

## 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 30-Jun-2025 Revision Number 2

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

#### 1.1. Product identifier

Product Code(s) CAT 1081

Product Name cetirizine impurity standard

Form Not applicable

Pure substance/mixture Mixture

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

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		

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Bulgaria	
Croatia	
Cyprus	
Czech Republic	
Denmark	
France	
Hungary	
Ireland	
Italy	
Lithuania	
Luxembourg	
Netherlands	
Norway	
Portugal	
Romania	
Slovakia	
Slovenia	
Spain	
Spain Sweden	
Switzerland	

### **SECTION 2: Hazards identification**

### 2.1. Classification of the substance or mixture

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

Acute toxicity - Oral	Category 4 - (H302)
Skin irritation	Category 2 - (H315)
Eye irritation	Category 2 - (H319)
Skin sensitisation	Category 1 - (H317)
Specific target organ toxicity (single exposure)	Category 3 - (H335, H336)
Category 3 Target organ effects: Respiratory irritation, Narcotic effects.	

### 2.2. Label elements

Contains Cetirizine Hydrochloride; (RS)-2-[4-[(4-chlorophenyl)phenylmethyl]piperazin-1-yl]acetic acid; 2-[4-[(RS)-4-chlorophenyl)phenylmethyl]piperazin-1-yl]ethanol; (RS)-1-[(4-chlorophenyl)phenylmethyl)piperazine

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Signal word Warning

#### **Hazard statements**

H302 - Harmful if swallowed.

H315 - Causes skin irritation.

H317 - May cause an allergic skin reaction.

H319 - Causes serious eye irritation.

H335 - May cause respiratory irritation.

H336 - May cause drowsiness or dizziness.

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

P264 - Wash face, hands and any exposed skin thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

P280 - Wear protective gloves, eye protection and face protection

P321 - Specific treatment (see supplemental first aid instructions on this label)

P330 - Rinse mouth

P501 - Dispose of contents and container in accordance with local, regional, national, and international regulations as applicable

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P337 + P313 - If eye irritation persists: Get medical advice/attention

### 2.3. Other hazards

No information available.

PBT & vPvB

This mixture contains no substance considered to be persistent, bioaccumulating or toxic (PBT). This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

Endocrine Disruptor Information

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

[ELL PEACH (1007/2006) Article 50(1) ELL PEACH (1007/2006)

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

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Cetirizine Hydrochloride	-	-
(RS)-1-[(4-chlorophenyl)phenylmethyl)piperazine	-	-

## **SECTION 3: Composition/information on ingredients**

#### 3.1 Substances

Not applicable

#### 3.2 Mixtures

**Chemical nature** 

Mixture of organic compounds.

Chemical name	Weight-%	REACH registration number	EC No. (Index No.)		Specific concentration limit (SCL)	M-Factor	M-Factor (long-ter m)	Notes
Cetirizine Hydrochloride 83881-52-1	80 - 100	-	620-533-8	Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) STOT SE 3 (H335) STOT SE 3 (H336)	-	-	-	-
2-[4-[(RS)-4-chloroph enyl)phenylmethyl]pip erazin-1-yl]ethanol		-	-	Acute Tox. 4 (H302) Acute Tox. 4 (H332)	-	-	-	-
(RS)-2-[4-[(4-chlorop henyl)phenylmethyl]pi perazin-1-yl]acetic acid	1 - <3	-	-	Acute Tox. 4 (H302) Acute Tox. 4 (H332)	-	-	-	-
(RS)-1-[(4-chlorophe nyl)phenylmethyl)pip erazine 303-26-4	1 - <3	-	206-137-4	Skin Irrit. 2 (H315) Eye Dam. 1 (H318) Skin Sens. 1 (H317) Repr. 2 (H361)	-	-	-	-

<sup>-</sup> Substances contained in this mixture with No registration number are under the REACH threshold in Article 6(1) and not subject to the registration requirements according to REACH Title II

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

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#### 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		Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapour - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Cetirizine Hydrochloride 83881-52-1	365	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. 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** May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a

doctor. Wash off immediately with soap and plenty of water for at least 15 minutes.

**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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**Symptoms** Itching. Rashes. Hives. 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.

**Effects of Exposure** No information available.

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

**Note to doctors**May cause sensitisation in susceptible persons. 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

Product is or contains a sensitiser. May cause sensitisation by skin contact.

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 Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal

protective equipment as required. Evacuate personnel to safe areas. Keep people away

from and upwind of spill/leak.

**Other information** Refer to protective measures listed in Sections 7 and 8.

**For emergency responders** Use personal protection recommended in Section 8.

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British
Pharmacopoeia

### Quality standards

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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

**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. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Take off

contaminated clothing and wash it before reuse. Avoid breathing vapours or mists.

**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, 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. Keep out of the reach

of children.

Storage class (TRGS 510) LGK 11.

7.3. Specific end use(s)

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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 regulatory bodies.

Derived No Effect Level (DNEL) - Workers No information available

Derived No Effect Level (DNEL) - General Public 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).

**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 nitrile 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

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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

Appearance Solid Physical state Solid

Colourwhite, to, off-whiteOdourNo information availableOdour thresholdNo information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

Melting point / freezing pointNo data availableNone knownInitial boiling point and boiling rangeNo data availableNone knownFlammabilityNo data availableNone knownFlammability Limit in AirNone known

**Upper flammability or explosive** No data available

limits

**Lower flammability or explosive** No data available

limits

Flash pointNo data availableNone knownAutoignition temperatureNo data availableNone known

Decomposition temperature No data available None known None known

SADT (°C) No data available None known No data available рH None known pH (as aqueous solution) No data available None known Kinematic viscosity No data available None known Dynamic viscosity No data available None known No data available Water solubility None known No data available Solubility(ies) None known No data available None known Partition coefficient No data available None known Vapour pressure

Relative density

Bulk density

Liquid Density

No data available

No data available

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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None known



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9.2. Other information

9.2.1. Information with regards to physical hazard classes

No information available

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** Strong acids. Strong bases. Strong oxidising agents.

10.6. Hazardous decomposition products

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

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**Inhalation** Specific test data for the substance or mixture is not available. 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** May cause sensitisation by skin contact. Specific test data for the substance or mixture is

not available. Repeated or prolonged skin contact may cause allergic reactions with

susceptible persons. (based on components). Causes skin irritation.

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

gastrointestinal irritation, nausea, vomiting and diarrhoea. Harmful if swallowed. (based on

components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Itching. Rashes. Hives. Redness. May cause redness and tearing of the eyes. Inhalation of

high vapour concentrations may cause symptoms like headache, dizziness, tiredness,

nausea and vomiting.

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

Acute toxicity Harmful if swallowed.

Numerical measures of toxicity

The following ATE values have been calculated for the mixture:

ATEmix (oral) 370.70 mg/kg ATEmix (dermal) 99,999.00 mg/kg ATEmix (inhalation-gas) 99,999.00 ppm ATEmix (inhalation-vapour) 99,999.00 mg/l ATEmix (inhalation-dust/mist) 75.00 mg/l

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Cetirizine Hydrochloride	= 365 mg/kg (Rat)	-	-
(RS)-1-[(4-chlorophenyl)phenylmethyl)	> 2000 mg/kg (Rat)	-	-
piperazine			

**Skin corrosion/irritation**Classification based on data available for ingredients. Causes skin irritation.

Serious eye damage/eye irritation Classification based on data available for ingredients. Causes serious eye irritation.

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**Respiratory or skin sensitisation** May cause an allergic skin reaction.

**Germ cell mutagenicity** Based on available data, the classification criteria are not met.

**Carcinogenicity** Based on available data, the classification criteria are not met.

**Reproductive toxicity** Based on available data, the classification criteria are not met.

**STOT - single exposure** May cause respiratory irritation. May cause drowsiness or dizziness.

**STOT - repeated exposure**Based on available data, the classification criteria are not met.

Aspiration hazard Based on available data, the classification criteria are not met.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

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

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**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**Based on available data, the classification criteria are not met.

12.6. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

12.7. Other adverse effects

Other adverse effects No information available.

**PMT or vPvM properties**Based on available data, the classification criteria are not met.

### **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**

#### 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
Not regulated
Not regulated
Not regulated
Not applicable

14.6 Special precautions for user

Special Provisions None

**IMDG** 

14.1 UN number or ID number
Not regulated
Not regulated
Not regulated

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14.3 Transport hazard class(es)
 14.4 Packing group
 14.5 Environmental hazards
 Not regulated
 Not applicable

14.6 Special precautions for user Special Provisions

14.7 Maritime transport in bulk according to IMO instruments

No information available

RID

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 applicable

14.6 Special precautions for user

Special Provisions 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 applicable

14.6 Special precautions for user

Special Provisions None

ADN

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 hazard

Not regulated
Not regulated
Not regulated
Not regulated
Not applicable

14.6 Special precautions for user

Special Provisions None

### SECTION 15: Regulatory information

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

**National regulations** 

Germany

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Water hazard class (WGK) **Chemical Prohibition Ordinance**  slightly hazardous to water (WGK 1) Not applicable

(ChemVerbotsV)

Not applicable **TRGS 905** 

### **Switzerland**

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018 Not applicable SC 11/13 Storage of Hazardous Material Class B WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20 Major Accidents Ordinance SR 814.012 Not applicable

#### **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) 2024/590

Not applicable

### **International Inventories**

**TSCA** U.S. INVENTORY (TSCA): Not listed on inventory. For purposes of 40 CFR 720.36, this

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product is for Research and Development (R&D) Use Only

DSL/NDSL
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 Chemicals Inventory

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 any hazard and/or precautionary statements referred to under Sections 2-15

H302 - Harmful if swallowed

H315 - Causes skin irritation

H317 - May cause an allergic skin reaction

H318 - Causes serious eye damage

H319 - Causes serious eye irritation

H332 - Harmful if inhaled

H335 - May cause respiratory irritation

H336 - May cause drowsiness or dizziness

H361 - Suspected of damaging fertility or the unborn child

P264 - Wash face, hands and any exposed skin thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell

P330 - Rinse mouth

P501 - Dispose of contents and container in accordance with local, regional, national, and international regulations as applicable

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P280 - Wear protective gloves

P302 + P352 - IF ON SKIN: Wash with plenty of water and soap

P321 - Specific treatment (see supplemental first aid instructions on this label)

P332 + P313 - If skin irritation occurs: Get medical advice/attention

P362 + P364 - Take off contaminated clothing and wash it before reuse

P280 - Wear protective gloves, protective clothing, eye protection and face protection

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P337 + P313 - If eye irritation persists: Get medical advice/attention

P261 - Avoid breathing dust, fume, gas, mist, vapors and spray

P272 - Contaminated work clothing should not be allowed out of the workplace

P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention

P271 - Use only outdoors or in a well-ventilated area

P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing

P312 - Call a POISON CENTER or doctor if you feel unwell

P403 + P233 - Store in a well-ventilated place. Keep container tightly closed

P405 - Store locked up

#### Legend

Logona		
ACGIH	American Conference of Governmental Industrial Hygienists	
AIDII	Italian Association of Industrial Hygienists	
ADN	Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Europe)	
ADR	Agreement concerning the International Carriage of Dangerous Goods by Road (Europe)	
AIIC	Australian Inventory of Industrial Chemicals	
ATE	Acute Toxicity Estimate	
ASTM	American Society for the Testing of Materials	
bar	Biological Reference Values for Chemical Compounds in the Work Area	
BAT	Biological tolerance values for occupational exposure	
BEL	Biological exposure limits	
bw	Body weight	
Ceiling	Maximum limit value	
CLP	Classification, Labelling and Packaging Regulation; Regulation (EC) No 1272/2008	
CMR	Carcinogen, Mutagen or Reproductive Toxicant	
DFG	German Research Foundation	
DOT	Department of Transportation (United States)	
DSL	Domestic Substances List (Canada)	
ECHA	European Chemicals Agency	
EC Number	European Community number	
EmS	Emergency Schedule	
ENCS	Existing and New Chemical Substances (Japan)	
EPA	Environmental Protection Agency	
EWC	European Waste Codes	

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GHS	Globally Harmonized System
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IBC	International Code for the Construction and Equipment of Ships carrying Dangerous
	Chemicals in Bulk
ICAO	International Civil Aviation Organisation
IECSC	Inventory of Existing Chemical Substances in China
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
ISO	International Organisation for Standardisation
KECI	Korean Existing Chemicals Inventory
LC50	Lethal Concentration to 50% of a test population
LD50	Lethal Dose to 50% of a test population (Median Lethal Dose)
MAL	Measuring Technical Hygienic Air Needs
MARPOL	International Convention for the Prevention of Pollution from Ships
MDLPS	Ministry of Labour and Social Policy
n.o.s.	Not Otherwise Specified
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NOELR	No Observable Effect Loading Rate
NZIoC	New Zealand Inventory of Chemicals
OECD	Organization for Economic Cooperation and Development
OEL	Occupational exposure limits
PBT	Persistent, Bioaccumulative and Toxic substance
PICCS	Philippines Inventory of Chemicals and Chemical Substances
PMT	Persistent, Mobile and Toxic
PPE	Personal protective equipment
QSAR	Quantitative Structure Activity Relationship
REACH	Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) Regulation (EC 1907/2006)
RID	Agreement concerning the International Carriage of Dangerous Goods by Rail (Europe)
SADT	Self-Accelerating Decomposition Temperature
SAR	Structure-activity relationship
SDS	Safety Data Sheet
SL	Surface Limit
STEL	Short Term Exposure Limit
STOT RE	Specific target organ toxicity - Repeated exposure
STOT SE	Specific target organ toxicity - Single exposure
SVHC	Substance of very high concern
TCSI	Taiwan Chemical Substance Inventory
TDG	Transport of Dangerous Goods (Canada)

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### CAT 1081 - cetirizine impurity standard

TRGS	Technical Rule for Hazardous Substances	
TSCA	Toxic Substances Control Act (United States)	
TWA	Time-Weighted Average	
UN	United Nations	
VOC	Volatile organic compounds	
vPvB	Very Persistent and Very Bioaccumulative	
vPvM	Very Persistent and Very Mobile	
Sen+	Sensitiser	
Sk*	Skin designation	
**	Hazard 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			
Reproductive toxicity	Calculation method			
STOT - single exposure	Calculation method			
STOT - repeated exposure	Calculation method			
Chronic aquatic toxicity	Calculation method			
Acute 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)

European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA\_RAC)

European Chemicals Agency (ECHA) (ECHA\_API)

**Environmental Protection Agency** 

Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

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U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

National Institute of Technology and Evaluation (NITE)

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)

U.S. 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 30-Jun-2025

Reason for revision Classification Gloves Material

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

Disclaimer

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**End of Safety Data Sheet** 

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