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 07-Sep-2023 **Revision Number** 1

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

1.1. Product identifier

Product Code(s)	CAT 196
Product Name	5-[1-Hydroxy-2-(1-Methyl-3-Phenylpropylamino)Ethyl] Salicylic Acid 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)	-
CAS No	-
Chemical name	5-[1-Hydroxy-2-(1-Methyl-3-Phenylpropylamino)Ethyl] Salicylic Acid Hydrochloride
Pure substance/mixture	Substance
Formula	C19H23NO4 · HCl
Molecular weight	366.5

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 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

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Revision date 07-Sep-2023 **Revision Number** 1

CAT 196 - 5-[1-Hydroxy-2-(1-Methyl-3-Phenylpropylamino)Ethyl] Salicylic Acid 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

Skin corrosion/irritation	Category 2 - (H315)
Serious eye damage/eye irritation	Category 2 - (H319)
Reproductive toxicity	Category 2 - (H361)
Specific target organ toxicity — single exposure	Category 3 - (H335)
Chronic aquatic toxicity	Category 2 - (H411)

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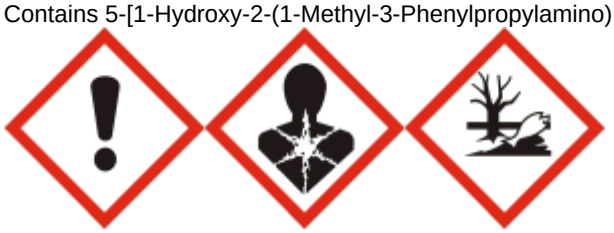
Revision date 07-Sep-2023 **Revision Number** 1

CAT 196 - 5-[1-Hydroxy-2-(1-Methyl-3-Phenylpropylamino)Ethyl] Salicylic Acid Hydrochloride

2.2. Label elements

Contains 5-[1-Hydroxy-2-(1-Methyl-3-Phenylpropylamino)Ethyl] Salicylic Acid Hydrochloride



Signal word
Warning

Hazard statements
H315 - Causes skin irritation
H319 - Causes serious eye irritation
H335 + H336 - May cause respiratory irritation. May cause drowsiness or dizziness
H361d - Suspected of damaging the unborn child
H411 - Toxic to aquatic life with long lasting effects

Precautionary Statements - EU (§28, 1272/2008)
P201 - Obtain special instructions before use
P264 - Wash face, hands and any exposed skin thoroughly after handling
P273 - Avoid release to the environment
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P391 - Collect spillage

2.3. Other hazards

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) - Candidate List of Substances of Very High Concern (SVHC) for Authorisation	EU - REACH (1907/2006) - Endocrine Disruptor Assessment List of Substances
5-[1-Hydroxy-2-(1-Methyl-3-Phenylpropylamino)Ethyl] Salicylic Acid Hydrochloride	-	-

SECTION 3: Composition/information on ingredients

3.1 Substances

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Revision date 07-Sep-2023 **Revision Number** 1

CAT 196 - 5-[1-Hydroxy-2-(1-Methyl-3-Phenylpropylamino)Ethyl] Salicylic Acid Hydrochloride

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
5-[1-Hydroxy-2-(1-Methyl-3-Phenylpropylamino)Ethyl] Salicylic Acid Hydrochloride -	90 - 100%	-	-	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Repr. 2 (H361d) STOT SE 3 (H335) Aquatic Chronic 2 (H411)			

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)

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. IF exposed or concerned: Get medical advice/attention. Get medical attention immediately if symptoms occur.

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 off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.

Ingestion Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. 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 effects, both acute and delayed

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Revision date 07-Sep-2023 **Revision Number** 1

CAT 196 - 5-[1-Hydroxy-2-(1-Methyl-3-Phenylpropylamino)Ethyl] Salicylic Acid Hydrochloride

Symptoms	May cause redness and tearing of the eyes. Burning sensation. Inhalation of high vapour concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting.

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-fighters	Firefighters 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	Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Avoid contact with skin, eyes or clothing.
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	Prevent further leakage or spillage if safe to do so.

6.3. Methods and material for containment and cleaning up

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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. Take off contaminated clothing and wash it before reuse. Ensure adequate ventilation. Avoid breathing vapours or mists. In case of insufficient ventilation, wear suitable respiratory equipment.
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. Store locked up. 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.

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Revision date 07-Sep-2023 **Revision Number** 1

CAT 196 - 5-[1-Hydroxy-2-(1-Methyl-3-Phenylpropylamino)Ethyl] Salicylic Acid Hydrochloride

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 (PNEC)	No information available.

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	Wear suitable gloves. Impervious gloves. 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.
Skin and body protection	Wear suitable protective clothing. Long sleeved 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	off-white
Odour	No information available.
Odour threshold	No information available

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Revision date 07-Sep-2023 **Revision Number** 1

CAT 196 - 5-[1-Hydroxy-2-(1-Methyl-3-Phenylpropylamino)Ethyl] Salicylic Acid Hydrochloride

Property	Values	Remarks • Method
Melting point / freezing point	No data available	None known
Initial boiling point and boiling range	No data available	None known
Flammability	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
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	No data available	None known
Solubility(ies)	No data available	None known
Partition coefficient	No data available	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	366.5
Molecular formula	C19H23NO4 · HCl

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

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Revision date 07-Sep-2023 **Revision Number** 1

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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 Strong acids. Strong bases. Strong oxidising agents.

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. May cause drowsiness or dizziness.

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. Causes skin irritation. (based on components).

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 Redness. May cause redness and tearing of the eyes. Inhalation of high vapour concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting.

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CAT 196 - 5-[1-Hydroxy-2-(1-Methyl-3-Phenylpropylamino)Ethyl] Salicylic Acid Hydrochloride

Numerical measures of toxicity

Acute toxicity

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	Classification based on data available for ingredients. Causes skin irritation. May cause skin irritation.
Serious eye damage/eye irritation	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	Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. Suspected of damaging fertility or the unborn child.
STOT - single exposure	May cause respiratory irritation. May cause drowsiness or dizziness.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

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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 Toxic to aquatic life with long lasting effects.

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.

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

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Revision date 07-Sep-2023 **Revision Number** 1

CAT 196 - 5-[1-Hydroxy-2-(1-Methyl-3-Phenylpropylamino)Ethyl] Salicylic Acid Hydrochloride

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	UN3077
14.2 UN proper shipping name	Environmentally hazardous substances, solid, n.o.s. (5-[1-Hydroxy-2-(1-Methyl-3-Phenylpropylamino)Ethyl] Salicylic Acid Hydrochloride)
14.3 Transport hazard class(es)	9
14.4 Packing group	III
Description	UN3077, Environmentally hazardous substances, solid, n.o.s. (5-[1-Hydroxy-2-(1-Methyl-3-Phenylpropylamino)Ethyl] Salicylic Acid Hydrochloride), 9, III
14.5 Environmental hazards	Yes
14.6 Special precautions for user	
Special Provisions	A97, A158, A179, A197, A215
ERG Code	9L

IMDG

14.1 UN number or ID number	UN3077
14.2 UN proper shipping name	Environmentally hazardous substances, solid, n.o.s. (5-[1-Hydroxy-2-(1-Methyl-3-Phenylpropylamino)Ethyl] Salicylic Acid Hydrochloride)
14.3 Transport hazard class(es)	9
14.4 Packing group	III
Description	UN3077, Environmentally hazardous substances, solid, n.o.s. (5-[1-Hydroxy-2-(1-Methyl-3-Phenylpropylamino)Ethyl] Salicylic Acid Hydrochloride), 9, III, Marine pollutant
14.5 Marine pollutant	P
Environmental hazards	Yes
14.6 Special precautions for user	
Special Provisions	274, 335, 966, 967, 969
EmS-No.	F-A, S-F No information available
14.7 Maritime transport in bulk according to IMO instruments	No information available

RID

14.1 UN number or ID number	UN3077
14.2 UN proper shipping name	Environmentally hazardous substances, solid, n.o.s. (5-[1-Hydroxy-2-(1-Methyl-3-Phenylpropylamino)Ethyl] Salicylic Acid Hydrochloride)
14.3 Transport hazard class(es)	9
14.4 Packing group	III
Description	UN3077, Environmentally hazardous substances, solid, n.o.s. (5-[1-Hydroxy-2-(1-Methyl-3-Phenylpropylamino)Ethyl] Salicylic Acid Hydrochloride), 9, III

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Revision date 07-Sep-2023 **Revision Number** 1

CAT 196 - 5-[1-Hydroxy-2-(1-Methyl-3-Phenylpropylamino)Ethyl] Salicylic Acid Hydrochloride

14.5 Environmental hazards	Yes
14.6 Special precautions for user	
Special Provisions	274, 335, 375, 601
Classification code	M7

ADR

14.1 UN number or ID number	UN3077
14.2 UN proper shipping name	Environmentally hazardous substances, solid, n.o.s. (5-[1-Hydroxy-2-(1-Methyl-3-Phenylpropylamino)Ethyl] Salicylic Acid Hydrochloride)
14.3 Transport hazard class(es)	9
14.4 Packing group	III
Description	UN3077, Environmentally hazardous substances, solid, n.o.s. (5-[1-Hydroxy-2-(1-Methyl-3-Phenylpropylamino)Ethyl] Salicylic Acid Hydrochloride), 9, III, (-)
14.5 Environmental hazards	Yes
14.6 Special precautions for user	
Special Provisions	274, 335, 601, 375
Classification code	M7
Tunnel restriction code	(-)

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)	obviously hazardous to water (WGK 2)

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

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Revision date 07-Sep-2023 **Revision Number** 1

CAT 196 - 5-[1-Hydroxy-2-(1-Methyl-3-Phenylpropylamino)Ethyl] Salicylic Acid Hydrochloride

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

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

E2 - Hazardous to the Aquatic Environment in Category Chronic 2

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

International Inventories

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

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CAT 196 - 5-[1-Hydroxy-2-(1-Methyl-3-Phenylpropylamino)Ethyl] Salicylic Acid Hydrochloride

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

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
H315 - Causes skin irritation
H319 - Causes serious eye irritation
H335 - May cause respiratory irritation
H361d - Suspected of damaging the unborn child
H411 - Toxic to aquatic life with long lasting effects

Legend
SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: Exposure controls/personal protection

TWA	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 inhalation toxicity - gas	Calculation method
Acute oral toxicity	Calculation method

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Revision date 07-Sep-2023 **Revision Number** 1

CAT 196 - 5-[1-Hydroxy-2-(1-Methyl-3-Phenylpropylamino)Ethyl] Salicylic Acid Hydrochloride

Acute inhalation toxicity - Vapour	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Acute inhalation toxicity - gas	Calculation method
Skin corrosion/irritation	Calculation method
Acute inhalation toxicity - Vapour	Calculation method
Serious eye damage/eye irritation	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Respiratory sensitisation	Calculation method
Skin corrosion/irritation	Calculation method
Skin sensitisation	Calculation method
Serious eye damage/eye irritation	Calculation method
Mutagenicity	Calculation method
Respiratory sensitisation	Calculation method
Carcinogenicity	Calculation method
Skin sensitisation	Calculation method
STOT - single exposure	Calculation method
Mutagenicity	Calculation method
STOT - repeated exposure	Calculation method
Carcinogenicity	Calculation method
Acute aquatic toxicity	Calculation method
STOT - single exposure	Calculation method
Chronic aquatic toxicity	Calculation method
STOT - repeated exposure	Calculation method
Aspiration hazard	Calculation method
Acute aquatic toxicity	Calculation method
Ozone	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)

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Revision date 07-Sep-2023 **Revision Number** 1

CAT 196 - 5-[1-Hydroxy-2-(1-Methyl-3-Phenylpropylamino)Ethyl] Salicylic Acid Hydrochloride

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

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End of Safety Data Sheet