

# **Doravirine Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
7.1	28.09.2024	59282-00027	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 t	he s	ubstance 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	saf	ety data sheet
	Company	:	MSD Piercetown A86 HD21 Dunboyne, Ireland
	Telephone	:	908-740-4000
	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. Commission Regulation (EU) 2020/878



# **Doravirine Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
7.1	28.09.2024	59282-00027	Date of first issue: 16.02.2015

Ecological information: 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.

Toxicological information: 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.

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

oompononto			
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	:	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 cau	use mechanical i	rritation of	or drying of
-------	---	---------------------------	------------------	--------------	--------------

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Doravirine Formulation**

Version 7.1	Revision Date: 28.09.2024		9S Number: 282-00027	Date of last issue: 06.07.2024 Date of first issue: 16.02.2015
			the skin. Dust contact wi	th the eyes can lead to mechanical irritation.
	-	med		nd special treatment needed
Tre	eatment	:	Treat symptom	atically and supportively.
SECTI	ON 5: Firefighting mea	sur	es	
5.1 Ext	inguishing media			
Su	itable extinguishing media	:	Water spray Alcohol-resistar Carbon dioxide Dry chemical	
	suitable extinguishing dia	:	None known.	
5.2 Spe	cial hazards arising from	n the	substance or r	nixture
	ecific hazards during fire- hting	:	concentrations, potential dust e	ng dust; fine dust dispersed in air in sufficient and in the presence of an ignition source is a xplosion hazard. mbustion products may be a hazard to health.
Ha uc	zardous combustion prod- s	:	Carbon oxides Nitrogen oxides Halogenated co Metal oxides	
5.3 Adv	vice for firefighters			
	ecial protective equipment firefighters	:		ained breathing apparatus for firefighting if nec rsonal protective equipment.
Sp od	ecific extinguishing meth- s	:	cumstances an Use water spra	ng measures that are appropriate to local cir- d the surrounding environment. y to cool unopened containers. naged containers from fire area if it is safe to d

# 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.	



# **Doravirine Formulation**

Version 7.1	Revision Date: 28.09.2024	SDS Number: 59282-00027	Date of last issue: 06.07.2024 Date of first issue: 16.02.2015
			spose of contaminated wash water. es should be advised if significant spillages tained.
6.3 Metho	ods and material for o	containment and cle	aning up
Methods for cleaning up :		tainer for disp Avoid disperse with compress Dust deposits es, as these n leased into the Local or nation posal of this n employed in th mine which re Sections 13 a	al of dust in the air (i.e., clearing dust surfaces

### 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

•	i rooddhorio ror oaro nanaing	
	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 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.



# **Doravirine Formulation**

Versio 7.1	n Revision Date: 28.09.2024	SDS Number: 59282-00027	Date of last issue: 06.07.2024 Date of first issue: 16.02.2015				
7.2 Co	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.				
A	dvice on common storage	: Do not store Strong oxidiz	with the following product types: ng agents				
•	ecific end use(s)						
S	pecific use(s)	: No data availa	able				
		No data availa	able				

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

### 8.1 Control parameters

### **Occupational Exposure Limits**

dusts non-specific

4 mg/m3 Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable dust) Basis: IE OEL

10 mg/m3 Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable dust) Basis: IE OEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Cellulose	9004-34-6	OELV - 8 hrs (TWA)	10 mg/m3	IE OEL
Doravirine	1338225- 97-0	TWA	500 ug/m3 (OEB2)	Internal
Magnesium stea- rate	557-04-0	OELV - 8 hrs (TWA)	10 mg/m3	IE OEL
Silicon, amorphous	112945-52- 5	OELV - 8 hrs (TWA) (Respira- ble dust)	2.4 mg/m3 (Silica)	IE OEL
		OELV - 8 hrs (TWA) (inhalable dust)	6 mg/m3 (Silica)	IE OEL

### 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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Doravirine Formulation**

Version 7.1	Revision Date: 28.09.2024	SDS Nur 59282-00	
Eye/fa	ace protection	lf the mists Wear	safety glasses with side shields or goggles. work environment or activity involves dusty conditions, or aerosols, wear the appropriate goggles. a faceshield or other full face protection if there is a ial for direct contact to the face with dusts, mists, or ols.
Hand	protection		
Ma	aterial	: Chem	ical-resistant gloves
Skin a	and body protection	: Work	uniform or laboratory coat.
Respi	ratory protection	sure a ommo Equip	quate local exhaust ventilation is not available or expo- ssessment demonstrates exposures outside the rec- inded guidelines, use respiratory protection. ment should conform to I.S. EN 143
Filt	ter type	: Partic	ulates type (P)

### **SECTION 9: Physical and chemical properties**

### 9.1 Information on basic physical and chemical properties

Physical state	:	powder
Colour	:	off-white
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, han- dling 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
Flash point	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
рН	:	No data available

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Doravirine Formulation**

Vers 7.1	sion	Revision Date: 28.09.2024		9S Number: 282-00027	Date of last issue: 06.07.2024 Date of first issue: 16.02.2015
		cosity, kinematic	:	Not applicable	
	Solubil Wa	ter solubility	:	No data availabl	9
	Partitic octano	on coefficient: n- I/water	:	Not applicable	
	Vapou	r pressure	:	Not applicable	
	Relativ	e density	:	No data availabl	e
	Density	y	:	No data available	e
	Relativ	e vapour density	:	Not applicable	
		e characteristics ticle size	:	No data availabl	e
9.2 (		nformation		<b>N 1 1 1</b>	
	Explos	IVES	:	Not explosive	
	Oxidizi	ng properties	:	The substance c	r mixture is not classified as oxidizing.
	Evapo	ration rate	:	Not applicable	
	Molecu	ular weight	:	No data availabl	e

### **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 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 Heat, flames and sparks. Avoid dust formation. 10.5 Incompatible materials Materials to avoid Oxidizing agents

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Doravirine Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
7.1	28.09.2024	59282-00027	Date of first issue: 16.02.2015

### **10.6 Hazardous decomposition products**

No hazardous decomposition products are known.

<b>SECTION 11</b>	Toxicological	information
-------------------	---------------	-------------

11.1	Information on hazard class	es	as defined in Regulation (EC) No 1272/2008
	Information on likely routes of exposure		
	Acute toxicity		
	Not classified based on availab	ole	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 availab	ole	information.
	Components:		
	Doravirine:		
	Remarks	:	No data available
	Serious eye damage/eye irrit	ati	on
	Not classified based on availab		
	Components:		
	Doravirine:		
	Remarks	:	No data available
	Respiratory or skin sensitisa	atio	n
	Skin sensitisation		
	Not classified based on availab	ole	information.

### Respiratory sensitisation

Not classified based on available information.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Doravirine Formulation**

ersion 1	Revision Date: 28.09.2024		0S Number: 282-00027	Date of last issue: 06.07.2024 Date of first issue: 16.02.2015
Com	ponents:			
<b>Dora</b> Rema	<b>virine:</b> arks	:	No data available	
	n <b>cell mutagenicity</b> lassified based on avai	lable	information.	
Com	ponents:			
Dora	virine:			
Geno	toxicity in vitro	:	Test Type: Bacter Result: negative	rial reverse mutation assay (AMES)
				nosomal aberration nese hamster ovary cells
Geno	toxicity in vivo	:	Test Type: Micror Species: Rat Cell type: Bone m Application Route Result: negative	narrow
Not c	i <b>nogenicity</b> lassified based on avai	lable	information.	
	ponents:			
Speci Applie	cation Route sure time It		Mouse Oral 6 Months negative No significant adv	verse effects were reported
-	oductive toxicity lassified based on avai	lable	information.	
Com	ponents:			
	virine:			
	ts on fertility	:	Test Type: Fertilit Species: Rat, ma Fertility: NOAEL: Result: No effects	le and female 450 mg/kg body weight
Effect ment	ts on foetal develop-	:	Species: Rat Application Route	oxicity: NOAEL: 450 mg/kg body weight

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Doravirine Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
7.1	28.09.2024	59282-00027	Date of first issue: 16.02.2015

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 NOAEL Application Route Exposure time Remarks	 Rat 450 mg/kg Oral 6 Months No significant adverse effects were reported
Species NOAEL Application Route Exposure time Remarks	 Mouse > 450 mg/kg Oral 3 Months No significant adverse effects were reported
Species NOAEL Application Route Exposure time Remarks	 Dog > 1,000 mg/kg Oral 9 Months No significant adverse effects were reported

### Aspiration toxicity

Not classified based on available information.

#### 11.2 Information on other hazards

### Endocrine disrupting properties

### Product:

Assessment

: 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.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Doravirine Formulation**

Version 7.1	Revision Date: 28.09.2024	SDS Number: 59282-00027		Date of last issue: 06.07.2024 Date of first issue: 16.02.2015
Exper	ience with human exp	osu	ire	
<u>Comp</u>	onents:			
<b>Dorav</b> Ingest		:		sion, Headache, Dizziness, Nausea, Rash, , flushing, Neurological disorders, mental
SECTION	12: Ecological infor	ma	tion	
12.1 Toxic	ity			
<u>Comp</u>	onents:			
Dorav	virine:			
	ty to daphnia and other c invertebrates	:	Exposure time: 48 Method: OECD Te	
			EC50 (Americamy Exposure time: 96	
Toxicit plants	ty to algae/aquatic	:	mg/l Exposure time: 72 Method: OECD Te	
			mg/l Exposure time: 72 Method: OECD Te	
Toxicit	ty to microorganisms	:	EC50 : > 1,000 m Exposure time: 3 Test Type: Respir Method: OECD Te	h ation inhibition
			NOEC : 1,000 mg Exposure time: 3 Test Type: Respir Method: OECD Te	h ration inhibition
Toxicil icity)	ty to fish (Chronic tox-	:	Method: OECD Te	ales promelas (fathead minnow)
Toxicit	ty to daphnia and other	:	NOEC: 6.7 mg/l	

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Doravirine Formulation**

Versio 7.1	on	Revision Date: 28.09.2024		DS Number: 282-00027	Date of last issue: 06.07.2024 Date of first issue: 16.02.2015		
	aquatic c toxic	c invertebrates (Chron- ity)		Method: OECD T	1 d a magna (Water flea) Test Guideline 211 icity at the limit of solubility		
12.2 F	Persis	tence and degradabi	lity				
<u>c</u>	Compo	onents:					
D	Doravi	rine:					
В	Biodeg	ıradability	:	Result: Not readil Biodegradation: Exposure time: 2	2 %		
12.3 E	Bioaco	cumulative potential					
<u>C</u>	Compo	onents:					
P		r <b>ine:</b> n coefficient: n- l/water	:	log Pow: 2.08			
12.4 N	Mobili	ty in soil					
<u>c</u>	Compo	onents:					
D			:	log Koc: 2.86			
12.5 F	Result	s of PBT and vPvB a	sse	ssment			
<u>P</u>	Produ	<u>ct:</u>					
A	Assess	sment	:	to be either persis	nixture contains no components considered stent, bioaccumulative and toxic (PBT), or nd very bioaccumulative (vPvB) at levels of		
12.6 E	12.6 Endocrine disrupting properties						
	Produ						
A	Assess	sment	:	ered to have end REACH Article 5	ixture does not contain components consid- ocrine disrupting properties according to 7(f) or Commission Delegated regulation or Commission Regulation (EU) 2018/605 at higher.		
4070	•						

### 12.7 Other adverse effects

No data available

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878

# **Doravirine Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
7.1	28.09.2024	59282-00027	Date of first issue: 16.02.2015

### **SECTION 13:** Disposal considerations

13.1 Waste treatment methods	
Product	<ul> <li>Dispose of in accordance with local regulations.</li> <li>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.</li> <li>Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.</li> <li>Do not dispose of waste into sewer.</li> </ul>
Contaminated packaging	<ul> <li>Empty containers should be taken to an approved waste han- dling site for recycling or disposal.</li> <li>If not otherwise specified: Dispose of as unused product.</li> </ul>

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

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
ΙΑΤΑ	:	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
ΙΑΤΑ	:	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
ΙΑΤΑ	:	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

### 14.1 UN number or ID number

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Doravirine Formulation**

Version 7.1	Revision Date: 28.09.2024	SDS Number: 59282-00027	Date of last issue: 06.07.2024 Date of first issue: 16.02.2015		
ΙΑΤΑ (	Cargo)	0	ed as a dangerous good		
IATA (Passenger)		: Not regulate	: Not regulated as a dangerous good		
<b>14.5 Environmental hazards</b> Not regulated as a dangerous		s good			
<b>14.6 Special precautions for user</b> Not applicable					
14.7 Maritime transport in bulk according to IMO instruments					
Remarks		: Not applicat	: Not applicable for product as supplied.		

### **SECTION 15: Regulatory information**

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	:	Not applicable
REACH - Candidate List of Substances of Very High	:	Not applicable
Concern for Authorisation (Article 59).		
Regulation (EC) on substances that deplete the ozone	:	Not applicable
layer		
Regulation (EU) 2019/1021 on persistent organic pollu-	:	Not applicable
tants (recast)		
Regulation (EU) No 649/2012 of the European Parlia-	:	Not applicable
ment and the Council concerning the export and import		
of dangerous chemicals		
REACH - List of substances subject to authorisation	:	Not applicable
(Annex XIV)		
Severa III: Directive 2012/18/ELL of the European Parlian	nent	and of the Council on

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

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

AICS	:	not determined
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.
-------------------	---	--



# **Doravirine Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
7.1	28.09.2024	59282-00027	Date of first issue: 16.02.2015

### Full text of H-Statements

#### Full text of other abbreviations

IE OEL

Ireland. List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1 and 2

IE OEL / OELV - 8 hrs (TWA) :

Occupational exposure limit value (8-hour 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 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### **Further information**

compile the Safety Data Sheet

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, 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 mate-



# **Doravirine Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
7.1	28.09.2024	59282-00027	Date of first issue: 16.02.2015

rial 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.

IE / EN