

# Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.05.2013

Version number 3

Revision: 09.05.2013

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

· **Product identifier**

· **Trade name: Simvastatin Assay Standard**

· **Reference number:** Cat 739

· **CAS Number:**

79902-63-9

· **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](mailto:bpcrs@mhra.gsi.gov.uk)

· **Further information obtainable from:** eMail: [bpcrs@mhra.gsi.gov.uk](mailto: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

Repr. 2

H361 Suspected of damaging fertility or the unborn child.



GHS09 environment

Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.



GHS07

Skin Irrit. 2

H315 Causes skin irritation.

Eye Irrit. 2

H319 Causes serious eye irritation.

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



Xn; Harmful

R62: Possible risk of impaired fertility.



Xi; Irritant

R36/38: Irritating to eyes and skin.



N; Dangerous for the environment

R51/53: Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

· **Information concerning particular hazards for human and environment:** Not applicable.

· **Label elements**

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

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

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· **Hazard pictograms**



GHS07 GHS08 GHS09

· **Signal word** Warning

· **Hazard statements**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H361 Suspected of damaging fertility or the unborn child.

H411 Toxic to aquatic life with long lasting effects.

· **Precautionary statements**

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P281 Use personal protective equipment as required.

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: Substances**

· **CAS No. Description**

79902-63-9 Simvastatin

· **Identification number(s)** -

### 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.

If symptoms persist consult doctor.

· **Information for doctor:**

· **Most important symptoms and effects, both acute and delayed** No further relevant information available.

· **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

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### 5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, 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** Wear protective clothing.
- **Environmental precautions:**  
Inform respective authorities in case of seepage into water course or sewage system.  
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**  
Dispose of contaminated material as waste according to item 13.
- **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:** The product is not flammable.
- **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:** Not required.
- **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.  
Immediately remove all soiled and contaminated clothing  
Wash hands before breaks and at the end of work.

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Avoid contact with the eyes and skin.

· **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.

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.

· **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:**

· <b>Form:</b>	Solid
· <b>Colour:</b>	Off white
· <b>Odour:</b>	Odourless
· <b>Odour threshold:</b>	Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

· <b>Melting point/Melting range:</b>	135-138 °C
· <b>Boiling point/Boiling range:</b>	Not determined.

· **Flash point:** Not applicable.

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

· **Ignition temperature:** 400 °C

· **Decomposition temperature:** Not determined.

· **Self-igniting:** Not determined.

· **Danger of explosion:** Not determined.

· **Explosion limits:**

· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.

· **Vapour pressure:** Not applicable.

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- |   |  |
|---|--|
| · <b>Density:</b>                                 | Not determined.                            |
| · <b>Relative density</b>                         | Not determined.                            |
| · <b>Vapour density</b>                           | Not applicable.                            |
| · <b>Evaporation rate</b>                         | Not applicable.                            |
| · <b>Solubility in / Miscibility with water:</b>  | Ethyl Acetate, Methanol<br>Negligible.     |
| · <b>Partition coefficient (n-octanol/water):</b> | 4.68 Log Pow                               |
| · <b>Viscosity:</b>                               |  |
| · <b>Dynamic:</b>                                 | Not applicable.                            |
| · <b>Kinematic:</b>                               | Not applicable.                            |
| · <b>Other information</b>                        | 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**  
Light.  
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:**

Oral	LD50	4438 mg/kg (rat)
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- **Primary irritant effect:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** Irritating effect.
- **Sensitization:** No sensitizing effects known.
- **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**  
Repr. 2

## 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:**

LC50/48	5.9 mg/l (daphnia)
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- **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.
- **Ecotoxicological effects:**
- **Remark:** Toxic for fish

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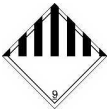

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- **Additional ecological information:**
- **General notes:**  
*Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water  
 Do not allow product to reach ground water, water course or sewage system, even in small quantities.  
 Danger to drinking water if even extremely small quantities leak into the ground.  
 Also poisonous for fish and plankton in water bodies.  
 Toxic for aquatic organisms*
- **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

- |  |  |
|--|--|
| <ul style="list-style-type: none"> <li>· <b>UN-Number</b></li> <li>· <b>ADR, IMDG, IATA</b></li> <li>· <b>ADR</b></li> <li>· <b>IMDG</b></li> <li>· <b>IATA</b></li> </ul>                               | <p>UN3077<br/>           3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE,<br/>           SOLID, N.O.S. (Simvastatin)<br/>           ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,<br/>           N.O.S. (Simvastatin), MARINE POLLUTANT<br/>           ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,<br/>           N.O.S. (Simvastatin)</p>  |
| <ul style="list-style-type: none"> <li>· <b>Transport hazard class(es)</b></li> <li>· <b>ADR, IMDG, IATA</b></li> </ul>  | <div style="display: flex; align-items: center; gap: 10px;">   </div> <p style="margin-top: 10px;">           · <b>Class</b> 9 Miscellaneous dangerous substances and articles.<br/>           · <b>Label</b> 9         </p> |
| <ul style="list-style-type: none"> <li>· <b>Packing group</b></li> <li>· <b>ADR, IMDG, IATA</b></li> </ul>   | <p>III</p>   |
| <ul style="list-style-type: none"> <li>· <b>Environmental hazards:</b></li> <li>· <b>Marine pollutant:</b></li> <li>· <b>Special marking (ADR):</b></li> <li>· <b>Special marking (IATA):</b></li> </ul> | <p>Yes (P)<br/>           Symbol (fish and tree)<br/>           Symbol (fish and tree)<br/>           Symbol (fish and tree)</p>   |
| <ul style="list-style-type: none"> <li>· <b>Special precautions for user</b></li> <li>· <b>Danger code (Kemler):</b></li> </ul>  | <p>Warning: Miscellaneous dangerous substances and articles.<br/>           90</p>   |

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· <b>EMS Number:</b>	F-A,S-F
· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	
· <b>ADR</b>	
· <b>Limited quantities (LQ)</b>	5 kg
· <b>Transport category</b>	3
· <b>Tunnel restriction code</b>	E
· <b>UN "Model Regulation":</b>	UN3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Simvastatin), 9, III

## 15 Regulatory information

- **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.

### · Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organization

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

P: Marine Pollutant

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

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.

- \* **Data compared to the previous version altered.** All sections have been updated.