## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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

### 1.1. Product identifier

Product form : Mixture

Product name : BARTOLINE PATCHING PLASTER

Product code : 4634
Product group : End product

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

#### 1.2.1. Relevant identified uses

Intended for general public

Use of the substance/mixture : General Purpose Filler

1.2.2. Uses advised against

Restrictions on use : Not to be used for making casts of body parts, during setting the product may heat up

causing skin burns.

### 1.3. Details of the supplier of the safety data sheet

#### Manufacturer

Bartoline Limited Ltd Barmston Close HU17 0LW Beverley United Kingdom

T 01482 678710 - F 01482 872606

infor@bartoline.co.uk - www.bartoline.co.uk

### **EU Address**

Bartoline Ireland Limited Unit 3D North Point House North Point Business Park New Mallow Road Cork T23 AT2P Ireland +353212066441 info@bartoline.eu

## 1.4. Emergency telephone number

Emergency number : 01482 678710

8.30am - 4.45pm Monday to Friday

NHS 111 - General Public (24 Hour service)

## **SECTION 2: Hazards identification**

# 2.1. Classification of the substance or mixture

### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

## 2.2. Label elements

### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Precautionary statements (CLP) : P101 - If medical advice is needed, have product container or label at hand.

P302+P352 - IF ON SKIN: Wash with plenty of water.

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove

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contact lenses, if present and easy to do. Continue rinsing. P332+P313 - If skin irritation occurs: Get medical advice/attention. P337+P313 - If eye irritation persists: Get medical advice/attention.

### 2.3. Other hazards

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

# **SECTION 3: Composition/information on ingredients**

#### 3.1. Substances

Not applicable

#### 3.2. Mixtures

Name	Product identifier		Classification according to Regulation (EC) No. 1272/2008 [CLP]
Dolomite (Substance with a workplace exposure limit) substance with a Community workplace exposure limit		≥ 50 – < 80	Not classified

### **SECTION 4: First aid measures**

## 4.1. Description of first aid measures

First-aid measures general : Call a poison center or a doctor if you feel unwell. If breathing is difficult, trained personnel should give oxygen.

First-aid measures after inhalation : Move affected person to fresh air and keep warm and at rest in a position comfortable for breathing. Rinse nose and mouth with water. Get medical attention if symptoms occur.

First-aid measures after skin contact : Wash immediately with plenty of soap and water. Get medical attention if irritation persists

after washing.

First-aid measures after eye contact : Immediately flush eyes thoroughly with water for at least 15 minutes. Remove contact

lenses, if present and easy to do. Continue rinsing. Get medical attention if symptoms are severe or persist after washing.

First-aid measures after ingestion : Rinse mouth out with water. Drink plenty of water. In all cases of doubt, or when symptoms persist, seek medical attention.

### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects : The severity of the symptoms described will vary dependent on the concentration and the length of exposure.

Symptoms/effects after inhalation : May cause shortness of breath, tightness of the chest, a sore throat and cough.

Symptoms/effects after skin contact : Repeated or prolonged skin contact may cause irritation. Rednesses.

Symptoms/effects after eye contact : May cause eye irritation. Pain.

Symptoms/effects after ingestion : None known.

# 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 : The product is non-combustible. Use extinguishing agent suitable for surrounding fire.

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Unsuitable extinguishing media : None known.

## 5.2. Special hazards arising from the substance or mixture

Fire hazard : None known.

Explosion hazard : None known.

Reactivity in case of fire : None known.

Hazardous decomposition products in case of fire : None known.

### 5.3. Advice for firefighters

Firefighting instructions : Control run-off water by containing and keeping it out of sewers and watercourses. Notify

authorities if product enters sewers or public waters.

Protection during firefighting : Wear recommended personal protective equipment.

### **SECTION 6: Accidental release measures**

### 6.1. Personal precautions, protective equipment and emergency procedures

General measures : Evacuate area.

#### 6.1.1. For non-emergency personnel

Protective equipment : In case of inadequate ventilation wear respiratory protection.

Emergency procedures : Do not touch or walk on the spilled product. Do NOT enter (storage areas, confined spaces)

unless adequately ventilated.

Measures in case of dust release : Avoid inhalation of dust and contact with skin and eyes. Keep unnecessary and unprotected

personnel away from the spillage.

#### 6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. Wear recommended

personal protective equipment. For further information refer to section 8: "Exposure

controls/personal protection".

Emergency procedures : For further information refer to section 8: "Exposure controls/personal protection". More

detailed information: See section 11. For disposal of residues refer to section 13: Disposal

considerations" ".

#### 6.2. Environmental precautions

Do not discharge into drains or the environment. Do not allow to enter drains or water courses. Spillages or uncontrolled discharges into watercourses must be reported immediately to the Environmental Agency or other appropriate regulatory body.

### 6.3. Methods and material for containment and cleaning up

For containment : Avoid dust formation. Avoid dust to spread. Sweep spilled substance into containers; if

appropriate, moisten first to prevent dusting.

Methods for cleaning up : Shovel or sweep up and put in a closed container for disposal. Other information : Dispose of materials or solid residues at an authorized site.

### 6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". For further information refer to section 13.

## **SECTION 7: Handling and storage**

#### 7.1. Precautions for safe handling

Precautions for safe handling : Do not handle until all safety precautions have been read and understood. Avoid inhalation

of dust and contact with skin and eyes. This product is not to be used under conditions of

poor ventilation.

Hygiene measures : Do not eat, drink or smoke when using this product. After contact with skin, wash

immediately and thoroughly with water and soap. Take off immediately all contaminated clothing and wash it before reuse. Wash hands and other exposed areas with mild soap and

water before eating, drinking or smoking and when leaving work.

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## 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : No special storage required.

Incompatible products : None known. : 5 - 25 °C Storage temperature

## 7.3. Specific end use(s)

Section 1.

## **SECTION 8: Exposure controls/personal protection**

### 8.1. Control parameters

# 8.1.1 National occupational exposure and biological limit values

Dolomite (Substance with a workplace exposure limit) (16389-88-1)		
EU - Indicative Occupational Exposure Limit (IOEL)		
IOEL TWA	10 mg/m³	
IOEL STEL	4 mg/m³	

#### 8.1.2. Recommended monitoring procedures

No additional information available

#### 8.1.3. Air contaminants formed

No additional information available

#### 8.1.4. DNEL and PNEC

······································			
Citric Acid (77-92-9)			
PNEC (Water)			
PNEC aqua (freshwater)	0.44 mg/l		
PNEC aqua (marine water) 0.044 mg/l			
PNEC (Sediment)			
PNEC sediment (freshwater)	34.6 mg/kg dwt		
PNEC sediment (marine water)	3.46 mg/kg dwt		
PNEC (Soil)			
PNEC soil	33.1 mg/kg dwt		
PNEC (STP)			
PNEC sewage treatment plant	1000 mg/l		

#### 8.1.5. Control banding

No additional information available

# 8.2. Exposure controls

## 8.2.1. Appropriate engineering controls

## Appropriate engineering controls:

Ensure adequate ventilation, especially in confined areas. Provide adequate ventilation to minimize dust concentrations. Mechanical ventilation is recommended.

## 8.2.2. Personal protection equipment

# Personal protective equipment:

Do not attempt to take action without suitable protective equipment. Appropriate engineering controls.

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### Personal protective equipment symbol(s):







#### 8.2.2.1. Eye and face protection

#### Eye protection:

Chemical goggles or safety glasses

Eye protection			
Туре	Field of application	Characteristics	Standard
Use eye protection according to EN 166, designed to protect against powders and dusts.	Dust	Dust-tight	EN 166

### 8.2.2.2. Skin protection

#### Skin and body protection:

Not required for normal conditions of use

#### Hand protection:

If repeated and/or prolonged skin exposure to the substance is likely, then wear suitable gloves tested to EN374 and provide employee skin care programmes. Gloves

#### Other skin protection

#### Materials for protective clothing:

Not required for normal conditions of use

# 8.2.2.3. Respiratory protection

#### Respiratory protection:

Where excessive dust may result, use approved respiratory protection equipment. In order to avoid inhalation of dust, all sanding must be done wearing adequate respirator. Dust production: dust mask with filter type P1

## 8.2.2.4. Thermal hazards

## Thermal hazard protection:

Not applicable.

#### 8.2.3. Environmental exposure controls

#### **Environmental exposure controls:**

Assure that emissions are compliant with all applicable air pollution control regulations. Do not exceed the occupational exposure limits (OEL). Keep container closed when not in use.

## Other information:

Always wash hands after handling the product.

## **SECTION 9: Physical and chemical properties**

# 9.1. Information on basic physical and chemical properties

: Solid Physical state : white. off-white. Colour Appearance : Dusty powder. Odour : Barely perceptible. Odour threshold : Not available. Melting point : Not applicable. Freezing point Not available Boiling point Not applicable. Not applicable Flammability Explosive properties Not explosive. Oxidising properties : Not oxidising.

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**Explosive limits** : Not applicable Lower explosion limit : Not applicable : Not applicable Upper explosion limit Flash point : Not applicable. Auto-ignition temperature : Not applicable. Decomposition temperature : Not available

: 7 in aqueous solution. In delivery state: not applicable.

pH solution : Not available Viscosity, kinematic : Not applicable

: 4300 - 5300 cP Lamy MS-R4. Ready to use state. Viscosity, dynamic

Solubility : soluble in water. Partition coefficient n-octanol/water (Log Kow) : Not available Vapour pressure : Not applicable. : Not available Vapour pressure at 50 °C Density : Not available Relative density : Not available Relative vapour density at 20 °C : Not applicable. Particle size : Not available Particle size distribution : Not available Particle shape : Not available Particle aspect ratio : Not available Particle aggregation state : Not available Particle agglomeration state : Not available Particle specific surface area : Not available Particle dustiness : Not available

### 9.2. Other information

### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

VOC content : There are no VOCs present.

Bulk density : 600 - 1200 kg/m<sup>3</sup>

## **SECTION 10: Stability and reactivity**

## 10.1. Reactivity

No dangerous reactions known under normal conditions of use.

## 10.2. Chemical stability

Stable at ambient temperature and under normal conditions of use.

## 10.3. Possibility of hazardous reactions

Sodium carbonate solution.

## 10.4. Conditions to avoid

Avoid contamination by sulphur-reducing bacteria and water under anaerobic conditions.

### 10.5. Incompatible materials

No dangerous reactions known under normal conditions of use.

# 10.6. Hazardous decomposition products

No additional information available

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### **SECTION 11: Toxicological information**

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

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

Dolomite (Substance with a workplace exposure limit) (16389-88-1)		
LD50 oral rat	≈ 5001 mg/kg	
LD50 dermal	≈ 2000.01 mg/kg	
LC50 Inhalation - Rat (Dust/Mist)	≈ 5.01 mg/l/4h	

Skin corrosion/irritation : Not classified

pH: 7 in aqueous solution. In delivery state: not applicable.

Serious eye damage/irritation : Not classified

pH: 7 in aqueous solution. In delivery state: not applicable.

Respiratory or skin sensitisation : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified
Reproductive toxicity : Not classified
STOT-single exposure : Not classified
STOT-repeated exposure : Not classified
Aspiration hazard : Not classified

## 11.2. Information on other hazards

No additional information available

## **SECTION 12: Ecological information**

# 12.1. Toxicity

Ecology - general : The product is not expected to be hazardous to the environment. However, large or frequent

spills may have hazardous effects on the environment.

Hazardous to the aquatic environment, short-term

(acute)

: Not classified

Hazardous to the aquatic environment, long-term

(chronic)

: Not classified

Not rapidly degradable

## 12.2. Persistence and degradability

BARTOLINE PATCHING PLASTER	
Persistence and degradability	Not biodegradable.

# 12.3. Bioaccumulative potential

No additional information available

## 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

No additional information available

# 12.6. Endocrine disrupting properties

No additional information available

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### 12.7. Other adverse effects

No additional information available

# **SECTION 13: Disposal considerations**

## 13.1. Waste treatment methods

HP Code

- : HP3 "Flammable:"
  - flammable liquid waste: liquid waste having a flash point below 60 °C or waste gas oil, diesel and light heating oils having a flash point > 55 °C and ≤ 75 °C;
  - flammable pyrophoric liquid and solid waste: solid or liquid waste which, even in small quantities, is liable to ignite within five minutes after coming into contact with air;
  - flammable solid waste: solid waste which is readily combustible or may cause or contribute to fire through friction;
  - flammable gaseous waste: gaseous waste which is flammable in air at 20 °C and a standard pressure of 101.3 kPa;
  - water reactive waste: waste which, in contact with water, emits flammable gases in dangerous quantities;
  - other flammable waste: flammable aerosols, flammable self-heating waste, flammable organic peroxides and flammable self-reactive waste.

# **SECTION 14: Transport information**

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID	
14.1. UN number or ID number					
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	
14.2. UN proper shipping name					
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	
14.3. Transport hazard class(es)					
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	
14.4. Packing group					
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	
14.5. Environmental hazards					
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	
No supplementary information available					

# 14.6. Special precautions for user

## Overland transport

Not applicable

#### Transport by sea

Not applicable

#### Air transport

Not applicable

# Inland waterway transport

Not applicable

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#### Rail transport

Not applicable

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## **SECTION 15: Regulatory information**

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### 15.1.1. EU-Regulations

### **REACH Annex XVII (Restriction List)**

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

#### **REACH Annex XIV (Authorisation List)**

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

#### **REACH Candidate List (SVHC)**

Contains no substance(s) listed on the REACH Candidate List

### **PIC Regulation (Prior Informed Consent)**

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

#### **POP Regulation (Persistent Organic Pollutants)**

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

#### Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

# VOC Directive (2004/42)

VOC content : There are no VOCs present.

#### **Explosives Precursors Regulation (2019/1148)**

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

## **Drug Precursors Regulation (273/2004)**

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

### 15.1.2. National regulations

#### Germany

Water hazard class (WGK) : WGK 3, Highly hazardous to water (Classification according to AwSV, Annex 1).

Storage class (LGK, TRGS 510) LGK 13 - Non-combustible solids.

Joint storage table

:	LGK 1	LGK 2A	LGK 2B	LGK 3	LGK 4.1A
	LGK 4.1B	LGK 4.2	LGK 4.3	LGK 5.1A	LGK 5.1B
	LGK 5.1C	LGK 5.2	LGK 6.1A	LGK 6.1B	LGK 6.1C
	LGK 6.1D	LGK 6.2	LGK 7	LGK 8A	LGK 8B
	LGK 10	LGK 11	LGK 12	LGK 13	LGK 10-13

: LGK 1, LGK 6.2, LGK 7. Joint storage not permitted for

Joint storage with restrictions permitted for : LGK 4.1A, LGK 5.1C.

Joint storage permitted for : LGK 2A, LGK 2B, LGK 3, LGK 4.1B, LGK 4.2, LGK 4.3, LGK 5.1A, LGK 5.1B, LGK 5.2, LGK 6.1A, LGK 6.1B, LGK 6.1C, LGK 6.1D, LGK 8A, LGK 8B, LGK 10, LGK 11, LGK 12,

LGK 13, LGK 10-13.

Hazardous Incident Ordinance (12. BlmSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

**Netherlands** 

ABM category : Z(1) - non biodegradable substances with hazardous properties for humans and the

environment (carcinogenicity/ mutagenicity/ reprotoxicity/bioacumulative potential/ toxicity or

persistence)

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SZW-lijst van kankerverwekkende stoffen

: None of the components are listed SZW-lijst van mutagene stoffen : None of the components are listed SZW-lijst van reprotoxische stoffen - Borstvoeding : None of the components are listed : None of the components are listed

SZW-lijst van reprotoxische stoffen -

Vruchtbaarheid

SZW-lijst van reprotoxische stoffen - Ontwikkeling

: None of the components are listed

**Denmark** 

**Danish National Regulations** : The requirements from the Danish Working Environment Authorities regarding work with

carcinogens must be followed during use and disposal

**Switzerland** 

Storage class (LK) : NG - Non-hazardous

### 15.2. Chemical safety assessment

No additional information available

# **SECTION 16: Other information**

#### Indication of changes:

Due to change of classification database the revision numbering has been reset. You should therefore look at the revision date rather than the revision number

to ensure you have the most up to date version.

: ATP 12 The classification complies with

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

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