

**Product Name:**

**Dasabuvir Film-Coated Tablets (ANZ)**

**Issued:**

**Sep-30-2015**



## **SAFETY DATA SHEET**

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

#### **1.1 Product Identifier**

**Product Name:** Dasabuvir Film-Coated Tablets (ANZ)

**Synonyms:** Dasabuvir film-coated tablets 250 mg; Dasabuvir tablets; Exviera tablets; Viekira Pak; Holkira Pak

**List Number:** 3075; kit: 3093

#### **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**

**Chronic aquatic toxicity** Chronic toxicity 4

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

**Risk Phrases:** R53 - May cause long-term adverse effects in the aquatic environment

#### **2.2 Label elements**

**Hazard Statements:** H413 - May cause long lasting harmful effects to aquatic life

#### **2.3 Other hazards**

Not determined

### **Section 3. Composition/information on ingredients**

**Product Name:** Dasabuvir Film-Coated Tablets (ANZ)  
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Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Dasabuvir Sodium	30-50	NA		Aquatic Chronic Cat. 4 (H413)	No data available
Cellulose Microcrystalline 9004-34-6	20-40	Present		Not Hazardous*	No data available
Copovidone 25086-89-9	5-20	NA		Not Hazardous*	No data available
Lactose monohydrate 10039-26-6	5-20	NA		Not Hazardous*	No data available
Croscarmellose sodium 74811-65-7	1-10	NA		Not Hazardous*	No data available
Magnesium Stearate 557-04-0	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**

### **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**

**Product Name:** Dasabuvir Film-Coated Tablets (ANZ)  
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**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.

## **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
Dasabuvir Sodium	80 mcg/m <sup>3</sup>	None
Cellulose Microcrystalline 9004-34-6	Not Applicable	None

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Copovidone 25086-89-9	Not Applicable	None
Lactose monohydrate 10039-26-6	Not Applicable	None
Croscarmellose sodium 74811-65-7	Not Applicable	None
Magnesium Stearate 557-04-0	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Cellulose Microcrystalline 9004-34-6	10 mg/m <sup>3</sup> TWA	TWA: 10 mg/m <sup>3</sup>		20 mg/m <sup>3</sup> (STEL) 12 mg/m <sup>3</sup> (STEL) 10 mg/m <sup>3</sup> (TWA) 4 mg/m <sup>3</sup> (TWA)	
Magnesium Stearate 557-04-0	10 mg/m <sup>3</sup> total dust				

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Cellulose Microcrystalline 9004-34-6		10 mg/m <sup>3</sup> (TWA)	3 mg/m <sup>3</sup> (TWA)	20 mg/m <sup>3</sup> (STEL) 12 mg/m <sup>3</sup> (STEL) 10 mg/m <sup>3</sup> (TWA) 4 mg/m <sup>3</sup> (TWA)

## 8.2. Exposure controls

<b>Engineering Controls:</b>	No special provisions are required under normal product use conditions. Use inside a process enclosure when handling the bulk formulation.
<b>Respiratory Protection:</b>	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.
<b>Eyes:</b>	Eye protection not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.
<b>Gloves:</b>	Gloves not required during normal product use conditions. Wear impervious gloves when handling the bulk formulation.
<b>Other PPE Data:</b>	Not needed during normal product use. Wear appropriate body coverings if contact may occur.
<b>Environmental Exposure Controls:</b>	Not determined

## Section 9. Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

<b>Appearance:</b>	Beige Ovaloid tablet
<b>Odor:</b>	Not determined.
<b>Odor Threshold:</b>	Not determined
<b>pH:</b>	Not determined.
<b>Boiling Pt. @ 760 mm Hg (°C):</b>	Not determined.
<b>Melting/Freezing Point (°C):</b>	Not determined
<b>Flash Point (°C):</b>	Not determined.
<b>Evaporation Rate at 20°C:</b>	Not determined.
<b>Flammability (Solid):</b>	Not determined.
<b>Lower Explosive Limit:</b>	Not determined.
<b>Upper Explosive Limit:</b>	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  
**Maximum Pressure Rise (bar):** 6.9  
**Max. rate of pressure rise** 407  
**(bar/sec):**  
**Kst Value (bar.m/s):** 110  
**Min. Ignition Energy-Cloud** > 1000  
**(mJ):**  
**Min. Ignit. Temp. Dust Cloud** 600  
**(°C):**  
**Min. Explosive Conc. (g/m³):** 80

## **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**

**Product Name:** Dasabuvir Film-Coated Tablets (ANZ)  
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**Routes of Exposure:**

**Oral:** Clinical Route  
**Dermal:** Yes  
**Inhalation:** Unlikely

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

Chemical Name	Acute Test	Value	Units	Species
Cellulose Microcrystalline 9004-34-6	LD50 >	5000	mg/kg	Rats
Copovidone 25086-89-9	LD50 >	630	mg/kg	Rats
Lactose monohydrate 10039-26-6	LD50 >	10000	mg/kg, for a similar material	Rats

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

Chemical Name	Acute Test	Value	Units	Species
Cellulose Microcrystalline 9004-34-6	LD50 >	2000	mg/kg	Rabbits

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

Chemical Name	Test	Value	Units	Species
Cellulose Microcrystalline 9004-34-6	LC 50 >	5800	mg/m <sup>3</sup> , 4 hour	Rats
Magnesium Stearate 557-04-0	LC 50 >	2000	mg/m <sup>3</sup> , 1 hour	Rats

**Corrosivity:** Not determined.

**Dermal Irritation:** Not determined.

**Eye Irritation:** Not determined.

**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
Dasabuvir Sodium	None	Rats Dogs Monkeys	800 60 150	mg/kg	Oral	6 months once weekly for 3 weeks 28 days

**Reproductive Effects:** Not determined.

**Carcinogenicity:** Not determined.

**Mutagenicity:** Data for component (s) given below.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Dasabuvir Sodium	No Data.	Negative	Negative	Negative
Lactose monohydrate 10039-26-6	No Data.	Negative	No Data.	Negative
Magnesium Stearate 557-04-0	No Data.	Negative	No Data.	No Data.

**Aspiration hazard:** Not determined

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**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. No aquatic toxicity detected at the limit of solubility

Chemical Name	Percent	LC 50 (mg/l)	Species	Duration
Dasabuvir Sodium	30-50	> 0.80	Lepomis macrochirus	96 Hours

Chemical Name	Percent	72h IC50 (algae - mg/l) (72HICA)	Species	Duration
Dasabuvir Sodium	30-50	> 0.55	Pseudokirchneriella subcapitata	72 Hours

### 12.2. Persistence and degradability

Data for component (s) given below.

Chemical Name	Percent	% Degradation	Duration
Dasabuvir Sodium	30-50	0.4	28 days

### 12.3. Bioaccumulative potential

Data for components given below.

Chemical Name	Percent	Log Po/w
Dasabuvir Sodium	30-50	4.23

### 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

**Product Name:** Dasabuvir Film-Coated Tablets (ANZ)  
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**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
Dasabuvir Sodium	-	-	-	Not listed.	-
Cellulose Microcrystalline 9004-34-6	Present	X	X	Not listed.	X
Copovidone 25086-89-9	-	X	X	Not listed.	X
Lactose monohydrate 10039-26-6	-	-	-	Not listed.	-
Croscarmellose sodium 74811-65-7	-	-	-	Not listed.	X
Magnesium Stearate 557-04-0	Present	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Dasabuvir Sodium	-	-	-	-	-	
Cellulose Microcrystalline 9004-34-6	Present	-	X	X	Present	
Copovidone 25086-89-9	Present	-	X	X	Present	
Lactose monohydrate 10039-26-6	-	-	X	-	-	
Croscarmellose sodium 74811-65-7	-	-	X	X	-	
Magnesium Stearate 557-04-0	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:**



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Chemical Name	Percent	NTP:	IARC:	ACGIH:
Dasabuvir Sodium	30-50	Not Listed	Not Listed	Not Listed
Cellulose Microcrystalline	20-40	Not Listed	Not Listed	Not Listed
Copovidone	5-20	Not Listed	Not Listed	Not Listed
Lactose monohydrate	5-20	Not Listed	Not Listed	Not Listed
Croscarmellose sodium	1-10	Not Listed	Not Listed	Not Listed
Magnesium Stearate	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):
Dasabuvir Sodium	30-50	No	Not Applicable	Not applicable
Cellulose Microcrystalline	20-40	No	Not Applicable	Not applicable
Copovidone	5-20	No	Not Applicable	Not applicable
Lactose monohydrate	5-20	No	Not Applicable	Not applicable
Croscarmellose sodium	1-10	No	Not Applicable	Not applicable
Magnesium Stearate	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.

**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:**

R53 - May cause long-term adverse effects in the aquatic environment

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

H413 - May cause long lasting harmful effects to aquatic life

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

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