

# Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.10.2014

Version number 1

Revision: 15.10.2014

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

· **1.1 Product identifier**

· **Trade name:** FEXOFENADINE IMPURITY STANDARD

· **Reference number:** Cat 1096

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

No further relevant information available.

· **Application of the substance / the mixture** Reference material for laboratory use only

· **Manufacturer/Supplier:**

British Pharmacopoeia Commission  
MHRA

10 South Colonnade, Canary Wharf  
London E14 4PU  
United Kingdom

Tel : +44 (0)20 3080 6561  
eMail: bpcrs@mhra.gov.uk

· **Further information obtainable from:** eMail: bpcrs@mhra.gov.uk

· **1.4 Emergency telephone number:** +44 (0) 20 3080 6561 (Monday - Friday: 8am - 5pm)

## SECTION 2: Hazards identification

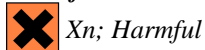
· **2.1 Classification of the substance or mixture**

· **Classification according to Regulation (EC) No 1272/2008**



Acute Tox. 4 H302 Harmful if swallowed.

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



R22: Harmful if swallowed.

· **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.

· **2.2 Label elements**

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

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

· **Hazard pictograms**



· **Signal word** Warning

· **Hazard-determining components of labelling:**

Fexofenadine hydrochloride

· **Hazard statements**

H302 Harmful if swallowed.

· **Precautionary statements**

P264 Wash thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P330 Rinse mouth.

(Contd. on page 2)

## Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.10.2014

Version number 1

Revision: 15.10.2014

**Trade name: FEXOFENADINE IMPURITY STANDARD**

(Contd. from page 1)

*P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.*

*P501 Dispose of contents/container in accordance with local/regional/national/international regulations.*

- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

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

· **Dangerous components:**

CAS: 153439-40-8 RTECS: CY1633377	Fexofenadine hydrochloride ☒ Xn R22 ⚠ Acute Tox. 4, H302	>99%
CAS: 76811-98-8 RTECS: -	2-[4-[4-[4-(Hydroxydiphenylmethyl)piperidin-1-yl]butanoyl]phenyl]-2-methylpropanoic Acid (Ketofexofenadine) ☒ Xn R22 ⚠ Acute Tox. 4, H302	0.2-0.6%
CAS: 185066-37-9 RTECS: -	(1RS)-4-[4-(Hydroxydiphenylmethyl)piperidin-1-yl]-1-[4-(1-methylethyl)phenyl]butan-1-ol ☒ Xn R22 ⚠ Acute Tox. 4, H302	<0.5%

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

### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:**  
Symptoms of poisoning may occur even after several hours; therefore medical observation for at least 48 hours after the accident is recommended.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:**  
Rinse mouth. Do not induce vomiting.  
Call for a doctor immediately.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture**  
Formation of toxic gases is possible during heating or in case of fire.

(Contd. on page 3)

## Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.10.2014

Version number 1

Revision: 15.10.2014

**Trade name: FEXOFENADINE IMPURITY STANDARD**

(Contd. from page 2)

- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Dispose of contaminated material as waste according to item 13.
- **6.4 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.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Store in cool, dry place in tightly closed receptacles.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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:** None.
- **7.3 Specific end use(s)** No further relevant information available.

### SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 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.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.
- **Protection of hands:**



Protective gloves

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

(Contd. on page 4)

## Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.10.2014

Version number 1

Revision: 15.10.2014

**Trade name: FEXOFENADINE IMPURITY STANDARD**

(Contd. from page 3)

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

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374

· **Material of gloves** Nitrile rubber, NBR

· **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:** Safety glasses

### SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· **Form:** Powder

· **Colour:** Off white

· **Odour:** Odourless

· **Odour threshold:** Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

· **Melting point/Melting range:** 188 - 192 °C (dec)

· **Boiling point/Boiling range:** Not determined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Not determined.

· **Ignition temperature:**

· **Decomposition temperature:** Not determined.

· **Self-igniting:** Product is not selfigniting.

· **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.

· **9.2 Other information** No further relevant information available.

GB

(Contd. on page 5)

# Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.10.2014

Version number 1

Revision: 15.10.2014

**Trade name: FEXOFENADINE IMPURITY STANDARD**

(Contd. from page 4)

## SECTION 10: Stability and reactivity

- **10.1 Reactivity** Stable under normal conditions.
- **10.2 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.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** Heat.
- **10.5 Incompatible materials:** Strong oxidizing agents.
- **10.6 Hazardous decomposition products:**  
Formation of toxic gases is possible during heating or in case of fire.

## SECTION 11: Toxicological information

### · 11.1 Information on toxicological effects

#### · Acute toxicity:

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

**153439-40-8 Fexofenadine hydrochloride**

Oral	LD0	20 mg/kg (guinea pig)
		5 mg/kg (mouse)

#### · Primary irritant effect:

· **on the skin:** No irritating effect.

· **on the eye:** No 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:  
Harmful

## SECTION 12: Ecological information

### · 12.1 Toxicity

· **Aquatic toxicity:** No further relevant information available.

· **12.2 Persistence and degradability** No further relevant information available.

· **12.3 Bioaccumulative potential** No further relevant information available.

· **12.4 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.

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

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **12.6 Other adverse effects** No further relevant information available.

## SECTION 13: Disposal considerations

### · 13.1 Waste treatment methods

#### · Recommendation

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

(Contd. on page 6)

## Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.10.2014

Version number 1

Revision: 15.10.2014

**Trade name: FEXOFENADINE IMPURITY STANDARD**

(Contd. from page 5)

- **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.

### SECTION 14: Transport information

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

### SECTION 15: Regulatory information

- **15.1 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 Medicines and Poisons**  
None of the ingredients is listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### SECTION 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**  
H302 Harmful if swallowed.

(Contd. on page 7)

**Safety data sheet**  
*according to 1907/2006/EC, Article 31*

Printing date 15.10.2014

Version number 1

Revision: 15.10.2014

**Trade name: FEXOFENADINE IMPURITY STANDARD**

(Contd. from page 6)

R22 Harmful 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

Acute Tox. 4: Acute toxicity, Hazard Category 4

· **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.