

Product Name: Klacid (R)
Issued: May-08-2013



SAFETY DATA SHEET

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

1.1 Product Identifier

Product Name: Klacid (R)
Synonyms: Clarithromycin Intravenous Injection; Klacid IV 10 x 1 vials; Klacid IV 1 vial
List Number: G565

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

Recommended use: Pharmaceuticals Scientific research and development

1.3 Details of the supplier of the safety data sheet

Supplier: AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064
USA
1-800-255-5162
+1-847-937-7433
Customer Service Telephone: 1-800-255-5162 (USA Only) or Access Code+703-527-3887
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 Medicinal products are exempt. Information provided below is for pure drug substance.

Acute oral toxicity	Category 4
Acute inhalation toxicity	Not classified
Skin corrosion/irritation	Not classified
Germ cell mutagenicity	Not classified

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

Indication of danger: Xn - Harmful
Risk Phrases: R22 - Harmful if swallowed

2.2 Label elements

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Section 2. Hazards identification



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.
Clarithromycin 81103-11-9	Proprietary	NA	Xn, R22	Acute Tox. 4 (H302)	No data available
Lactobionic Acid 96-82-2	Proprietary	Present		Not classified	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.

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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

Additional Information: Clarithromycin : Pseudomembranous colitis has been reported with use of nearly all antibiotics including clarithromycin. Excessive lactose may produce gastrointestinal upset in persons with lactose intolerance. Excessive galactose may produce ocular toxicity in persons with galactosemia. Excessive glucose may produce vomiting, nausea, hyperglycemia and glucosuria.

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.

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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

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 Scientific research and development

Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

Chemical Name	Employee Exposure Limit	Skin Notation
Clarithromycin 81103-11-9	1 mg/m ³	None
Lactobionic Acid 96-82-2	Not Applicable	None

8.2. Exposure controls

Engineering Controls: No special provisions are required under normal product use conditions.

Respiratory Protection: 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 exposures when handling the product formulation.

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

9.1. Information on basic physical and chemical properties

Appearance: Not determined

Odor: Odor not determined.

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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: n-octanol/water	Not determined.
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

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:

Product Name: Klacid (R)
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Oral: Unlikely (intact container)
Dermal: Unlikely (intact container)
Inhalation: Unlikely (intact container)

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

Chemical Name	Acute Test	Value	Units	Species
Clarithromycin 81103-11-9	LD50 >=	1230	mg/kg	Rats Mice

Acute Toxicity - Dermal: Not determined.

Acute Toxicity - Inhalation: Not determined.

Other Toxicology Data: No effect anticipated from intact clinical product. Data for component (s) given below:

Chemical Name	Test Type	Value	Units	Species	Comments
Lactobionic Acid 96-82-2	LD50 (iv) =	4710	mg/kg	Mice	None.

Corrosivity: Not determined.

Dermal Irritation: Not determined.

Eye Irritation: Not determined.

Sensitization: Not determined.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: None expected from normal clinical use of this product. Data for component (s) given below. 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: None expected from normal clinical use of this product. 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

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.

Mutagenicity: None expected from normal clinical use of this product. Data for component (s) given below. Negative in mutagenicity assays.

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

Notes to Toxicologist: .

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

Status: Not regulated

Product Name: Klacid (R)
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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 according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable

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
Clarithromycin 81103-11-9	-	-	-	Not listed.	-
Lactobionic Acid 96-82-2	Present	-	-	Not listed.	-

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Clarithromycin 81103-11-9	-	Present	-	-	-	HSR007090
Lactobionic Acid 96-82-2	-	-	-	-	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:
Clarithromycin	Proprietary	Not Listed	Not Listed	Not Listed
Lactobionic Acid	Proprietary	Not Listed	Not Listed	Not Listed

SARA 313 Information

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Clarithromycin	Proprietary	No	Not Applicable	Not applicable
Lactobionic Acid	Proprietary	No	Not Applicable	Not applicable

RCRA Status: Not determined.

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

Chemical Name	Percent	Proposition 65 Listed Materials
Clarithromycin	Proprietary	Developmental toxicity, initial date 5/1/97

WHMIS Hazard Class: Exempt.

Health: 1

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: R22 - Harmful if swallowed

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

H302 - Harmful if swallowed

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