

Product Name: Clarithromycin Modified Release Tablets
Issued: Jan-26-2016



SAFETY DATA SHEET

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

1.1. Product identifier

Product Name: Clarithromycin Modified Release Tablets
Synonyms: KLARICID OD Tablets; Zeclaren OD 500 mg; KLACID MR 500 mg; KLARICID UD; Clarithromycin tablets
List Number: M299
Drug Code Number: 9382

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: Manufactured by:
AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064
USA
+1-847-932-7900
Manufacturer European: AbbVie Inc.
via Pontina, km 52
Campoverde - LT 04010
Italia
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

General Note AbbVie

Acute oral toxicity Category 4
Skin corrosion/irritation Category 2

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Serious eye damage/eye irritation Category 2

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

Indication of danger: Xi - Irritant
Xn - Harmful

Risk Phrases: R36/38 - Irritating to eyes and skin
R22 - Harmful if swallowed

2.2. Label elements



Signal Word: Warning

Hazard Statements: H302 - Harmful if swallowed
H315 - Causes skin irritation
H319 - Causes serious eye irritation
H335 - May cause respiratory irritation

Precautionary Statements P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P280 - Wear protective gloves/protective clothing/eye protection/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
P264 - Wash face, hands and any exposed skin thoroughly after handling
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P501 - Dispose of contents/container to an approved waste disposal plant

2.3. Other hazards

Not determined

SECTION 3: Composition/information on ingredients

Chemical Name	Weight-%	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH Reg. No
Clarithromycin 81103-11-9	40-60	Present		Acute Oral Cat. 4 (H302)	No data available
Citric Acid 77-92-9	10-20	Present	Xi; R36/37/38	STOT SE 3 (H335) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)	No data available
Sodium Alginate 9005-40-7	10-20	NA		Not Hazardous*	No data available
Lactose 63-42-3	10-20	Present		Not Hazardous*	No data available

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Talc, Nonasbestos Containing 14807-96-6	1-5	Present		Not Hazardous*	No data available
Kollidon 9003-39-8	1-5	NA		Not Hazardous*	No data available
Stearic Acid 57-11-4	1-5	Present		Not Hazardous*	No data available
Sodium Calcium Alginate 12698-40-7	1-5	NA		Not Hazardous*	No data available
Magnesium Stearate 557-04-0	1-5	Present		Not Hazardous*	No data available
Hydroxypropyl Methylcellulose 9004-65-3	1-5	NA		Not Hazardous*	No data available
Polyethylene Glycols 25322-68-3	0.1-1	NA	Xi, R37	STOT SE 3 (H335)	No data available
Titanium Dioxide 13463-67-7	0.1-1	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.

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

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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

7.1. Precautions for safe handling

Avoid contact with skin, eyes and clothing. 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:

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Chemical Name	Employee Exposure Limit	Skin Notation
Clarithromycin 81103-11-9	830 mcg/m ³	None
Citric Acid 77-92-9	Not applicable	None
Sodium Alginate 9005-40-7	Not applicable	None
Lactose 63-42-3	Not applicable	None
Talc, Nonasbestos Containing 14807-96-6	Not applicable	None
Kollidon 9003-39-8	Not applicable	None
Stearic Acid 57-11-4	Not applicable	None
Sodium Calcium Alginate 12698-40-7	Not applicable	None
Magnesium Stearate 557-04-0	Not applicable	None
Hydroxypropyl Methylcellulose 9004-65-3	Not applicable	None
Polyethylene Glycols 25322-68-3	Not applicable	None
Titanium Dioxide 13463-67-7	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Sodium Alginate 9005-40-7	10 mg/m ³ total dust; 3 mg/m ³ respirable particulate				
Lactose 63-42-3	10 mg/m ³ total dust, 3 mg/m ³ respirable dust				
Talc, Nonasbestos Containing 14807-96-6	2 mg/m ³ TWA			30 mg/m ³ (STEL) 2.4 mg/m ³ (STEL) 10 mg/m ³ (TWA) 0.8 mg/m ³ (TWA)	
Kollidon 9003-39-8	10 mg/m ³ for nuisance dust; 3 mg/m ³ respirable particulate				
Stearic Acid 57-11-4	10 mg/m ³ for nuisance dust; 3 mg/m ³ respirable particulate				
Magnesium Stearate 557-04-0	10 mg/m ³ total dust				
Hydroxypropyl Methylcellulose 9004-65-3	10 mg/m ³ total dust; 3 mg/m ³ respirable dust				
Polyethylene Glycols 25322-68-3			1000 mg/m ³ TWA 8000 mg/m ³ Peak		
Titanium Dioxide 13463-67-7	10 mg/m ³ TWA	TWA: 10 mg/m ³		30 mg/m ³ (STEL) 12 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)	

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Talc, Nonasbestos Containing 14807-96-6	0.25 mg/m ³ (TWA)	2 mg/m ³ (TWA)	2 mg/m ³ (TWA)	3 mg/m ³ (STEL) 1 mg/m ³ (TWA)
Polyethylene Glycols 25322-68-3			1000 mg/m ³ (TWA)	
Titanium Dioxide 13463-67-7		10 mg/m ³ (TWA)	3 mg/m ³ (TWA)	30 mg/m ³ (STEL) 12 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)

8.2. Exposure controls

Engineering Controls:

No special provisions are required under normal conditions. When handling bulk formulation, use in a well-ventilated area.

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Respiratory Protection: Respiratory protection is not needed during normal product use. 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: Eye protection not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.

Gloves: Gloves not required during normal product use conditions. Wear impervious gloves when handling the bulk formulation.

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

Environmental Exposure Controls: Not determined

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance: Yellow Ovaloid tablet

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

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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

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Clinical Route
Dermal: Unlikely
Inhalation: Unlikely

Acute Toxicity - Oral: Data for component (s) given below:

Chemical Name	Acute Test	Value	Units	Species
Clarithromycin 81103-11-9	LD50 >=	1230	mg/kg	Rats Mice
Citric Acid 77-92-9	LD50 >=	3000	mg/kg	Animals
Sodium Alginate 9005-40-7	LD50 >	5000	mg/kg	Rats
Lactose 63-42-3	LD50 >	10000	mg/kg	Rats
Kollidon 9003-39-8	LD50 = LD50 >	100000 1040 40000	mg/kg	Rats Rabbits Mice
Stearic Acid 57-11-4	LD50 >	4640	mg/kg	Rats
Hydroxypropyl Methylcellulose 9004-65-3	LD50 >	2250	mg/kg	Rats
Polyethylene Glycols 25322-68-3	LD50 =	47,000 28,000 33,750	mg/kg	Mice Rats Rats

Acute Toxicity - Dermal: Data for component (s) given below:

Chemical Name	Acute Test	Value	Units	Species
Stearic Acid 57-11-4	LD50 >	5000	mg/kg	Rabbits
Polyethylene Glycols 25322-68-3	LD50 >	20,000	mg/kg	Rabbits

Acute Toxicity - Inhalation: Data for component (s) given below:

Chemical Name	Test	Value	Units	Species
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Magnesium Stearate 557-04-0	LC 50 >	2000	mg/m ³ , 1 hour	Rats
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Corrosivity Not determined

Dermal Irritation: Minor ingredient: May be a skin irritant.

Eye irritation Minor ingredient: May be an eye irritant.

Sensitization Not determined

Toxicokinetics/Metabolism: Not determined

Target Organ Effects Minor Ingredient : May cause respiratory tract irritation
 Data for component (s) given below:

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
Polyethylene Glycols 25322-68-3	Lungs	Rats	567 mg/m ³		Inhalation	2 weeks
Titanium Dioxide 13463-67-7	Lungs	Rats	10,000	mg/L	Inhalation	2 years

Reproductive Effects Active Ingredient : In animals adverse reproductive effects include: fetal abnormalities. fetal toxicity. Based on the mechanism of action, may impair fertility or cause effects on the unborn child.
 Data for component (s) given below:

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

Carcinogenicity Data for component (s) given below:

Chemical Name	Site of Tumors	Species	Dosage	Route	Units	Duration
Talc, Nonasbestos Containing 14807-96-6	Lungs	Rats	18	Inhalation	mg/m ³ , 6 hours	2 years
Titanium Dioxide 13463-67-7	Lungs	Rats	250,000	Inhalation	mg/L	2 years

Mutagenicity: Data for component (s) given below:

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Clarithromycin 81103-11-9	Negative	Negative	Negative	Negative
Magnesium Stearate 557-04-0	No Data.	Negative	No Data.	No Data.
Polyethylene Glycols 25322-68-3	No Data.	Negative	No Data.	No Data.

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

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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 and 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

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

Product Name: Clarithromycin Modified Release Tablets
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15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Clarithromycin 81103-11-9	Present	-	-	Not listed	-
Citric Acid 77-92-9	Present	X	X	Not listed	X
Sodium Alginate 9005-40-7	-	-	-	Not listed	-
Lactose 63-42-3	Present	X	X	Not listed	X
Talc, Nonasbestos Containing 14807-96-6	Present	X	X	Not listed	X
Kollidon 9003-39-8	-	X	X	Not listed	X
Stearic Acid 57-11-4	Present	X	X	Not listed	X
Sodium Calcium Alginate 12698-40-7	-	-	-	Not listed	-
Magnesium Stearate 557-04-0	Present	X	X	Not listed	X
Hydroxypropyl Methylcellulose 9004-65-3	-	X	X	Not listed	X
Polyethylene Glycols 25322-68-3	-	X	X	Not listed	X
Titanium Dioxide 13463-67-7	Present	X	X	Not listed	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Clarithromycin 81103-11-9	-	Present	-	-	-	HSR007090
Citric Acid 77-92-9	Present	-	X	X	Present	HSR003138
Sodium Alginate 9005-40-7	-	-	-	-	-	
Lactose 63-42-3	-	Present	X	X	Present	
Talc, Nonasbestos Containing 14807-96-6	Present	-	X	X	Present	
Kollidon 9003-39-8	Present	-	X	X	Present	
Stearic Acid 57-11-4	Present	-	X	X	Present	
Sodium Calcium Alginate 12698-40-7	-	-	-	-	-	
Magnesium Stearate 557-04-0	Present	-	X	X	Present	
Hydroxypropyl Methylcellulose 9004-65-3	Present	-	X	X	Present	
Polyethylene Glycols 25322-68-3	Present	-	X	X	Present	
Titanium Dioxide 13463-67-7	Present	-	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:

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Chemical Name	Weight-%	NTP:	IARC:	ACGIH:
Clarithromycin	40-60	Not listed	Not listed	Not listed
Citric Acid	10-20	Not listed	Not listed	Not listed
Sodium Alginate	10-20	Not listed	Not listed	Not listed
Lactose	10-20	Not listed	Not listed	Not listed
Talc, Nonasbestos Containing	1-5	Not listed	Not listed	A4 - Not Classifiable as a Human Carcinogen (containing no asbestos fibers)
Kollidon	1-5	Not listed	Not listed	Not listed
Stearic Acid	1-5	Not listed	Not listed	Not listed
Sodium Calcium Alginate	1-5	Not listed	Not listed	Not listed
Magnesium Stearate	1-5	Not listed	Not listed	Not listed
Hydroxypropyl Methylcellulose	1-5	Not listed	Not listed	Not listed
Polyethylene Glycols	0.1-1	Not listed	Not listed	Not listed
Titanium Dioxide	0.1-1	Not listed	Not listed	A4 - Not Classifiable as a Human Carcinogen

SARA 313 Information

Chemical Name	Weight-%	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Clarithromycin	40-60	No	Not applicable	Not applicable
Citric Acid	10-20	No	Not applicable	Not applicable
Sodium Alginate	10-20	No	Not applicable	Not applicable
Lactose	10-20	No	Not applicable	Not applicable
Talc, Nonasbestos Containing	1-5	No	Not applicable	Not applicable
Kollidon	1-5	No	Not applicable	Not applicable
Stearic Acid	1-5	No	Not applicable	Not applicable
Sodium Calcium Alginate	1-5	No	Not applicable	Not applicable
Magnesium Stearate	1-5	No	Not applicable	Not applicable
Hydroxypropyl Methylcellulose	1-5	No	Not applicable	Not applicable
Polyethylene Glycols	0.1-1	No	Not applicable	Not applicable
Titanium Dioxide	0.1-1	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	Weight-%	Proposition 65 Listed Materials
Clarithromycin 81103-11-9 (40-60)	40-60	developmental toxicity, 5/1/1997
Titanium Dioxide 13463-67-7 (0.1-1)	0.1-1	carcinogen, 9/2/2011 (airborne, unbound particles of respirable size)

WHMIS Hazard Class Not determined

NFPA Rating:

Health: 2

Fire: 1

Reactivity: 0

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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

Risk Phrases:

R36/38 - Irritating to eyes and skin

R22 - Harmful if swallowed

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

H335 - May cause respiratory irritation

H315 - Causes skin irritation

H319 - Causes serious eye irritation

H302 - Harmful if swallowed

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Supersedes the SDS dated: Nov-14-2011

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