

Product Name:
Issued:

Moderiba
Jul-09-2014



SAFETY DATA SHEET

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

1.1 Product Identifier

Product Name: Moderiba

Synonyms: Moderiba (ribavirin); Ribavirin tablets; Moderiba 200 mg tablets; Moderiba 400 mg tablets; Moderiba 600 mg tablets

List Number: 3197; 3245; 3281; Packs: 3224; 3239; 3271; 3282

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: Manufactured for:
AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064
USA
+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

Skin sensitization	Category 1
Germ cell mutagenicity	Category 2
Reproductive toxicity	Category 1B

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

2.2 Label elements

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Section 2. Hazards identification



Signal Word: Warning

Hazard Statements:
H317 - May cause an allergic skin reaction
H341 - Suspected of causing genetic defects
H360 - May damage fertility or the unborn child

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.
Ribavirin	60-80	NA		Skin Cat 1 (H317); Mutag. Cat 2 (H341); Repro Cat 1B (H360)	No data available
Cellulose Microcrystalline 9004-34-6	5-20	Present		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
Polyvinyl Pyrrolidone 9003-39-8	1-10	NA		Not Hazardous*	No data available
Titanium dioxide 13463-67-5	0.1-1	236-675-5		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.

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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

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.

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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
Ribavirin	Not Applicable	None
Cellulose Microcrystalline 9004-34-6	Not Applicable	None
Lactose monohydrate 10039-26-6	Not Applicable	None
Croscarmellose sodium 74811-65-7	Not Applicable	None
Polyvinyl Pyrrolidone 9003-39-8	Not Applicable	None
Titanium dioxide 13463-67-5	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Cellulose Microcrystalline 9004-34-6	10 mg/m ³ total dust	TWA: 10 mg/m ³		20 mg/m ³ (STEL) 4 mg/m ³ (TWA)	
Polyvinyl Pyrrolidone 9003-39-8	10 mg/m ³ for nuisance dust; 3 mg/m ³ respirable particulate				

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

8.2. Exposure controls

Engineering Controls:

No special provisions are required under normal product use conditions.
Use inside a process enclosure when handling the bulk formulation.

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.

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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: Blue 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: n-octanol/water Not determined.

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

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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: Clinical Route
Dermal: Unlikely
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
Lactose monohydrate 10039-26-6	LD50 >	10000	mg/kg, for a similar material	Rats
Polyvinyl Pyrrolidone 9003-39-8	LD50 >	40,000	mg/kg	Rats Mice

Ribavirin: Rat oral LD50 = 2700 mg/kg; Mouse oral LD50 = 4000 mg/kg

Acute Toxicity - Dermal: Not determined.

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

Acute Toxicity - Inhalation: Not determined.

Chemical Name	Test	Value	Units	Species
Cellulose Microcrystalline 9004-34-6	LC 50 >	5800	mg/m ³ , 4 hour	Rats

Corrosivity: Not determined.

Dermal Irritation: Not determined.

Eye Irritation: Not determined.

Sensitization: The active ingredient is a skin sensitizer.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: Not determined.

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Reproductive Effects: Pregnancy Category X : Contraindicated in Pregnancy
Carcinogenicity: Not determined.
Mutagenicity: Mutagenic in Mouse Lymphoma assay. Mutagenic in Micronucleus assay.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Lactose monohydrate 10039-26-6	No Data.	Negative	No Data.	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

Not determined.

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 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
Ribavirin	-	-	-	Not listed.	-
Cellulose Microcrystalline 9004-34-6	Present	X	X	Not listed.	X
Lactose monohydrate 10039-26-6	-	-	-	Not listed.	-
Croscarmellose sodium 74811-65-7	-	-	-	Not listed.	X
Polyvinyl Pyrrolidone 9003-39-8	-	X	X	Not listed.	X
Titanium dioxide 13463-67-5	-	-	-	Not listed.	-

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Ribavirin	Present	-	-	-	-	
Cellulose Microcrystalline 9004-34-6	Present	-	X	X	Present	
Lactose monohydrate 10039-26-6	-	-	X	-	-	
Croscarmellose sodium 74811-65-7	-	-	X	X	-	
Polyvinyl Pyrrolidone 9003-39-8	Present	-	X	X	Present	
Titanium dioxide 13463-67-5	-	-	-	-	-	

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

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KECL - Korean Existing and Evaluated Chemical Substances

Carcinogenicity Rating:

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Ribavirin	60-80	Not Listed	Not Listed	Not Listed
Cellulose Microcrystalline	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
Polyvinyl Pyrrolidone	1-10	Not Listed	Not Listed	Not Listed
Titanium dioxide	0.1-1	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):
Ribavirin	60-80	No	Not Applicable	Not applicable
Cellulose Microcrystalline	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
Polyvinyl Pyrrolidone	1-10	No	Not Applicable	Not applicable
Titanium dioxide	0.1-1	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.

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

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

H317 - May cause an allergic skin reaction, H341 - Suspected of causing genetic defects, H360 - May damage fertility or the unborn child

Document Authored By: Occupational and Environmental Toxicology

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