

Product Name:

CLARITHROMYCIN COATED PARTICLES

Issued:

Jun-19-2015



SAFETY DATA SHEET

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product Identifier

Product Name: CLARITHROMYCIN COATED PARTICLES

Synonyms: Clarithromycin Coated Particles; CLARITHROMYCIN COATED PARTICLES (F.E. 2); CLARI AQU. COATED PARTICLES, 30-100 MESH, AI (API) (F.E. 2); CLARI COATED PARTICLES 30-80 MESH, FOR AI (AUSTRALIA) (F.E. 2); CLARITHROMYCIN COATED PARTICLES (ABBOTT PARK) (F.E. 2); CLARITHROMYCIN AQUEOUS COATED PARTICLES, 30-100 MESH (AP) (F.E. 2); CLARITHROMYCIN AQUEOUS COATED PARTICLES 30-100 MESH (PR); CLARI COATED PARTICLES 30-80 MESH (ITALY) (API); Claritromicina Particelle Ricop

Drug Code Number: 12234: 20935: 29809: 30589: 38351:39858: 50883: 54585: 65521: 66755: 65522: 74159: 80944: 93547

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended use: Pharmaceuticals

1.3 Details of the supplier of the safety data sheet

Supplier: AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064
USA
+1-847-932-7900

Customer Service Telephone: 1-800-255-5162 (US and Canada only)
+1-847-937-7433

E-mail Address: AbbVie.SDS@abbvie.com

1.4 Emergency telephone number

Emergency Telephone: CHEMTREC: 1(800) 424-9300 (in USA and Canada)
or +1-703-527-3887 (international)

Section 2. Hazards identification

2.1 Classification of the substance or mixture

Regulation (EC) No 1272/2008

Acute oral toxicity Category 4

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Indication of danger: Exempt

2.2 Label elements

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Signal Word: Warning

Hazard Statements: H302 - Harmful if swallowed

2.3 Other hazards

Not determined

Section 3. Composition/information on ingredients

Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Hypromellose phthalate 9050-31-1	20-40	NA		Not Hazardous*	No data available
Clarithromycin 81103-11-9	20-40	NA		Acute Oral Cat. 4 (H302)	No data available
Carbomers EP	15-30	NA		Not Hazardous*	No data available
Povidone	1-10	NA		Not Hazardous*	No data available
Castor Oil 8001-79-4	1-10	Present		Not Hazardous*	No data available

Not Hazardous* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

For the full text of the R-phrases mentioned in this Section, see Section 16

For the full text of the H-Statements mentioned in this Section, see Section 16

Section 4. First aid measures

4.1 Description of first aid measures

Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

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Protection of First-aiders: Use personal protective equipment

4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms: None known from occupational exposure. Clinical data suggests the following: diarrhea, nausea, vomiting, headaches, abnormal liver function, abnormal kidney function, gastrointestinal upset, taste alterations.

Medical Conditions Aggravated by Exposure: None known from occupational exposure. Data suggest any pre-existing ailments in the following organs: kidney, liver, gastrointestinal system. Hypersensitivity to the material and/or similar materials. Pregnancy.

4.3 Indication of any immediate medical attention and special treatment needed

Notes To Physician: Treat symptomatically

Additional Information: Clarithromycin : Pseudomembranous colitis has been reported with use of nearly all antibiotics including clarithromycin.

Section 5. Firefighting measures

5.1 Extinguishing Media

Suitable Extinguishing Media: Use extinguishing agent suitable for type of surrounding fire

Unsuitable Extinguishing Media: Not determined

5.2 Special hazards arising from the substance or mixture

Special Exposure Hazards: Not determined

5.3 Advice for firefighters

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus and full protective gear

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal Precautions: For personal protection see section 8.

6.2. Environmental precautions

Environmental Precautions: Contain material and prevent release to waterways or soil.

6.3. Methods and material for containment and cleaning up

Methods for Cleaning Up: Recover product and place in an appropriate container for disposal.

6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

Section 7. Handling and storage

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7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions.

7.3. Specific end use(s)

Recommended use: Pharmaceuticals

Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

Chemical Name	Employee Exposure Limit	Skin Notation
Hypromellose phthalate 9050-31-1	Not Applicable	None
Clarithromycin 81103-11-9	830 mcg/m ³	None
Carbomers EP	Not Applicable	None
Povidone	Not Applicable	None
Castor Oil 8001-79-4	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Hypromellose phthalate 9050-31-1	10 mg/m ³ total dust 3 mg/m ³ respirable dust				
Povidone	10 mg/m ³ for nuisance dust; 3 mg/m ³ respirable particulate				

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Carbomers EP			0.05 mg/m ³ (TWA) 0.05 mg/m ³ (STEL)	

8.2. Exposure controls

Engineering Controls: Local exhaust ventilation as necessary to maintain exposures to within applicable limits.

Respiratory Protection: When handling the bulk formulation, an approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

Eyes: Wear eye protection appropriate to handling activities.

Gloves: Impervious gloves.

Other PPE Data: Wear appropriate body coverings if contact may occur.

Environmental Exposure Controls: Not determined

Section 9. Physical and chemical properties

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9.1. Information on basic physical and chemical properties

Appearance:	White to off-white Granules
Odor:	Not determined.
Odor Threshold:	Not determined
pH:	Not determined.
Boiling Pt. @ 760 mm Hg (°C):	Not determined.
Melting/Freezing Point (°C):	Not determined
Flash Point (°C):	Not determined.
Evaporation Rate at 20°C:	Not determined.
Flammability (Solid):	Not determined.
Lower Explosive Limit:	Not determined.
Upper Explosive Limit:	Not determined.
Vapor Pressure (mm Hg):	Not determined.
Vapor Density (Air = 1):	Not determined.
Specific Gravity:	Not determined.
Solubility(ies):	Not determined.
Partition coefficient:	Not determined.
n-octanol/water	
Autoignition Temp. (°C):	Not determined.
Decomposition temperature (°C):	Not determined.
Viscosity (centipoise):	Not determined.
Explosion Severity:	Not determined.
Oxidizer Properties:	Not determined.

9.2. Other information

Not determined

Section 10. Stability and reactivity

10.1. Reactivity

Not determined

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

Hazardous reactions: Not determined.

10.4. Conditions to avoid

Not determined.

10.5 Incompatible materials

Not determined

10.6 Hazardous decomposition products

Not determined

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Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: No
Dermal: Not determined.
Inhalation: Yes

Acute Toxicity - Oral: Data for component (s) given below. Non-toxic by ingestion.

Chemical Name	Acute Test	Value	Units	Species
Hypromellose phthalate 9050-31-1	LD50 >	15000	mg/kg	Rats
Clarithromycin 81103-11-9	LD50 >=	1230	mg/kg	Rats Mice
Carbomers EP	LD50 >	10,000	mg/kg	Rats
Povidone	LD50 = LD50 >	100000 1040 40000	mg/kg	Rats Rabbits Mice

Acute Toxicity - Dermal: Not determined.

Chemical Name	Acute Test	Value	Units	Species
Carbomers EP	LD50 >	5,000	mg/kg	Rabbits

Acute Toxicity - Inhalation: Not determined.

Corrosivity: Not determined.

Dermal Irritation: Not determined.

Eye Irritation: Not determined.

Sensitization: Not determined.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: In animal testing, target organs include: liver, kidneys, eyes, testes, central nervous system, gastrointestinal tract.

Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
Clarithromycin 81103-11-9	Liver Kidney Eyes Gastrointestinal Tract	Monkeys Dogs Rats	100 100 600	mg/kg	Oral	28 days 1 Month 30 days

Clarithromycin : Animal studies have revealed liver injury, kidney injury, testicular atrophy, corneal opacity and lymphoid depletion at dosages of 2 to 12 times the maximum clinical dose.

Reproductive Effects: In animals adverse reproductive effects include: fetal abnormalities.

Chemical Name	Species	Dosage	Units	Route	Duration
Clarithromycin 81103-11-9	Mice Rats	1000 160	mg/kg	Oral	During Gestation

Clarithromycin : In some reproductive studies in animals, clarithromycin has produced embryo-fetal toxicity and /or fetal abnormalities at dosages that produced blood levels of 2 to 17 times those at the maximum clinical dose.

Carcinogenicity: Not determined.

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Mutagenicity: Negative in mutagenicity assays.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Clarithromycin 81103-11-9	Negative	Negative	Negative	Negative

Notes to Toxicologist: Negative in six different in vitro mutagenicity assays. Weakly positive in one in vitro chromosomal aberration test and negative in another.

Aspiration hazard: Not determined

Notes:

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

Section 12. Ecological information

12.1. Toxicity

Not determined.

12.2. Persistence and degradability

Not determined.

12.3. Bioaccumulative potential

Not determined

12.4. Mobility in soil

Not determined.

12.5. Results of PBT or vPvB assessment

Chemical safety report is not required for this substance/product.

12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Notes:

1. EC50: Concentration in water that produces 50% mortality in *Daphnia* sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

Section 13. Disposal considerations

13.1 Waste treatment methods

Waste Disposal Methods: Disposal should be made in accordance with country, federal, state and local regulations.

Section 14. Transport information

ADR, DOT, ICAO/IATA, IMDG/IMO

Product Name: CLARITHROMYCIN COATED PARTICLES
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Status: Not regulated
14.1. UN Number: Not applicable
14.2. Proper shipping name: Not applicable
14.3. Hazard class: Not applicable
14.4. Packing group: Not applicable
14.5. Environmental hazard: Not applicable
14.6. Special Provisions: Not applicable
14.7. Transport in bulk Not applicable
according to Annex II of
MARPOL 73/78 and the IBC
Code:

Section 15. Regulatory Information

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

International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Hypromellose phthalate 9050-31-1	-	X	-	X	X
Clarithromycin 81103-11-9	-	-	-	Not listed.	-
Carbomers EP	-	X	X	Not listed.	X
Povidone	-	X	X	Not listed.	X
Castor Oil 8001-79-4	Present	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Hypromellose phthalate 9050-31-1	Present	-	X	X	Present	
Clarithromycin 81103-11-9	-	Present	-	-	-	HSR007090
Carbomers EP	Present	-	X	X	Present	
Povidone	Present	-	X	X	Present	
Castor Oil 8001-79-4	-	-	X	X	Present	

Legend

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

ISHL - Japan Industrial Safety and Health Law

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

Carcinogenicity Rating:

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Hypromellose phthalate	20-40	Not Listed	Not Listed	Not Listed
Clarithromycin	20-40	Not Listed	Not Listed	Not Listed
Carbomers EP	15-30	Not Listed	Not Listed	Not Listed
Povidone	1-10	Not Listed	Not Listed	Not Listed

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Castor Oil	1-10	Not Listed	Not Listed	Not Listed
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SARA 313 Information

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Hypromellose phthalate	20-40	No	Not Applicable	Not applicable
Clarithromycin	20-40	No	Not Applicable	Not applicable
Carbomers EP	15-30	No	Not Applicable	Not applicable
Povidone	1-10	No	Not Applicable	Not applicable
Castor Oil	1-10	No	Not Applicable	Not applicable

Immediate Health: Yes

Delayed Health: No

Fire: No

Sudden Pressure: No

Reactivity: No

RCRA Status: Not determined.

Proposition 65 Status: Chemicals known to the State of California to cause cancer or reproductive harm listed below.

Component	Percent	Proposition 65 Listed Materials
Clarithromycin 81103-11-9 (20-40)	20-40	developmental toxicity, initial date 5/1/97

WHMIS Hazard Class: Not determined.

NFPA Rating:

Health: 1

Fire: 1

Reactivity: 0

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

Section 16. Other information

Full text of H-Statements referred to under sections 2 and 3

H302 - Harmful if swallowed

Document Authored By: Occupational and Environmental Toxicology

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