

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

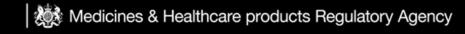
Revision date 23-Oct-2023

**Revision Number** 1

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

1.1. Product identifier	
Product Code(s)	CAT 599
Product Name	Zuclopenthixol acetate dihydrochloride Assay Standard
Form	Not applicable
	nber is given for this substance because it is under the threshold in REACH Article istration requirements according to REACH Title II
EC No (EU Index No)	-
CAS No.	-
Pure substance/mixture	Substance
Formula	C24 H27 CI N2 O2 S . 2 (H CI)
Molecular weight	518
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	fety 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, places contact	

For further information, please contact





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#### CAT 599 - Zuclopenthixol acetate dihydrochloride Assay Standard

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] This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

#### 2.2. Label elements





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This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP] **Hazard statements** This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

#### 2.3. Other hazards

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

#### Endocrine Disruptor Information

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
Zuclopenthixol acetate dihydrochloride Assay	-	_
Standard		

### SECTION 3: Composition/information on ingredients

#### 3.1 Substances

Chemical name	Weight-%	REACH registration number	· ·	<b>U U U</b>	concentration	M-Factor	M-Factor (long-term)
				1272/2008 [CLP]	limit (SCL)		
Zuclopenthixol acetate dihydrochloride Assay Standard -	90 - 100%	-	-	-			

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

Acute Toxicity Estimate No information 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)





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SECTION 4: First aid measures

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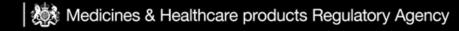
### CAT 599 - Zuclopenthixol acetate dihydrochloride Assay Standard

4.1. Description of first aid measure	<u>28</u>
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.
4.2. Most important symptoms and	effects, both acute and delayed
Symptoms	No information available.
4.3. Indication of any immediate me	edical attention and special treatment needed
Note to doctors	Treat symptomatically.
SECTION 5: Firefighting m	easures
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	e substance or mixture
Cupatific haranda anising from the	No information available

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.





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precautions for fire-fighters Use personal protection equipment.

#### SECTION 6: Accidental release measures

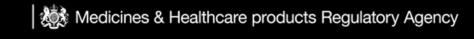
6.1. Personal precaut	ions, protective	equipment and en	nergency procedures

Personal precautions	Ensure adequate ventilation.	
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.	
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	Ensure adequate ventilation.
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.
7.2. Conditions for safe storage, inc	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.





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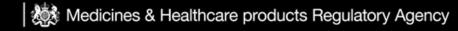
7.3. Specific end use(s)

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

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

This product, as supplied, does not contain any hazardous materials with occupational **Exposure Limits** 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 No information available. **Derived No Effect Level (DNEL)** 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. Natural rubber. Wear suitable protective clothing. Skin and body protection





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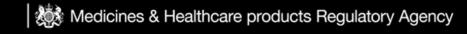
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General hygiene considerations	Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection.
Environmental exposure controls	Do 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 off-white No information available. Odour **Odour threshold** No information available Property Values Remarks • Method No data available Melting point / freezing point None known Initial boiling point and boiling rangeNo data available None known No data available Flammability 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 pН No data available None known pH (as aqueous solution) No data available No information available **Kinematic viscosity** No data available None known No data available **Dynamic viscosity** None known Water solubility No data available None known No data available None known Solubility(ies) **Partition coefficient** No data available None known No data available Vapour pressure None known No data available **Relative density** None known No data available **Bulk density** 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





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9.2. Other information Molecular weight Molecular formula

518 C24 H27 CI N2 O2 S . 2 (H CI)

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 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.

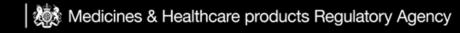
10.5. Incompatible materials

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





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#### Information on likely routes of exposure

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.	
Skin contact	Specific test data for the substance or mixture is not available.	
Ingestion	Specific test data for the substance or mixture is not available.	
Symptoms related to the physical, chemical and toxicological characteristics		

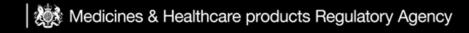
Symptoms

No information available.

Numerical measures of toxicity No information available

Acute toxicity

Delayed and immediate effects as well as chronic effects from short and long-term exposure		
Skin corrosion/irritation	Based on available data, the classification criteria are not met.	
Serious eye damage/eye irritation	No information available.	
Respiratory or skin sensitisation	No information available.	
Germ cell mutagenicity	No information available.	
Carcinogenicity	No information available.	





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Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.
11.2. Information on other hazards	_
11.2.1. Endocrine disrupting prope	rties
Endocrine disrupting properties	No information available.
11.2.2. Other information	
Other adverse effects	No information available.
SECTION 12: Ecological int	formation
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	No information available.
12.4. Mobility in soil	
Mobility in soil	No information available.





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

PBT and vPvB assessment No information available.

Chemical name	PBT and vPvB assessment
Zuclopenthixol acetate dihydrochloride Assay Standard	The substance is not PBT / vPvB

#### 12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

#### 12.7. Other adverse effects

No information available.

### SECTION 13: Disposal considerations

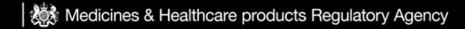
#### 13.1. Waste treatment methods

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**

l	A	١.	T	1	١	

Not regulated Not regulated
Not regulated
Not regulated
Not applicable
None
Not regulated Not regulated





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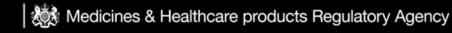
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<ul> <li>14.3 Transport hazard class(es)</li> <li>14.4 Packing group</li> <li>14.5 Marine pollutant</li> <li>14.6 Special precautions for user Special Provisions</li> <li>14.7 Maritime transport in bulk according to IMO instruments</li> </ul>	Not regulated 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 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 14.6 Special precautions for user Special Provisions	Not regulated Not regulated Not regulated Not regulated Not applicable None

### **SECTION 15: Regulatory information**

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

Water hazard class (WGK)	non-hazardous to water (nwg)
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





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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** Not applicable

Persistent Organic Pollutants Not applicable

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





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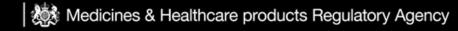
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International Inventories TSCA DSL/NDSL EINECS/ELINCS ENCS IECSC KECL PICCS AIIC	Complies under research government agency. Contact supplier for inve Contact supplier for inve	ntory compliance st ntory compliance st ntory compliance st ntory compliance st ntory compliance st ntory compliance st	atus atus atus atus atus
Legend: TSCA - United States Toxic Substal DSL/NDSL - Canadian Domestic Su EINECS/ELINCS - European Invent ENCS - Japan Existing and New Ch IECSC - China Inventory of Existing KECL - Korean Existing and Evalua PICCS - Philippines Inventory of Chen AICS - Australian Inventory of Chen 15.2. Chemical safety assessment	ubstances List/Non-Domestory of Existing Chemical Substances Chemical Substances Chemical Substances Ited Chemical Substances emicals and Chemical Sub	stic Substances List Substances/Europea	an List of Notified Chemical Substances
Chemical Safety Report	A Chemical Safety Asse	ssment is not requir	ed for this substance
<b>SECTION 16: Other inform</b>	ation		
Key or legend to abbreviations and	acronyms used in the sa	afety data sheet	
Legend SVHC: Substances of Very High Cond	cern for Authorisation:		
Legend         Section 8: Exposure contr           TWA         TWA (time-weighter           Ceiling         Maximum limit value	ed average)	STEL *	STEL (Short Term Exposure Limit) Skin designation
Classification procedure	(EC) No. 4070/0000 [C] 5		ad
Classification according to Regulation	(EC) NO. 1272/2008 [CLP	P] Method Us	





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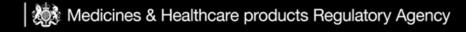
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Acute oral toxicity	Calculation method	
Acute dermal toxicity	Calculation method	
Acute inhalation toxicity - gas	Calculation method	
Acute inhalation toxicity - Vapour	Calculation method	
Acute inhalation toxicity - dust/mist	Calculation method	
Skin 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	
Reproductive toxicity	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) 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

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