

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 24.07.2013

Version number 1

Revision: 24.07.2013

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

- **Product identifier**
- **Trade name: Budesonide impurity Standard**
- **Reference number: Cat 894**
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the preparation** Reference material for laboratory use only
- **Manufacturer/Supplier:**
British Pharmacopoeia Commission
MHRA
151 Buckingham Palace Road
London SW1W 9SZ
United Kingdom
Tel : +44 (0)20 3080 6561
eMail: bpcrs@mhra.gsi.gov.uk
- **Further information obtainable from:** eMail: bpcrs@mhra.gsi.gov.uk
- **Emergency telephone number:** +44 (0) 20 3080 6561 (Monday - Friday: 8am - 5pm)

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS08 health hazard

STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.



GHS07

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

STOT SE 3 H335 May cause respiratory irritation.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**



Xi; Irritant

R36/37/38: Irritating to eyes, respiratory system and skin.

R33: Danger of cumulative effects.

- **Information concerning particular hazards for human and environment:**

The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

- **Classification system:**

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

- **Label elements**

- **Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labelled according to the CLP regulation.

- **Hazard pictograms**



GHS07



GHS08

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- **Signal word** Warning
- **Hazard-determining components of labelling:**
Budesonide
- **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H373 May cause damage to organs through prolonged or repeated exposure.
- **Precautionary statements**
P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P305+P351+P338 **IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P321 Specific treatment (see on this label).
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture: consisting of the following components.

· **Dangerous components:**

CAS: 51333-22-3 RTECS: TU3723000	Budesonide ☒ Xi R36/37/38 R33 ☒ STOT RE 2, H373; ☒ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	>99%
CAS: 85234-63-5	Budesonide Impurity D ☒ Xn R48/20/21/22; ☒ Xi R36/37/38 ☒ STOT RE 2, H373; ☒ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	< 2.5%

- **Additional information:** For the wording of the listed risk phrases refer to section 16.

4 First aid measures

- **Description of first aid measures**
- **After inhalation:** In case of unconsciousness place patient in recovery position for transport.
- **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.
If skin irritation continues, consult a doctor.
- **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:** Rinse mouth. Do not induce vomiting.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.

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- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
- **Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Avoid formation of dust.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Ensure adequate ventilation.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling** Store in cool, dry place in tightly closed receptacles.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
Store in a cool location.
Please refer to the manufacturer's certificate for specific storage and transport temperature conditions.
Store only in the original receptacle.
Keep container in a well-ventilated place. Keep away from sources of ignition and heat.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:** Keep container tightly sealed.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** Lists used were valid at the time of SDS preparation.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.

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Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

· Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection:



Tightly sealed goggles

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

Form: Solid

Colour: White

· Odour: Odourless

· Odour threshold: Not determined.

· pH-value: Not applicable.

· Change in condition

Melting point/Melting range: Not determined.

Boiling point/Boiling range: Not determined.

· Flash point: Not applicable.

· Flammability (solid, gaseous): Not determined.

· Ignition temperature:

Decomposition temperature: Not determined.

· Self-igniting: Not determined.

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· Danger of explosion:	Not determined.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure:	Not applicable.
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with water:	Insoluble.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** Stable under normal conditions.
- **Chemical stability** Stable under normal conditions.
- **Thermal decomposition / conditions to be avoided:**
Formation of toxic gases is possible during heating or in case of fire.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** Heat.
- **Incompatible materials:** Strong oxidizing agents.
- **Hazardous decomposition products:** Formation of toxic gases is possible during heating or in case of fire.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

· **LD/LC50 values relevant for classification:**

51333-22-3 Budesonide

Oral	LD50	>3200 mg/kg (rat)
	LD 50 (Intraperitoneal)	138 mg/kg (rat)
	LD 50 (Intravenous)	99 mg/kg (rat)

- **Primary irritant effect:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** Irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
Irritant

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12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **European waste catalogue**
Waste disposal key numbers from EWC have to be assigned depending on origin and processing.
- **Uncleaned packaging:**
- **Recommendation:** Dispose of in accordance with national regulations.

14 Transport information

- | | |
|--|-----------------|
| · UN-Number | |
| · ADR, ADN, IMDG, IATA | Not applicable |
| · ADR, ADN, IMDG, IATA | Not applicable |
| · Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | Not applicable |
| · Packing group | |
| · ADR, IMDG, IATA | Not applicable |
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | - |

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15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Philippines Inventory of Chemicals and Chemical Substances**

None of the ingredients is listed.

· **Australian Inventory of Chemical Substances**

None of the ingredients is listed.

· **Standard for the Uniform Scheduling of Drugs and Poisons**

None of the ingredients is listed.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. British Pharmacopoeia Commission Office makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.

· **Relevant phrases**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H373 May cause damage to organs through prolonged or repeated exposure.

R33 Danger of cumulative effects.

R36/37/38 Irritating to eyes, respiratory system and skin.

R48/20/21/22 Harmful: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed.

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

· **Sources**

Tables 3.1 and 3.2 from Annex 6 of EC 1272/2008, EC 1907/2006, EH40/2005 as amended 2011, Registry of Toxic Effects of Chemical Substances (RTECS), The Dictionary of Substances and their Effects, 1st Edition, IUCLID.