

SAFETY DATA SHEETS

This SDS packet was issued with item:

078942099

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078949378

SAFETY DATA SHEET

Issuing Date 11-Jul-2019

Revision Date 11-Jul-2019

Revision Number 2

NGHS / English



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1. IDENTIFICATION

Product identifier

Product Name Cetirizine Hydrochloride Tablets 10 mg

Other means of identification

Product Code(s) 1528229

Recommended use of the chemical and restrictions on use

Recommended Use Allergy Relief (Antihistamine)

Restrictions on use No information available

Details of the supplier of the safety data sheet

Supplier Identification Aurohealth LLC

Address 2572 Brunswick Pike
Lawrenceville
NJ
08648
US

Telephone Phone: 732-839-9400
Fax: 609-771-4244

E-mail ktajudeen@aurohealth.com

Emergency telephone number

Company Emergency Phone Number 732-266-7357

2. HAZARDS IDENTIFICATION

Classification

Acute toxicity - Oral	Category 4
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Appearance White**Physical state** Solid**Odor** No information available**GHS Label elements, including precautionary statements****Warning****Hazard statements**

Harmful if swallowed

**Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling

Do not eat, drink or smoke when using this product

Precautionary Statements - Response**Ingestion**

IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell

Rinse mouth

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information**Unknown acute toxicity** 80 % of the mixture consists of ingredient(s) of unknown toxicity

66 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

80 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity

80 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)

80 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)

80 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

3. COMPOSITION/INFORMATION ON INGREDIENTS**Substance**

Not applicable.

Mixture

Chemical name	CAS No.	Weight-%	Hazardous Material Information Review Act registry number (HMIRA registry #)	Date HMIRA filed and date exemption granted (if applicable)
Microcrystalline cellulose	9004-34-6	20	-	-

Magnesium stearate	557-04-0	3	-	-
Titanium dioxide	13463-67-7	1.25	-	-

4. FIRST AID MEASURES

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 physician.
Skin contact	Wash skin with soap and water.
Ingestion	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician.

Most important symptoms and effects, both acute and delayed

Symptoms	No information available.
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Indication of any immediate medical attention and special treatment needed

Note to physicians	Treat symptomatically.
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5. FIRE-FIGHTING MEASURES

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.
Specific hazards arising from the chemical	No information available.
Hazardous Combustion Products	Carbon oxides.
Explosion Data	
Sensitivity to Mechanical Impact	None.
Sensitivity to Static Discharge	None.
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions	Avoid contact with eyes.
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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 Pick up and transfer to properly labeled containers.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters**Exposure Limits**

Chemical name		ACGIH TLV	OSHA PEL	NIOSH IDLH
Microcrystalline cellulose 9004-34-6		TWA: 10 mg/m ³	TWA: 15 mg/m ³ total dust TWA: 5 mg/m ³ respirable fraction (vacated) TWA: 15 mg/m ³ total dust (vacated) TWA: 5 mg/m ³ respirable fraction	TWA: 10 mg/m ³ total dust TWA: 5 mg/m ³ respirable dust
Magnesium stearate 557-04-0		TWA: 10 mg/m ³	-	
Titanium dioxide 13463-67-7		TWA: 10 mg/m ³	TWA: 15 mg/m ³ total dust (vacated) TWA: 10 mg/m ³ total dust	IDLH: 5000 mg/m ³
Chemical name	Alberta	British Columbia	Ontario TWA/EV	Quebec
Microcrystalline cellulose 9004-34-6	TWA: 10 mg/m ³	TWA: 10 mg/m ³ TWA: 3 mg/m ³	TWA: 10 mg/m ³	TWA: 10 mg/m ³
Magnesium stearate 557-04-0	TWA: 10 mg/m ³	TWA: 10 mg/m ³	TWA: 10 mg/m ³	
Titanium dioxide 13463-67-7	TWA: 10 mg/m ³	TWA: 10 mg/m ³ TWA: 3 mg/m ³	TWA: 10 mg/m ³	TWA: 10 mg/m ³

Other Exposure Guidelines Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

Appropriate engineering controls

Engineering controls Showers

Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection	No special protective equipment required.
Skin and body protection	No special protective equipment required.
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	Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical and Chemical Properties

Physical state	Solid
Appearance	White
Odor	No information available
Color	No information available
Odor Threshold	Not applicable

<u>Property</u>	<u>Values</u>	<u>Remarks</u>	<u>Method</u>
pH	No data available	None known	
Melting / freezing point	No data available	None known	
Boiling point / boiling range	No data available	None known	
Flash Point	No data available	None known	
Evaporation Rate	No data available	None known	
Flammability (solid, gas)	No data available	None known	
Flammability Limit in Air		None known	
Upper flammability limit	No data available		
Lower flammability limit	No data available		
Vapor pressure	No data available	None known	
Vapor density	No data available	None known	
Relative density	No data available	None known	
Water Solubility	Decomposes		
Solubility(ies)	No data available	None known	
Partition coefficient: n-octanol/water	0		
Autoignition temperature	No data available	None known	
Decomposition temperature	No data available	None known	
Kinematic viscosity	No data available	None known	
Dynamic viscosity	No data available	None known	

Other Information

Explosive properties	No information available
Oxidizing properties	No information available
Softening Point	No information available
Molecular Weight	No information available
VOC Content (%)	No information available
Liquid Density	No information available
Bulk Density	No information available
Particle Size	No information available
Particle Size Distribution	No information available

10. STABILITY AND REACTIVITY

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of Hazardous Reactions	None under normal processing.
Hazardous Polymerization	Hazardous polymerization does not occur.
Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.
Hazardous Decomposition Products	Carbon oxides.

11. TOXICOLOGICAL INFORMATION

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.
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. Harmful if swallowed. (based on components).

Information on toxicological effects

Symptoms	No information available.
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Numerical measures of toxicity

Acute Toxicity

The following values are calculated based on chapter 3.1 of the GHS document .

ATEmix (oral)	1,235.40 mg/kg
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Unknown acute toxicity	80 % of the mixture consists of ingredient(s) of unknown toxicity
	66 % of the mixture consists of ingredient(s) of unknown acute oral toxicity
	80 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity
	80 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
	80 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)
	80 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Microcrystalline cellulose	> 5 g/kg (Rat)	> 2 g/kg (Rabbit) > 2000 mg/kg (Rabbit)	> 5800 mg/m ³ (Rat) 4 h
Titanium dioxide	> 10000 mg/kg (Rat)	-	-

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

Skin corrosion/irritation	No information available.
Serious eye damage/eye irritation	No information available.
Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	Classification based on data available for ingredients. This product contains titanium dioxide in a non-respirable form. Inhalation of titanium dioxide is unlikely to occur from exposure to this product.

The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical name	ACGIH	IARC	NTP	OSHA
Titanium dioxide 13463-67-7	-	Group 2B	-	X

Legend

IARC (International Agency for Research on Cancer)

Group 2B - Possibly Carcinogenic to Humans

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

X - Present

Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity	The environmental impact of this product has not been fully investigated.
Persistence and Degradability	No information available.
Bioaccumulation	There is no data for this product.
Mobility	No information available.
Other adverse effects	No information available.

13. DISPOSAL CONSIDERATIONS

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.



California Waste Codes 311

14. TRANSPORT INFORMATION

DOT
Proper Shipping Name NOT REGULATED
Hazard Class NON-REGULATED
N/A

TDG Not regulated

MEX Not regulated

ICAO Not regulated

IATA
Proper Shipping Name Not regulated
Hazard Class NON REGULATED
N/A

IMDG/IMO
Hazard Class Not regulated
N/A

RID Not regulated

ADR Not regulated

ADN Not regulated

15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture****International Regulations**

Ozone-depleting substances (ODS) Not applicable

Persistent Organic Pollutants Not applicable

Export Notification requirements Not applicable

International Inventories

TSCA	Contact supplier for inventory compliance status.
DSL/NDSL	Contact supplier for inventory compliance status.
EINECS/ELINCS	Contact supplier for inventory compliance status.
ENCS	Contact supplier for inventory compliance status.
KECL	Contact supplier for inventory compliance status.
PICCS	Contact supplier for inventory compliance status.
AICS	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
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications. Under the amended regulations at 40 CFR 370, EPCRA 311/312 Tier II reporting for the 2017 calendar year will need to be consistent with updated hazard classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

US State Regulations

California Proposition 65

This product contains the following Proposition 65 chemicals.

Chemical name	California Proposition 65
Titanium dioxide - 13463-67-7	Carcinogen

U.S. State Right-to-Know Regulations

This product may contain substances regulated by state right-to-know regulations.

Chemical name	New Jersey	Massachusetts	Pennsylvania	Rhode Island	Illinois
Microcrystalline cellulose 9004-34-6	X	X	X	-	X
Titanium dioxide 13463-67-7	X	X	X		

16. OTHER INFORMATION

NFPA	Health hazards 1	Flammability 0	Instability 0	Physical and Chemical Properties -
HMIS	Health hazards 1	Flammability 0	Physical hazards 0	Personal Protection X

Prepared By

Product Stewardship
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 Latham, NY 12110
 1-800-572-6501



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Revision Note	No information available

Disclaimer

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End of Safety Data Sheet