

Product Name: Maviret Film-Coated Tablets
Issued: Sep-11-2017

abbvie
SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Name: Maviret Film-Coated Tablets
Synonyms: Mavyret Film-Coated Tablets; Glecaprevir/Pibrentasvir Film-Coated Tablets; ABT-493/ABT-530 Film-Coated Tablets
List Number: 0074-2625-28

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended use: Pharmaceuticals

Scientific research and development

1.3. Details of the supplier of the safety data sheet

Supplier: 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

Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

2.2. Label elements

Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

2.3. Other hazards

Not determined

SECTION 3: Composition/information on ingredients

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Chemical Name	Weight-%	EINECS/ELINCS Number	EU - GHS Substance Classification	REACH Reg. No
Copovidone 25086-89-9	60-80	NA	Not Hazardous*	No data available
Glecaprevir 1365970-03-1	5-20	NA	Not Hazardous*	No data available
Vitamin E TPGS 30999-06-5	5-20	NA	Not Hazardous*	No data available
Pibrentasvir 1353900-92-1	1-10	NA	STOT SE 3 (H335) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)	No data available
Opadry II L-02-231	1-10	NA	Not Hazardous*	No data available
Croscarmellose sodium 74811-65-7	1-10	NA	Not Hazardous*	No data available
Colloidal Silicon Dioxide 7631-86-9	1-9.9	Present	Not Hazardous*	No data available
Propylene glycol monocaprylate 31565-12-5	<5	NA	Not Hazardous*	No data available
Sodium Stearyl Fumarate 4070-80-8	<1	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.

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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.

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
Scientific research and development

SECTION 8: Exposure controls/personal protection

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8.1. Control parameters

Exposure limits:

Chemical Name	Employee Exposure Limit	Skin Notation
Copovidone 25086-89-9	Not Applicable	None
Glecaprevir 1365970-03-1	110 mcg/m ³	None
Vitamin E TPGS 30999-06-5	Not applicable	None
Pibrentasvir 1353900-92-1	130 mcg/m ³	None
Opadry II L-02-231	Not applicable	None
Croscarmellose sodium 74811-65-7	Not applicable	None
Colloidal Silicon Dioxide 7631-86-9	Not Applicable	None
Propylene glycol monocaprylate 31565-12-5	Not applicable	None
Sodium Stearyl Fumarate 4070-80-8	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
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)	

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)

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.

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

Product Name:	Maviret Film-Coated Tablets
Issued:	Sep-11-2017
Appearance:	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):	Water solubility: 343 mg/L for Glecaprevir, <0.09 mg/L for Pibrentasvir
Partition coefficient: n-octanol/water	Not determined
Log Po/w	7.47 (pH 7.4) for Pibrentasvir 2.48 (pH 7.4) for Glecaprevir
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

Hazardous reactions: Not determined

10.4. Conditions to avoid

Not determined

10.5. Incompatible materials

Not determined

10.6. Hazardous decomposition products

Not determined

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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
Copovidone 25086-89-9	LD50 >	630	mg/kg	Rats
Colloidal Silicon Dioxide 7631-86-9	LD50 =	3160	mg/kg	Rats

Acute Toxicity - Dermal: Not determined

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

Other Toxicology Data: Data for component (s) given below:

Chemical Name	Test Type	Value	Units	Species	Comments
Glecaprevir 1365970-03-1	NOAEL =	120 200	mg/kg	Rats Dogs	Oral 26 weeks 39 weeks

Corrosivity: Not determined

Dermal Irritation: By analogy, ABT-530 is an irritant

Eye irritation: By analogy, ABT-530 is an irritant

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
Colloidal Silicon Dioxide 7631-86-9	Respiratory System	Rats	126	mg/L	Inhalation	2 years

Reproductive Effects

There were no adverse effects in the fertility and early embryonic development study or the definitive GLP embryofetal toxicity study of ABT-493 in rats. The NOAEL for maternal and developmental/fetal toxicity was the highest oral dose evaluated of 120 mg/kg/day (53 times the exposure in humans at recommended human dose (RHD)). In the definitive GLP embryofetal study in rabbits there was no maternal or fetal toxicity at the highest dose evaluated of 60 mg/kg/day (0.07 times the exposure in humans at the RHD). In the pre/post-natal developmental study in rats there were no effects seen up to the highest dose of 120 mg/kg/day (47 times the exposure in humans at the RHD).

There were no adverse effects in the fertility and early embryonic development study at doses up to 100 mg/kg/day for ABT-530. In the definitive GLP embryofetal development studies there were no adverse effects on embryofetal development at doses up to 100 mg/kg/day in mice and rabbits, 51 times and 1.5

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times the exposures in humans at the RHD, respectively. In the pre/post-natal developmental study in mice there were no effects seen up to 100 mg/kg/day (about 74 times the exposure in humans at the RHD).

Carcinogenicity Not determined

Mutagenicity: Data for component (s) given below:

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Glecaprevir 1365970-03-1	Negative	Negative	No Data.	Negative
Pibrentasvir 1353900-92-1	Negative	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

Data for component (s) given below: For Glecaprevir, the EC50 for activated sludge respiration inhibition test (OECD 209) was >1000 mg/L at 30 min and 3 hrs. The 21 day NOEC for survival, reproduction, and growth in daphnia magna (OECD 211) were all 4.91 mg/L. The 28 day NOEC for all measured endpoints in the fish early life stage toxicity test (OECD 210) was 10.2 mg/L. The sediment-water chironomid NOEC was 813 mg/kg for all endpoints (OECD 218). For Pibrentasvir, the NOEC for activated sludge respiration inhibition test (OECD 209) was 1000 mg/L at 3 hrs.

Chemical Name	Weight-%	LC 50 (mg/l)	Species	Duration
Colloidal Silicon Dioxide 7631-86-9	1-9.9	5000	Brachydanio rerio	96 Hours

Chemical Name	Weight-%	48h EC50 (daphnia - mg/l) (48HLCD)	Species	Duration
Colloidal Silicon Dioxide 7631-86-9	1-9.9	7600	Daphnia magna	48 Hours

Chemical Name	Weight-%	72h IC50 (algae - mg/l) (72HICA)	Species	Duration
Glecaprevir 1365970-03-1	5-20	> 81	Pseudokirchneriella subcapitata	72 Hours
Pibrentasvir 1353900-92-1	1-10	>0.0044	Pseudokirchneriella subcapitata	72 Hours
Colloidal Silicon Dioxide 7631-86-9	1-9.9	440	Unicellular Green Algae	72 Hours

12.2. Persistence and degradability

Not determined

12.3. Bioaccumulative potential

Data for components given below.

Chemical Name	Weight-%	Log Po/w
Glecaprevir 1365970-03-1	5-20	2.48

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Pibrentasvir 1353900-92-1	1-10	7.47
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12.4. Mobility in soil

For Glecaprevir the Koc adsorption values for soils ranged from 1,243 to 2,506 L/kg and the values for sludges were 211 and 605 L/kg.

12.5. Results of PBT and 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
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
Copovidone 25086-89-9	4.8 mg/L	X	X	Not listed	X
Glecaprevir 1365970-03-1	4.8 mg/L	4.8 mg/L	4.8 mg/L	Not listed	4.8 mg/L

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Vitamin E TPGS 30999-06-5	4.8 mg/L	4.8 mg/L	4.8 mg/L	Not listed	4.8 mg/L
Pibrentasvir 1353900-92-1	4.8 mg/L	4.8 mg/L	4.8 mg/L	Not listed	4.8 mg/L
Opadry II L-02-231	4.8 mg/L	4.8 mg/L	4.8 mg/L	Not listed	4.8 mg/L
Croscarmellose sodium 74811-65-7	4.8 mg/L	4.8 mg/L	4.8 mg/L	Not listed	X
Colloidal Silicon Dioxide 7631-86-9	Present	X	X	Not listed	X
Propylene glycol monocaprylate 31565-12-5	4.8 mg/L	4.8 mg/L	4.8 mg/L	Not listed	4.8 mg/L
Sodium Stearyl Fumarate 4070-80-8	Present	4.8 mg/L	4.8 mg/L	Not listed	4.8 mg/L

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Copovidone 25086-89-9	Present	Present	X	X	Present	
Glecaprevir 1365970-03-1	4.8 mg/L	4.8 mg/L	4.8 mg/L	4.8 mg/L	4.8 mg/L	
Vitamin E TPGS 30999-06-5	4.8 mg/L	4.8 mg/L	4.8 mg/L	4.8 mg/L	4.8 mg/L	
Pibrentasvir 1353900-92-1	4.8 mg/L	4.8 mg/L	4.8 mg/L	4.8 mg/L	4.8 mg/L	
Opadry II L-02-231	4.8 mg/L	4.8 mg/L	4.8 mg/L	4.8 mg/L	4.8 mg/L	
Croscarmellose sodium 74811-65-7	4.8 mg/L	4.8 mg/L	X	X	4.8 mg/L	
Colloidal Silicon Dioxide 7631-86-9	Present	Present	X	X	Present	
Propylene glycol monocaprylate 31565-12-5	Present	Present	4.8 mg/L	4.8 mg/L	4.8 mg/L	
Sodium Stearyl Fumarate 4070-80-8	4.8 mg/L	4.8 mg/L	4.8 mg/L	4.8 mg/L	4.8 mg/L	HSR007040

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	Weight-%	NTP:	IARC:	ACGIH:
Copovidone	60-80	Not listed	Not listed	Not listed
Glecaprevir	5-20	Not listed	Not listed	Not listed
Vitamin E TPGS	5-20	Not listed	Not listed	Not listed
Pibrentasvir	1-10	Not listed	Not listed	Not listed
Opadry II	1-10	Not listed	Not listed	Not listed
Croscarmellose sodium	1-10	Not listed	Not listed	Not listed
Colloidal Silicon Dioxide	1-9.9	Not listed	Not listed	Not listed
Propylene glycol monocaprylate	<5	Not listed	Not listed	Not listed
Sodium Stearyl Fumarate	<1	Not listed	Not listed	Not listed

SARA 313 Information

Chemical Name	Weight-%	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Copovidone	60-80	No	Not applicable	Not applicable
Glecaprevir	5-20	No	Not applicable	Not applicable
Vitamin E TPGS	5-20	No	Not applicable	Not applicable
Pibrentasvir	1-10	No	Not applicable	Not applicable
Opadry II	1-10	No	Not applicable	Not applicable

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Croscarmellose sodium	1-10	No	Not applicable	Not applicable
Colloidal Silicon Dioxide	1-9.9	No	Not applicable	Not applicable
Propylene glycol monocaprylate	<5	No	Not applicable	Not applicable
Sodium Stearyl Fumarate	<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

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

R37 - Irritating to respiratory system

R38 - Irritating to skin

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

H315 - Causes skin irritation

H319 - Causes serious eye irritation

H335 - May cause respiratory irritation

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