

**Product Name:** Venclexta Tablets (10, 50 and 100 mg)  
**Issued:** Nov-09-2017

**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; ABT-199 Tablets  
**List Number:** 0579, 0561, 0566, 0576, 0561, 0566 and 0576  
**Drug Code Number:** 0074-0579-28, 0074-0561-14, 0074-0566-07, 0074-0576-22, 0074-0561-11, 0075-0566-11 and 0074-0576-11

**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 1B

**2.2. Label elements**



**Signal Word:** Danger

**Hazard Statements:** H360 - May damage fertility or the unborn child

**Product Name:** Venclexta Tablets (10, 50 and 100 mg)  
**Issued:** Nov-09-2017

**Precautionary Statements** P202 - Do not handle until all safety precautions have been read and understood  
P281 - Use personal protective equipment as required  
P308 + P313 - IF exposed or concerned: Get medical advice/attention  
P405 - Store locked up

### 2.3. Other hazards

Not determined

## **SECTION 3: Composition/information on ingredients**

Chemical Name	Weight-%	EINECS/ELINCS Number	EU - GHS Substance Classification	REACH Reg. No
Copovidone 25086-89-9	50-70	NA	Not Hazardous*	No data available
Venetoclax (ABT-199) 1257044-40-8	10-70	NA	Repro 1B (H360)	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.

**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

**Product Name:** Venclexta Tablets (10, 50 and 100 mg)  
**Issued:** Nov-09-2017

**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**

#### **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.

**Product Name:** Venclaxta Tablets (10, 50 and 100 mg)  
**Issued:** Nov-09-2017

**7.3. Specific end use(s)**

**Recommended use:** Pharmaceuticals

**SECTION 8: Exposure controls/personal protection**

**8.1. Control parameters**

**Exposure limits:**

Chemical Name	AbbVie Employee Exposure Limit	Skin Notation
Copovidone 25086-89-9	Not Applicable	None
Venetoclax (ABT-199) 1257044-40-8	30 mcg/m <sup>3</sup>	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 <sup>3</sup> total dust for carbonate and sulfate salts of calcium				
Colloidal Silicon Dioxide 7631-86-9	10 mg/m <sup>3</sup> for nuisance dust; 3 mg/m <sup>3</sup> respirable particulate		4 mg/m <sup>3</sup> TWA	18 mg/m <sup>3</sup> (STEL) 7.2 mg/m <sup>3</sup> (STEL) 6 mg/m <sup>3</sup> (TWA) 2.4 mg/m <sup>3</sup> (TWA)	

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Colloidal Silicon Dioxide 7631-86-9			4 mg/m <sup>3</sup> (TWA)	18 mg/m <sup>3</sup> (STEL) 7.2 mg/m <sup>3</sup> (STEL) 6 mg/m <sup>3</sup> (TWA) 2.4 mg/m <sup>3</sup> (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.

**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**

**Product Name:** Venclexta Tablets (10, 50 and 100 mg)  
**Issued:** Nov-09-2017

**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):** 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

**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

### 10.5. Incompatible materials

Not determined

### 10.6. Hazardous decomposition products

Not determined

**Product Name:** Venclaxta Tablets (10, 50 and 100 mg)  
**Issued:** Nov-09-2017

**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
Venetoclax (ABT-199) 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 (ABT-199) 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** Data for component (s) given below: In mice: decreased fetal bodyweight, increased post-implantation loss,

Chemical Name	Species	Dosage	Units	Route	Duration
Venetoclax (ABT-199) 1257044-40-8	Mice	300	mg/kg	Oral	During Gestation

**Carcinogenicity** Not determined

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

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay

**Product Name:** Venclaxta Tablets (10, 50 and 100 mg)  
**Issued:** Nov-09-2017

Venetoclax (ABT-199) 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:

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

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

<b>Chemical Name</b>	<b>Weight-%</b>	<b>72h IC50 (algae - mg/l)</b>	<b>Species</b>	<b>Duration</b>
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.

**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**

**Product Name:** Venclexta Tablets (10, 50 and 100 mg)  
**Issued:** Nov-09-2017

**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
Venetoclax (ABT-199) 1257044-40-8	4.8 mg/L	4.8 mg/L	4.8 mg/L	Not listed	4.8 mg/L
Calcium Phosphate, Dibasic 7757-93-9	Present	X	X	Not listed	X
Polysorbate 80 9005-65-6	4.8 mg/L	X	X	Not listed	X
OPADRY II Yellow	4.8 mg/L	4.8 mg/L	4.8 mg/L	Not listed	4.8 mg/L
Colloidal Silicon Dioxide 7631-86-9	Present	X	X	Not listed	X
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	
Venetoclax (ABT-199) 1257044-40-8	4.8 mg/L	4.8 mg/L	4.8 mg/L	4.8 mg/L	4.8 mg/L	
Calcium Phosphate, Dibasic 7757-93-9	Present	Present	X	X	Present	HSR003703
Polysorbate 80 9005-65-6	Present	Present	X	X	Present	
OPADRY II Yellow	4.8 mg/L	4.8 mg/L	4.8 mg/L	4.8 mg/L	4.8 mg/L	
Colloidal Silicon Dioxide 7631-86-9	Present	Present	X	X	Present	
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



**Product Name:** Venclaxta Tablets (10, 50 and 100 mg)  
**Issued:** Nov-09-2017

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 (ABT-199)	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	Not listed	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 (ABT-199)	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  
 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**

**Product Name:** Venclexta Tablets (10, 50 and 100 mg)  
**Issued:** Nov-09-2017

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

H360 - May damage fertility or the unborn child

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

**Issued:** Nov-09-2017

**Supersedes the SDS dated:** May-20-2013

**Disclaimer:**

*The information and recommendations contained herein are based upon tests believed to be reliable. However, AbbVie Inc. does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage may be required. AbbVie Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.*