

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

abbvie
SAFETY DATA SHEET

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

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 ³ 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 ³ TWA: 1000 ppm TWA: 1900 mg/m ³	500 ppm TWA 960 mg/m ³ TWA 1000 ppm Peak 1920 mg/m ³ Peak	1000 ppm (STEL)	
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)	

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Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Ethyl Alcohol 64-17-5	1900 mg/m ³ (STEL) 260 mg/m ³ (TWA)	1000 ppm (STEL) 1910 mg/m ³ (STEL)	500 ppm (TWA) 960 mg/m ³ (TWA) 1000 ppm (STEL) 1920 mg/m ³ (STEL)	3000 ppm (STEL) 5760 mg/m ³ (STEL) 1000 ppm (TWA) 1920 mg/m ³ (TWA)
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

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_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
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 according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable

ADR

Product Name: Norvir Oral Solution (ANZ)
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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

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