

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 22-Jan-2024

Revision Number 2

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

1.1. Product identifier	
Product Code(s)	CAT 692
Product Name	Fenbendazole

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)	256-145-7
CAS No.	43210-67-9
Pure substance/mixture	Substance
Formula	C15H13N3O2S
Molecular weight	299.35
1.2. Relevant identified uses of the s	substance or mixture and uses advised against
Recommended use	Laboratory use

Uses advised against No information available

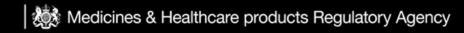
1.3. Details of the supplier of the safety data sheet

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

For further information, please contact





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 22-Jan-2024

Revision Number 2

CAT 692 - Fenbendazole

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		

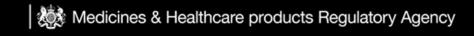
SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to

Regulation (EC) No. 1272/2008 [CLP]

Reproductive toxicity	Category 2 - (H361)
Acute aquatic toxicity	Category 1 - (H400)
Chronic aquatic toxicity	Category 1 - (H410)





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 22-Jan-2024

Revision Number 2

CAT 692 - Fenbendazole

2.2. Label elements

Contains Fenbendazole



Warning

Hazard statements

H361 - Suspected of damaging fertility or the unborn child H410 - Very toxic to aquatic life with long lasting effects

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

P201 - Obtain special instructions before use

P273 - Avoid release to the environment

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

P308 + P313 - IF exposed or concerned: Get medical advice/attention

P391 - Collect spillage

P501 - Dispose of contents/ container to an approved waste disposal plant

2.3. Other hazards

No information available.

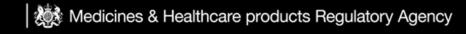
This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors.

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
Fenbendazole	-	-

SECTION 3: Composition/information on ingredients

3.1 Substances





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 22-Jan-2024

Revision Number 2

CAT 692 - Fenbendazole

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)
				1272/2008 [CLP]	limit (SCL)		
Fenbendazole	90 -	-	256-145-7	Repr. 2 (H361)			
43210-67-9	100%			Aquatic Acute 1 (H400)			
				Aquatic Chronic 1			
				(H410)			

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

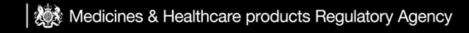
Chemical name	Oral LD50 mg/kg	Dermal LD50	Inhalation LC50 - 4	Inhalation LC50 - 4	Inhalation LC50 - 4
		mg/kg	hour - dust/mist - mg/L	hour - vapour - mg/L	hour - gas - ppm
Fenbendazole 43210-67-9	10000	No data available	No data available	No data available	No data available

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 thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a doctor.
Skin contact	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a doctor.
Ingestion	Rinse mouth.





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 22-Jan-2024

Revision Number 2

CAT 692 - Fenbendazole

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

Symptoms No information available.

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

Note to doctors Treat symptomatically.

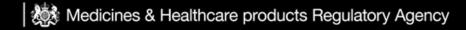
SECTION 5: Firefighting measures 5.1. Extinguishing media Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Large Fire CAUTION: Use of water spray when fighting fire may be inefficient. Unsuitable extinguishing media Do not scatter spilled material with high pressure water streams. 5.2. Special hazards arising from the substance or mixture Specific hazards arising from the No information available. chemical 5.3. Advice for firefighters Special protective equipment and Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment. precautions for fire-fighters SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions





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 22-Jan-2024

Revision Number 2

CAT 692 - Fenbendazole

Environmental precautions	See Section 12 for additional Ecological Information.
6.3. Methods and material for conta	inment and cleaning up
Methods for containment	Prevent further leakage or spillage if safe to do so.
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

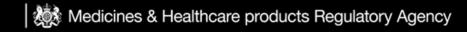
7.1. Precautions for safe handling

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, in	cluding 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. Store locked up.
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





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 22-Jan-2024

Revision Number 2

CAT 692 - Fenbendazole

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 regulatory bodies

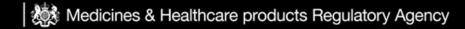
Derived No Effect Level (DNEL)	No information available.
Predicted No Effect Concentration	No information available.
(PNEC)	

8.2. Exposure controls

Personal protective equipment	
Eye/face protection	Avoid contact with eyes. Wear safety glasses with side shields (or goggles).
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 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





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 22-Jan-2024

Solid

Revision Number 2

CAT 692 - Fenbendazole

Physical state

Filysical state	Solid	
Appearance	Solid	
Colour	white to off-white	
Odour	No information available.	
Odour threshold	No information available	
Property	Values	Remarks • Method
Melting point / freezing point	234 - 236 °C	None known
Initial boiling point and boiling rang	eNo data available	None known
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
рН	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	No data available	None known
Solubility(ies)	DMSO, slightly soluble, Ethyl acetate,	
	Methanol, partially soluble	
Partition coefficient	3.85	None known
Vapour pressure	No data available	None known
Relative density	1.40	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	299.35	
Molecular formula	C15H13N3O2S	

9.2.1. Information with regards to physical hazard classes Not applicable

9.2.2. Other safety characteristics



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 22-Jan-2024

CAT 692 - Fenbendazole

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 Sensitivity to mechanical impact Sensitivity to static discharge	None.
10.3. Possibility of hazardous reacti	ons
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

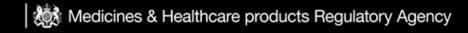
11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure

Product Information

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.

Revision Number 2





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 22-Jan-2024

Revision Number 2

CAT 692 - Fenbendazole

Ingestion Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms

No information available.

Numerical measures of toxicity

Acute toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50	
Fenbendazole	> 10000 mg/kg (Rat)			
Delayed and immediate effects as well as chronic effects from short and long-term exposure				
kin corrosion/irritation Based on available data, the classification criteria are not met.			net.	
Serious eye damage/eye irritation	n No information available.			

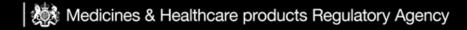
Respiratory or skin sensitisation No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity

Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. Suspected of damaging fertility or the unborn child.





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 22-Jan-2024

 CAT 692 - Fenbendazole

 STOT - single exposure
 No information available.

 STOT - repeated exposure
 No information available.

 Aspiration hazard
 No information available.

 11.2. Information on other hazards
 Information available.

 11.2.1. Endocrine disrupting properties
 No information available.

 11.2.2. Other information
 No information available.

Other adverse effects

No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity

Very toxic to aquatic life with long lasting effects.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Fenbendazole	-	40µg/L (96h, Oncorhynchus mykiss)	-	0.0165mg/L (48h, Daphnia magna)

12.2. Persistence and degradability

Persistence and degradability No information available.

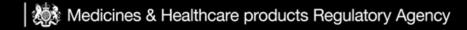
12.3. Bioaccumulative potential

Bioaccumulation There is no data for this product.

Component Information

Chemical name	Partition coefficient
Fenbendazole	3.85

Revision Number 2





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 22-Jan-2024

Revision Number 2

CAT 692 - Fenbendazole

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

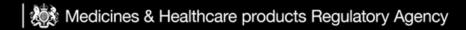
13.1. Waste treatment methods

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

UN3077 Environmentally hazardous substances, solid, n.o.s. (Fenbendazole) 9 III UN3077, Environmentally hazardous substances, solid, n.o.s. (Fenbendazole), 9, III Yes
A97, A158, A179, A197, A215 9L

IMDG





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 22-Jan-2024

Revision Number 2

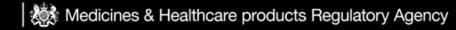
CAT 692 - Fenbendazole

 14.1 UN number or ID number 14.2 UN proper shipping name 14.3 Transport hazard class(es) 14.4 Packing group Description 14.5 Marine pollutant Environmental hazards 14.6 Special precautions for user Special Provisions EmS-No. 14.7 Maritime transport in bulk according to IMO instruments 	UN3077 Environmentally hazardous substances, solid, n.o.s. (Fenbendazole) 9 III UN3077, Environmentally hazardous substances, solid, n.o.s. (Fenbendazole), 9, III, Marine pollutant P Yes 274, 335, 966, 967, 969 F-A, S-F No information available No information available
RID14.1UN number or ID number14.2UN proper shipping name14.3Transport hazard class(es)14.4Packing groupDescription14.5Environmental hazards14.6Special precautions for userSpecial ProvisionsClassification code	UN3077 Environmentally hazardous substances, solid, n.o.s. (Fenbendazole) 9 III UN3077, Environmentally hazardous substances, solid, n.o.s. (Fenbendazole), 9, III Yes 274, 335, 375, 601 M7
ADR 14.1 UN number or ID number 14.2 UN proper shipping name 14.3 Transport hazard class(es) 14.4 Packing group Description 14.5 Environmental hazards 14.6 Special precautions for user Special Provisions Classification code Tunnel restriction code	UN3077 Environmentally hazardous substances, solid, n.o.s. (Fenbendazole) 9 III UN3077, Environmentally hazardous substances, solid, n.o.s. (Fenbendazole), 9, III, (-) Yes 274, 335, 601, 375 M7 (-)

SECTION 15: Regulatory information

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

National regulations





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 22-Jan-2024

Revision Number 2

CAT 692 - Fenbendazole

Germany

Water hazard class (WGK)

strongly hazardous to water (WGK 3)

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).

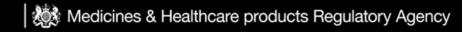
European Union

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





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 22-Jan-2024

Revision Number 2

CAT 692 - Fenbendazole

Not applicable

Persistent Organic Pollutants Not applicable

Dangerous substance category per Seveso Directive (2012/18/EU)

E1 - Hazardous to the Aquatic Environment in Category Acute 1 or Chronic 1

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

International Inventories TSCA

TSCA	Complies under research and development exemption or is regulated by a different government agency.
DSL/NDSL	Contact supplier for inventory compliance status
EINECS/ELINCS	Contact supplier for inventory compliance status
ENCS	Contact supplier for inventory compliance status
IECSC	Contact supplier for inventory compliance status
KECL	Contact supplier for inventory compliance status
PICCS	Contact supplier for inventory compliance status
AIIC	Contact supplier for inventory compliance status

Legend:

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

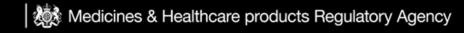
PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report

A Chemical Safety Assessment is not required for this substance





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 22-Jan-2024

Revision Number 2

CAT 692 - Fenbendazole

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

H361 - Suspected of damaging fertility or the unborn child

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

Legend

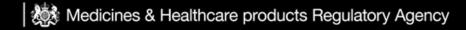
SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: Exposure controls/personal protection

TWĀ	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	Sk*	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	On basis of test data
Chronic aquatic toxicity	On basis of test data
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





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 22-Jan-2024

Revision Number 2

CAT 692 - Fenbendazole

Agency for Toxic Substances and Disease Registry (ATSDR) U.S. Environmental Protection Agency ChemView Database European Food Safety Authority (EFSA) 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

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

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