg
PNEC terrestrial (soil) 28 mg/kg

- N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]
  DNEL (inhalational) 24.5 mg/m3 Industry, Long Term, Systemic Effects
  DNEL (inhalational) 45.5 mg/m3 Industry, Acute/Short Term, Systemic Effects
  DNEL (dermal) 2.8 mg/kg (bw/day) Industry, Long Term, Systemic Effects
  DNEL (dermal) 160 mg/kg (bw/day) Industry, Acute/Short Term, Systemic Effects
  DNEL (oral) 1.4 mg/kg (bw/day) Consumer, Long Term, Systemic Effects
  PNEC aqua (freshwater) 5.78 ug/l
  PNEC aqua (marine water) 0.58 ug/l
  PNEC aqua (intermittent releases) (freshwater) 57.8 ug/l
  PNEC (STP) 20 mg/l
  PNEC sediment (freshwater) 88.78 ug/kg
  PNEC sediment (marine water) 8.88 ug/kg
  PNEC terrestrial (soil) 14.35 ug/kg

8.2 Exposure controls

- Ensure adequate ventilation
- Engineering controls should be provided which maintain airborne concentrations below the relevant guidelines
- In case of insufficient ventilation, wear suitable respiratory equipment
- Wear suitable protective clothing, including eye/face protection and gloves (nitrile are recommended)
- 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.
- Eyewash bottles should be available


Gloves


Suit


Goggles


Respirator


No Smoking


No Flames

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

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

- Appearance: Light; beige; viscous; paste
- Odour: Alcohol odour
- Odour threshold: No information available
- pH: No information available
- Melting point/freezing point: No information available
- Initial boiling point and boiling range: No information available
- Flashpoint: (as ethanol) 12°C
- Evaporation Rate: No information available
- Flammability (solid,gas): Combustible
- Upper/lower flammability or explosive limits: No information available
- Vapour Pressure: No information available
- Vapour Density: No information available
- Relative Density: No information available
- Solubility(ies): No information available
- Partition Coefficient (n-Octanol/Water): No information available
- Autoignition Temperature: No information available
- Decomposition temperature: No information available
- Viscosity: Viscous
- Explosive Properties: No information available
- Oxidising Properties: No information available

9.2 Other information

- This product is classified as a solid according to ASTM D 4539-90

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

- Avoid overheating
- Keep away from heat and sources of ignition

10.5 Incompatible materials

- Incompatible with acid
- Incompatible with alkalis (strong bases)
- Incompatible with aluminium
- Incompatible with ammonia solution
- Incompatible with alkali metals
- Incompatible with halogenated substances
- Incompatible with oxidizing substances

10.6 Hazardous decomposition products

- Decomposition products may include nitrogen oxides
- Decomposition products may include hydrocarbons

SECTION 11: Toxicological information

11.1 Information on toxicological effects

- Acute Toxicity
  No experimental test data available for the mixture
  LD50 (oral,rat): (ethanol) 1187 - 15 010 mg/kg
  LD50 (oral,rat): (butanol) 2292 mg/kg
  LD50 (oral,rat): (propanol) 5840 mg/kg
  LC50 (inhalation, rat) (ethanol) 115.9 - 133.8 mg/l/4h
  LC50 (inhalation, rat) (butanol) 17.76 mg/l/4h
  LC50 (inhalational, rat) : (propanol) 10 000 ppm/6 h
  LDLo (dermal) : (rabbit) (ethanol) 20000 mg/kg
  LD50 (dermal,rabbit) (butanol) 3430 mg/kg
  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
  Contains N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea].
  May produce an allergic reaction.
  Classification based on calculation and concentration thresholds
- Germ cell mutagenicity
  No evidence of mutagenic effects
- Carcinogenicity
  No evidence of carcinogenic effects
- Reproductive toxicity
  No evidence of reproductive effects
- Specific target organ toxicity (STOT) - single exposure
  STOT SE 3
  Inhalation of solvent vapours may give rise to nausea, headaches and dizziness
  Classification based on calculation and concentration thresholds
- Specific target organ toxicity (STOT) - repeated exposure
  STOT RE 2
  Can cause damage to the liver
  Can cause damage to the central nervous system
  Can cause damage to the testes
  Classification based on calculation and concentration thresholds
- Aspiration hazard
  No information available but must be considered harmful
- Contact with eyes
  Causes serious eye irritation.
  Causes redness and swelling
  May cause blurred vision
- Contact with skin

SECTION 11: Toxicological information (....)

May cause an allergic skin reaction.
Prolonged skin contact will result in defatting of the skin, leading to irritation, and in some cases, dermatitis

- Ingestion
  Causes gastro-intestinal disturbances
  Causes nausea/vomiting
  Causes diarrhoea
  Can cause damage to the central nervous system
  Can cause damage to the liver
  Can cause damage to the testes

- Inhalation
  Inhalation of solvent vapours may give rise to nausea, headaches and dizziness
  May cause respiratory tract irritation.
  May cause coughing
  In cases of severe exposure, respiratory failure may develop

SECTION 12: Ecological information

12.1 Toxicity

- ethanol; ethyl alcohol
  LC50 (fish) 14.2 - 15.4 g/l (4 days)
  EC50 (aquatic invertebrates) 10 g/l (48 hr)
  EC50 (aquatic algae) 275 mg/l (72 hr)

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

- butan-1-ol; n-butanol
  LC50 (fish) 1.376 g/l (4 days)
  EC50 (aquatic invertebrates) 1.328 g/l (48 hr)
  EC50 (aquatic algae) 225 mg/l (96 hr)

- N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]
  LC50 (fish): 1000 mg/l (24 hr)
  EC50 (aquatic invertebrates) 58 mg/l (48 hr)
  EC50 (aquatic algae) 5.78 mg/l (72 hr)

12.2 Persistence and degradability

- Not readily biodegradable

12.3 Bioaccumulative potential

- No information available

12.4 Mobility in soil

- No information available

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.
- Empty containers may contain flammable vapours
- Do not pierce or burn container, even after use
- Do not discharge into drains or the environment, dispose to an authorised waste collection point
- 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

Flammable Solid

14.1 UN number

- UN No.: 1325

14.2 UN proper shipping name

- Proper Shipping Name: FLAMMABLE SOLID, ORGANIC, N.O.S. (ethanol, propan-2-ol)

14.3 Transport hazard class(es)

- Hazard Class: 4.1

14.4 Packing group

- Packing Group: II

14.5 Environmental hazards

- No information available.

14.6 Special precautions for user

- No information available

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: FLAMMABLE SOLID, ORGANIC, N.O.S. (ethanol, propan-2-ol)
- ADR UN No.: 1325
- ADR Hazard Class: 4.1
- ADR Packing Group: II
- Tunnel Code: E

14.9 Sea (IMDG)

- Proper Shipping Name: FLAMMABLE SOLID, ORGANIC, N.O.S. (ethanol, propan-2-ol)
- IMDG UN No.: 1325
- IMDG Hazard Class: 4.1
- IMDG Pack Group.: II

14.10 Air (ICAO/IATA)

SECTION 14: Transport information (....)

- Proper Shipping Name: FLAMMABLE SOLID, ORGANIC, N.O.S. (ethanol, propan-2-ol)
- ICAO UN No.: 1325
- ICAO Hazard Class: 4.1
- ICAO Packing Group: II

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

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. 2.0. Revised 24/05/2017.
Changes made: 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. Sol. 2, H228: Classification based on bridging principles of similar tested mixtures
Eye Irrit. 2, H319: Classification based on calculation and concentration thresholds
STOT SE 3, H336: Classification based on calculation and concentration thresholds
STOT RE 2, H373: 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
- H228: Flammable solid
- H302: Harmful if swallowed
- H315: Causes skin irritation.
- H317: May cause an allergic skin reaction.
- H318: Causes serious eye damage
- H319: Causes serious eye irritation.
- H335: May cause respiratory irritation
- H336: May cause drowsiness or dizziness
- H372: Causes damage to organs through prolonged or repeated exposure
- EUH208: Contains (name of sensitising substance). May produce an allergic reaction.

--- end of safety datasheet ---