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: Stoma Paste/Salts Stoma Paste
- Product Part Number: SP60

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) 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. Sol. 2, H228; Eye Irrit. 2, H319; STOT SE 3, H336; EUH208
- 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
- May cause skin sensitisation. Stop using product if skin sensitisation occurs.
- 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

- Not applicable

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

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
Ethanol; ethyl alcohol	10-20%	64-17-5	200-578-6	Flam. Liq. 2, H225 Eye Irrit. 2, H319	-	01-2119457610-43-XXXX	Yes
Propan-2-ol; isopropyl alcohol; isopropanol	10-20%	67-63-0	200-661-7	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336	-	01-2119457558-25-XXXX	Yes
Butan-1-ol; n-butanol	1-5%	71-36-3	200-751-6	Flam. Liq. 3, H226 Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT SE 3, H335 STOT SE 3, H336	-	-	Yes
N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]	< 1%	39236-46-9	254-372-6	Skin Sens. 1B, H317	-	01-2119983788-11-XXXX	None

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

If skin irritation or rash occurs: gently wash with plenty of soap and water
May cause skin sensitisation. Stop using product if skin sensitisation occurs.

Ingestion

Rinse mouth with water (do not swallow)
Do not induce vomiting because of risk of aspiration into the lungs. If aspiration is suspected obtain immediate medical attention
Never give anything by mouth to an unconscious person
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

Causes redness and irritation
May cause stinging, pain, and discomfort

Contact with skin

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

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

dermatitis

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 tract irritation.

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

- Suitable extinguishing media: Sand/earth; alcohol resistant foam; water spray; water fog; carbon dioxide; dry powder
- Unsuitable extinguishing media: Do not use halons; Do not use water jets

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, nitrogen oxides, hydrocarbons

5.3 Advice for firefighters

- 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 dust/ fume/gas/mist/vapours/spray; Wear protective clothing as per section 8; Eyewash bottles should be available
- Personal precautions for emergency responders: Wear chemical protection suit; Wear self-contained breathing apparatus (SCBA); Ventilate the area and wash spill site after material pick-up is complete; Wash thoroughly after dealing with spillage

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

6.3 Methods and material for containment and cleaning up

- Small spills
  Wipe up spillage with damp absorbent cloth or towel

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

- Large spills
  Ground and bond container and receiving equipment.
  Use 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(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.
- Wash thoroughly after handling.

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
- Keep container tightly closed.
- Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- Incompatible with acids, alkalis, oxidisers, aluminium, ammonia solution, 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

- 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.

Ethanol; ethyl alcohol

WEL (long term) 1 000 ppm, 1 920 mg/m³ (UK)
DNEL (inhalational) 950 mg/m³ Industry, Long Term, Systemic Effects
DNEL (inhalational) 1 900 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

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

PNEC aqua (freshwater) 960 µg/L
PNEC aqua (intermittent releases, freshwater) 2.75 mg/L
PNEC aqua (marine water) 790 µg/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 µg/kg
PNEC secondary poisoning (food) 380 - 720 mg/kg

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

Butan-1-ol; n-butanol

WEL (short term) 50 ppm, 154 mg/m³ (UK. Sk - Can be absorbed through the skin)
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 µg/L
PNEC aqua (intermittent releases, freshwater) 2.25 mg/L
PNEC aqua (marine water) 8.2 µg/L
PNEC (STP) 2.476 g/L
PNEC sediment (freshwater) 324 µg/kg
PNEC sediment (marine water) 32.4 µg/kg
PNEC terrestrial (soil) 16.6 µg/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 µg/L
PNEC aqua (intermittent releases) (freshwater) 57.8 µg/L
PNEC aqua (marine water) 580 ng/L
PNEC (STP) 20 mg/L
PNEC sediment (freshwater) 88.78 µg/kg
PNEC sediment (marine water) 8.88 µg/kg
PNEC terrestrial (soil) 14.35 µg/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

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

- 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
  For prolonged or repeated skin contact wear suitable protective gloves
  The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and standard EN 374.
  The selection of a suitable glove depends on work conditions and whether the product is present on its own or in combination with other substances. Breakthrough time is dependent on the characteristics of the brand of glove used and the supplier should be consulted.
  Butyl rubber or nitrile rubber are recommended

- 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: Paste
- Colour: Light beige
- Odour: Alcohol odour
- Melting point/freezing point: Not determined
- Boiling point or initial boiling point and boiling range: Not determined
- Flammability: Flammable solid
- Lower and upper explosion limit: Not determined
- Flash point: Not determined
- Auto-ignition temperature: Not determined
- Decomposition temperature: Not determined
- pH: Not applicable
- Kinematic viscosity: Not determined
- Solubility: Negligible in water
- Partition coefficient n-octanol/water (log value): Not determined
- Vapour pressure: Not determined
- Density and/or relative density: Not determined

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

- Relative vapour density: Not determined
- Particle characteristics: No information available

9.2 Other information

- This product is classified as a solid according to ASTM D 4359-90
- 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 acids, alkalis, oxidisers, aluminium, ammonia solution, halogenated substances

10.6 Hazardous decomposition products

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

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)
Ethanol; ethyl alcohol	1 187 - 15 010 mg/kg	(4 h) 4.178 mg/L	> 2 000 mg/kg
Propan-2-ol; isopropyl alcohol; isopropanol	5 840 mg/kg	(6 h) 10 000 ppm	16.4 mL/kg
Butan-1-ol; n-butanol	2 292 mg/kg	LC_0 (4 h) 17.76 mg/L	3 430 mg/kg
N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]	5 000 - 8 000 mg/kg	No data available	No data available

- Skin corrosion/irritation
  Based on available data, the classification criteria are not met

Substances

Chemical Name	Irritation/corrosion
Ethanol; ethyl alcohol	No adverse effect observed (not irritating)

SECTION 11: Toxicological information (....)

Propan-2-ol; isopropyl alcohol; isopropanol	No adverse effect observed (not irritating)
Butan-1-ol; n-butanol	Adverse effect observed (irritating)
N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]	No adverse effect observed (not irritating)

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

Substances

Chemical Name	Irritation/corrosion
Ethanol; ethyl alcohol	Adverse effect observed (irritating)
Propan-2-ol; isopropyl alcohol; isopropanol	Adverse effect observed (irritating)
Butan-1-ol; n-butanol	Adverse effect observed (irreversible damage)
N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]	No adverse effect observed (not irritating)

- Respiratory or skin sensitisation
  This mixture is not classified as sensitising but contains at least one substance classified as sensitising and present in a concentration that may trigger an allergic reaction

Substances

Chemical Name	Skin sensitisation	Respiratory sensitisation
Ethanol; ethyl alcohol	No adverse effect observed (not sensitising)	No adverse effect observed (not sensitising)
Propan-2-ol; isopropyl alcohol; isopropanol	No adverse effect observed (not sensitising)	No study available
Butan-1-ol; n-butanol	No adverse effect observed (not sensitising)	No study available
N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]	Adverse effect observed (sensitising)	No data available

- Germ cell mutagenicity
  No evidence of mutagenic effects

Substances

Chemical Name	Toxicity - In Vitro	Toxicity - In Vivo
Ethanol; ethyl alcohol	No data available	No data available
Propan-2-ol; isopropyl alcohol; isopropanol	No adverse effect observed (negative)	No study available
Butan-1-ol; n-butanol	No adverse effect observed (negative)	No adverse effect observed (negative)
N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]	No data available	No adverse effect observed (negative)

- Carcinogenicity
  No evidence of carcinogenic effects

SECTION 11: Toxicological information (....)

Substances

Chemical Name	NOAEL (oral, rat)	NOAEC (inhalation, rat)	NOAEL (dermal, rat)
Ethanol; ethyl alcohol	No data available	No data available	No data available
Propan-2-ol; isopropyl alcohol; isopropanol	No data available	No data available	No data available
Butan-1-ol; n-butanol	No data available	No data available	No data available
N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]	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, (oral, rat)	NOAEC (inhalation, rat)	NOAEL (dermal, rat)
Ethanol; ethyl alcohol	20 700 mg/kg bw/day (Effect on fertility)	30 400 mg/m³ (Effect on developmental toxicity)	No data available
Propan-2-ol; isopropyl alcohol; isopropanol	No data available	No data available	No data available
Butan-1-ol; n-butanol	500 mg/kg bw/day (Effect on fertility) 1 454 mg/kg bw/day (Effect on developmental toxicity)	6 189 mg/m³ (Effect on fertility) 10 800 mg/m³ (Effect on developmental toxicity)	No data available
N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]	300 mg/kg bw/day (Effect on developmental toxicity)	No data available	300 mg/kg bw/day (Effect on developmental toxicity)

- Specific target organ toxicity (STOT) - single exposure
  STOT SE 3, H336
  Classification based on calculation and concentration thresholds

Substances

Chemical Name	Route	Remarks
Ethanol; ethyl alcohol	Respiratory	No data available
Propan-2-ol; isopropyl alcohol; isopropanol	Respiratory	No data available
Butan-1-ol; n-butanol	Respiratory	Adverse effect observed (irritating)
N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]	Respiratory	No data available

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

Substances

Chemical Name	NOAEL (oral, rat)	NOAEC (inhalation, rat)	NOAEL (dermal, rat)
Ethanol; ethyl alcohol	1 730 mg/kg bw/day	6.66 mg/L	No data available
Propan-2-ol	No data available	5 000 ppm	No data available

SECTION 11: Toxicological information (....)

Butan-1-ol; n-butanol	125 mg/kg bw/day	1 500 mg/m³	No data available
N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]	280 mg/kg bw/day	No data available	200 mg/kg bw/day (rabbit)

- Aspiration hazard
  No information available
- Contact with eyes
  May cause redness and irritation
  May cause stinging, pain, and discomfort
- Contact with skin
  May cause allergic reaction in susceptible people
  Prolonged skin contact will result in defatting of the skin, leading to irritation, and in some cases, dermatitis
- 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 tract irritation.

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)
Ethanol; ethyl alcohol	(4 days) 14.2 - 15.4 g/L	(48 h) 10 g/L	(72 h) 275 mg/L
Propan-2-ol; isopropyl alcohol; isopropanol	(4 days) 9.64 - 10 g/L	(24 h) 10 g/L	9.17 g/L
Butan-1-ol; n-butanol	(4 days) 1.376 g/L	(48 h) 1.328 g/L	(4 days) 225 mg/L
N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]	(24 h) 1 g/L	(48 h) 58 mg/L	(72 h) 5.78 mg/L

12.2 Persistence and degradability

- Some ingredients are biodegradable

Substances

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

SECTION 12: Ecological information (....)

Butan-1-ol; n-butanol	Readily biodegradable in water (100%)
N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]	Inherently biodegradable but not readily biodegradable

12.3 Bioaccumulative potential

- Low bioaccumulation potential

Substances

Chemical Name	Bioconcentration Factor (BCF)	Log Kow
Ethanol; ethyl alcohol	Low potential for bioaccumulation (Log Pow < 3)	(Log Pow) -0.35 @ 20 - 24 °C
Propan-2-ol; isopropyl alcohol; isopropanol	Low potential for bioaccumulation (Log Pow < 3)	(Log Pow) 0.05 @ 25 °C
Butan-1-ol; n-butanol	Low potential for bioaccumulation (Log Pow < 3)	(Log Pow) 1 @ 25 °C
N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]	Low potential for bioaccumulation (Log Kow ≤ 3)	0.9 @ 20 °C

12.4 Mobility in soil

- Low potential for adsorption

Substances

Chemical Name	Adsorption/desorption
Ethanol; ethyl alcohol	Koc 1 (estimated)
Propan-2-ol; isopropyl alcohol; isopropanol	Low potential for adsorption
Butan-1-ol; n-butanol	Koc 3.471 @ 20°C
N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]	Koc 117 @ 20°C

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
- Empty containers may contain flammable vapours
- Do not pierce or burn container, even after use

13.2 Classification

SECTION 13: Disposal considerations (....)

- The waste must be identified according to the List of Wastes (2000/532/EC)
- Hazardous Property Code(s): HP 3 Flammable; HP 4 Irritant; HP 5 Specific Target Organ Toxicity (STOT)/Aspiration Toxicity

SECTION 14: Transport information

14.1 UN number or ID 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

- Not applicable

14.6 Special precautions for user

- No information available

14.7 Maritime transport in bulk according to IMO instruments

- 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 Packing Group: II

14.10 Air (ICAO/IATA)

- 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

SECTION 15: Regulatory information (....)

- 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

- 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.

Sources of data: Information from company data, published literature and supplier safety data sheets

Created by ChemRegs (UK) Ltd June 2017

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Changes made: Updated sections to conform to latest version of REACH

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Changes made: Updated classification in section 2 and to conform to the latest version of REACH Annex II

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

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
- EUH208: Contains (name of sensitising substance). May produce an allergic reaction

Acronyms

- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstracts Service
- DNEL: Derived No-Effect Level
- EC: European Community
- EC_{50}: Effective Concentration, 50%
- EL_{50}: Effective Loading Rate resulting in 50% effect.

SECTION 16: Other information (....)

- GHS: Globally Harmonised System
- LC_{50}: Lethal Concentration, 50%
- LD_{50}: 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 ---