

Product Name: Venclexta Tablets (10, 50 and 100 mg)
Issued: Sep-16-2016

abbvie
SAFETY DATA SHEET

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

1.1. Product identifier

Product Name: Venclexta Tablets (10, 50 and 100 mg)
Synonyms: Venetoclax (10, 50 and 100 mg); Venclexta Tablets; Venetoclax Tablets

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 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

Reproductive toxicity Category 2
Specific target organ systemic toxicity (repeated exposure) Category 1

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

Indication of danger: Xn - Harmful
Risk Phrases: R48/25 - Toxic: danger of serious damage to health by prolonged exposure if swallowed
R62 - Possible risk of impaired fertility

2.2. Label elements



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Signal Word: Warning

Hazard Statements: H361 - Suspected of damaging fertility or the unborn child
H372 - Causes damage to organs through prolonged or repeated exposure

Precautionary Statements P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P314 - Get medical advice/attention if you feel unwell
P501 - Dispose of contents/container to an approved waste disposal plant

2.3. Other hazards

Not determined

SECTION 3: Composition/information on ingredients

Chemical Name	Weight-%	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH Reg. No
Copovidone 25086-89-9	50-70	NA		Not Hazardous*	No data available
Venetoclax (CAS# 1257044-40-8)	10-70	NA	T, R48/25, R62	Repro 2 (H361); STOT RE1 (H372)	No data available
Calcium Phosphate, Dibasic 7757-93-9	5-80	Present		Not Hazardous*	No data available
Polysorbate 80 9005-65-6	5-30	NA		Not Hazardous*	No data available
OPADRY II Yellow	1-10	NA		Not Hazardous*	No data available
Colloidal Silicon Dioxide 7631-86-9	1-10	Present		Not Hazardous*	No data available
Sodium Stearyl Fumarate 4070-80-8	0.1-1	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.

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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. Available information support the following: altered white blood cells and thrombocytes, nausea, fatigue, respiratory infection, loss of appetite, spasms, headaches, vomiting.

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.

6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

SECTION 7: Handling and storage

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7.1. Precautions for safe handling

Avoid contact with skin, eyes and clothing.

7.2. Conditions for safe storage, including any incompatibilities

Keep container closed when not in use.

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
Copovidone 25086-89-9	Not Applicable	None
Venetoclax (CAS# 1257044-40-8)	30 mcg/m ³	None
Calcium Phosphate, Dibasic 7757-93-9	Not applicable	None
Polysorbate 80 9005-65-6	Not applicable	None
OPADRY II Yellow	Not applicable	None
Colloidal Silicon Dioxide 7631-86-9	Not Applicable	None
Sodium Stearyl Fumarate 4070-80-8	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Calcium Phosphate, Dibasic 7757-93-9	10 mg/m ³ total dust for carbonate and sulfate salts of calcium				
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: Utilize appropriate engineering controls (i.e. hood, glovebox, or process enclosure) when handling open containers of this compound.

Respiratory Protection: An approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

Eyes: Wear eye protection appropriate to handling activities.

Gloves: Impervious gloves.

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Other PPE Data: Wear chemical protective clothing 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:	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 recommended storage conditions

10.3. Possibility of hazardous reactions

Hazardous reactions: Not determined

10.4. Conditions to avoid

Not determined

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10.5. Incompatible materials

Not determined

10.6. Hazardous decomposition products

Not determined

SECTION 11: Toxicological information
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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
Venetoclax (CAS# 1257044-40-8)	ALD =	1000 2000 2000	mg/kg	Male Mice Female Mice Rats
Calcium Phosphate, Dibasic 7757-93-9	LD50 >	5000	mg/kg	Guinea Pigs
Polysorbate 80 9005-65-6	LD50 =	25,000 - 36,570	mg/kg	Mice 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

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
Venetoclax (CAS# 1257044-40-8)	Male Reproductive System	Dogs	3 5	mg/kg	Oral	14 days 28 days
Colloidal Silicon Dioxide 7631-86-9	Respiratory System	Rats	126	mg/L	Inhalation	2 years

Reproductive Effects Based on animal data, may impair fertility or cause other reproductive effects.

Chemical Name	Species	Dosage	Units	Route	Duration
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Venetoclax (CAS# 1257044-40-8)	Mice	50	mg/kg	Oral	During Gestation
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Carcinogenicity Not determined

Mutagenicity: Data for component (s) given below:

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Venetoclax (CAS# 1257044-40-8)	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:

Chemical Name	Weight-%	LC 50 (mg/l)	Species	Duration
Colloidal Silicon Dioxide 7631-86-9	1-10	5000	Brachydanio rerio	96 Hours

Chemical Name	Weight-%	48h EC50 (daphnia - mg/l) (48HLCD)	Species	Duration
Colloidal Silicon Dioxide 7631-86-9	1-10	7600	Daphnia magna	48 Hours

Chemical Name	Weight-%	72h IC50 (algae - mg/l) (72HICA)	Species	Duration
Colloidal Silicon Dioxide 7631-86-9	1-10	440	Unicellular Green Algae	72 Hours

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 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.

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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 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
Copovidone 25086-89-9	-	X	X	Not listed	X
Venetoclax (CAS# 1257044-40-8)	-	-	-	Not listed	-
Calcium Phosphate, Dibasic 7757-93-9	Present	X	X	Not listed	X
Polysorbate 80 9005-65-6	-	X	X	Not listed	X
OPADRY II Yellow	-	-	-	Not listed	-
Colloidal Silicon Dioxide 7631-86-9	Present	X	X	Not listed	X
Sodium Stearyl Fumarate 4070-80-8	Present	-	-	Not listed	-

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Copovidone 25086-89-9	Present	-	X	X	Present	

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Venetoclax (CAS# 1257044-40-8)	-	-	-	-	-	
Calcium Phosphate, Dibasic 7757-93-9	Present	-	X	X	Present	HSR003703
Polysorbate 80 9005-65-6	Present	Present	X	X	Present	
OPADRY II Yellow	-	-	-	-	-	
Colloidal Silicon Dioxide 7631-86-9	Present	-	X	X	Present	
Sodium Stearyl Fumarate 4070-80-8	-	-	-	-	-	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	50-70	Not listed	Not listed	Not listed
Venetoclax (CAS# 1257044-40-8)	10-70	Not listed	Not listed	Not listed
Calcium Phosphate, Dibasic	5-80	Not listed	Not listed	Not listed
Polysorbate 80	5-30	Not listed	Not listed	Not listed
OPADRY II Yellow	1-10	Not listed	Not listed	Not listed
Colloidal Silicon Dioxide	1-10	Reasonably Anticipated To Be A Human Carcinogen (listed under Ceramic fibers)	Not listed	Not listed
Sodium Stearyl Fumarate	0.1-1	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	50-70	No	Not applicable	Not applicable
Venetoclax (CAS# 1257044-40-8)	10-70	No	Not applicable	Not applicable
Calcium Phosphate, Dibasic	5-80	No	Not applicable	Not applicable
Polysorbate 80	5-30	No	Not applicable	Not applicable
OPADRY II Yellow	1-10	No	Not applicable	Not applicable
Colloidal Silicon Dioxide	1-10	No	Not applicable	Not applicable
Sodium Stearyl Fumarate	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

NFPA Rating:

Health: 0
Fire: 1

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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:

R48/25 - Toxic: danger of serious damage to health by prolonged exposure if swallowed
R62 - Possible risk of impaired fertility

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

H361 - Suspected of damaging fertility or the unborn child
H372 - Causes damage to organs through prolonged or repeated exposure

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Supersedes the SDS dated: May-20-2013

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