

**Product Name:** Norvir Oral Solution (ANZ)  
**Issued:** Sep-22-2015



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

**1.1 Product Identifier**

**Product Name:** Norvir Oral Solution (ANZ)  
**Synonyms:** Norvir Liquid 80 mg/ml; Ritonavir Liquid; Norvir Oral Solution: Norvir 80 mg/ml, solution buvable; Ritonavir Oral Solution  
**Trade name:** Norvir  
**List Number:** 1940; M171

**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**

**Serious eye damage/eye irritation** Category 2  
**Reproductive toxicity** Category 2  
**Carcinogenicity** Category 2  
**Flammable liquids** Category 3

Category 3

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

**Indication of danger:** Xi - Irritant  
**Risk Phrases:** R10 - Flammable  
R36 - Irritating to eyes  
R40 - Limited evidence of a carcinogenic effect  
R63 - Possible risk of harm to the unborn child

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**2.2 Label elements**



**Signal Word:** Warning

**Hazard Statements:** H226 - Flammable liquid and vapor  
 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  
 P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking  
 P403 + P235 - Store in a well-ventilated place. Keep cool  
 P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
 P280 - Wear protective gloves/protective clothing/eye protection/face protection  
 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.
Ethyl Alcohol 64-17-5	30-50	Present	F; R11	Flam. Liq. 2 (H225)	No data available
Propylene Glycol 57-55-6	20-40	Present		Not Hazardous*	No data available
Water 7732-18-5	5-20	Present		Not Hazardous*	No data available
Castor Oil 8001-79-4	5-20	Present		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
Saccharin Sodium 128-44-9	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**

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#### **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: stinging, tearing, eye irritation.

**Medical Conditions Aggravated by Exposure:** Clinical data suggests any pre-existing ailments of the following organs: eyes, liver, gastrointestinal system, skin, or hematopoietic system. nervous system, thyroid. Hypersensitivity to the material and/or similar materials.

#### **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 water spray, alcohol-resistant foam, dry chemical or carbon dioxide

**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**

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**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. Keep away from open flames, hot surfaces and sources of ignition.

**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
Ethyl Alcohol 64-17-5	Not Applicable	None
Propylene Glycol 57-55-6	Not Applicable	None
Water 7732-18-5	Not Applicable	None
Castor Oil 8001-79-4	Not Applicable	None
Ritonavir 155213-67-5	160 mcg/m <sup>3</sup> TWA	None
Saccharin Sodium 128-44-9	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Ethyl Alcohol 64-17-5	1000 ppm STEL	STEL: 5000 ppm STEL: 9500 mg/m <sup>3</sup> TWA: 1000 ppm TWA: 1900 mg/m <sup>3</sup>	500 ppm TWA 960 mg/m <sup>3</sup> TWA 1000 ppm Peak 1920 mg/m <sup>3</sup> Peak	1000 ppm (STEL)	
Propylene Glycol 57-55-6				450 ppm (STEL) 1410 mg/m <sup>3</sup> (STEL) 30 mg/m <sup>3</sup> (STEL) 150 ppm (TWA) 470 mg/m <sup>3</sup> (TWA) 10 mg/m <sup>3</sup> (TWA)	

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Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Ethyl Alcohol 64-17-5	1900 mg/m <sup>3</sup> (STEL) 260 mg/m <sup>3</sup> (TWA)	1000 ppm (STEL) 1910 mg/m <sup>3</sup> (STEL)	500 ppm (TWA) 960 mg/m <sup>3</sup> (TWA) 1000 ppm (STEL) 1920 mg/m <sup>3</sup> (STEL)	3000 ppm (STEL) 5760 mg/m <sup>3</sup> (STEL) 1000 ppm (TWA) 1920 mg/m <sup>3</sup> (TWA)
Propylene Glycol 57-55-6				450 ppm (STEL) 1422 mg/m <sup>3</sup> (STEL) 30 mg/m <sup>3</sup> (STEL) 150 ppm (TWA) 474 mg/m <sup>3</sup> (TWA) 10 mg/m <sup>3</sup> (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:** Orange Liquid

**Odor:** Peppermint and caramel odor; slight sulphurous odor may also be present.

**Odor Threshold:** Not determined

**pH:** 3.7-4.7

**Boiling Pt. @ 760 mm Hg (°C):** Not determined.

**Melting/Freezing Point (°C):** Not determined

**Flash Point (°C):** 25

**Flash Point Method:** Tag Closed Cup (TCC)

**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.

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**Decomposition temperature** Not determined.  
**(°C):**  
**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

Keep away from open flames, hot surfaces and sources of ignition

### 10.5 Incompatible materials

Strong oxidizing agents, Strong acids, Strong bases

### 10.6 Hazardous decomposition products

Carbon oxides, Nitrogen oxides (NO<sub>x</sub>)

## **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
Ethyl Alcohol 64-17-5	LD50 =	3450-7060	mg/kg	Mice Rats
Propylene Glycol 57-55-6	LD50 =	10,000-33,700	mg/kg	Animals
Ritonavir 155213-67-5	LD50 =	1030 - 1970	mg/kg	Mice
Saccharin Sodium 128-44-9	LD50 =	1280 - 17,500	mg/kg	Mice Rats

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

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Chemical Name	Acute Test	Value	Units	Species
Ethyl Alcohol 64-17-5	LD50 =	20000	mg/kg	Rabbits
Propylene Glycol 57-55-6	LD50 =	20,800	mg/kg	Rabbits
Ritonavir 155213-67-5	LD50 >	2000	mg/kg	Rats

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

Chemical Name	Test	Value	Units	Species
Ethyl Alcohol 64-17-5	LC 50 =	20000	ppm	Rats

**Corrosivity:** Not determined.

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

**Eye Irritation:** Active Ingredient : Produced mild eye irritation in animal testing. 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
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 : In animals adverse reproductive effects include: maternal toxicity, fetal abnormalities.  
 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
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**

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Not determined.

Chemical Name	Percent	48h EC50 (daphnia - mg/l) (48HLCD)	Species	Duration
Propylene Glycol 57-55-6	20-40	1000		

### 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**

### IMDG/IMO

**Status:** Regulated

- 14.1. UN Number:** UN1170  
**14.2. Proper shipping name:** Ethanol solution  
**14.3. Hazard class:** 3  
**14.4. Packing group:** III  
**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:**

**ADR**

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**Status:** Not regulated

**DOT**

**Status:** Regulated  
**14.2. Proper shipping name:** Consumer commodity  
**14.3. Hazard class:** ORM-D

**ICAO/IATA**

**Status:** Regulated  
**14.1. UN Number:** ID8000  
**14.2. Proper shipping name:** Consumer Commodity  
**14.3. Hazard Class:** 9

**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
Ethyl Alcohol 64-17-5	Present	X	X	Not listed.	X
Propylene Glycol 57-55-6	Present	X	X	Not listed.	X
Water 7732-18-5	Present	X	X	Not listed.	X
Castor Oil 8001-79-4	Present	X	X	Not listed.	X
Ritonavir 155213-67-5	-	-	-	Not listed.	-
Saccharin Sodium 128-44-9	Present	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Ethyl Alcohol 64-17-5	Present	-	X	X	Present	HSR001144
Propylene Glycol 57-55-6	Present	Present	X	X	Present	
Water 7732-18-5	-	-	X	X	Present	
Castor Oil 8001-79-4	-	-	X	X	Present	
Ritonavir 155213-67-5	-	-	-	-	-	
Saccharin Sodium 128-44-9	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:
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Ethyl Alcohol	30-50	Not Listed	Monograph 100E [2012] (in alcoholic beverages); Monograph 96 [2010] (in alcoholic beverages)	A3 - Confirmed Animal Carcinogen with Unknown Relevance to Humans
Propylene Glycol	20-40	Not Listed	Not Listed	Not Listed
Water	5-20	Not Listed	Not Listed	Not Listed
Castor Oil	5-20	Not Listed	Not Listed	Not Listed
Ritonavir	5-20	Not Listed	Not Listed	Not Listed
Saccharin Sodium	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):
Ethyl Alcohol	30-50	No	Not Applicable	Not applicable
Propylene Glycol	20-40	No	Not Applicable	Not applicable
Water	5-20	No	Not Applicable	Not applicable
Castor Oil	5-20	No	Not Applicable	Not applicable
Ritonavir	5-20	No	Not Applicable	Not applicable
Saccharin Sodium	1-10	No	Not Applicable	Not applicable

**Immediate Health:** Yes  
**Delayed Health:** No  
**Fire:** Yes  
**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	Percent	Proposition 65 Listed Materials
Ethyl Alcohol 64-17-5 ( 30-50 )	30-50	carcinogen, initial date 4/29/11 (in alcoholic beverages) developmental toxicity, initial date 10/1/87 (in alcoholic beverages)

**WHMIS Hazard Class:** Not determined.

**NFPA Rating:**  
 Health: 1  
 Fire: 3  
 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**

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**Risk Phrases:**

R10 - Flammable  
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**

H226 - Flammable liquid and vapor  
H319 - Causes serious eye irritation  
H351 - Suspected of causing cancer  
H361 - Suspected of damaging fertility or the unborn child

**Document Authored By:** Occupational and Environmental Toxicology

**Issued:** Sep-22-2015

**Supersedes the SDS dated:** Sep-07-2011

**Disclaimer:**

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