

# **Doravirine Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 8.1 28.09.2024 58389-00026 Date of first issue: 16.02.2015

### 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- : Pharmaceutical

stance/Mixture

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

117 16th Road

1685 Halfway house, Midrand, South Africa

Telephone : +27 11 655 3000

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)

Not a hazardous substance or mixture.

### 2.2 Label elements

#### Labelling (REGULATION (EC) No 1272/2008)

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

### 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.



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

#### 3.2 Mixtures

#### Components

Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	Registration number		
Doravirine	1338225-97-0		>= 10 - < 20

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 ad-

vice 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, DO NOT induce vomiting.

Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

#### 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.





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### **SECTION 5: Firefighting measures**

5.1 Extinguishing media

Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

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 prod- :

ucts

Carbon oxides

Nitrogen oxides (NOx) Halogenated compounds

Metal oxides

5.3 Advice for firefighters

Special protective equipment:

for firefighters

Wear self-contained breathing apparatus for firefighting if nec-

essary. Use personal protective equipment.

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

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 pro-

tective equipment recommendations (see section 8).

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.

Local authorities should be advised if significant spillages

cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up Sweep up or vacuum up spillage and collect in suitable con-

tainer for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces





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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. Use only with adequate ventilation.

Local/Total 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 as-

sessment

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 contami-

nated 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.

## 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.

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

Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s) No data available

No data available



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

# 8.1 Control parameters

### **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis	
Cellulose	9004-34-6	OEL-RL	10 mg/m3	ZA OEL	
	Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents				
Doravirine	1338225- 97-0	TWA	500 ug/m3 (OEB2)	Internal	

#### 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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

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

Flash point

: Not applicable

No data available



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Evaporation rate : Not applicable

Flammability (solid, gas) : May form explosive dust-air mixture during processing, han-

dling or other means.

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)

Water solubility
Partition coefficient: n-

octanol/water

No data available

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

Flammability (liquids) : No data available

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, han-



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dling 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

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 : Inhalation exposure 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.

Skin corrosion/irritation

Not classified based on available information.

**Components:** 

Doravirine:

Remarks : No data available

Serious eye damage/eye irritation

Not classified based on available information.

**Components:** 

Doravirine:



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Remarks : No data available

## 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

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

# 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

### Reproductive toxicity

Not classified based on available information.

#### Components:

### **Doravirine:**

Effects on fertility : Test Type: Fertility

Species: Rat, male and female



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Fertility: NOAEL: 450 mg/kg body weight

Result: No effects on fertility

Effects on foetal develop-

ment

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

#### 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

# **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



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## **SECTION 12: Ecological information**

#### 12.1 Toxicity

### **Components:**

**Doravirine:** 

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 39 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: No toxicity at the limit of solubility

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 tox-

icity)

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 (Chron-

ic toxicity)

NOEC: 6,7 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

Remarks: No toxicity at the limit of solubility

### 12.2 Persistence and degradability

#### **Components:**

**Doravirine:** 



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Biodegradability : Result: Not readily biodegradable.

Biodegradation: 2 % Exposure time: 28 d

### 12.3 Bioaccumulative potential

### **Components:**

Doravirine:

Partition coefficient: n-

octanol/water

: log Pow: 2,08

# 12.4 Mobility in soil

#### **Components:**

**Doravirine:** 

Distribution among environ-

mental 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 poten-

tial

The substance/mixture does not contain components considered to have endocrine disrupting properties according to

REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### **SECTION 14: Transport information**

### 14.1 UN number



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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
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

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

AICS : not determined



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DSL : not determined

IECSC : 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

ZA OEL : South Africa. The Regulations for Hazardous Chemical

Agents, Occupational Exposure Limits

ZA OEL / OEL-RL : Occupational Exposure Limit Restricted limit - 8- hour expo-

sure or equivalent (12 hour shifts)

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 Harmonized 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 Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; 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 - Organization 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; 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



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**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 Agen-

cy, http://echa.europa.eu/

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.

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