SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH) (as amended by Regulation (EU) 2020/878), and UK REACH

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

1.1 Product identifier

Product Name: Hydrocolloid Formulation 0803
Product Description: Gelatine free 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 St,
Aston,
Birmingham
United Kingdom
B7 4AA
Telephone: +44 (0) 121 333 2000
Email: hello@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]: 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

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

Not applicable

3.2 Mixtures

Consisting of poly-isobutylene, synthetic rubber mixture, pectin, rosin free adhesion improver/tackifier and sodium carboxy-methyl-cellulose. Latex Free.

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
Amorphous silicon dioxide	≤ 1%	7631-86-9	231-545-4	Not classified (Substance with a workplace exposure limit)	-	-	Yes
Talc ($Mg_3H_2(SiO_3)_4$)	≤ 1%	14807-96-6	238-877-9	Not classified (Substance with a workplace exposure limit)	-	-	Yes
Kaolin	≤ 1%	1332-58-7	310-194-1	Not classified (Substance with a workplace exposure limit)	-	-	Yes

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

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

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

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

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

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 7: Handling and storage (....)

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.

Amorphous silicon dioxide

WEL (long term) 6 mg/m³ (UK, inhalable dust)
WEL (long term) 2.4 mg/m³ (UK, respirable dust)
DNEL (inhalational) 4 mg/m³ (derived by Synthetic Amorphous Silica REACH Consortium)

Talc ($Mg_3H_2(SiO_3)_4$)

WEL (long term) 1 mg/m³ (UK, respirable dust)
DNEL (inhalational) 0.434 mg/m³ Industry, Long Term, Systemic Effects
DNEL (inhalational) 2.16 mg/m³ Industry, Acute/Short Term, Systemic Effects
DNEL (inhalational) 3.6 mg/m³ Industry, Long Term, Local Effects
DNEL (inhalational) 3.6 mg/m³ Industry, Acute/Short Term, Local Effects
DNEL (dermal) 37.5 mg/kg bw/day Industry, Long Term, Systemic Effects
DNEL (dermal) 4.54 mg/cm² Industry, Long Term, Local Effects
DNEL (inhalational) 77.1 µg/m³ Consumer, Long Term, Systemic Effects
DNEL (inhalational) 1.08 mg/m³ Consumer, Acute/Short Term, Systemic Effects
DNEL (inhalational) 1.8 mg/m³ Consumer, Long Term, Local Effects
DNEL (inhalational) 1.8 mg/m³ Consumer, Acute/Short Term, Local Effects
DNEL (dermal) 4.46 µg/kg bw/day Consumer, Long Term, Systemic Effects
DNEL (dermal) 2.27 mg/cm² Consumer, Long Term, Local Effects
DNEL (oral) 1 mg/kg bw/day Consumer, Long Term, Systemic Effects
DNEL (oral) 160 mg/kg bw/day Consumer, Acute/Short Term, Systemic Effects
PNEC aqua (freshwater) 91.8 mg/L
PNEC aqua (intermittent releases, freshwater) 72 mg/L
PNEC aqua (marine water) 0.918 mg/L
PNEC aqua (intermittent releases, marine water) 0.72 mg/L
PNEC sediment (freshwater) 0.627 mg/kg
PNEC sediment (marine water) 62.7 µg/kg
PNEC (air) 10 mg/m³
PNEC terrestrial (soil) 70.6 mg/kg

Kaolin

WEL (long term) 2 mg/m³ (UK, respirable dust)

8.2 Exposure controls

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

Engineering controls

Engineering controls are not required for normal handling

Respiratory protection

No respiratory protection is needed during normal handling

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

In case of fire: Wear suitable respiratory protection
If dust is formed, wear approved dust mask

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

Use good personal hygiene practices

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 (adhesive polymer)
Colour:	Pale straw to light brown
Odour:	No information available
Melting point/freezing point:	No data available
Boiling point or initial boiling point and boiling range:	Not applicable
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:	Not applicable
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

10.2 Chemical stability

Considered stable under normal conditions

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

10.3 Possibility of hazardous reactions

No information available

10.4 Conditions to avoid

Avoid overheating

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

Substances

Chemical Name	LD_{50} (oral, rat)	LC_{50} (inhalation, rat)	LD_{50} (dermal, rabbit)
Amorphous silicon dioxide	7 900 mg/kg	(4 h) > 58.8 mg/L	> 5 000 mg/kg
Talc ($Mg_3H_2(SiO_3)_4$)	5 000 mg/kg	(4 h) 2.1 mg/L	2 000 mg/kg (rat)
Kaolin	> 5 000 mg/kg	> 5 mg/L	> 5 000 mg/kg (rat)

Skin corrosion/irritation

Based on available data, the classification criteria are not met

Substances

Chemical Name	Irritation/corrosion
Amorphous silicon dioxide	No adverse effect observed (not irritating)
Talc ($Mg_3H_2(SiO_3)_4$)	No adverse effect observed (not irritating)
Kaolin	No adverse effect observed (not irritating)

Serious eye damage/irritation

Based on available data, the classification criteria are not met

Substances

Chemical Name	Irritation/corrosion
Amorphous silicon dioxide	No adverse effect observed (not irritating)
Talc ($Mg_3H_2(SiO_3)_4$)	No adverse effect observed (not irritating)
Kaolin	No adverse effect observed (not irritating)

Respiratory or skin sensitisation

Based on available data, the classification criteria are not met

SECTION 11: Toxicological information (....)

Substances

Chemical Name	Skin sensitisation	Respiratory sensitisation
Amorphous silicon dioxide	No adverse effect observed (not sensitising)	No adverse effect observed (not sensitising)
Talc ($Mg_3H_2(SiO_3)_4$)	No adverse effect observed (not sensitising)	No adverse effect observed (not sensitising)
Kaolin	No adverse effect observed (not sensitising)	No adverse effect observed (not sensitising)

Germ cell mutagenicity

Based on available data, the classification criteria are not met

Substances

Chemical Name	Toxicity - In Vitro	Toxicity - In Vivo
Amorphous silicon dioxide	No adverse effect observed (negative)	No adverse effect observed (negative)
Talc ($Mg_3H_2(SiO_3)_4$)	No adverse effect observed (negative)	No adverse effect observed (negative)
Kaolin	No data available	No data available

Carcinogenicity

Based on available data, the classification criteria are not met
Talc is classified by IARC as Group 2A (probably carcinogenic to humans)

Substances

Chemical Name	NOAEL (oral, rat)	NOAEC (inhalation, rat)	NOAEL (dermal, rat)
Amorphous silicon dioxide	≥ 1 300 mg/kg bw/day	No data available	No data available
Talc ($Mg_3H_2(SiO_3)_4$)	100 mg/kg bw/day	18 mg/m³ (mouse)	2.5 mg/kg bw/day
Kaolin	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, rat)	NOAEC (inhalation, rat)	NOAEL (dermal, rat)
Amorphous silicon dioxide	1 000 mg/kg bw/day (Effect on fertility) ≥1 000 mg/kg bw/day (Effect on developmental toxicity)	No data available	No data available
Talc ($Mg_3H_2(SiO_3)_4$)	900 mg/kg bw/day (Effect on fertility) 1 600 mg/kg bw/day (Effect on developmental toxicity)	69.57 mg/m³ (Effect on fertility) 69.57 mg/m³ (Effect on developmental toxicity)	216 mg/kg bw/day (rabbit) (Effect on fertility) 40 mg/kg bw/day (Effect on developmental toxicity)
Kaolin	No data available	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
Amorphous silicon dioxide	Respiratory	No data available
Talc ($Mg_3H_2(SiO_3)_4$)	Respiratory	No adverse effect observed (not irritating)
Kaolin	Respiratory	No data available

Specific target organ toxicity (STOT) - repeated exposure

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)
Amorphous silicon dioxide	No data available	No data available	No data available
Talc ($Mg_3H_2(SiO_3)_4$)	100 mg/kg bw/day	2 - 18 mg/m³	2.5 mg/cm²
Kaolin	No data available	No data available	No data available

Aspiration hazard

Based on available data, the classification criteria are not met

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

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

Based on available data, the classification criteria are not met

Substances

Chemical Name	LC_{50} (fish)	EC_{50} (aquatic invertebrates)	EC_{50} (aquatic algae)
Amorphous silicon dioxide	(4 days) 5 g/L	(48 h) 7.6 g/L	(72 h) 4.4 g/L
Talc ($Mg_3H_2(SiO_3)_4$)	(4 days) > 100 g/L	LC_{50} (48 h) 36.812 g/L	(4 days) 7.203 g/L
Kaolin	(4 days) > 1 000 mg/L	(48 h) > 1 000 mg/L	(72 h) > 1 000 mg/L

12.2 Persistence and degradability

No information available

Substances

Chemical Name	Biodegradation
Amorphous silicon dioxide	Not applicable, inorganic
Talc ($Mg_3H_2(SiO_3)_4$)	Not applicable, inorganic
Kaolin	Not applicable, inorganic

12.3 Bioaccumulative potential

No information available

Substances

Chemical Name	Bioconcentration Factor (BCF)	Log Kow
Amorphous silicon dioxide	Low bioaccumulation potential	Not applicable, inorganic

SECTION 12: Ecological information (....)

Talc ($Mg_3H_2(SiO_3)_4$)	3.16 L/kg ww	-9.4 @ 25 °C
Kaolin	Bioaccumulation is not expected	Not applicable, inorganic

12.4 Mobility in soil

No information available

Substances

Chemical Name	Adsorption/desorption
Amorphous silicon dioxide	Koc 21.73 (estimate from MCI)
Talc ($Mg_3H_2(SiO_3)_4$)	Koc 31.82 at 20°C
Kaolin	Insoluble in water

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

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

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

Presents little or no hazard to the environment

14.6 Special precautions for user

SECTION 14: Transport information (....)

No special precautions are required for this product

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

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 July 2017

Revision No. 2.0.0. Revised April 2026.
Changes made: Change of ingredients in sections 3, 8, 11 and 12. Updated and 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]:

SECTION 16: Other information (....)

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

BOELV: Binding Occupational Exposure Limit Value

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