

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Doravirine Formulation

Version  
6.0

Revision Date:  
20.11.2025

SDS Number:  
9371601-00011

Date of last issue: 14.04.2025  
Date of first issue: 27.08.2021

---

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

#### 1.1 Product identifier

Trade name : Doravirine Formulation

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

Use of the Sub-  
stance/Mixture : Pharmaceutical

Recommended restrictions  
on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
120 Moorgate  
EC2M 6UR London, United Kingdom

Telephone : +44 (0) 2081548000

E-mail address of person  
responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

+1-908-423-6000

---

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

**Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK  
SI 2019/720, and UK SI 2020/1567)**

Not a hazardous substance or mixture.

#### 2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI  
2019/720, and UK SI 2020/1567)**

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

EUH210 Safety data sheet available on request.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Doravirine Formulation

Version  
6.0

Revision Date:  
20.11.2025

SDS Number:  
9371601-00011

Date of last issue: 14.04.2025  
Date of first issue: 27.08.2021

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Dust contact with the eyes can lead to mechanical irritation.

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

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

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Doravirine	1338225-97-0		>= 10 - < 20
Substances with a workplace exposure limit :			
Cellulose	9004-34-6 232-674-9		>= 20 - < 30
Silicon, amorphous	112945-52-5		>= 1 - < 10

For explanation of abbreviations see section 16.

## SECTION 4: First aid measures

### 4.1 Description of 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.

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

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.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Doravirine Formulation

Version  
6.0

Revision Date:  
20.11.2025

SDS Number:  
9371601-00011

Date of last issue: 14.04.2025  
Date of first issue: 27.08.2021

---

### 4.2 Most important symptoms and effects, both acute and delayed

Risks : Contact with dust can cause mechanical irritation or drying of the skin.  
Dust contact with the eyes can lead to mechanical irritation.

### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

---

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

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

Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

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

### 5.3 Advice for firefighters

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

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.

---

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Doravirine Formulation

Version  
6.0

Revision Date:  
20.11.2025

SDS Number:  
9371601-00011

Date of last issue: 14.04.2025  
Date of first issue: 27.08.2021

---

### 6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Retain and dispose of contaminated wash water.  
If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

### 6.3 Methods and material for containment and cleaning up

Methods for 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.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

---

## SECTION 7: Handling and storage

### 7.1 Precautions for safe 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.  
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.

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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Doravirine Formulation

Version  
6.0

Revision Date:  
20.11.2025

SDS Number:  
9371601-00011

Date of last issue: 14.04.2025  
Date of first issue: 27.08.2021

use of administrative controls.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents

### 7.3 Specific end use(s)

Specific use(s) : No data available

No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

dust of any kind 10 mg/m<sup>3</sup>  
Value type (Form of exposure): TWA (Inhalable)  
Basis: GB EH40

4 mg/m<sup>3</sup>  
Value type (Form of exposure): TWA (Respirable fraction)  
Basis: GB EH40

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Cellulose	9004-34-6	TWA (inhalable dust)	10 mg/m <sup>3</sup>	GB EH40
		TWA (Respirable dust)	4 mg/m <sup>3</sup>	GB EH40
		STEL (inhalable dust)	20 mg/m <sup>3</sup>	GB EH40
Doravirine	1338225-97-0	TWA	500 ug/m <sup>3</sup> (OEB2)	Internal
Silicon, amorphous	112945-52-5	TWA (inhalable dust)	6 mg/m <sup>3</sup> (Silica)	GB EH40
		TWA (Respirable dust)	2.4 mg/m <sup>3</sup> (Silica)	GB EH40

#### Predicted No Effect Concentration (PNEC)

Substance name	Environmental Compartment	Value
Doravirine	Fresh water	0.04 mg/l
	Marine water	0.04 mg/l

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Doravirine Formulation

Version  
6.0

Revision Date:  
20.11.2025

SDS Number:  
9371601-00011

Date of last issue: 14.04.2025  
Date of first issue: 27.08.2021

### 8.2 Exposure controls

#### 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

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.
Hand protection	
Material	: Chemical-resistant gloves
Skin and body protection	: Work uniform or laboratory coat.
Respiratory protection	: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to BS EN 143
Filter type	: Particulates type (P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic 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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Doravirine Formulation

Version 6.0	Revision Date: 20.11.2025	SDS Number: 9371601-00011	Date of last issue: 14.04.2025 Date of first issue: 27.08.2021
----------------	------------------------------	------------------------------	-------------------------------------------------------------------

---

Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
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.

### 9.2 Other information

Molecular weight	:	No data available
Particle size	:	No data available

---

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
---------------------	---	----------------------------------------------------------------------------------------------------------------------------

### 10.4 Conditions to avoid

Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
---------------------	---	---------------------------------------------------

### 10.5 Incompatible materials

Materials to avoid	:	Oxidizing agents
--------------------	---	------------------

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Doravirine Formulation

Version  
6.0

Revision Date:  
20.11.2025

SDS Number:  
9371601-00011

Date of last issue: 14.04.2025  
Date of first issue: 27.08.2021

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Components:

##### 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.

##### Cellulose:

Acute oral toxicity	: LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity	: LC50 (Rat): > 5.8 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute dermal toxicity	: LD50 (Rabbit): > 2,000 mg/kg

##### Silicon, amorphous:

Acute oral toxicity	: LD50 (Rat): > 5,000 mg/kg Method: OECD Test Guideline 401 Remarks: Based on data from similar materials
Acute inhalation toxicity	: LC50 (Rat): > 2.08 mg/l Exposure time: 4 h Test atmosphere: dust/mist Assessment: The substance or mixture has no acute inhalation toxicity Remarks: Based on data from similar materials
Acute dermal toxicity	: LD50 (Rabbit): > 5,000 mg/kg

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Doravirine Formulation

Version  
6.0

Revision Date:  
20.11.2025

SDS Number:  
9371601-00011

Date of last issue: 14.04.2025  
Date of first issue: 27.08.2021



Remarks: Based on data from similar materials

### **Skin corrosion/irritation**

Not classified based on available information.

#### **Components:**

##### **Doravirine:**

||| Remarks : No data available

##### **Silicon, amorphous:**

Species	:	Rabbit
Method	:	OECD Test Guideline 404
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

##### **Silicon, amorphous:**

Species	:	Rabbit
Method	:	OECD Test Guideline 405
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

### **Germ cell mutagenicity**

Not classified based on available information.

#### **Components:**

##### **Doravirine:**

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES)
		Result: negative

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Doravirine Formulation

Version  
6.0

Revision Date:  
20.11.2025

SDS Number:  
9371601-00011

Date of last issue: 14.04.2025  
Date of first issue: 27.08.2021

		Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: negative
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Rat Cell type: Bone marrow Application Route: Oral Result: negative
<b>Cellulose:</b>		
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
<b>Silicon, amorphous:</b>		
Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative Remarks: Based on data from similar materials
Genotoxicity in vivo	:	Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials

### Carcinogenicity

Not classified based on available information.

### Components:

#### **Doravirine:**

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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Doravirine Formulation

Version 6.0      Revision Date: 20.11.2025      SDS Number: 9371601-00011      Date of last issue: 14.04.2025  
Date of first issue: 27.08.2021

---

### Cellulose:

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

### Silicon, amorphous:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	103 weeks
Result	:	negative
Remarks	:	Based on data from similar materials

### Reproductive toxicity

Not classified based on available information.

### Components:

#### 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

#### 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

#### Silicon, amorphous:

Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat
-------------------------------	---	------------------------------------------------------

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Doravirine Formulation

Version  
6.0

Revision Date:  
20.11.2025

SDS Number:  
9371601-00011

Date of last issue: 14.04.2025  
Date of first issue: 27.08.2021



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:

##### Doravirine:

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

##### Cellulose:

Species	:	Rat
NOAEL	:	>= 9,000 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days

##### Silicon, amorphous:

Species	:	Rat
NOAEL	:	1.3 mg/l
Application Route	:	inhalation (dust/mist/fume)
Exposure time	:	13 Weeks
Remarks	:	Based on data from similar materials

### Aspiration toxicity

Not classified based on available information.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Doravirine Formulation

Version  
6.0

Revision Date:  
20.11.2025

SDS Number:  
9371601-00011

Date of last issue: 14.04.2025  
Date of first issue: 27.08.2021

### Experience with human exposure

#### Components:

##### **Doravirine:**

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

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

##### **Doravirine:**

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

||| 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 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

||| Toxicity to fish (Chronic toxicity) : NOEC: 1 mg/l  
Exposure time: 32 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210  
Remarks: No toxicity at the limit of solubility

||| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0.38 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211  
Remarks: No toxicity at the limit of solubility

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Doravirine Formulation

Version 6.0      Revision Date: 20.11.2025      SDS Number: 9371601-00011      Date of last issue: 14.04.2025  
Date of first issue: 27.08.2021

---

### Cellulose:

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

### Silicon, amorphous:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 10,000 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 1,000 mg/l  
Exposure time: 24 h  
Method: OECD Test Guideline 202  
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 10,000 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials  
  
NOEC (Desmodesmus subspicatus (green algae)): 10,000 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

## 12.2 Persistence and degradability

### Components:

#### Doravirine:

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

#### Cellulose:

Biodegradability : Result: Readily biodegradable.

## 12.3 Bioaccumulative potential

### Components:

#### Doravirine:

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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Doravirine Formulation

Version 6.0 Revision Date: 20.11.2025 SDS Number: 9371601-00011 Date of last issue: 14.04.2025 Date of first issue: 27.08.2021

---

### 12.4 Mobility in soil

#### Components:

#### **Doravirine:**

Distribution among environmental compartments : log Koc: 2.86

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Other adverse effects

#### Product:

Endocrine disrupting potential : This substance/mixture does not contain components considered to have endocrine disrupting properties for environment according to UK REACH Article 57(f) at levels of 0.1% or higher.

---

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.  
Do not dispose of waste into sewer.

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.

---

## SECTION 14: Transport information

### 14.1 UN number

**ADN** : Not regulated as a dangerous good  
**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA** : Not regulated as a dangerous good

### 14.2 UN proper shipping name

**ADN** : Not regulated as a dangerous good

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Doravirine Formulation

---

Version 6.0	Revision Date: 20.11.2025	SDS Number: 9371601-00011	Date of last issue: 14.04.2025 Date of first issue: 27.08.2021
----------------	------------------------------	------------------------------	-------------------------------------------------------------------

---

**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA** : Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

**ADN** : Not regulated as a dangerous good  
**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA** : Not regulated as a dangerous good

### 14.4 Packing group

**ADN** : Not regulated as a dangerous good  
**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA (Cargo)** : Not regulated as a dangerous good  
**IATA (Passenger)** : Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Not applicable

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

---

## SECTION 15: Regulatory information

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) : Not applicable  
UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation : Not applicable  
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain) : Not applicable  
Regulation (EU) No 2024/590 on substances that deplete the ozone layer : Not applicable  
UK REACH List of substances subject to authorisation (Annex XIV) : Not applicable

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## Doravirine Formulation

Version Revision Date: SDS Number: Date of last issue: 14.04.2025  
6.0 20.11.2025 9371601-00011 Date of first issue: 27.08.2021

GB Export and import of hazardous chemicals - Prior : Not applicable  
Informed Consent (PIC) Regulation  
Control of Major Accident Hazards Regulations 2015 (COMAH)  
Not applicable

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

AICS : not determined  
CA. DSL : not determined  
IFCSC : not determined

## 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

---

**SECTION 16: Other information**

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

### Full text of other abbreviations

GB EH40 : UK. EH40 WEL - Workplace Exposure Limits  
GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)  
GB EH40 / STEL : Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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) Subchronic Assessment Report.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Doravirine Formulation

Version  
6.0

Revision Date:  
20.11.2025

SDS Number:  
9371601-00011

Date of last issue: 14.04.2025  
Date of first issue: 27.08.2021

---

tative) 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

### 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.

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.

GB / EN