
SAFETY DATA SHEET

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

1.1 Product identifier

Product Name: Formulation 0103/0303/0303B

Product Description: Hydrocolloid Adhesive

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 Ostomy Device

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]: Not classified

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

2.2 Label elements

Hazard pictograms: None

Signal Word: None

Hazard statements

None

Precautionary statements

None

Supplemental Hazard information (EU)

None

2.3 Other hazards

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

Does not contain any substances with endocrine disrupting properties at levels of 0.1% or higher

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

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

3.2 Mixtures

Contains synthetic elastomers and hydrophilic polysaccharides. Latex Free.

This product does not contain any hazardous ingredients at levels above the relevant thresholds or any ingredients with a workplace exposure limit.

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

No hazard expected under normal conditions of use

If substance has got into eyes, immediately wash out with plenty of water

Contact with skin

No hazard expected under normal conditions of use

If skin irritation or rash occurs: gently wash with soap and water

Ingestion

No hazard expected under normal conditions of use

Inhalation

Not applicable in supplied form

4.2 Most important symptoms and effects, both acute and delayed

Contact with eyes

No hazard expected under normal conditions of use

Contact with skin

No hazard expected under normal conditions of use

Ingestion

The ingestion of significant quantities may cause nausea/vomiting

Inhalation

Inhalation is unlikely to occur

4.3 Indication of any immediate medical attention and special treatment needed

No hazard expected under normal conditions of use

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: In case of fire use water, alcohol resistant foam, carbon dioxide or dry agent

Unsuitable extinguishing media: No information available

5.2 Special hazards arising from the substance or mixture

Spillage may cause slippery surface

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

Revision: 13 February 2025

SECTION 5: Firefighting measures (....)

Decomposition products may include carbon oxides

5.3 Advice for firefighters

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

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

No respiratory protection is needed during normal handling, if dust is formed, wear approved dust mask

Only trained and authorised personnel should carry out emergency response

Personal precautions for non-emergency personnel: No special precautions are required for this product

Personal precautions for emergency responders: Wear protective clothing as per section 8

6.2 Environmental precautions

Do not allow to enter public sewers and watercourses

6.3 Methods and material for containment and cleaning up

No special precautions are required for this product

Spillage may cause slippery surface

6.4 Reference to other sections

See section(s): 7, 8 & 13

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

No special precautions are required for this product

7.2 Conditions for safe storage, including any incompatibilities

Keep in a cool, dry place

Protect from heat

7.3 Specific end use(s)

Application to skin as part of an Ostomy Device

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

No exposure limits have been set for this product

8.2 Exposure controls

Selection and use of personal protective equipment should be based on a risk assessment of exposure potential

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

Engineering controls

Engineering controls are not required for normal handling

Respiratory protection

No respiratory protection is needed during normal handling

In case of fire: Wear suitable respiratory protection

Skin protection

None required for normal handling of product

Eye/face protection

None required for normal handling of product

Thermal hazards

Not applicable

Hygiene measures

Not applicable

Environmental exposure controls

Do not allow to enter public sewers and watercourses

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state:	Solid (putty)
Colour:	Brown
Odour:	No information available
Melting point/freezing point:	No data available
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:	Not applicable
Decomposition temperature:	No data available
pH:	No data available
Kinematic viscosity:	No data available
Solubility:	No data available
Partition coefficient n-octanol/water (log value):	No data available
Vapour pressure:	No data available
Density and/or relative density:	No data available
Relative vapour density:	No data available
Particle characteristics:	No data available

9.2 Other information

No information available

SECTION 10: Stability and reactivity

10.1 Reactivity

No information available

SECTION 10: Stability and reactivity (....)

10.2 Chemical stability

Considered stable under normal conditions

10.3 Possibility of hazardous reactions

No information available

10.4 Conditions to avoid

Keep away from heat and sources of ignition

10.5 Incompatible materials

No information available

10.6 Hazardous decomposition products

Decomposition products may include carbon oxides

SECTION 11: Toxicological information

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

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

Acute Toxicity

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

Based on available data, the classification criteria are not met

Respiratory or skin sensitisation

Based on available data, the classification criteria are not met

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

Based on available data, the classification criteria are not met

Specific target organ toxicity (STOT) - repeated exposure

Based on available data, the classification criteria are not met

Aspiration hazard

Based on available data, the classification criteria are not met

Contact with eyes

No hazard expected under normal conditions of use

SECTION 11: Toxicological information (....)

Contact with skin

No hazard expected under normal conditions of use

Ingestion

The ingestion of significant quantities may cause nausea/vomiting

Inhalation

Inhalation is unlikely to occur

11.2 Information on other hazards

Does not contain any substances with endocrine disrupting properties at levels of 0.1% or higher

SECTION 12: Ecological information

12.1 Toxicity

No information available

12.2 Persistence and degradability

Some ingredients are 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 Endocrine disrupting properties

Does not contain any substances with endocrine disrupting properties at levels of 0.1% or higher

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

13.2 Classification

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

Hazardous Property Code(s): None assigned

SECTION 14: Transport information

Not classified as hazardous for transport

SECTION 14: Transport information (....)

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)

Hazard Class: Not applicable

14.4 Packing group

Packing Group: Not applicable

14.5 Environmental hazards

Not classified

14.6 Special precautions for user

No special precautions are required for this product

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: 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: Not applicable

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

SECTION 15: Regulatory information (....)

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

Revision No. 2.0.0. Revised March 2017.

Changes made: Revised to conform to latest version of REACH. Minor changes to layout.

Revision No. 3.0.0. Revised February 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]:

Not classified as hazardous for supply

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

None assigned

Acronyms

ATE: Acute Toxicity Estimate

CAS: Chemical Abstracts Service

DNEL: Derived No-Effect Level

EC: European Community

EC₅₀: Effective Concentration, 50%

GHS: Globally Harmonised System

IARC: International Agency for Research on Cancer

IOELV: Indicative Occupational Exposure Limit Value

LC₅₀: Lethal Concentration, 50%

LD₅₀: 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

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

WEL: Workplace Exposure Limit