

# Budesonide

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830  
Date of issue: 9/18/2019 Version: 1.0

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

#### 1.1. Product identifier

Product form	: Substance
Substance name	: Budesonide
IUPAC name	: (11.beta.,16.alpha.)-16,17-[butylidenebis(oxy)]-11,21-dihydroxy-pregna-1,4-diene-3,20-dione
EC-No.	: 257-139-7
CAS-No.	: 51333-22-3
Product code	: 37869156
Formula	: C25H34O6
Product group	: Raw material

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

##### 1.2.1. Relevant identified uses

Main use category	: Laboratory use,Industrial use,Professional use
Industrial/Professional use spec	: For professional use only
Use of the substance/mixture	: For analytical purposes Scientific research and development Not for human consumption or veterinary purposes.

##### 1.2.2. Uses advised against

No additional information available

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

##### Supplier

Scafell Organics  
Molekula Ltd  
Lingfield Way  
Darlington - England  
T +44 (0) 1949 823777 / +44 (0) 7590 545705  
[info@molekula.com](mailto:info@molekula.com) / [kbowen@molekula.com](mailto:kbowen@molekula.com) - [www.molekula.com](http://www.molekula.com)

#### 1.4. Emergency telephone number

Emergency number : +44 (0) 7590 545705

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

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

Skin corrosion/irritation, Category 2	H315
Serious eye damage/eye irritation, Category 2	H319
Reproductive toxicity, Category 1B	H360
Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation	H335
Full text of H statements : see section 16	

##### Adverse physicochemical, human health and environmental effects

No additional information available

#### 2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07

GHS08

Signal word (CLP) :

Danger

Hazard statements (CLP) :

H315 - Causes skin irritation.  
H319 - Causes serious eye irritation.  
H335 - May cause respiratory irritation.  
H360 - May damage fertility or the unborn child.

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Precautionary statements (CLP) : P201 - Obtain special instructions before use.  
P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.  
P263 - Avoid contact during pregnancy and while nursing.  
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.

### 2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Name	Product identifier	%
Budesonide	(CAS-No.) 51333-22-3 (EC-No.) 257-139-7	100

Full text of H-statements: see section 16

### 3.2. Mixtures

Not applicable

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures general : If possible show this sheet, if not available show packaging or label. Never give anything by mouth to an unconscious person. Do not leave affected person unattended.

First-aid measures after inhalation : If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. Give oxygen or artificial respiration if necessary. If breathing difficulties persist : Get medical advice/attention.

First-aid measures after skin contact : After contact with skin, take off immediately all contaminated clothing, and wash immediately with plenty of water. Do not remove clothing if it sticks to the skin. If irritation persists, consult a doctor.

First-aid measures after eye contact : Rinse immediately with plenty of water. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion : Rinse mouth out with water. Do not induce vomiting. Get medical advice/attention.

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

Symptoms/effects after inhalation : Inhalation may cause irritation (cough, short breathing, difficulty in breathing).

Symptoms/effects after skin contact : Causes skin irritation. irritation (itching, redness, blistering).

Symptoms/effects after eye contact : Causes serious eye irritation. stinging. Redness, pain.

Symptoms/effects after ingestion : May cause irritation to the digestive tract. Ingestion may cause nausea and vomiting.

Chronic symptoms : May damage fertility. May damage the unborn child.

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

If exposed or concerned, get medical advice and attention.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media : Dry powder. Sand. Water spray. Carbon dioxide. Foam.

Unsuitable extinguishing media : Do not use a heavy water stream.

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

Hazardous decomposition products in case of fire : Carbon oxides (CO, CO<sub>2</sub>).

### 5.3. Advice for firefighters

Precautionary measures fire : Keep container tightly closed and away from heat, sparks and flame. Keep away from combustible materials.

Firefighting instructions : Exercise caution when fighting any chemical fire. Use water spray or fog for cooling exposed containers. Prevent fire fighting water from entering the environment.

Protection during firefighting : Wear recommended personal protective equipment. Use self-contained breathing apparatus and chemically protective clothing.

Other information : Warn all persons of toxic hazard.

## SECTION 6: Accidental release measures

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

General measures : Isolate from fire, if possible, without unnecessary risk. Avoid dust formation. No flames, no sparks. Eliminate all sources of ignition.

#### 6.1.1. For non-emergency personnel

Protective equipment : Wear recommended personal protective equipment.

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Emergency procedures : Evacuate unnecessary personnel. Mark out the contaminated area with signs and prevent access to unauthorized personnel. Do not touch or walk on the spilled product. Avoid contact with skin, eyes and clothing.

Measures in case of dust release : Keep upwind. Avoid creating or spreading dust. Ventilate the area thoroughly, especially low lying areas (basements, workpits etc).

### 6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. Use self-contained breathing apparatus and chemically protective clothing.

Emergency procedures : Ventilate area.

### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

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

Methods for cleaning up : On land, sweep or shovel into suitable containers. Shovel or sweep up and put in a closed container for disposal.

### 6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Avoid creating or spreading dust. Avoid contact with skin, eyes and clothing. Do not handle until all safety precautions have been read and understood. Ensure that there is a suitable ventilation system. Do not handle in a confined space.

Hygiene measures : Take off immediately all contaminated clothing and wash it before reuse. Contaminated work clothing should not be allowed out of the workplace. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not eat, drink or smoke when using this product.

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

Technical measures : Ensure adequate ventilation, especially in confined areas.

Storage conditions : Keep only in the original container in a cool, well ventilated place away from : Heat sources, Direct sunlight. Keep container closed when not in use.

Incompatible products : Strong oxidizing agents.

Incompatible materials : Sources of ignition. Direct sunlight. Heat sources.

Heat and ignition sources : Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Storage area : Store below 20 °C. Store in a dry place. Store in a closed container.

### 7.3. Specific end use(s)

For analytical purposes. Scientific research and development. Not for human consumption or veterinary purposes.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No additional information available

### 8.2. Exposure controls

#### Appropriate engineering controls:

Handle in accordance with good industrial hygiene and safety procedures.

#### Personal protective equipment:

Avoid all unnecessary exposure.

#### Materials for protective clothing:

Wear suitable protective clothing, gloves and eye/face protection

#### Hand protection:

The protective gloves to be used must comply with the specifications of the regulation 2016/425 and the resultant standard EN 374

Type	Material	Permeation	Thickness (mm)	Penetration	Standard
Disposable gloves	Butyl rubber	6 (> 480 minutes)	0.3		EN 374

#### Eye protection:

Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure. Use eye protection according to EN 166, designed to protect against powders and dusts.

Type	Use	Characteristics	Standard
Safety goggles, Face shield	Fine dust, Dust	tightly fitting safety goggles, With side shields	EN 166

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<b>Skin and body protection:</b>			
Emergency safety showers should be available in the immediate vicinity of any potential exposure. Keep suitable chemically resistant protective clothing readily available for emergency use			
<b>Type</b>		<b>Standard</b>	
Total impervious protective suits, gloves, and boots must be worn to prevent any contact with the product		EN ISO 13982	
<b>Respiratory protection:</b>			
Keep self contained breathing apparatus readily available for emergency use. Where exposure through inhalation may occur from use, respiratory protection equipment is recommended			
<b>Device</b>	<b>Filter type</b>	<b>Condition</b>	<b>Standard</b>
Air-Purifying Respirator (APR), reusable	Type P3	Protection for Solid particles, Mist formation, Dust protection	EN 14387

### Other information:

Do not eat, drink or smoke during use.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Powder.
Molecular mass	: 430.53 g/mol
Colour	: White to off-white.
Odour	: No data available.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

Stable under normal conditions of use.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

Protect from sunlight. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

### 10.5. Incompatible materials

Strong oxidizers.

### 10.6. Hazardous decomposition products

No hazardous decomposition products known at room temperature. Thermal decomposition generates : Carbon oxides (CO, CO<sub>2</sub>).

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### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

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

#### Budesonide (51333-22-3)

LD50 oral rat	> 3200 mg/kg
Skin corrosion/irritation	: Causes skin irritation.
Additional information	: Based on available data, the classification criteria are not met
Serious eye damage/irritation	: Causes serious eye irritation.
Additional information	: Based on available data, the classification criteria are not met
Respiratory or skin sensitisation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Reproductive toxicity	: May damage fertility or the unborn child.
Additional information	: Based on available data, the classification criteria are not met
STOT-single exposure	: May cause respiratory irritation.
Additional information	: Based on available data, the classification criteria are not met
STOT-repeated exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

### SECTION 12: Ecological information

#### 12.1. Toxicity

Acute aquatic toxicity	: Not classified
Chronic aquatic toxicity	: Not classified

#### 12.2. Persistence and degradability

##### Budesonide (51333-22-3)

Persistence and degradability	No data available.
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#### 12.3. Bioaccumulative potential

##### Budesonide (51333-22-3)

Bioaccumulative potential	No data available.
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#### 12.4. Mobility in soil

No additional information available

#### 12.5. Results of PBT and vPvB assessment

##### Budesonide (51333-22-3)

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

#### 12.6. Other adverse effects

Additional information : Avoid release to the environment.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Product/Packaging disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials	: Avoid release to the environment.

### SECTION 14: Transport information

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

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ADR	IMDG	IATA	ADN	RID
<b>14.1. UN number</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.2. UN proper shipping name</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.3. Transport hazard class(es)</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.4. Packing group</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.5. Environmental hazards</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

### 14.6. Special precautions for user

#### Overland transport

Not regulated

#### Transport by sea

Not regulated

#### Air transport

Not regulated

#### Inland waterway transport

Not regulated

#### Rail transport

Not regulated

### 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

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

No REACH Annex XVII restrictions

Budesonide is not on the REACH Candidate List

Directive 2012/18/EU (SEVESO III)

#### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out for the substance or the mixture by the supplier

## SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

Full text of H- and EUH-statements:	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Repr. 1B	Reproductive toxicity, Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
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SDS EU (REACH Annex II)

*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.*