

This safety data sheet was created pursuant to the requirements of:
US OSHA Hazard Communication Standard 1910.1200, Canada WHMIS 2015

Issue Date 17-Dec-2013

Revision Date 19-Jul-2023

Version 2

1. IDENTIFICATION

Product identifier

Product Name Zyrtec Orally Disintegrating Tablets / Zyrtec Allergy Orally Disintegrating Cetirizine HCl Tablet 10mg / Reactine Allergy Extra Strength Rapid Dissolve Tablet - Cetirizine Hydrochloride

Other means of identification

Safety Data Sheet Code MCNEIL-NA-C-1263/JJI-CA-043-01

Reference document No. PR-010277, PR-013766, C-1263, CA-043-01, TAB2296361A-001

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended Use This SDS is only intended for occupational use and not for consumer use (see packaging label and or insert). This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished product. For health and safety information during manufacturing of this product, please refer to the appropriate SDS for each component.

Uses advised against Use according to package label instructions.

Details of the supplier of the safety data sheet

United States of America Johnson & Johnson Consumer Inc.
McNeil Consumer Healthcare Division
7050 Camp Hill Road, Fort Washington, PA 19034
215-273-7000

Canada Johnson & Johnson Inc.
88 McNabb Street, Markham, Ontario, Canada
L3R 5L2
Canada 1-877-223-9807

Emergency telephone number

24 Hour Emergency Phone Number: Call 3E company at 1-877-236-9871. Provide Technician with the following tracking code: 2277, Hours Open: 24 hours emergency assistance.

Restrictions on emergency number: None

2. HAZARDS IDENTIFICATION

Classification

Regulatory information This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200), Canada WHMIS 2015

Label elements

Signal word:
None

Hazard statements
None

Precautionary Statements - Prevention
None

Precautionary Statements - Response

Eyes: None
Skin: None
Inhalation: None
Ingestion: None
Fire: None.
Spill: None

Precautionary Statements - Storage
None

Precautionary Statements - Disposal
None

Other hazards
None known

Numerical measures of toxicity The acute toxicity of all ingredients has been evaluated for all applicable exposure routes associated with the product's intended use.

3. COMPOSITION/INFORMATION ON INGREDIENTS

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	3-7	-	-
Magnesium Stearate	557-04-0	1 - 5	-	-
Cetirizine Hydrochloride USP	83881-52-1	1 - 5	-	-
Citric Acid	77-92-9	1 - 5	-	-
Limonene	5989-27-5	0.1 - 1	-	-

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

Description of first aid measures

Inhalation If the product is crushed: Do not breathe dust. IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. If symptoms persist, call a physician.

Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If symptoms persist, call a physician.
Skin contact	If skin irritation or rash occurs: Get medical advice/attention.
Ingestion	May cause drowsiness or dizziness. See clinical drug insert information for treatment of overdose. Call a POISON CENTER or doctor if you feel unwell.

Most important symptoms and effects, both acute and delayed

Symptoms	May cause drowsiness or dizziness. Ingestion above therapeutic dose: May cause severe drowsiness.
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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.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No information available.
Hazardous combustion products	None known.
Explosion data	
Sensitivity to Mechanical Impact	None.
Sensitivity to Static Discharge	None.
Special protective equipment for fire-fighters	As in any fire, wear self-contained breathing apparatus pressure-demand and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions	In the event of an accidental release, the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate.
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Environmental precautions

Environmental precautions	Avoid release to the environment.
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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. Clean contaminated surface thoroughly.
Methods for cleaning up	Pick up and transfer to properly labeled containers.
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling No special precautions are needed in handling this material.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep at temperatures between 20 %25 %68 and 77 °C (20 %25 %68 3 and 20 %25 %68 4 °F). Store in accordance with: Product packaging.

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/m³	TWA: 15 mg/m³ total dust TWA: 5 mg/m³ respirable fraction (vacated) TWA: 15 mg/m³ total dust (vacated) TWA: 5 mg/m³ respirable fraction	TWA: 10 mg/m³ total dust TWA: 5 mg/m³ respirable dust	
Magnesium Stearate 557-04-0	TWA: 10 mg/m³ inhalable particulate matter TWA: 3 mg/m³ respirable particulate matter TWA: 10 mg/m³ inhalable particulate matter except stearates of toxic metals TWA: 3 mg/m³ respirable particulate matter except stearates of toxic metals	-	-	
Chemical name	Alberta	British Columbia	Ontario	Quebec
Microcrystalline Cellulose 9004-34-6	TWA: 10 mg/m³	TWA: 10 mg/m³ TWA: 3 mg/m³	TWA: 10 mg/m³	TWA: 10 mg/m³
Magnesium Stearate 557-04-0	-	TWA: 10 mg/m³ TWA: 3 mg/m³	TWA: 10 mg/m³ TWA: 3 mg/m³	TWA: 10 mg/m³

Other Information

ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value. NIOSH IDLH: National Institute for Occupational Safety and Health - Immediately Dangerous to Life or Health. OSHA PEL: Occupational Safety and Health Administration - Permissible Exposure Limits. TWA (Time-Weighted Average). 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 All personal protective equipment should be based on a risk assessment. Consult an Environmental Health and Safety Expert if necessary.

Individual protection measures, such as personal protective equipment

Eye/face protection None under normal use conditions. Avoid contact with eyes.

Hand protection None under normal use conditions.

Skin and body protection	None under normal use conditions.
Respiratory protection	None under normal use conditions.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Solid
Appearance	tablet
Color	white to Off-white
Odor	No information available
Odor threshold	No information available

Property	Values	Remarks • Method
pH	No data available	
Melting point / freezing point	No data available	
Initial boiling point and boiling range	No data available	
Flash point	No data available	
Evaporation rate	No data available	
Flammability (solid, gas)	No data available	
Flammability Limit in Air		
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	
Vapor density	No data available	
Relative density	No data available	
Water solubility	No data available	
Solubility in other solvents	No data available	
Partition coefficient	No data available	
Autoignition temperature	No data available	
Hyphen	No data available	
Kinematic viscosity	No data available	
Dynamic viscosity	No data available	
Explosive properties	No information available	
Oxidizing properties	No information available	

Other information

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

10. STABILITY AND REACTIVITY

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.

Conditions to avoid None known based on information supplied.

Incompatible materials None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation	If the product is crushed: Do not breathe dust. May cause irritation of respiratory tract.
Eye contact	If the product is crushed: Contact with eyes may cause irritation.
Skin contact	If the product is crushed: May cause skin irritation.
Ingestion	May cause drowsiness or dizziness. Ingestion above therapeutic dose: May cause severe drowsiness.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms May cause drowsiness or dizziness. Ingestion above therapeutic dose: May cause severe drowsiness.

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

Skin corrosion/irritation	If the product is crushed: May cause skin irritation.
Serious eye damage/eye irritation	If the product is crushed: May be irritating to the eyes.
Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.
Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Other adverse effects	Ingestion above therapeutic dose: May cause severe drowsiness.
Aspiration hazard	No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Citric Acid 77-92-9	-	LC50: =1516mg/L (96h, Lepomis macrochirus)	-	-

Limonene 5989-27-5	-	LC50: 0.619 - 0.796mg/L (96h, Pimephales promelas) LC50: =35mg/L (96h, Oncorhynchus mykiss)	-	-
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Persistence and degradability No information available.

Bioaccumulation

Component Information

Chemical name	Partition coefficient
Citric Acid 77-92-9	-1.72
Limonene 5989-27-5	4.38

Other adverse effects No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Waste from residues/unused products Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated packaging Do not reuse empty containers. Disposal should be in accordance with applicable regional, national and local laws and regulations.

14. TRANSPORT INFORMATION

Note: The information provided in section 14 is intended to provide the user with guidance only on the proper shipping requirements for the finished product in the final packaging - NOT BULK. Transport classifications may vary by container volume and may be influenced by regional or country variations in regulations. It is the responsibility of the Shipper to ensure this product is shipped in accordance with all applicable regulations. Consult your company's Hazardous/Dangerous Goods Expert for information specific to your situation.

DOT

UN/ID no	Not applicable
Proper shipping name	Not applicable
Transport hazard class(es)	Not applicable
Packing Group	Not applicable
Environmental Hazards	Not applicable
Special Provisions	Not applicable

TDG

UN/ID no	Not applicable
Proper shipping name	Not applicable
Transport hazard class(es)	Not applicable
Packing Group	Not applicable

Environmental Hazards Not applicable
Special Provisions Not applicable

IMDG

UN number or ID number Not applicable
UN proper shipping name Not applicable
Transport hazard class(es) Not applicable
Packing Group Not applicable
Marine pollutant Not applicable
Special Provisions Not applicable

ICAO, TI, IATA

UN number or ID number Not applicable
Proper shipping name Not applicable
Transport hazard class(es) Not applicable
Packing group Not applicable
Environmental hazards Not applicable
Special Provisions Not applicable

Transport in bulk according to Annex II of MARPOL and the IBC Code Not applicable

15. REGULATORY INFORMATION

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

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

See Section 2 for any applicable physical or health hazard categories.

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

U.S. State Right-to-Know Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
Microcrystalline Cellulose 9004-34-6	X	X	X
Silica 7631-86-9	-	X	X

16. OTHER INFORMATION

Issue Date 17-Dec-2013

Revision Date 19-Jul-2023

Revision Note SDS sections updated: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16.

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End of Safety Data Sheet