

Product Name: Kaletra Capsules
Issued: Sep-24-2015



SAFETY DATA SHEET

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

1.1 Product Identifier

Product Name: Kaletra Capsules
Synonyms: Liponavir/Ritonavir capsules; Kaletra Capsulas; Lopinavir/Ritonavir Soft Gelatin Capsules; Kaletra Soft Gelatin Capsules
Trade name: Kaletra
List Number: 3959

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

Reproductive toxicity Category 2
Carcinogenicity Category 2

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

Risk Phrases: R40 - Limited evidence of a carcinogenic effect
R63 - Possible risk of harm to the unborn child

2.2 Label elements

Product Name:
Issued:

Kaletra Capsules
Sep-24-2015



Signal Word: Warning

Hazard Statements:
H351 - Suspected of causing cancer
H361 - Suspected of damaging fertility or the unborn child

Precautionary Statements
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P405 - Store locked up
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	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Oleic Acid 112-80-1	50-80	Present		Not Hazardous*	No data available
Lopinavir 192725-17-0	5-20	NA		Acute Oral Cat 4 (H302); Repeat Chron Tox Cat 2 (H373)	No data available
Propylene Glycol 57-55-6	5-20	Present		Not Hazardous*	No data available
Ritonavir 155213-67-5	1-9	NA	Xn, R22; Xi; R36; R40; R63	Eye Irrit. 2 (H319) Acute Tox. 4 (H302) Carc. 2 (H351) Repro 2 (H361D)	No data available
Polyoxyl 35 Castor Oil 61791-12-6	1-10	NA		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

Product Name: Kaletra Capsules
Issued: Sep-24-2015

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: headaches, vomiting, nausea, diarrhea, rash, abnormal liver function, alterations in serum lipid concentrations.

Medical Conditions Aggravated by Exposure: None known from occupational exposure. Data suggest any pre-existing ailments in the following organs: liver, testes, gastrointestinal system, thyroid, or hematopoietic system. A GLP-compliant embryo-fetal development study has been conducted with ABT-414 in mice resulting in post-implantation loss of all fetuses at a human equivalent dose near the anticipated clinical dose. This result is consistent with the pharmacology of ABT-414.

4.3 Indication of any immediate medical attention and special treatment needed

Notes To Physician: Treat symptomatically

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.

Product Name: Kaletra Capsules
Issued: Sep-24-2015

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

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
Oleic Acid 112-80-1	Not Applicable	None
Lopinavir 192725-17-0	1300 mcg/m ³ TWA	None
Propylene Glycol 57-55-6	Not Applicable	None
Ritonavir 155213-67-5	160 mcg/m ³ TWA	None
Polyoxyl 35 Castor Oil 61791-12-6	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Propylene Glycol 57-55-6				450 ppm (STEL) 1410 mg/m ³ (STEL) 30 mg/m ³ (STEL) 150 ppm (TWA) 470 mg/m ³ (TWA) 10 mg/m ³ (TWA)	

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Propylene Glycol 57-55-6				450 ppm (STEL) 1422 mg/m ³ (STEL) 30 mg/m ³ (STEL) 150 ppm (TWA) 474 mg/m ³ (TWA) 10 mg/m ³ (TWA)

8.2. Exposure controls

Product Name: Kaletra Capsules
Issued: Sep-24-2015

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

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: Liquid Opaque Soft elastic capsule (SEC)
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

Product Name: Kaletra Capsules
Issued: Sep-24-2015

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

Carbon oxides, Nitrogen oxides (NOx)

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Clinical Route
Dermal: Not determined.
Inhalation: Not determined.

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

Chemical Name	Acute Test	Value	Units	Species
Oleic Acid 112-80-1	ALD > LD50 =	44,500 74,500	mg/kg	Mice Rats
Lopinavir 192725-17-0	LD50 >	2500	mg/kg	Rats
Propylene Glycol 57-55-6	LD50 =	10,000-33,700	mg/kg	Animals
Ritonavir 155213-67-5	LD50 =	1030 - 1970	mg/kg	Mice
Polyoxyl 35 Castor Oil 61791-12-6	LD50 >	6400	mg/kg	Rats Cats Rabbits

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

Chemical Name	Acute Test	Value	Units	Species
Propylene Glycol 57-55-6	LD50 =	20,800	mg/kg	Rabbits
Ritonavir 155213-67-5	LD50 >	2000	mg/kg	Rats
Polyoxyl 35 Castor Oil 61791-12-6	LD50 >	2500	mg/kg	Rats Rabbits

Acute Toxicity - Inhalation: Not determined.

Corrosivity: Not determined.

Dermal Irritation: Active Ingredient : Produced mild skin irritation in rabbits.

Product Name: Kaletra Capsules
Issued: Sep-24-2015

Eye Irritation: Active Ingredient : Produced mild eye irritation in rabbits. Recovery after 72 hours.

Sensitization: Active Ingredient : Negative in the maximization assay in guinea pigs at challenge concentrations.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: Data for component (s) given below.

Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
Lopinavir 192725-17-0	Liver Gastrointestinal Tract Blood	Rats Mice Dogs	50 - 100 co-dosed ritonavir	mg/kg	Oral	Variable exposure periods
Ritonavir 155213-67-5	Eyes Gastrointestinal Tract Liver Thyroid Kidney	Rats Dogs	25 50	mg/kg	Oral	Variable exposure periods 6 months 3 months

Reproductive Effects: Active Ingredient : fetal abnormalities. maternal toxicity.
Data for component (s) given below.

Chemical Name	Species	Dosage	Units	Route	Duration
Ritonavir 155213-67-5	Rats	35	mg/kg	Oral	During Gestation

Carcinogenicity: Data for component(s) given below.

Chemical Name	Site of Tumors	Species	Dosage	Route	Units	Duration
Ritonavir 155213-67-5	Liver	Mice	100	Oral	mg/kg	2 years

Mutagenicity: Data for component (s) given below.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Lopinavir 192725-17-0	Negative	Negative	Negative	Negative
Ritonavir 155213-67-5	Negative	Negative	Negative	Negative
Polyoxyl 35 Castor Oil 61791-12-6	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

Data for component (s) given below.

Chemical Name	Percent	48h EC50 (daphnia - mg/l) (48HLCD)	Species	Duration
Propylene Glycol 57-55-6	5-20	1000	Daphnia magna	48 Hours

12.2. Persistence and degradability

Not determined.

Product Name: Kaletra Capsules
Issued: Sep-24-2015

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

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
Oleic Acid 112-80-1	Present	X	X	Not listed.	X

Product Name: Kaletra Capsules
Issued: Sep-24-2015

Lopinavir 192725-17-0	-	-	-	Not listed.	-
Propylene Glycol 57-55-6	Present	X	X	Not listed.	X
Ritonavir 155213-67-5	-	-	-	Not listed.	-
Polyoxyl 35 Castor Oil 61791-12-6	-	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Oleic Acid 112-80-1	Present	-	X	X	Present	HSR003153
Lopinavir 192725-17-0	-	-	-	-	-	
Propylene Glycol 57-55-6	Present	Present	X	X	Present	
Ritonavir 155213-67-5	-	-	-	-	-	
Polyoxyl 35 Castor Oil 61791-12-6	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/NDL - 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:
Oleic Acid	50-80	Not Listed	Not Listed	Not Listed
Lopinavir	5-20	Not Listed	Not Listed	Not Listed
Propylene Glycol	5-20	Not Listed	Not Listed	Not Listed
Ritonavir	1-9	Not Listed	Not Listed	Not Listed
Polyoxyl 35 Castor Oil	1-10	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):
Oleic Acid	50-80	No	Not Applicable	Not applicable
Lopinavir	5-20	No	Not Applicable	Not applicable
Propylene Glycol	5-20	No	Not Applicable	Not applicable
Ritonavir	1-9	No	Not Applicable	Not applicable
Polyoxyl 35 Castor Oil	1-10	No	Not Applicable	Not applicable

Immediate Health: No

Delayed Health: No

Fire: No

Sudden Pressure: No

Reactivity: No

RCRA Status: Not determined.

Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

WHMIS Hazard Class: Not determined.

NFPA Rating:

Health: 0

Product Name:
Issued:

Kaletra Capsules
Sep-24-2015

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

Risk Phrases:

R40 - Limited evidence of a carcinogenic effect
R63 - Possible risk of harm to the unborn child

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

H319 - Causes serious eye irritation
H302 - Harmful if swallowed
H351 - Suspected of causing cancer if inhaled
H361 - Suspected of damaging fertility or the unborn child if inhaled

Document Authored By: Occupational and Environmental Toxicology

Issued: Sep-24-2015

Supersedes the SDS dated: Sep-09-2011

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