

Product Name:
Issued:

Ritonavir Tablets
Sep-23-2015

abbvie
SAFETY DATA SHEET

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

1.1 Product Identifier

Product Name: Ritonavir Tablets
Synonyms: A-84538.0; HIV Protease Inhibitor A-84538.0; ABT-538

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

Recommended use: Scientific research and development

1.3 Details of the supplier of the safety data sheet

Supplier: AbbVie Inc.
North Chicago, IL 60064
U.S.A.
+1-847-932-7900

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
Serious eye damage/eye irritation	Category 2
Reproductive toxicity	Category 3
Carcinogenicity	Category 3
Chronic aquatic toxicity	Chronic toxicity 4

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

Risk Phrases: R22 - Harmful if swallowed
R36 - Irritating to eyes
R40 - Limited evidence of a carcinogenic effect
R53 - May cause long-term adverse effects in the aquatic environment
R62 - Possible risk of impaired fertility
R63 - Possible risk of harm to the unborn child

2.2 Label elements

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Signal Word:

Warning

Hazard Statements:

H302 - Harmful if swallowed
H319 - Causes serious eye irritation
H350 - May cause cancer
H360 - May damage fertility or the unborn child
H413 - May cause long lasting harmful effects to aquatic life

Precautionary Statements

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
P337 + P313 - If eye irritation persists: Get medical advice/attention
P273 - Avoid release to the environment
Dispose of contents/container to an approved incineration plant
P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
P321 - Specific treatment (see supplemental first aid instructions on this label)
P405 - Store locked up
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P330 - Rinse mouth
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.
Copovidone 25086-89-9	55-65	NA		Not Hazardous*	No data available
Methacrylic acid co-polymer 25212-88-8	35-50	NA	R53	Aquatic Chronic 4 (H413)	No data available
Ritonavir 155213-67-5	0-20	NA	Xn, R22; Xi; R36; R40; R63	Eye Irrit. 2 (H319) Acute Tox. 4 (H302) Carc. 2 (H351) Repro 2 (H361D)	No data available
Sorbitan, Monolaurate 1338-39-2	5-10	Present		Not Hazardous*	No data available

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Opadry II L-02-231	0-15	NA		Not Hazardous*	No data available
Glycerol Monostearate (Arlacel 165) 31566-31-1	0-15	Present		Not Hazardous*	No data available
Triethyl Citrate 77-93-0	0-5	Present		Not Hazardous*	No data available
Colloidal Silicon Dioxide 7631-86-9	1-2	Present		Not Hazardous*	No data available
Sodium Stearyl Fumarate 4070-80-8	0-1	Present		Not Hazardous*	No data available
Polysorbate 80 9005-65-6	0-1	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

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.

**Medical Conditions
Aggravated by Exposure:** None known from occupational exposure.

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

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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

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: Scientific research and development

Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

Chemical Name	Employee Exposure Limit	Skin Notation
Copovidone 25086-89-9	Not Applicable	None
Methacrylic acid co-polymer 25212-88-8	Not Applicable	None
Ritonavir 155213-67-5	160 mcg/m ³ TWA	None

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Sorbitan, Monolaurate 1338-39-2	Not Applicable	None
Opadry II L-02-231	Not Applicable	None
Glycerol Monostearate (Arlacel 165) 31566-31-1	Not Applicable	None
Triethyl Citrate 77-93-0	Not Applicable	None
Colloidal Silicon Dioxide 7631-86-9	Not Applicable	None
Sodium Stearyl Fumarate 4070-80-8	Not Applicable	None
Polysorbate 80 9005-65-6	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Colloidal Silicon Dioxide 7631-86-9	10 mg/m ³ for nuisance dust; 3 mg/m ³ respirable particulate		4 mg/m ³ TWA	18 mg/m ³ (STEL) 7.2 mg/m ³ (STEL) 6 mg/m ³ (TWA) 2.4 mg/m ³ (TWA)	

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Colloidal Silicon Dioxide 7631-86-9			4 mg/m ³ (TWA)	18 mg/m ³ (STEL) 7.2 mg/m ³ (STEL) 6 mg/m ³ (TWA) 2.4 mg/m ³ (TWA)

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:	Tablet Solid
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):	Product is not expected to be combustible.
Lower Explosive Limit:	Not determined.
Upper Explosive Limit:	Not determined.

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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

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Yes
Dermal: Unlikely
Inhalation: Unlikely

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

Chemical Name	Acute Test	Value	Units	Species
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Copovidone 25086-89-9	LD50 >	630	mg/kg	Rats
Ritonavir 155213-67-5	LD50 =	1030 - 1970	mg/kg	Mice
Sorbitan, Monolaurate 1338-39-2	LD50 =	33,600	mg/kg	Rats
Glycerol Monostearate (Arlacel 165) 31566-31-1	LD50 >			
Triethyl Citrate 77-93-0	LD50 =	3500 5900	mg/kg	Cats Rats
Colloidal Silicon Dioxide 7631-86-9	LD50 =	3160	mg/kg	Rats
Polysorbate 80 9005-65-6	LD50 =	25,000 - 36,570	mg/kg	Mice Rats

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

Chemical Name	Acute Test	Value	Units	Species
Ritonavir 155213-67-5	LD50 >	2000	mg/kg	Rats
Triethyl Citrate 77-93-0	LD50 >	5000	mg/kg	Rabbits

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

Chemical Name		Test	Value	Units	Species	
Colloidal Silicon Dioxide 7631-86-9		LC 50 >	200	mg/L, 1 hour	Rats	
Chemical Name		Test Type	Value	Units	Species	Comments
Triethyl Citrate 77-93-0		LD50 (ip) =	4000	mg/kg	Rats	None.

Corrosivity: Not determined.

Dermal Irritation: Not determined.

Eye Irritation: A minor ingredient is not an eye irritant.

Sensitization: Not determined.

Toxicokinetics/Metabolism: Not determined.

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

Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
Ritonavir 155213-67-5	Eyes Gastrointestinal Tract Liver Thyroid Kidney	Rats Dogs	25 50	mg/kg	Oral	Variable exposure periods 6 months 3 months
Colloidal Silicon Dioxide 7631-86-9	Respiratory System	Rats	126	mg/L	Inhalation	2 years

Reproductive Effects: 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: Limited evidence of carcinogenicity in animal studies

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

Mutagenicity: Negative in mutagenicity assays.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
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Ritonavir 155213-67-5	Negative	Negative	Negative	Negative
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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	LC 50 (mg/l)	Species	Duration
Colloidal Silicon Dioxide 7631-86-9	1-2	5000	Brachydanio rerio	96 Hours

Chemical Name	Percent	48h EC50 (daphnia - mg/l) (48HLCD)	Species	Duration
Colloidal Silicon Dioxide 7631-86-9	1-2	7600	Daphnia magna	48 Hours

Chemical Name	Percent	72h IC50 (algae - mg/l) (72HICA)	Species	Duration
Colloidal Silicon Dioxide 7631-86-9	1-2	440	Unicellular Green Algae	72 Hours

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.

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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
Copovidone 25086-89-9	-	X	X	Not listed.	X
Methacrylic acid co-polymer 25212-88-8	-	X	X	Not listed.	X
Ritonavir 155213-67-5	-	-	-	Not listed.	-
Sorbitan, Monolaurate 1338-39-2	Present	X	X	Not listed.	X
Opadry II L-02-231	-	-	-	Not listed.	-
Glycerol Monostearate (Arlacel 165) 31566-31-1	Present	X	X	Not listed.	X
Triethyl Citrate 77-93-0	Present	X	X	Not listed.	X
Colloidal Silicon Dioxide 7631-86-9	Present	X	X	Not listed.	X
Sodium Stearyl Fumarate 4070-80-8	Present	-	-	Not listed.	-
Polysorbate 80 9005-65-6	-	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Copovidone 25086-89-9	Present	-	X	X	Present	
Methacrylic acid co-polymer 25212-88-8	Present	-	X	X	Present	
Ritonavir 155213-67-5	-	-	-	-	-	
Sorbitan, Monolaurate 1338-39-2	Present	-	X	X	Present	
Opadry II L-02-231	-	-	-	-	-	
Glycerol Monostearate (Arlacel 165) 31566-31-1	Present	-	X	X	Present	

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Triethyl Citrate 77-93-0	Present	-	X	X	Present	
Colloidal Silicon Dioxide 7631-86-9	Present	-	X	X	Present	
Sodium Stearyl Fumarate 4070-80-8	-	-	-	-	-	HSR007040
Polysorbate 80 9005-65-6	Present	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:

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Copovidone	55-65	Not Listed	Not Listed	Not Listed
Methacrylic acid co-polymer	35-50	Not Listed	Not Listed	Not Listed
Ritonavir	0-20	Not Listed	Not Listed	Not Listed
Sorbitan, Monolaurate	5-10	Not Listed	Not Listed	Not Listed
Opadry II	0-15	Not Listed	Not Listed	Not Listed
Glycerol Monostearate (Arlacel 165)	0-15	Not Listed	Not Listed	Not Listed
Triethyl Citrate	0-5	Not Listed	Not Listed	Not Listed
Colloidal Silicon Dioxide	1-2	Not Listed	Not Listed	Not Listed
Sodium Stearyl Fumarate	0-1	Not Listed	Not Listed	Not Listed
Polysorbate 80	0-1	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):
Copovidone	55-65	No	Not Applicable	Not applicable
Methacrylic acid co-polymer	35-50	No	Not Applicable	Not applicable
Ritonavir	0-20	No	Not Applicable	Not applicable
Sorbitan, Monolaurate	5-10	No	Not Applicable	Not applicable
Opadry II	0-15	No	Not Applicable	Not applicable
Glycerol Monostearate (Arlacel 165)	0-15	No	Not Applicable	Not applicable
Triethyl Citrate	0-5	No	Not Applicable	Not applicable
Colloidal Silicon Dioxide	1-2	No	Not Applicable	Not applicable
Sodium Stearyl Fumarate	0-1	No	Not Applicable	Not applicable
Polysorbate 80	0-1	No	Not Applicable	Not applicable

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.

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

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

Section 16. Other information

Risk Phrases:

R22 - Harmful if swallowed
R36 - Irritating to eyes
R40 - Limited evidence of a carcinogenic effect
R53 - May cause long-term adverse effects in the aquatic environment
R62 - Possible risk of impaired fertility
R63 - Possible risk of harm to the unborn child

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

H302 - Harmful if swallowed
H319 - Causes serious eye irritation
H350 - May cause cancer
H360 - May damage fertility or the unborn child
H413 - May cause long lasting harmful effects to aquatic life

Document Authored By: Global Occupational Toxicology (D-03QC)

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