SAFETY DATA SHEET

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

1.1 Product identifier

Product Name: Salts No-Roma

Product Description: No Roma – Odourless Ostomy Appliance Deodorant. Supplied in 28 mL and 227 mL bottles

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

Use of the substance/mixture: Deodorising of ostomy bags by the application of 1-2 drops into bag

Use advised against: No information available

1.3 Details of the supplier of the safety data sheet

Name of Supplier: Salts Healthcare UK

Address of Supplier: Richard Street
Aston, Birmingham
B7 4AA
United Kingdom

Telephone: +44 (0) 121 333 2000

Email: hello@salts.co.uk

1.4 Emergency telephone number

Emergency Telephone: +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]: Eye Irrit. 2, H319

Additional information: For full text of Hazard- and EU Hazard-statements: see section 16

2.2 Label elements

Signal Word: Warning

Hazard statements

H319 - Causes serious eye irritation.

Precautionary statements

P264 - Wash thoroughly after handling.
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.

Supplemental Hazard information (EU)

None

SECTION 2: Hazards identification (....)

2.3 Other hazards

Does not contain any substances considered to be PBT or vPvB at levels of 0.1% or higher

Bronopol (INN) (2-bromo-2-nitropropane-1,3-diol) is being assessed for endocrine disrupting properties

SECTION 3: Composition/information on ingredients

3.1 Substances

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
Bronopol (INN); 2-bromo-2-nitropropane -1,3-diol	< 3%	52-51-7	200-143-0	Acute Tox. 4, H302 Acute Tox. 4, H312 Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 1, H400	M=10	-	No

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

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

After contact with skin, take off immediately all contaminated clothing, and wash immediately with plenty of water
If skin irritation or rash occurs: Get medical advice/attention.

Ingestion

Give plenty of water to drink
Do NOT induce vomiting.
IF exposed or concerned: Get 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

4.2 Most important symptoms and effects, both acute and delayed

Contact with eyes

Causes redness and irritation

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

Contact with skin

May cause redness and irritation

Ingestion

May cause gastro-intestinal irritation
May cause nausea/vomiting

Inhalation

Vapour in high concentrations may irritate the respiratory system

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Not flammable. In case of fire use extinguishing media appropriate to surrounding conditions

Unsuitable extinguishing media: No information available

5.2 Special hazards arising from the substance or mixture

Gives off irritating or toxic fumes (or gases) in a fire.

Decomposition products may include carbon oxides, nitrogen oxides, formaldehyde, hydrogen bromide

5.3 Advice for firefighters

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.

Clothing for firefighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents

Special protective equipment: Wear self-contained breathing apparatus (SCBA). Wear full protective clothing including chemical protection suit.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions for non-emergency personnel: Avoid breathing vapours, mist or gas; Avoid contact with skin and eyes; Wash thoroughly after handling.

Personal precautions for emergency responders: Do not breathe dust/fume/gas/mist/vapours/spray; Do not touch or walk through spilt material; Wear protective clothing as per section 8; 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

Stop leak if safe to do so.

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

Cover drains to prevent the product from entering the environment.

Absorb spillage in earth or sand

Sweep or shovel-up spillage and remove to a safe place

Place in appropriate 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

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 contact with skin and eyes

Do not breathe spray/mists

Do not eat, drink or smoke when using this product.

Eyewash bottles should be available

7.2 Conditions for safe storage, including any incompatibilities

Store in a cool, dry well-ventilated place. Keep container tightly closed.

Keep only in original packaging.

Keep away from food, drink and animal feedingstuffs

Incompatible with strong oxidizing agents, strong reducing agents, alkalis (strong bases)

7.3 Specific end use(s)

Deodorising of ostomy bags by the application of 1-2 drops into bag

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.

Bronopol (INN); 2-bromo-2-nitropropane-1,3-diol

DNEL (inhalational) 3.5 mg/m³ Industry, Long Term, Systemic Effects

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

DNEL (inhalational) 10.5 mg/m³ Industry, Acute/Short Term, Systemic Effects
DNEL (inhalational) 2.5 mg/m³ Industry, Long Term, Local Effects
DNEL (inhalational) 2.5 mg/m³ Industry, Acute/Short Term, Local Effects
DNEL (dermal) 2 mg/kg bw/day Industry, Long Term, Systemic Effects
DNEL (dermal) 6 mg/kg bw/day Industry, Acute/Short Term, Systemic Effects
DNEL (dermal) 8 µg/cm² Industry, Long Term, Local Effects
DNEL (dermal) 8 µg/cm² Industry, Acute/Short Term, Local Effects
DNEL (inhalational) 600 µg/m³ Consumer, Long Term, Systemic Effects
DNEL (inhalational) 1.8 mg/m³ Consumer, Acute/Short Term, Systemic Effects
DNEL (inhalational) 600 µg/m³ Consumer, Long Term, Local Effects
DNEL (inhalational) 600 µg/m³ Consumer, Acute/Short Term, Local Effects
DNEL (dermal) 700 µg/kg bw/day Consumer, Long Term, Systemic Effects
DNEL (dermal) 2.1 mg/kg bw/day Consumer, Acute/Short Term, Systemic Effects
DNEL (oral) 180 µg/kg bw/day Consumer, Long Term, Systemic Effects
DNEL (oral) 500 µg/kg bw/day Consumer, Acute/Short Term, Systemic Effects
PNEC aqua (freshwater) 1.25 µg/L
PNEC aqua (intermittent releases, freshwater) 265 ng/L
PNEC aqua (marine water) 520 ng/L
PNEC (STP) 430 µg/L
PNEC sediment (freshwater) 21.5 µg/kg
PNEC sediment (marine water) 8.944 µg/kg
PNEC terrestrial (soil) 210 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

Respiratory protection

None required for normal handling of product
Respiratory protection may be required under exceptional circumstances when excessive air contamination exists

Skin protection

None required for normal handling of product
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.
Nitrile rubber are recommended

Glove material: Nitrile rubber (NBR)
Thickness: 0.4 mm
Breakthrough time: 480 min
Reference: ECHA

Eye/face protection

Wear safety glasses or goggles giving complete eye protection approved to standard EN 166

Thermal hazards

Not applicable

Hygiene measures

Use good personal hygiene practices
Do not eat, drink or smoke when using this product.

Environmental exposure controls

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

Do not empty into drains
Do not allow to penetrate the ground/soil.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	Clear
Odour:	None
Melting point/freezing point:	No data available
Boiling point or initial boiling point and boiling range:	No data available
Flammability:	Not flammable
Lower and upper explosion limit:	Not applicable
Flash point:	Not applicable
Auto-ignition temperature:	No data available
Decomposition temperature:	No information available
pH:	7 - 8
Kinematic viscosity:	No data available
Solubility:	Miscible with water
Partition coefficient n-octanol/water (log value):	No data available
Vapour pressure:	No data available
Density and/or relative density:	1 - 1.01 (H_2O = 1 @ 20 °C)
Relative vapour density:	No data available
Particle characteristics:	Not applicable

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

No hazardous reactions known if used for its intended purpose

10.4 Conditions to avoid

Avoid extremes of temperature

10.5 Incompatible materials

Incompatible with strong oxidizing agents, strong reducing agents, alkalis (strong bases)

10.6 Hazardous decomposition products

Decomposition products may include carbon oxides, nitrogen oxides, formaldehyde, hydrogen bromide

SECTION 11: Toxicological information

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)	LC_{50} (inhalation, rat)	LD_{50} (dermal, rabbit)
Bronopol (INN)	500 mg/kg	(4 h) > 0.588 mg/m³	4 750 mg/kg (rat)

Skin corrosion/irritation

Based on available data, the classification criteria are not met

Substances

Chemical Name	Irritation/corrosion
Bronopol (INN)	Adverse effect observed (irritating)

Serious eye damage/irritation

Causes serious eye irritation.
Classification based on calculation and concentration thresholds

Substances

Chemical Name	Irritation/corrosion
Bronopol (INN)	Adverse effect observed (irreversible damage)

Respiratory or skin sensitisation

Based on available data, the classification criteria are not met

Substances

Chemical Name	Skin sensitisation	Respiratory sensitisation
Bronopol (INN)	No adverse effect observed (not sensitising)	No study available

Germ cell mutagenicity

Based on available data, the classification criteria are not met

Substances

Chemical Name	Toxicity - In Vitro	Toxicity - In Vivo
Bronopol (INN)	Adverse effect observed (positive)	No adverse effect observed (negative)

Carcinogenicity

Based on available data, the classification criteria are not met

Substances

Chemical Name	NOAEL (oral, rat)	NOAEC (inhalation, rat)	NOAEL (dermal, rat)
Bronopol (INN)	No data available	No data available	No data available

Reproductive toxicity

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)
Bronopol (INN)	150 mg/kg bw/day (Effect on fertility) 10 mg/kg bw/day (Effect on developmental toxicity)	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
Bronopol (INN)	Respiratory	No study 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)
Bronopol (INN)	7 mg/kg bw/day	No data available	5 mg/kg bw/day

Aspiration hazard

Based on available data, the classification criteria are not met

Contact with eyes

Causes redness and irritation

Contact with skin

May cause redness and irritation

Ingestion

May cause gastro-intestinal irritation
May cause nausea/vomiting

Inhalation

Vapour in high concentrations may irritate the respiratory system

11.2 Information on other hazards

Bronopol (INN) (2-bromo-2-nitropropane-1,3-diol) is being assessed for endocrine disrupting properties

SECTION 12: Ecological information

12.1 Toxicity

Based on available data, the classification criteria are not met

Substances

Chemical Name	LC_{50} (fish)	EC_{50} (aquatic invertebrates)	EC_{50} (aquatic algae)
Bronopol (INN)	(4 days) 35.7 mg/L	(48 h) 1.4 mg/L	(72 h) 0.25 mg/L

12.2 Persistence and degradability

Not determined

SECTION 12: Ecological information (....)

Substances

Chemical Name	Biodegradation
Bronopol (INN)	Not readily biodegradable

12.3 Bioaccumulative potential

Not determined

Substances

Chemical Name	Bioconcentration Factor (BCF)	Log Kow
Bronopol (INN)	Bioaccumulation is not expected	(Log Pow) 0.15 @ 23 °C

12.4 Mobility in soil

Miscible with water

Substances

Chemical Name	Adsorption/desorption
Bronopol (INN)	Koc 1 - 5 @ 25 °C (dimensionless)

12.5 Results of PBT and vPvB assessment

Does not contain any substances considered to be PBT or vPvB at levels of 0.1% or higher

12.6 Endocrine disrupting properties

Bronopol (INN) (2-bromo-2-nitropropane-1,3-diol) is being assessed for 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.

Do not reuse empty containers without commercial cleaning or reconditioning

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)

Hazardous Property Code(s): HP 4 Irritant

SECTION 14: Transport information

Not classified as hazardous for transport

14.1 UN number or ID number

UN No.: Not applicable

14.2 UN proper shipping name

Proper Shipping Name: Not applicable

14.3 Transport hazard class(es)

SECTION 14: Transport information (....)

Hazard Class: Not applicable

14.4 Packing group

Packing Group: Not applicable

14.5 Environmental hazards

Not applicable

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Not applicable

14.8 Road/Rail (ADR/RID)

Proper Shipping Name:	Not applicable
ADR UN No.:	Not applicable
ADR Hazard Class:	Not applicable
ADR Packing Group:	Not applicable
Tunnel Restriction Code:	Not applicable

14.9 Sea (IMDG)

Proper Shipping Name:	Not applicable
IMDG UN No.:	Not applicable
IMDG Hazard Class:	Not applicable
IMDG Packing Group:	Not applicable

14.10 Air (ICAO/IATA)

Proper Shipping Name:	Not applicable
ICAO UN No.:	Not applicable
ICAO Hazard Class:	Not applicable
ICAO Packing Group:	Not applicable

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) 2020/878) and UK REACH

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

Restrictions on use according to Annex XVII to REACH Regulation: None

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

SECTION 16: Other information (....)

Revision No. 1.0.0. Revised 2017.
Changes made: N/A New SDS

Revision No. 2.0.0. Revised January 2025.
Changes made: Revised to conform to latest version of REACH Annex II

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

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:

H302: Harmful if swallowed

H312: Harmful in contact with skin.

H315: Causes skin irritation.

H318: Causes serious eye damage

H319: Causes serious eye irritation.

H335: May cause respiratory irritation

H400: Very toxic to aquatic life

Acronyms

ATE: Acute Toxicity Estimate

CAS: Chemical Abstracts Service

DNEL: Derived No-Effect Level

EC: European Community

EC_{50}: Effective Concentration, 50%

GHS: Globally Harmonised System

IARC: International Agency for Research on Cancer

IOELV: Indicative Occupational Exposure Limit Value

LC_{50}: Lethal Concentration, 50%

LD_{50}: Lethal Dose, 50%

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