



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: REACH Regulation (EC) No 1907/2006, as retained in UK law by (SI 2019/758 as amended)

SOVEREIGN INJECTION CREAM
Supersedes date 22-Apr-2024

Revision date 05-Jul-2024
Revision Number 1.09

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

1.1. Product identifier

Product Name SOVEREIGN INJECTION CREAM

Pure substance/mixture Mixture

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

Recommended use Building and construction work, Coatings

Uses advised against None known

1.3. Details of the supplier of the safety data sheet

Company Name

Bostik Limited
Common Rd
ST16 3EH
Stafford UK
Tel: +44 (1785) 27 26 25
Fax: +44 (1785) 25 72 36

E-mail address SDS.box-EU@bostik.com

1.4. Emergency telephone number

United Kingdom Bostik: +44 (1785) 272650 (9am to 5pm Mon-Fri)
NHS: 111

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GB CLP (SI 2020/1567 as amended)

Serious eye damage/eye irritation	Category 2 - (H319)
-----------------------------------	---------------------

2.2. Label elements



Signal word
Warning

Hazard statements
H319 - Causes serious eye irritation.

SAFETY DATA SHEET

SOVEREIGN INJECTION CREAM
Supersedes date 22-Apr-2024

Revision date 05-Jul-2024
Revision Number 1.09

EU Specific Hazard Statements

EUH066 - Repeated exposure may cause skin dryness or cracking

EUH208 - Contains N-(3-(trimethoxysilyl)propyl)ethylenediamine & 1,2-benzisothiazol-3(2H)-one [BIT] & reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) [C(M)IT/MIT]. May produce an allergic reaction

Precautionary Statements - EU (§28, 1272/2008)

P101 - If medical advice is needed, have product container or label at hand

P102 - Keep out of reach of children

P264 - Wash face, hands and any exposed skin thoroughly after handling

P280 - Wear protective gloves and eye/face protection

P337 + P313 - If eye irritation persists: Get medical advice/attention

P501 - Dispose of contents/ container to an approved waste disposal plant

2.3. Other hazards

Small amounts of methanol (CAS 67-56-1) are formed by hydrolysis and released upon curing. Small amounts of ethanol (CAS 64-17-5) are formed by hydrolysis and released upon curing.

PBT & vPvB

This mixture contains no substance considered to be persistent, bioaccumulating or toxic (PBT). This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical name	EC No (EU Index No).	CAS No..	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)	REACH registration number
Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, <2% aromatics 40 - <80 %	926-141-6	RR-108541-2	Asp. Tox. 1 (H304) (EUH066)	-	-	-	01-2119456620-43-XXXX
Poly(oxy-1,2-ethanediyl), .alpha.-isotridecyl-.omega.a.-hydroxy-1 - <2.5 %	-	9043-30-5	Eye Dam. 1 (H318) Acute Tox. 4 (H302)	-	-	-	[7]
N-(3-(trimethoxysilyl)propyl)ethylenediamine 0.1 - <0.3 %	217-164-6	1760-24-3	Eye Dam. 1 (H318) Skin Sens. 1 (H317) Acute Tox. 4 (H332) STOT SE 3 (H335)	-	-	-	01-2119970215-39-XXXX
Bronopol 0.01 < 0.036 %	200-143-0 (603-085-00-8)	52-51-7	Acute Tox. 4 (H302) Acute Tox. 4 (H312) Skin Irrit. 2 (H315) Eye Dam. 1 (H318) STOT SE 3 (H335) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	-	10	1	01-2119980938-15-XXXX
1,2-benzisothiazol-3(2H)-one [BIT] 0.0025 - <0.01 %	220-120-9 (613-088-00-6)	2634-33-5	Acute Tox. 4 (H302) Acute Tox. 2 (H330) Skin Irrit. 2 (H315) Eye Dam. 1 (H318) Skin Sens. 1A (H317) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	Skin Sens. 1A :: C>=0.036%	1	1	01-2120761540-60-XXXX
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-	611-341-5	55965-84-9	Acute Tox. 3 (H301) Acute Tox. 2 (H310) Acute Tox. 2 (H330) Skin Corr. 1C (H314)	Eye Dam. 1 :: C>=0.6% Eye Irrit. 2 :: 0.06%<=C<0.6% Skin Corr. 1C ::	100	100	-

SAFETY DATA SHEET

SOVEREIGN INJECTION CREAM
Supersedes date 22-Apr-2024

Revision date 05-Jul-2024
Revision Number 1.09

one (3:1) [C(M)IT/MIT] <0.0015 %			Eye Dam. 1 (H318) Skin Sens. 1A (H317) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) (EUH071)	C>=0.6% Skin Irrit. 2 :: 0.06%<=C<0.6% Skin Sens. 1 :: C>=0.0015%			
-------------------------------------	--	--	--	---	--	--	--

Substances identified by a number starting "RR-" in the CAS-field are substances for which the CAS# is not adopted in EU and we use an internal numbering system to track within our SDS software

Full text of H- and EUH-phrases: see section 16

NOTE [7] - No registration number is given for this substance because it is a polymer exempted from registration according to the provisions of Article 2(9) of REACH. All monomers or other substances within the polymer are registered or exempt from registration

Acute Toxicity Estimate

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components

Chemical name	EC No (EU Index No)	CAS No.	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapour - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, <2% aromatics	926-141-6	RR-108541-2	-	-	-	-	-
Poly(oxy-1,2-ethanediyl), .alpha.-isotridecyl-omega-hydroxy-	-	9043-30-5	500	-	-	-	-
N-(3-(trimethoxysilyl)propyl)ethylenediamine	217-164-6	1760-24-3	-	-	1.5	-	-
Bronopol	200-143-0 (603-085-00-8)	52-51-7	300	1100	-	-	-
1,2-benzisothiazol-3(2H)-one [BIT]	220-120-9 (613-088-00-6)	2634-33-5	450	-	=0.21 mg/L (ATE dust/mist)	0.21+	0.21+
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) [C(M)IT/MIT]	611-341-5	55965-84-9	100	87.12	0.33	-	-

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59)

Notes

See section 16 for more information

Chemical name	Notes
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) [C(M)IT/MIT] - 55965-84-9	B

SECTION 4: First aid measures

SAFETY DATA SHEET

SOVEREIGN INJECTION CREAM
Supersedes date 22-Apr-2024

Revision date 05-Jul-2024
Revision Number 1.09

4.1. Description of first aid measures

General advice	Show this safety data sheet to the doctor in attendance.
Inhalation	Remove to fresh air.
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and persists.
Skin contact	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a doctor.
Ingestion	Rinse mouth. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Call a doctor.
Self-protection of the first aider	Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

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

Symptoms	May cause redness and tearing of the eyes. Burning sensation.
Effects of Exposure	No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Note to doctors	No information available.
------------------------	---------------------------

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	No information available.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	No information available.
---	---------------------------

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
---	--

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.
Other information	Refer to protective measures listed in Sections 7 and 8.
For emergency responders	Use personal protection recommended in Section 8.

6.2. Environmental precautions

SAFETY DATA SHEET

SOVEREIGN INJECTION CREAM
Supersedes date 22-Apr-2024

Revision date 05-Jul-2024
Revision Number 1.09

Environmental precautions See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Take up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product.

General hygiene considerations Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Keep from freezing.

Recommended storage temperature Keep at temperatures between 5 and 35 °C.

7.3. Specific end use(s)

Specific use(s)
Building and construction work. Coatings.

Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

Other information Observe technical data sheet.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits Small amounts of methanol (CAS 67-56-1) are formed by hydrolysis and released upon curing

Chemical name	European Union	United Kingdom
Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, <2% aromatics RR-108541-2	TWA:1200 mg/m ³	-

Derived No Effect Level (DNEL) No information available

Derived No Effect Level (DNEL)			
N-(3-(trimethoxysilyl)propyl)ethylenediamine (1760-24-3)			
Type	Exposure route	Derived No Effect Level (DNEL)	Safety factor
worker	Inhalation	35.5 mg/m ³	

SAFETY DATA SHEET

SOVEREIGN INJECTION CREAM
Supersedes date 22-Apr-2024

Revision date 05-Jul-2024
Revision Number 1.09

Systemic health effects Long term worker	Dermal	5 mg/kg bw/d	
Systemic health effects Long term			

1,2-benzisothiazol-3(2H)-one [BIT] (2634-33-5)			
Type	Exposure route	Derived No Effect Level (DNEL)	Safety factor
worker Long term Systemic health effects	Inhalation	6.81 mg/m ³	
worker Long term Systemic health effects	Dermal	0.966 mg/kg bw/d	

Derived No Effect Level (DNEL)			
N-(3-(trimethoxysilyl)propyl)ethylenediamine (1760-24-3)			
Type	Exposure route	Derived No Effect Level (DNEL)	Safety factor
Consumer Systemic health effects Long term	Oral	2.5 mg/kg bw/d	
Consumer Systemic health effects Long term	Inhalation	8.7 mg/m ³	
Consumer Systemic health effects Long term	Dermal	2.5 mg/kg bw/d	

1,2-benzisothiazol-3(2H)-one [BIT] (2634-33-5)			
Type	Exposure route	Derived No Effect Level (DNEL)	Safety factor
Consumer Long term Systemic health effects	Inhalation	1.2 mg/m ³	
Consumer Long term Systemic health effects	Dermal	0.345 mg/kg bw/d	

Predicted No Effect Concentration (PNEC) No information available.

Predicted No Effect Concentration (PNEC)	
N-(3-(trimethoxysilyl)propyl)ethylenediamine (1760-24-3)	
Environmental compartment	Predicted No Effect Concentration (PNEC)
Freshwater	0.062 mg/l
Marine water	0.0062 mg/l
Sewage treatment plant	25 mg/l

1,2-benzisothiazol-3(2H)-one [BIT] (2634-33-5)	
Environmental compartment	Predicted No Effect Concentration (PNEC)
Freshwater	4.03 µg/l
Marine water	0.403 µg/l
Sewage treatment plant	1.03 mg/l
Freshwater sediment	49.9 µg/l
Marine sediment	4.99 µg/l
Soil	3 mg/kg dry weight

SAFETY DATA SHEET

SOVEREIGN INJECTION CREAM
Supersedes date 22-Apr-2024

Revision date 05-Jul-2024
Revision Number 1.09

8.2. Exposure controls

Engineering controls Ensure adequate ventilation, especially in confined areas.

Personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles). Avoid contact with eyes. Eye protection must conform to standard EN 166.

Hand protection Wear protective gloves. Gloves must conform to standard EN 374. Ensure that the breakthrough time of the glove material is not exceeded. Refer to glove supplier for information on breakthrough time for specific gloves. The breakthrough time of the gloves depends on the material and the thickness as well as the temperature. Gloves should be replaced regularly and if there is any sign of damage to the glove material.

Skin and body protection Wear protective gloves and protective clothing. Avoid contact with skin, eyes or clothing.
Respiratory protection During spraying wear suitable respiratory equipment.

Environmental exposure controls Do not allow into any sewer, on the ground or into any body of water.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state Liquid
Appearance Viscous
Colour Cream
Odour Odourless.

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
Melting point / freezing point	No data available	
Initial boiling point and boiling range	No data available	None known
Flammability	No data available	
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Flash point	> 100 °C	
Autoignition temperature	No data available	None known
Decomposition temperature		None known
pH	No data available	None known.
pH (as aqueous solution)	No data available	None known
Kinematic viscosity	> 30 mm ² /s	@ 40°C
Dynamic viscosity	No data available	
Water solubility	Miscible in water.	
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Vapour pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Density	0.84 g/cm ³	
Relative vapour density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	

9.2. Other information

Solid content (%) No information available
VOC content No data available

9.2.1. Information with regards to physical hazard classes
Not applicable

9.2.2. Other safety characteristics

SAFETY DATA SHEET

SOVEREIGN INJECTION CREAM
Supersedes date 22-Apr-2024

Revision date 05-Jul-2024
Revision Number 1.09

No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid Do not freeze.

10.5. Incompatible materials

Incompatible materials None known based on information supplied.

10.6. Hazardous decomposition products

Hazardous decomposition products Carbon monoxide. Carbon dioxide (CO₂). Hydrocarbons.

SECTION 11: Toxicological information

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

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.

Eye contact Specific test data for the substance or mixture is not available. Causes serious eye irritation. (based on components). May cause redness, itching, and pain.

Skin contact Specific test data for the substance or mixture is not available. May cause irritation. Prolonged contact may cause redness and irritation.

Ingestion Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhoea.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms May cause redness and tearing of the eyes.

Acute toxicity

SAFETY DATA SHEET

SOVEREIGN INJECTION CREAM
Supersedes date 22-Apr-2024

Revision date 05-Jul-2024
Revision Number 1.09

Numerical measures of toxicity

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral)	33,734.10 mg/kg
ATEmix (dermal)	>2000 mg/kg
ATEmix (inhalation-gas)	>20000 ppm
ATEmix (inhalation-dust/mist)	>5 mg/l
ATEmix (inhalation-vapour)	>20 mg/l

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, <2% aromatics	>5000 mg/Kg (Rattus) (OECD 401)	-	>4000 mg/m ³ 4h Vapour (Rattus) (OECD 403)
Poly(oxy-1,2-ethanediyl), .alpha.-isotridecyl-.omega.-hydroxy-	=1000 mg/kg (Rattus)	-	-
N-(3-(trimethoxysilyl)propyl)ethylenediamine	=2295 mg/kg (Rattus)	>2000 mg/Kg (Rattus)	LC50 4H (Aerosol)1.5 - 2.44 mg/L air
Bronopol	300 - 400 mg/Kg (Rattus)	= 1600 mg/kg (Rattus)	=800 mg/m ³ (Rattus) 4 h > 5 g/m ³ (Rattus) 6 h
1,2-benzisothiazol-3(2H)-one [BIT]	=450 mg/kg (ATE)	LD50 > 2000 mg/kg (Rattus)	-
reaction mass of 5-chloro-2-methyl-2H-isothiazol-1-3-one and 2-methyl-2H-isothiazol-3-one (3:1) [C(M)IT/MIT]	= 53 mg/kg (Rat)	LD50 = 87.12 mg/kg (Oryctolagus cuniculus)	= 0.33 mg/L (Rat) 4h

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation

Based on available data, the classification criteria are not met.

N-(3-(trimethoxysilyl)propyl)ethylenediamine (1760-24-3)					
Method	Species	Exposure route	Effective dose	Exposure time	Results
OECD Test No. 404: Acute Dermal Irritation/Corrosion	Rabbit				Mild skin irritant

Serious eye damage/eye irritation Classification based on data available for ingredients. Causes serious eye irritation.

N-(3-(trimethoxysilyl)propyl)ethylenediamine (1760-24-3)

Method	Species	Exposure route	Effective dose	Exposure time	Results
OECD Test No. 405: Acute Eye Irritation/Corrosion	Rabbit	eye			Eye Damage

Respiratory or skin sensitisation Based on available data, the classification criteria are not met.

Germ cell mutagenicity

Based on available data, the classification criteria are not met.

Component Information

N-(3-(trimethoxysilyl)propyl)ethylenediamine (1760-24-3)

Method	Species	Results
OECD Test No. 471: Bacterial Reverse	Mammalian cells in vitro	Negative

SAFETY DATA SHEET

SOVEREIGN INJECTION CREAM
Supersedes date 22-Apr-2024

Revision date 05-Jul-2024
Revision Number 1.09

Mutation Test		
OECD Test No. 476: In Vitro Mammalian Cell Gene Mutation Tests using the Hprt and xprt genes	Mammalian cells in vitro	Negative

Carcinogenicity Based on available data, the classification criteria are not met.

Reproductive toxicity Based on available data, the classification criteria are not met.

N-(3-(trimethoxysilyl)propyl)ethylenediamine (1760-24-3)

Method	Species	Results
OECD Test No. 422: Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test	Rat Oral	NOAEL >500 mg/Kg

STOT - single exposure Based on available data, the classification criteria are not met.

STOT - repeated exposure Based on available data, the classification criteria are not met.

N-(3-(trimethoxysilyl)propyl)ethylenediamine (1760-24-3)

Method	Species	Exposure route	Effective dose	Exposure time	Results
OECD Test No. 422: Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test	Rat	Sub-acute oral toxicity gavage		28 days	NOAEL >500 mg/kg

Aspiration hazard Based on available data, the classification criteria are not met.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea	M-Factor	M-Factor (long-term)
N-(3-(trimethoxysilyl)propyl)ethylenediamine	-	LC50 (96H) =597 mg/L	-	EC50 (48h) =81mg/L		

SAFETY DATA SHEET

SOVEREIGN INJECTION CREAM
Supersedes date 22-Apr-2024

Revision date 05-Jul-2024
Revision Number 1.09

1760-24-3		(Danio rerio)Semi-static		Daphnia magna Static		
Bronopol 52-51-7	EC50 (72h) = 0,068 mg/l (Anabaena flos aqua) (OECD 201)	LC50 (96h) = 3 mg/L (Oncorhynchus mykiss) (OECD 203)	EC50 = 0.41 mg/L 30 min EC50 = 0.50 mg/L 15 min EC50 = 0.91 mg/L 5 min	EC50 (48h) =1.4 mg/L (Daphnia magna, static) (OECD 202)	10	1
1,2-benzisothiazol-3(2H)-one [BIT] 2634-33-5	EC50 3Hr 13mg/l (activated sludge) (OECD 209)	LC50 (96hr) 2.15 mg/l Cyprinodon variegatus EPA 540/9-85-006	-	EC50(48hr) 2.94 mg/l (Daphnia Magna) OECD 202	1	1
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) [C(M)IT/MIT] 55965-84-9	EC50 (72h) =0.048 mg/L (Pseudokirchneriella subcapitata) (OECD 201)	EC50 (96h) = 0.22 mg/L (Oncorhynchus mykiss) (OECD 211)	-	EC50 (48h) =0.1 mg/L (Daphnia magna) (OECD 202)	100	100

12.2. Persistence and degradability

Persistence and degradability No information available.

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) [C(M)IT/MIT] (55965-84-9)

Method	Exposure time	Value	Results
OECD Test No. 301B: Ready Biodegradability: CO2 Evolution Test (TG 301 B)	28 days	biodegradation	Not readily biodegradable

12.3. Bioaccumulative potential

Bioaccumulation

Component Information

Chemical name	Partition coefficient
N-(3-(trimethoxysilyl)propyl)ethylenediamine	-0.3
Bronopol	0.22
1,2-benzisothiazol-3(2H)-one [BIT]	0.7
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) [C(M)IT/MIT]	0.7

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment The product does not contain any substance(s) classified as PBT or vPvB above the threshold of declaration.

Chemical name	PBT and vPvB assessment
Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, <2% aromatics	The substance is not PBT / vPvB
N-(3-(trimethoxysilyl)propyl)ethylenediamine	The substance is not PBT / vPvB
Bronopol	The substance is not PBT / vPvB
1,2-benzisothiazol-3(2H)-one [BIT]	The substance is not PBT / vPvB
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) [C(M)IT/MIT]	The substance is not PBT / vPvB

12.6. Endocrine disrupting properties

SAFETY DATA SHEET

SOVEREIGN INJECTION CREAM
Supersedes date 22-Apr-2024

Revision date 05-Jul-2024
Revision Number 1.09

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

Other information Waste codes should be assigned by the user based on the application for which the product was used.

SECTION 14: Transport information

Note: Keep from freezing.

Land transport (ADR/RID)

14.1 UN number or ID number Not regulated
14.2 UN proper shipping name -
14.3 Transport hazard class(es) Not regulated
14.4 Packing group Not regulated
14.5 Environmental hazards Not applicable
14.6 Special precautions for user
Special Provisions None

IMDG

14.1 UN number or ID number Not regulated
14.2 UN proper shipping name Not regulated
14.3 Transport hazard class(es) Not regulated
14.4 Packing group Not regulated
14.5 Marine pollutant NP
14.6 Special precautions for user
Special Provisions None
14.7 Maritime transport in bulk according to IMO instruments
Transport in bulk according to Annex II of MARPOL and the IBC Code Not applicable

Air transport (ICAO-TI / IATA-DGR)

14.1 UN number or ID number Not regulated
14.2 UN proper shipping name Not regulated
14.3 Transport hazard class(es) Not regulated
14.4 Packing group Not regulated
14.5 Environmental hazards Not applicable
14.6 Special precautions for user
Special Provisions None

Section 15: REGULATORY INFORMATION

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

European Union

United Kingdom - BE

SAFETY DATA SHEET

SOVEREIGN INJECTION CREAM
Supercedes date 22-Apr-2024

Revision date 05-Jul-2024
Revision Number 1.09

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Check whether measures in accordance with Directive 94/33/EC for the protection of young people at work must be taken.

Take note of Directive 92/85/EC on the protection of pregnant and breastfeeding women at work

Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) Regulation (EC 1907/2006)

SVHC: Substances of Very High Concern for Authorisation:

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59)

EU-REACH (1907/2006) - Annex XVII - Substances subject to Restriction

This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII).

Substance subject to authorisation per REACH Annex XIV

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV)

Biocidal Products Regulation (EU) No 528/2012 (BPR)

Contains a biocide : Contains C(M)IT/MIT (3:1). May produce an allergic reaction

Export Notification requirements

This product does not contain substances which are regulated pursuant to Regulation (EC) No. 649/2012 of the European parliament and of the council concerning the export and import of dangerous chemicals above the level that triggers a labeling obligation under Regulation (EC) No 1272/2008. Therefore this product is not subject to prior informed consent notification.

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Persistent Organic Pollutants

Not applicable

REGULATION (EU) 2019/1148 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 20 June 2019 on the marketing and use of explosives precursors

Not applicable

National regulations

15.2. Chemical safety assessment

Exposure scenario

SECTION 16: Other information

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

H301 - Toxic if swallowed

H302 - Harmful if swallowed

H304 - May be fatal if swallowed and enters airways

H310 - Fatal in contact with skin

SAFETY DATA SHEET

SOVEREIGN INJECTION CREAM
Supersedes date 22-Apr-2024

Revision date 05-Jul-2024
Revision Number 1.09

H312 - Harmful in contact with skin
H314 - Causes severe skin burns and eye damage
H315 - Causes skin irritation
H317 - May cause an allergic skin reaction
H318 - Causes serious eye damage
H330 - Fatal if inhaled
H332 - Harmful if inhaled
H335 - May cause respiratory irritation
H400 - Very toxic to aquatic life
H410 - Very toxic to aquatic life with long lasting effects

Notes relating to the identification, classification and labelling of substances

Note B: Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: 'nitric acid ... %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis

Legend

TWA	TWA (time-weighted average)
STEL	STEL (Short Term Exposure Limit)
Ceiling	Ceiling Limit Value
Sk*	Skin designation
SVHC	Substance(s) of Very High Concern
PBT	Persistent, Bioaccumulative, and Toxic (PBT) Chemicals
vPvB	Very Persistent and very Bioaccumulative (vPvB) Chemicals
STOT RE	Specific target organ toxicity - Repeated exposure
STOT SE	Specific target organ toxicity - Single exposure
EWC	European Waste Catalogue
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
IMDG	International Maritime Dangerous Goods (IMDG)
IATA	International Air Transport Association (IATA)
RID	Regulations concerning the International Transport of Dangerous Goods by Rail

Key literature references and sources for data

No information available

Prepared By Product Safety & Regulatory Affairs
Revision date 05-Jul-2024

Indication of changes

Revision note Not applicable.
Training Advice No information available
Further information No information available

This SDS complies with the requirements of UK REACH Regulations SI 2019/758 (as amended)

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet