

Medicines & Healthcare products Regulatory Agency

British Pharmacopoeia

Quality standards

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 25-May-2023

Revision Number 1

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

1.1. Product identifier

Product Code(s) CAT 394

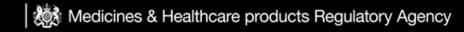
Product Name Minocycline Hydrochloride

Form Not applicable

NOTE [8] - No registration number is given for this substance because it is under the threshold in REACH Article 6(1) and not subject to the registration requirements according to REACH Title II

EC No (EU Index No)	237-099-7
CAS No	13614-98-7
Chemical name	Minocycline Hydrochloride
Pure substance/mixture	Substance
Formula	C 23H 28C IN 3O 7
Molecular weight	493.94
1.2. Relevant identified uses of the	substance or mixture and uses advised against
Recommended use	Laboratory use
Uses advised against	No information available
1.3. Details of the supplier of the sa	afety data sheet
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





SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 25-May-2023

Revision Number 1

CAT 394 - Minocycline Hydrochloride

For further information, please contact

E-mail address bpcrs@mhra.gov.uk

1.4. Emergency telephone number

Emergency Telephone

+44 (0)20 3080 6561 (Monday - Friday: 8am - 5pm)

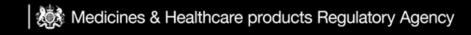
Emergency Telephone - §45 - (EC)1272/2008				
Europe	112			
Austria	No information available			
Bulgaria				
Croatia				
Cyprus				
Czech Republic				
Denmark				
France				
Hungary				
Ireland				
Italy				
Lithuania				
Luxembourg				
Netherlands				
Norway				
Portugal				
Romania				
Slovakia				
Slovenia				
Spain				
Sweden				
Switzerland				

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008	
Serious eye damage/eye irritation	Category 2 - (H319)
Reproductive toxicity	Category 2 - (H361)
Effects on or via lactation	Yes - (H362)

2.2. Label elements





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This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 25-May-2023

Revision Number 1

CAT 394 - Minocycline Hydrochloride



Warning

Hazard statements

- H319 Causes serious eye irritation
- H361 Suspected of damaging fertility or the unborn child
- H362 May cause harm to breast-fed children

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

P201 - Obtain special instructions before use

- P260 Do not breathe dust/fume/gas/mist/vapours/spray
- P263 Avoid contact during pregnancy and while nursing
- P280 Wear protective gloves/protective clothing/eye protection/face protection
- P308 + P313 IF exposed or concerned: Get medical advice/attention
- P501 Dispose of contents/ container to an approved waste disposal plant

2.3. Other hazards

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

Chemical name	EU - REACH (1907/2006) - Article 59(1)	EU - REACH (1907/2006) - Endocrine
	- Candidate List of Substances of Very	Disruptor Assessment List of
	High Concern (SVHC) for Authorisation	Substances
Minocycline Hydrochloride	-	-

SECTION 3: Composition/information on ingredients

3.1 Substances

Chemical name	Weight-%	REACH registration	EC No (EU	Classification according	Specific	M-Factor	M-Factor
		number	Index No)	to Regulation (EC) No.	concentration		(long-term)





SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 25-May-2023

Revision Number 1

CAT 394 - Minocycline Hydrochloride

				1272/2008 [CLP]	limit (SCL)	
Minocycline Hydrochloride 13614-98-7	90 - 100%	-	237-099-7	Eye Irrit. 2 (H319) Repr. 2 (H361) Lact. (H362)		

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

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

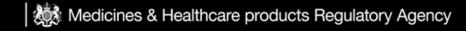
Chemical name	Oral LD50 mg/kg	Dermal LD50	Inhalation LC50 - 4	Inhalation LC50 - 4	Inhalation LC50 - 4
		mg/kg	hour - dust/mist - mg/L	hour - vapour - mg/L	hour - gas - ppm
Minocycline Hydrochloride 13614-98-7	2380	No data available	No data available	No data available	No data available

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

SECTION 4: First aid measures

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	l effects, both acute and delayed





SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 25-May-2023

Revision Number 1

CAT 394 - Minocycline Hydrochloride

Symptoms	May cause redness and tearing of the eyes. Burning sensation.
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4.3. Indication of any immediate medical attention and special treatment needed

Note to doctors

Treat symptomatically.

SECTION 5: Firefighting measures			
5.1. Extinguishing media			
Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.		
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.		
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.		
5.2. Special hazards arising from the substance or mixture			
Specific hazards arising from the chemical	No information available.		

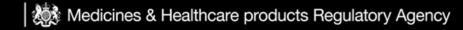
5.3. Advice for firefighters

Special protective equipment and
precautions for fire-fightersFirefighters 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		
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.	





SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 25-May-2023

Revision Number 1

CAT 394 - Minocycline Hydrochloride

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. Remove contaminated clothing and shoes.	
General hygiene considerations	Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection. Wash hands before breaks and immediately after handling the product.	
7.2. Conditions for safe storage, including any incompatibilities		
Storage Conditions	Please refer to the manufacturer's certificate for specific storage and transport temperature conditions. Store only in the original receptacle unless other advice is given on the CoA. Keep containers tightly closed in a dry, cool and well-ventilated place.	

7.3. Specific end use(s)

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

SECTION 8: Exposure controls/personal protection

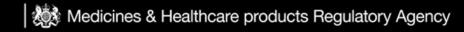
8.1. Control parameters

Exposure Limits

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific





SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 25-May-2023

Revision Number 1

CAT 394 - Minocycline Hydrochloride

regulatory bodies

Derived No Effect Level (DNEL) No information available. Predicted No Effect Concentration (PNEC)

8.2. Exposure controls

Personal protective equipment

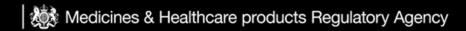
Eye/face protection	Avoid contact with eyes. Wear safety glasses with side shields (or goggles). If splashes are likely to occur, wear safety glasses with side-shields.
Hand protection	The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374. Wear protective butyl rubber gloves. Wear protective Viton [™] gloves. Wear suitable gloves.
Skin and body protection	Wear suitable protective clothing.
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
General hygiene considerations	Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection. Wash hands before breaks and immediately after handling the product.
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	Solid	
Appearance	Solid	
Colour	yellow	
Odour	No information available.	
Odour threshold	No information available	

Property	Va	lues	_
Melting point / freezing point	>	150	°C
Initial boiling point and boiling range	geNo	o data	available

Remarks • Method Decomposes None known





SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 25-May-2023

Revision Number 1

CAT 394 - Minocycline Hydrochloride

Flammability	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive	No data available	
limits		
Lower flammability or explosive	No data available	
limits		
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
pH	No data available	None known
pH (as aqueous solution)	No data available	No information available
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	Slightly soluble	None known
Solubility(ies)	slightly soluble, DMSO, Methanol	
Partition coefficient	0.05	None known
Vapour pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
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		
Molecular weight	493.94	
Molecular formula	C 23H 28C IN 3O 7	

9.2.1. Information with regards to physical hazard classes Not applicable

9.2.2. Other safety characteristics No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity

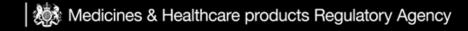
No information available.

10.2. Chemical stability

Stability

Stable under normal conditions.

Explosion data





SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 25-May-2023

Revision Number 1

CAT 394 - Minocycline Hydrochloride

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 None known based on information supplied.

10.5. Incompatible materials

Incompatible materials None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

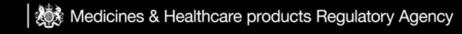
11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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.	
Numerical measures of toxicity		

Acute toxicity





SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 25-May-2023

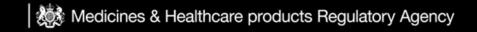
Revision Number 1

CAT 394 - Minocycline Hydrochloride

Component Information

Component Information					
Chemical name	Oral LD50	Dermal LD50	Inhalation LC50		
Minocycline Hydrochloride	= 2380 mg/kg (Rat)				
Delayed and immediate effects as	s well as chronic effects from	short and long-term exposure	e		
Skin corrosion/irritation	May cause skin irritation.	May cause skin irritation.			
Serious eye damage/eye irritation	n Classification based on dat	Classification based on data available for ingredients. Causes serious eye irritation.			
Respiratory or skin sensitisation	No information available.				
Germ cell mutagenicity	No information available.				
Carcinogenicity	No information available.				
Reproductive toxicity	Suspected of damaging fertility or the unborn child. Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. May cause harm to breast-fed children.				
STOT - single exposure	No information available.				
STOT - repeated exposure	No information available.				
Aspiration hazard	No information available.				
11.2. Information on other hazar	<u>ds</u>				

11.2.1. Endocrine disrupting properties





SAFETY DATA SHEET

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Revision date 25-May-2023

Revision Number 1

CAT 394 - Minocycline Hyd	Irochloride
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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

The environmental impact of this product has not been fully investigated.

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

There is no data for this product.

Component Information

Chemical name	Partition coefficient
Minocycline Hydrochloride	0.05

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.

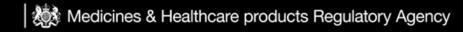
12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations





SAFETY DATA SHEET

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Revision date 25-May-2023

Revision Number 1

CAT 394 - Minocycline Hydrochloride

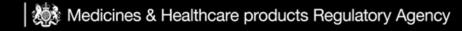
13.1. Waste treatment methods

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.

SECTION 14: Transport information

IATA

 14.1 UN number or ID number 14.2 UN proper shipping name 14.3 Transport hazard class(es) 14.4 Packing group 14.5 Environmental hazards 14.6 Special precautions for user Special Provisions 	Not regulated Not regulated Not regulated Not regulated Not applicable
IMDG14.1UN number or ID number14.2UN proper shipping name14.3Transport hazard class(es)14.4Packing group14.5Marine pollutant14.6Special precautions for user Special Provisions14.7Maritime transport in bulk according to IMO instruments	Not regulated Not regulated Not regulated Not regulated Not applicable None No information available No information available
RID14.1UN number or ID number14.2UN proper shipping name14.3Transport hazard class(es)14.4Packing group14.5Environmental hazards14.6Special precautions for user Special Provisions	Not regulated Not regulated Not regulated Not applicable None
ADR 14.1 UN number or ID number 14.2 UN proper shipping name 14.3 Transport hazard class(es) 14.4 Packing group 14.5 Environmental hazards	Not regulated Not regulated Not regulated Not regulated Not applicable





SAFETY DATA SHEET

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Revision date 25-May-2023

Revision Number 1

CAT 394 - Minocycline Hydrochloride

14.6 Special precautions for user
Special ProvisionsNone

SECTION 15: Regulatory information

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

National regulations

Germany

Water hazard class (WGK)

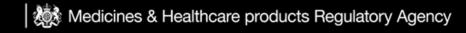
slightly hazardous to water (WGK 1)

Poland

SDS created according to the following Polish regulation: Act of February 25, 2011 on chemical substances and their mixtures (Journal of Laws of 2018, item 143, as amended). Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency (EC) as amended. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, as amended. Regulation of the Minister of Health of 10 August 2012 on the criteria and method of classifying chemical substances and their mixtures (Journal of Laws of 2012, item 1018). Regulation of the Minister of Health of 20 April 2012 on labeling packaging of hazardous substances and mixtures and some mixtures (Journal of Laws of 2012, item 445). Regulation of the Minister of Family, Labor and Social Policy of 12 June 2018 on the maximum allowable concentrations and intensities of factors harmful to health in the work environment (Journal of Laws of 2018, item 1286). Announcement of the Minister of Economy, Labor and Social Policy of August 28, 2003 on the publication of the unified text of the Ordinance of the Minister of Labor and Social Policy on general health and safety at work regulations (Journal of Laws of 2003, No. 169, item 1650). Regulation of the Minister of Health of 30 December 2004 on occupational safety and health related to the presence of chemical agents in the workplace (Journal of Laws of 2005, No. 11, item 86). Act of December 14, 2012 on waste (Journal of Laws of 2013, item 21) Regulation of the Minister of Health of December 30, 2004 on occupational health and safety related to the presence of chemical agents in the workplace (Journal U. of 2005, No. 11, item 86). Waste Act of December 14, 2012 (Journal of Laws of 2013, item 21). Act of 13 June 2013 on the management of packaging and packaging waste, Journal of Laws 2013, item 888). Government statement of September 24, 2002 - European Agreement on the International Carriage of Dangerous Goods by Road (ADR) (Journal of Laws No. 194, item 1629 and Journal of Laws of 2003, No. 207, item 2013 and 2014).

European Union

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





SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 25-May-2023

Revision Number 1

CAT 394 - Minocycline Hydrochloride

at work.

Authorisations and/or restrictions on use:

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

DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors

Not applicable

Persistent Organic Pollutants Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

International Inventorie	s
TSCA	

Complies under research and development exemption or is regulated by a different government agency. Contact supplier for inventory compliance status Contact supplier for inventory compliance status

Legend:

DSL/NDSL

ENCS

IECSC

KECL

PICCS

AIIC

EINECS/ELINCS

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances **ENCS** - Japan Existing and New Chemical Substances

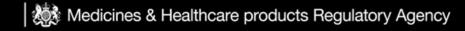
IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment





SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 25-May-2023

Revision Number 1

CAT 394 - Minocycline Hydrochloride

Chemical Safety Report A Chemical Safety Assessment is not required for this substance

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

H319 - Causes serious eye irritation

- H361 Suspected of damaging fertility or the unborn child
- H362 May cause harm to breast-fed children

Legend

SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: Exposure controls/personal protection

TWĂ	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

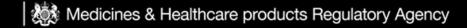
Classification procedure		
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used	
Acute oral toxicity	Calculation method	
Acute dermal toxicity	Calculation method	
Acute inhalation toxicity - gas	Calculation method	
Acute inhalation toxicity - Vapour	Calculation method	
Acute inhalation toxicity - dust/mist	Calculation method	
Skin corrosion/irritation	Calculation method	
Serious eye damage/eye irritation	Calculation method	
Respiratory sensitisation	Calculation method	
Skin sensitisation	Calculation method	
Mutagenicity	Calculation method	
Carcinogenicity	Calculation method	
STOT - single exposure	Calculation method	
STOT - repeated exposure	Calculation method	
Acute aquatic toxicity	Calculation method	
Chronic aquatic toxicity	Calculation method	
Aspiration hazard	Calculation method	
Ozone	Calculation method	

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)





SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 25-May-2023

Revision Number 1

CAT 394 - Minocycline Hydrochloride

EPA (Environmental Protection Agency) Acute Exposure Guideline Level(s) (AEGL(s)) U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act U.S. Environmental Protection Agency High Production Volume Chemicals Food Research Journal Hazardous Substance Database International Uniform Chemical Information Database (IUCLID) Japan GHS Classification Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS) NIOSH (National Institute for Occupational Safety and Health) National Library of Medicine's ChemID Plus (NLM CIP) National Library of Medicine's PubMed database (NLM PUBMED) National Toxicology Program (NTP) New Zealand's Chemical Classification and Information Database (CCID) Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme Organisation for Economic Co-operation and Development Screening Information Data Set World Health Organization

Revision date 25-May-2023

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006 Disclaimer

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 heldresponsible 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. End of Safety Data Sheet