

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Doravirine Formulation

Version  
10.0

Revision Date:  
2025/11/20

SDS Number:  
58376-00027

Date of last issue: 2025/04/14  
Date of first issue: 2015/02/16

---

### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Doravirine Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : 199 Wenhai North Road  
HEDA, Hangzhou - Zhejiang Province - CHINA 310018

Telephone : +1-908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

---

### 2. HAZARDS IDENTIFICATION

#### Emergency Overview

Appearance	: powder
Colour	: off-white
Odour	: No data available

Not a hazardous substance or mixture.

#### GHS Classification

||| Not a hazardous substance or mixture.

#### GHS label elements

||| No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

#### Physical and chemical hazards

Not classified based on available information.

#### Health hazards

Not classified based on available information.

#### Environmental hazards

Not classified based on available information.

#### Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Doravirine Formulation

Version  
10.0

Revision Date:  
2025/11/20

SDS Number:  
58376-00027

Date of last issue: 2025/04/14  
Date of first issue: 2015/02/16

May form explosive dust-air mixture during processing, handling or other means.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	>= 20 -< 30
Doravirine	1338225-97-0	>= 10 -< 20
Magnesium stearate	557-04-0	>= 1 -< 10

### 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.  
Get medical attention if symptoms occur.

In case of skin contact : Wash with water and soap.  
Get medical attention if symptoms occur.

In case of eye contact : If in eyes, rinse well with water.  
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention if symptoms occur.  
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : Contact with dust can cause mechanical irritation or drying of the skin.  
Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders : No special precautions are necessary for first aid responders.

Notes to physician : Treat symptomatically and supportively.

### 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire-fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.  
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
Halogenated compounds  
Metal oxides

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Doravirine Formulation

Version 10.0	Revision Date: 2025/11/20	SDS Number: 58376-00027	Date of last issue: 2025/04/14 Date of first issue: 2015/02/16
-----------------	------------------------------	----------------------------	---

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.  
Use personal protective equipment.

## 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

## 7. HANDLING AND STORAGE

### Handling

Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not breathe dust.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Minimize dust generation and accumulation.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Doravirine Formulation

Version  
10.0

Revision Date:  
2025/11/20

SDS Number:  
58376-00027

Date of last issue: 2025/04/14  
Date of first issue: 2015/02/16

	Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.
Avoidance of contact	: Oxidizing agents
<b>Storage</b>	
Conditions for safe storage	: Keep in properly labelled containers. Store in accordance with the particular national regulations.
Materials to avoid	: Do not store with the following product types: Strong oxidizing agents
Packaging material	: Unsuitable material: None known.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Cellulose	9004-34-6	PC-TWA	10 mg/m3	CN OEL
		TWA	10 mg/m3	ACGIH
Doravirine	1338225-97-0	TWA	500 ug/m3 (OEB2)	Internal
Magnesium stearate	557-04-0	TWA (Inhal- able particu- late matter)	10 mg/m3	ACGIH
		TWA (Res- pirable par- ticulate mat- ter)	3 mg/m3	ACGIH

**Engineering measures** : Use feasible engineering controls to minimize exposure to compound.  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

### Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Eye/face protection : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.

Hand protection

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Doravirine Formulation

Version 10.0	Revision Date: 2025/11/20	SDS Number: 58376-00027	Date of last issue: 2025/04/14 Date of first issue: 2015/02/16
-----------------	------------------------------	----------------------------	---

Material	: Chemical-resistant gloves
Hygiene measures	: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: powder
Colour	: off-white
Odour	: No data available
Odour Threshold	: No data available
pH	: No data available
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: No data available
Flash point	: Not applicable
Evaporation rate	: Not applicable
Flammability (solid, gas)	: May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	: No data available
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Vapour pressure	: Not applicable
Relative vapour density	: Not applicable
Relative density	: No data available
Density	: No data available
Solubility(ies)	

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Doravirine Formulation

Version 10.0	Revision Date: 2025/11/20	SDS Number: 58376-00027	Date of last issue: 2025/04/14 Date of first issue: 2015/02/16
-----------------	------------------------------	----------------------------	---

Water solubility	: No data available
Partition coefficient: n-octanol/water	: Not applicable
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	
Viscosity, kinematic	: Not applicable
Explosive properties	: Not explosive
Oxidizing properties	: The substance or mixture is not classified as oxidizing.
Molecular weight	: No data available
Particle characteristics	
Particle size	: No data available

## 10. STABILITY AND REACTIVITY

Reactivity	: Not classified as a reactivity hazard.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	: Heat, flames and sparks. Avoid dust formation.
Incompatible materials	: Oxidizing agents
Hazardous decomposition products	: No hazardous decomposition products are known.

## 11. TOXICOLOGICAL INFORMATION

Exposure routes	: Inhalation Skin contact Ingestion Eye contact
-----------------	--

### Acute toxicity

Not classified based on available information.

### Components:

#### **Cellulose:**

Acute oral toxicity	: LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity	: LC50 (Rat): > 5.8 mg/l Exposure time: 4 h

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Doravirine Formulation

Version  
10.0

Revision Date:  
2025/11/20

SDS Number:  
58376-00027

Date of last issue: 2025/04/14  
Date of first issue: 2015/02/16

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

### Doravirine:

Acute oral toxicity : LD50 (Rat): > 750 mg/kg  
Remarks: No mortality observed at this dose.

(Rat): Method: Phototoxicity  
Remarks: No evidence of phototoxicity was observed

LD50 (Dog): > 1,000 mg/kg  
Remarks: No mortality observed at this dose.

LD50 (Mouse): > 450 mg/kg  
Remarks: No mortality observed at this dose.

### Magnesium stearate:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 423  
Assessment: The substance or mixture has no acute oral toxicity  
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Remarks: Based on data from similar materials

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### Doravirine:

Remarks : No data available

#### Magnesium stearate:

Species : Rabbit  
Result : No skin irritation  
Remarks : Based on data from similar materials

### Serious eye damage/eye irritation

Not classified based on available information.

### Components:

#### Doravirine:

Remarks : No data available

#### Magnesium stearate:

Species : Rabbit

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Doravirine Formulation

Version 10.0      Revision Date: 2025/11/20      SDS Number: 58376-00027      Date of last issue: 2025/04/14  
Date of first issue: 2015/02/16

Result	:	No eye irritation
Remarks	:	Based on data from similar materials

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### Components:

##### Doravirine:

Remarks	:	No data available
---------	---	-------------------

##### Magnesium stearate:

Test Type	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative
Remarks	:	Based on data from similar materials

### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### Cellulose:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		Test Type: In vitro mammalian cell gene mutation test Result: negative
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Result: negative

##### Doravirine:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: negative
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Rat

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Doravirine Formulation

Version  
10.0

Revision Date:  
2025/11/20

SDS Number:  
58376-00027

Date of last issue: 2025/04/14  
Date of first issue: 2015/02/16

Cell type: Bone marrow  
Application Route: Oral  
Result: negative

### **Magnesium stearate:**

Genotoxicity in vitro	: Test Type: In vitro mammalian cell gene mutation test Result: negative Remarks: Based on data from similar materials
	Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Remarks: Based on data from similar materials
	Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials

### **Carcinogenicity**

Not classified based on available information.

### **Components:**

#### **Cellulose:**

Species	: Rat
Application Route	: Ingestion
Exposure time	: 72 weeks
Result	: negative

#### **Doravirine:**

Species	: Mouse
Application Route	: Oral
Exposure time	: 6 Months
Result	: negative
Remarks	: No significant adverse effects were reported

### **Reproductive toxicity**

Not classified based on available information.

### **Components:**

#### **Cellulose:**

Effects on fertility	: Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative
Effects on foetal development	: Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Doravirine Formulation

Version  
10.0

Revision Date:  
2025/11/20

SDS Number:  
58376-00027

Date of last issue: 2025/04/14  
Date of first issue: 2015/02/16

II

### Doravirine:

Effects on fertility	: Test Type: Fertility Species: Rat, male and female Fertility: NOAEL: 450 mg/kg body weight Result: No effects on fertility
Effects on foetal development	: Test Type: Embryo-foetal development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 450 mg/kg body weight Result: No adverse effects
	Test Type: Embryo-foetal development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: 300 mg/kg body weight Result: No adverse effects

### Magnesium stearate:

Effects on fertility	: Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test Species: Rat Application Route: Ingestion Method: OECD Test Guideline 422 Result: negative Remarks: Based on data from similar materials
Effects on foetal development	: Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

### Repeated dose toxicity

### Components:

#### Cellulose:

Species	: Rat
NOAEL	: $\geq 9,000$ mg/kg
Application Route	: Ingestion
Exposure time	: 90 Days

### Doravirine:

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Doravirine Formulation

Version 10.0	Revision Date: 2025/11/20	SDS Number: 58376-00027	Date of last issue: 2025/04/14 Date of first issue: 2015/02/16
-----------------	------------------------------	----------------------------	---

---

Species	:	Rat
NOAEL	:	450 mg/kg
Application Route	:	Oral
Exposure time	:	6 Months
Remarks	:	No significant adverse effects were reported

Species	:	Mouse
NOAEL	:	> 450 mg/kg
Application Route	:	Oral
Exposure time	:	3 Months
Remarks	:	No significant adverse effects were reported

Species	:	Dog
NOAEL	:	> 1,000 mg/kg
Application Route	:	Oral
Exposure time	:	9 Months
Remarks	:	No significant adverse effects were reported

### **Magnesium stearate:**

Species	:	Rat
NOAEL	:	> 100 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days
Remarks	:	Based on data from similar materials

### **Aspiration toxicity**

Not classified based on available information.

### **Experience with human exposure**

#### **Components:**

#### **Doravirine:**

Ingestion	:	Symptoms: confusion, Headache, Dizziness, Nausea, Rash, abnormal dreams, flushing, Neurological disorders, mental depression
-----------	---	--

---

## 12. ECOLOGICAL INFORMATION

### **Ecotoxicity**

#### **Components:**

#### **Cellulose:**

Toxicity to fish	:	LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
------------------	---	--

---

#### **Doravirine:**

Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Americamysis): 9.1 mg/l Exposure time: 96 h
---	---	--

---

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Doravirine Formulation

Version 10.0	Revision Date: 2025/11/20	SDS Number: 58376-00027	Date of last issue: 2025/04/14 Date of first issue: 2015/02/16
-----------------	------------------------------	----------------------------	---

Toxicity to algae/aquatic plants	: EC50 (Pseudokirchneriella subcapitata (green algae)): > 5.8 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility
	NOEC (Pseudokirchneriella subcapitata (green algae)): 5.8 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility
Toxicity to fish (Chronic toxicity)	: NOEC (Pimephales promelas (fathead minnow)): 1 mg/l Exposure time: 32 d Method: OECD Test Guideline 210 Remarks: No toxicity at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 0.38 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 Remarks: No toxicity at the limit of solubility
Toxicity to microorganisms	: EC50: > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209  NOEC: 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209

### Magnesium stearate:

Toxicity to fish	: LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l Exposure time: 48 h Method: DIN 38412 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	: EL50 (Daphnia magna (Water flea)): > 1 mg/l Exposure time: 47 h Test substance: Water Accommodated Fraction Method: Directive 67/548/EEC, Annex V, C.2. Remarks: Based on data from similar materials No toxicity at the limit of solubility
Toxicity to algae/aquatic plants	: EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: Based on data from similar materials No toxicity at the limit of solubility

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Doravirine Formulation

Version  
10.0

Revision Date:  
2025/11/20

SDS Number:  
58376-00027

Date of last issue: 2025/04/14  
Date of first issue: 2015/02/16

		NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
Toxicity to microorganisms	:	EC10 (Pseudomonas putida): > 100 mg/l Exposure time: 16 h Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

### Persistence and degradability

#### Components:

##### **Cellulose:**

Biodegradability	:	Result: Readily biodegradable.
------------------	---	--------------------------------

##### **Doravirine:**

Biodegradability	:	Result: Not readily biodegradable. Biodegradation: 2 % Exposure time: 28 d
------------------	---	--

##### **Magnesium stearate:**

Biodegradability	:	Result: Not biodegradable Remarks: Based on data from similar materials
------------------	---	--

### Bioaccumulative potential

#### Components:

##### **Doravirine:**

Partition coefficient: n-octanol/water	:	log Pow: 2.08
--	---	---------------

##### **Magnesium stearate:**

Partition coefficient: n-octanol/water	:	log Pow: > 4
--	---	--------------

### Mobility in soil

#### Components:

##### **Doravirine:**

Distribution among environmental compartments	:	log Koc: 2.86
---	---	---------------

### Other adverse effects

No data available

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Doravirine Formulation

Version 10.0	Revision Date: 2025/11/20	SDS Number: 58376-00027	Date of last issue: 2025/04/14 Date of first issue: 2015/02/16
-----------------	------------------------------	----------------------------	---

### 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

### 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

Not regulated as a dangerous good

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Environmentally hazardous : no

##### IATA-DGR

Not regulated as a dangerous good

UN/ID No. : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Packing instruction (cargo aircraft) : Not applicable  
Packing instruction (passenger aircraft) : Not applicable

##### IMDG-Code

Not regulated as a dangerous good

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
EmS Code : Not applicable  
Marine pollutant : no

#### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

#### National Regulations

##### GB 6944/12268

Not regulated as a dangerous good

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Doravirine Formulation

Version 10.0	Revision Date: 2025/11/20	SDS Number: 58376-00027	Date of last issue: 2025/04/14 Date of first issue: 2015/02/16
-----------------	------------------------------	----------------------------	---

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Marine pollutant	:	no

### Special precautions for user

Not applicable

## 15. REGULATORY INFORMATION

### National regulatory information

#### Law on the Prevention and Control of Occupational Diseases

#### Regulations on Safety Management of Hazardous Chemicals

Catalogue of Hazardous Chemicals	:	This product is not listed in the catalogue of hazardous chemicals and it does not meet the definition of hazardous chemicals and its principles of determination.
----------------------------------	---	--

Identification of Major Hazard Installations for Hazardous Chemicals (GB 18218)	:	Not listed
---	---	------------

Hazardous Chemicals for Priority Management under SAWS	:	Not listed
--	---	------------

Catalogue of Specially Controlled Hazardous Chemicals	:	Not listed
---	---	------------

List of Explosive Precursors	:	Not listed
------------------------------	---	------------

#### Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals	:	Not listed
-------------------------------------	---	------------

#### Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import and Export	:	Not listed
---	---	------------

#### Regulation on the Administration of Precursor Chemicals

Catalogue and Classification of Precursor Chemicals	:	Not listed
---	---	------------

#### Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

#### Regulations of Ozone Depleting Substances Management

List of Controlled Ozone Depleting Substances Import	:	Not listed
--	---	------------

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Doravirine Formulation

Version  
10.0

Revision Date:  
2025/11/20

SDS Number:  
58376-00027

Date of last issue: 2025/04/14  
Date of first issue: 2015/02/16

---

### and Export

List of Controlled Ozone Depleting Substances : Not listed

### Environmental Protection Law

List of Priority Controlled Chemicals : Not listed

List of Key Controlled New Pollutants : Not listed

List of Toxic and Hazardous Water Pollutants : Not listed

List of Toxic and Hazardous Air Pollutants : Not listed

List of Toxic and Hazardous Soil Pollutants : Not listed

### Measures for the Administration of Non-Medical Use of Narcotic Drugs and Psychotropic Substances

Catalogue of Controlled Narcotic Drugs and Psychotropic Substances with Non-Medical Use : Not listed

### Measures for the Administration on Import and Export Licenses for Dual-Use Items and Technologies

Catalogue for Dual-Use Items and Technologies : Not listed

### The components of this product are reported in the following inventories:

AICS : not determined

CA. DSL : not determined

IECSC : not determined

---

## 16. OTHER INFORMATION

Revision Date : 2025/11/20

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

CN OEL : Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.

ACGIH / TWA : 8-hour, time-weighted average

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Doravirine Formulation

Version 10.0	Revision Date: 2025/11/20	SDS Number: 58376-00027	Date of last issue: 2025/04/14 Date of first issue: 2015/02/16
-----------------	------------------------------	----------------------------	---

CN OEL / PC-TWA : Permissible concentration - time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonised System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organisation; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organisation for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

### Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

CN / EN