

Product Name: Norvir Tablets (ANZ)
Issued: Sep-22-2015



SAFETY DATA SHEET

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

1.1 Product Identifier

Product Name: Norvir Tablets (ANZ)
Synonyms: Ritonavir Film-Coated Tablets; Norvir Tablets; Ritonavir Tablets
Trade name: Norvir
List Number: 3333

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
L1, 32-34 Lord St.
Botany, NSW 2019
Australia
Customer Service Telephone: 1800 043 460 (AU)
0800 900 030 (NZ)
E-mail Address: medinfoanz@abbvie.com

1.4 Emergency telephone number

Emergency Telephone: 1800 043 460 (AU)
0800 900 030 (NZ)

Section 2. Hazards identification

2.1 Classification of the substance or mixture

Regulation (EC) No 1272/2008

General Note

Serious eye damage/eye irritation	Category 2
Reproductive toxicity	Category 2
Carcinogenicity	Category 2

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

Indication of danger: Xi - Irritant
Risk Phrases: R36 - Irritating to eyes
R40 - Limited evidence of a carcinogenic effect
R63 - Possible risk of harm to the unborn child

2.2 Label elements

Product Name:
Issued:

Norvir Tablets (ANZ)
Sep-22-2015



Signal Word: Warning

Hazard Statements:
H319 - Causes serious eye irritation
H351 - Suspected of causing cancer
H361 - Suspected of damaging fertility or the unborn child

Precautionary Statements
P202 - Do not handle until all safety precautions have been read and understood
P264 - Wash face, hands and any exposed skin thoroughly after handling
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P281 - Use personal protective equipment as required
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P308 + P313 - IF exposed or concerned: Get medical advice/attention

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	50-70	NA		Not Hazardous*	No data available
Ritonavir 155213-67-5	5-20	NA	Xn, R22; Xi; R36; R40; R63	Eye Irrit. 2 (H319) Acute Tox. 4 (H302) Carc. 2 (H351) Repro 2 (H361D)	No data available
Calcium Phosphate, Dibasic 7757-93-9	5-20	Present		Not Hazardous*	No data available
Sorbitan, Monolaurate 1338-39-2	5-20	Present		Not Hazardous*	No data available
Colloidal Silicon Dioxide 7631-86-9	1-10	Present		Not Hazardous*	No data available
Opadry White 122985-54-0	1-10	NA		Not Hazardous*	No data available
Titanium Dioxide 13463-67-7	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

Product Name: Norvir Tablets (ANZ)
Issued: Sep-22-2015

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: headaches, vomiting, nausea, diarrhea, abnormal liver function, gastrointestinal upset, altered acid/ base balance, abnormal thyroid function, taste alterations. Direct contact with the eyes could result in the following: eye irritation.

Medical Conditions Aggravated by Exposure: Clinical data suggests any pre-existing ailments of the following organs: eyes, liver, gastrointestinal system, thyroid.

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: Norvir Tablets (ANZ)
Issued: Sep-22-2015

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
Copovidone 25086-89-9	Not Applicable	None
Ritonavir 155213-67-5	160 mcg/m ³ TWA	None
Calcium Phosphate, Dibasic 7757-93-9	Not Applicable	None
Sorbitan, Monolaurate 1338-39-2	Not Applicable	None
Colloidal Silicon Dioxide 7631-86-9	Not Applicable	None
Opadry White 122985-54-0	Not Applicable	None
Titanium Dioxide 13463-67-7	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Calcium Phosphate, Dibasic 7757-93-9	10 mg/m ³ total dust for carbonate and sulfate salts of calcium				
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)	
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)	

Product Name: Norvir Tablets (ANZ)
Issued: Sep-22-2015

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)
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 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: White 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.

Product Name: Norvir Tablets (ANZ)
Issued: Sep-22-2015

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

Carbon oxides, Nitrogen oxides (NO_x)

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
Copovidone 25086-89-9	LD50 >	630	mg/kg	Rats
Ritonavir 155213-67-5	LD50 =	1030 - 1970	mg/kg	Mice
Calcium Phosphate, Dibasic 7757-93-9	LD50 >	5000	mg/kg	Guinea Pigs
Sorbitan, Monolaurate 1338-39-2	LD50 =	33,600	mg/kg	Rats
Colloidal Silicon Dioxide 7631-86-9	LD50 =	3160	mg/kg	Rats

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

Chemical Name	Acute Test	Value	Units	Species
---------------	------------	-------	-------	---------

Product Name: Norvir Tablets (ANZ)
Issued: Sep-22-2015

Ritonavir 155213-67-5	LD50 >	2000	mg/kg	Rats
--------------------------	--------	------	-------	------

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

Corrosivity: Not determined.

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

Eye Irritation: Active Ingredient : Produced mild eye irritation in rabbits.

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
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
Titanium Dioxide 13463-67-7	Lungs	Rats	10,000	mg/L	Inhalation	2 years

Reproductive Effects: Active Ingredient : testicular atrophy, fetal abnormalities. fetal behavior abnormalities, fetal 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
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
Ritonavir 155213-67-5	Negative	Negative	Negative	Negative

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

Product Name: Norvir Tablets (ANZ)
Issued: Sep-22-2015

Data for component (s) given below.

Chemical Name	Percent	LC 50 (mg/l)	Species	Duration
Colloidal Silicon Dioxide 7631-86-9	1-10	5000	Brachydanio rerio	96 Hours

Chemical Name	Percent	48h EC50 (daphnia - mg/l) (48HLCD)	Species	Duration
Colloidal Silicon Dioxide 7631-86-9	1-10	7600	Daphnia magna	48 Hours

Chemical Name	Percent	72h IC50 (algae - mg/l) (72HICA)	Species	Duration
Colloidal Silicon Dioxide 7631-86-9	1-10	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.

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

Product Name: Norvir Tablets (ANZ)
Issued: Sep-22-2015

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
Copovidone 25086-89-9	-	X	X	Not listed.	X
Ritonavir 155213-67-5	-	-	-	Not listed.	-
Calcium Phosphate, Dibasic 7757-93-9	Present	X	X	Not listed.	X
Sorbitan, Monolaurate 1338-39-2	Present	X	X	Not listed.	X
Colloidal Silicon Dioxide 7631-86-9	Present	X	X	Not listed.	X
Opadry White 122985-54-0	-	-	-	Not listed.	-
Titanium Dioxide 13463-67-7	Present	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Copovidone 25086-89-9	Present	-	X	X	Present	
Ritonavir 155213-67-5	-	-	-	-	-	
Calcium Phosphate, Dibasic 7757-93-9	Present	-	X	X	Present	HSR003703
Sorbitan, Monolaurate 1338-39-2	Present	-	X	X	Present	
Colloidal Silicon Dioxide 7631-86-9	Present	-	X	X	Present	
Opadry White 122985-54-0	-	-	-	-	-	
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:

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Copovidone	50-70	Not Listed	Not Listed	Not Listed
Ritonavir	5-20	Not Listed	Not Listed	Not Listed
Calcium Phosphate, Dibasic	5-20	Not Listed	Not Listed	Not Listed
Sorbitan, Monolaurate	5-20	Not Listed	Not Listed	Not Listed
Colloidal Silicon Dioxide	1-10	Not Listed	Not Listed	Not Listed
Opadry White	1-10	Not Listed	Not Listed	Not Listed

Product Name: Norvir Tablets (ANZ)
Issued: Sep-22-2015

Titanium Dioxide	1-10	Not Listed	Not Listed	A4 - Not Classifiable as a Human Carcinogen
------------------	------	------------	------------	---

SARA 313 Information

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Copovidone	50-70	No	Not Applicable	Not applicable
Ritonavir	5-20	No	Not Applicable	Not applicable
Calcium Phosphate, Dibasic	5-20	No	Not Applicable	Not applicable
Sorbitan, Monolaurate	5-20	No	Not Applicable	Not applicable
Colloidal Silicon Dioxide	1-10	No	Not Applicable	Not applicable
Opadry White	1-10	No	Not Applicable	Not applicable
Titanium Dioxide	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: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

Component	Percent	Proposition 65 Listed Materials
Titanium Dioxide 13463-67-7 (1-10)	1-10	carcinogen, initial date 9/2/11 (airborne, unbound particles of respirable size)

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

Risk Phrases:

R36 - Irritating to eyes

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

Product Name: Norvir Tablets (ANZ)
Issued: Sep-22-2015

Document Authored By: Occupational and Environmental Toxicology

Issued: Sep-22-2015

Supersedes the SDS dated: Sep-09-2011

Disclaimer:

The information and recommendations contained herein are based upon tests believed to be reliable. However, AbbVie Inc. does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage may be required. AbbVie Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.