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

Vorinostat Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	44853-00024	Date of first issue: 06.01.2015

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

1.1	Product identifier		
	Trade name	:	Vorinostat 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	e saf	ety data sheet
	Company	:	MSD
			Piercetown
			A86 HD21 Dunboyne, Ireland
	Telephone	:	A86 HD21 Dunboyne, Ireland 908-740-4000

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)

Germ cell mutagenicity, Category 2	H341: Suspected of causing genetic defects.
Reproductive toxicity, Category 1B	H360FD: May damage fertility. May damage the unborn child.
Specific target organ toxicity - repeated	H372: Causes damage to organs through pro-
exposure, Category 1	longed or repeated exposure.
Short-term (acute) aquatic hazard, Cate- gory 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Cat- egory 1	H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)



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

Vorinostat Formulation

Version 4.3	Revision Date: 28.09.2024	-	DS Number: 4853-00024	Date of last issue: 06.04.2024 Date of first issue: 06.01.2015
Haza	rd pictograms	:		¥_2
Signa	al word	:	Danger	•
Haza	rd statements	:	H341 H360FD	Suspected of causing genetic defects. May damage fertility. May damage the unborn child.
			H372	Causes damage to organs through prolonged or repeated exposure.
			H410	Very toxic to aquatic life with long lasting effects.
Preca	autionary statements	:	Prevention	:
			P201	Obtain special instructions before use.
			P260 P273	Do not breathe dust. Avoid release to the environment.
			P280	Wear protective gloves/ protective clothing/ eye protection/ face protection.
			Response:	
			P308 + P31	3 IF exposed or concerned: Get medical advice/ attention.
			P391	Collect spillage.

Hazardous components which must be listed on the label:

Vorinostat

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.

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					
Chemical name	CAS-No. EC-No.	Classification	Concentration (% w/w)		



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

Vorinostat Formulation

Repr. 1B; H360FD STOT RE 1; H372 (Blood, thymus gland, Bone marrow, spleen, Gastrointesti-	Version 4.3	Revision Date: 28.09.2024	SDS Number: 44853-00024	Date of last issue: 06.04.2024 Date of first issue: 06.01.2015	
Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1	Vorine	ostat	Registration nu	Muta. 2; H341 Repr. 1B; H360FD STOT RE 1; H372 (Blood, thymus gland, Bone marrow, spleen, Gastrointesti- nal tract) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic	>= 50 - < 70

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	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
If inhaled	:	If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	:	In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
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. Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed



Vorinostat Formulation

Version 4.3	Revision Date: 28.09.2024	SDS Number: 44853-00024	Date of last issue: 06.04.2024 Date of first issue: 06.01.2015	
Risks		May damage f	causing genetic defects. ertility. May damage the unborn child. ge to organs through prolonged or repeated	
		the skin.	ust can cause mechanical irritation or drying of vith the eyes can lead to mechanical irritation.	
4.3 Indica	tion of any immediat	e medical attention a	and special treatment needed	
Treati	ment	: Treat symptom	natically and supportively.	
SECTION 5: Firefighting measures				
5.1 Exting	uishing media			

 Exanguishing meala		
Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
 Created beroude existing from	416 0	

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 Metal oxides

5.3 Advice for firefighters

Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. 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 so. Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	:	Use personal protective equipment.
		Follow safe handling advice (see section 7) and personal pro-



Vorinostat Formulation

Version 4.3	Revision Date: 28.09.2024	SDS Number: 44853-00024	Date of last issue: 06.04.2024 Date of first issue: 06.01.2015
		tective equipm	ent recommendations (see section 8).
6.2 Enviror	nmental precautions		
Environmental precautions		Prevent furthe Retain and dis	to the environment. r leakage or spillage if safe to do so. pose of contaminated wash water. es should be advised if significant spillages tained.
6.3 Method	Is and material for co	ontainment and clea	aning up
6.3 Methods and material for conta Methods for cleaning up :		: Sweep up or v tainer for dispo Avoid dispersa with compress Dust deposits es, as these m leased into the Local or nation posal of this m employed in th mine which re Sections 13 ar	acuum up spillage and collect in suitable con- osal. 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

	•	
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	:	If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	:	Do not get on skin or clothing. Do not breathe dust. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as- sessment Keep container tightly closed. 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. Do not eat, drink or smoke when using this product.

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



Vorinostat Formulation

Version 4.3	Revision Date: 28.09.2024	SDS Number:Date of last issue: 06.04.202404853-00024Date of first issue: 06.01.2015			
Hygiene measures		 Take care to prevent spills, waste and minimize release to the environment. 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. 			
7.2 Cond	itions for safe storage,	cluding any incompatibilities			
Requirements for storage areas and containers		Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.			
Advice on common storage		Do not store with the following product types: Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives Gases			
7.3 Specific end use(s) Specific use(s)		No data available			

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Occupational Exposure Emilis	
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

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
Vorinostat	149647-78- 9	TWA	5 µg/m3	Internal
		Wipe limit	50 µg/100 cm ²	Internal
Cellulose	9004-34-6	OELV - 8 hrs (TWA)	10 mg/m3	IE OEL

8.2 Exposure controls

Engineering measures

Minimize workplace exposure concentrations. Apply measures to prevent dust explosions.



Vorinostat Formulation

Version 4.3	Revision Date: 28.09.2024		DS Number: 853-00024	Date of last issue: 06.04.2024 Date of first issue: 06.01.2015
cessi (i.e., t		ned the	l in a manner to pre equipment).	t ducts, dust collectors, vessels, and pro- event the escape of dust into the work area exhaust ventilation.
Pers	onal protective equipm	ent		
Eye/f	ace protection	:	Safety goggles	g personal protective equipment: I conform to I.S. EN 166
Hand	l protection			
М	aterial	:	Chemical-resistar	nt gloves
R	emarks	:	on the concentrat stance and specif determined for the applications, we r chemicals of the a	protect hands against chemicals depending ion and quantity of the hazardous sub- ic to place of work. Breakthrough time is not e product. Change gloves often! For special ecommend clarifying the resistance to aforementioned protective gloves with the er. Wash hands before breaks and at the
Skin	and body protection	 Select appropriate protective clothing based on ch resistance data and an assessment of the local ex potential. Skin contact must be avoided by using impervious clothing (gloves, aprons, boots, etc). 		nd an assessment of the local exposure t be avoided by using impervious protective
Resp	iratory protection	 If adequate local exhaust ventilation is not available o sure assessment demonstrates exposures outside the ommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143 		exhaust ventilation is not available or expo- demonstrates exposures outside the rec- lines, use respiratory protection.
Fi	lter type	:	Particulates type	

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	powder
Colour	:	No data available
Odour	:	odourless
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.

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



Vers 4.3	sion	Revision Date: 28.09.2024		S Number: 53-00024	Date of last issue: 06.04.2024 Date of first issue: 06.01.2015
	Flamma	ability (liquids)	:	No data available	9
		explosion limit / Upper bility limit	:	No data available	3
		explosion limit / Lower bility limit	:	No data available	3
	Flash p	oint	:	No data available	9
	Auto-ig	nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	9
	рН		:	No data available	
	Viscosi Visc	ty :osity, dynamic	:	No data available	
	Visc	osity, kinematic	:	No data available	9
	Solubili Wat	ty(ies) er solubility	:	No data available	
	Partition octanol	n coefficient: n- /water	:	No data available	9
	Vapour	pressure	:	No data available)
	Density	,	:	No data available	9
	Relative	e vapour density	:	No data available	9
		characteristics icle size	:	No data available	3
9.2		formation			
	Explosi		:	Not explosive	
		ng properties	:		r mixture is not classified as oxidizing.
	Evapor	ation rate	:	No data available	9
	Molecu	lar weight	:	No data available	



Vorinostat Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	44853-00024	Date of first issue: 06.01.2015

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- 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 hazard classes as defined in Regulation (EC) No 1272/2008

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

Acute toxicity

Not classified based on available information.

Components:

Vorinostat:

Acute oral toxicity	:	LD50 (Mouse): > 2,000 mg/kg
		LD50 (Rat): > 750 mg/kg
Acute toxicity (other routes of administration)	:	LDLo (Mouse): 1,250 mg/kg Application Route: Intravenous Exposure time: 4 h

Skin corrosion/irritation

Not classified based on available information.

Components:

Vorinostat:

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



Vorinostat Formulation

Version 4.3	Revision Date: 28.09.2024	SDS Number: 44853-00024	Date of last issue: 06.04.2024 Date of first issue: 06.01.2015
Speci Resul		: Rabbit : No skin irritation	
Serious eye damage/eye irritation Not classified based on available information.			
Comp	oonents:		
	ostat:		
Speci	62	: Bovine cornea	

Species	:	Bovine cornea
Result	:	No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Vorinostat:

Test Type	:	Local lymph node assay (LLNA)
Exposure routes	:	Skin contact
Species	:	Mouse
Result	:	Not a skin sensitizer.

Germ cell mutagenicity

Suspected of causing genetic defects.

Components:

Vorinostat:	
Genotoxicity in vitro :	Test Type: Bacterial reverse mutation assay (AMES) Result: positive
	Test Type: Chromosome aberration test in vitro Test system: Chinese hamster ovary cells Result: positive
	Test Type: Chromosome aberration test in vitro Test system: Human lymphocytes Result: negative
Genotoxicity in vivo :	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Oral Result: positive
Germ cell mutagenicity- As- : sessment	Positive result(s) from in vivo mammalian somatic cell muta- genicity tests.

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



Vorinostat Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	44853-00024	Date of first issue: 06.01.2015

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:

Vorinostat:	
Effects on fertility :	Test Type: Fertility/early embryonic development Species: Rat, female Application Route: Oral Fertility: LOAEL: 15 mg/kg body weight Result: Preimplantation loss, Increased resorptions.
	Test Type: Fertility/early embryonic development Species: Rat, male Application Route: Oral Fertility: NOAEL: 150 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: LOAEL: 50 mg/kg body weight Result: positive
	Test Type: Embryo-foetal development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 15 mg/kg body weight Result: positive
	Test Type: Embryo-foetal development Species: Rabbit Application Route: Oral Developmental Toxicity: LOAEL: 150 mg/kg body weight Result: Embryotoxic effects.
	Test Type: Embryo-foetal development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: 50 mg/kg body weight Result: Embryotoxic effects.
	Test Type: Embryo-foetal development Species: Rabbit Application Route: Oral Developmental Toxicity: LOAEL: 15 mg/kg body weight Result: Malformations were observed.
Reproductive toxicity - As- :	Clear evidence of adverse effects on sexual function and fertil-

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



Vorinostat Formulation

t ingle exposure ified based on ava epeated exposur damage to organs ents: at: a routes rgans ent d dose toxicity <u>ents:</u>	r e through	effects on dev information. h prolonged or Ingestion Blood, thymus tract	animal experiments., Clear evidence of advers relopment, based on animal experiments. repeated exposure. s gland, Bone marrow, spleen, Gastrointestinal ge to organs through prolonged or repeated
ified based on ava epeated exposur damage to organs ents: at: a routes rgans ent d dose toxicity	r e through	h prolonged or Ingestion Blood, thymus tract Causes dama	s gland, Bone marrow, spleen, Gastrointestina
epeated exposur damage to organs <u>ents:</u> at: e routes rgans ent d dose toxicity	r e through	h prolonged or Ingestion Blood, thymus tract Causes dama	s gland, Bone marrow, spleen, Gastrointestina
damage to organs ents: at: e routes rgans ent d dose toxicity	throug	Ingestion Blood, thymus tract Causes dama	s gland, Bone marrow, spleen, Gastrointestina
ents: at: e routes rgans ent d dose toxicity		Ingestion Blood, thymus tract Causes dama	s gland, Bone marrow, spleen, Gastrointestina
at: e routes rgans ent d dose toxicity	::	Blood, thymus tract Causes damag	-
e routes rgans ent d dose toxicity	:	Blood, thymus tract Causes damag	-
rgans ent d dose toxicity	:	Blood, thymus tract Causes damag	-
d dose toxicity	:	Causes dama	ge to organs through prolonged or repeated
-			
onts:			
unta.			
at:			
	:	Rat	
on Route		20 mg/kg Oral	
e time	:	6 Months	
rgans	:		s gland, Bone marrow, spleen
	:	Dog	
	:	60 mg/kg	
5	:		
	÷		
	:		al tract
iguno	•	Cuotionitootini	
	:	Dog	
	:		
on Pouto	÷		
	:		
rgans	:	Blood	
-			
	on Route rgans on Route time rgans on toxicity	e time : rgans : on Route : e time : rgans :	i 60 mg/kg i 160 mg/kg i 160 mg/kg i 0ral i 6 Months i Gastrointestin i Dog i 40 mg/kg i 100 mg/kg i 100 mg/kg i 40 mg/kg i 8 Oral i Weeks i gans i Blood

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



Version 4.3	Revision Date: 28.09.2024		98 Number: 853-00024	Date of last issue: 06.04.2024 Date of first issue: 06.01.2015
				(f) or Commission Delegated regulation r Commission Regulation (EU) 2018/605 at higher.
Exp	erience with human exp	osu	ire	
<u>Com</u>	nponents:			
Vori	nostat:			
Inge	stion	:	: Symptoms: Diarrhoea, Fatigue, Nausea, anorexia	
SECTIO	N 12: Ecological infor	ma	tion	
12.1 Tox	icity			
Con	<u>nponents:</u>			
Vori	nostat:			
Toxi	city to fish	:	LC50 (Pimephales Exposure time: 96	s promelas (fathead minnow)): > 10 mg/l s h
			LC50 (Cyprinodor mg/l Exposure time: 96	n variegatus (sheepshead minnow)): > 10 5 h
	city to daphnia and other atic invertebrates	:	EC50 (Daphnia m Exposure time: 48	agna (Water flea)): > 10 mg/l s h
			EC50 (Americamy Exposure time: 96	
Toxi plan	city to algae/aquatic ts	:	EC50 (Pseudokiro mg/l Exposure time: 96 Method: OECD Te	
			NOEC (Pseudokir mg/l Exposure time: 96 Method: OECD Te	
M-Fa icity)	actor (Acute aquatic tox-)	:	1	
Toxi	city to microorganisms	:	EC50 : > 1,000 m Exposure time: 3 Test Type: Respir	ĥ
Toxi icity)	city to fish (Chronic tox-)	:	NOEC: 1.5 mg/l Exposure time: 33 Species: Pimepha Method: OECD Te	lles promelas (fathead minnow)

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



Version 4.3	Revision Date: 28.09.2024		DS Number: 1853-00024	Date of last issue: 06.04.2024 Date of first issue: 06.01.2015
	ity to daphnia and other tic invertebrates (Chron- icity)			
M-Fa toxici	ctor (Chronic aquatic ty)	:	1	
12.2 Pers	istence and degradabi	lity		
Com	ponents:			
	iostat: egradability	:	Biodegradation: Exposure time: 2	39.5 %
12.3 Bioa	ccumulative potential			
<u>Com</u>	ponents:			
Partit	nostat: ion coefficient: n- nol/water	:	log Pow: 1.42	
12.4 Mobi	ility in soil			
Com	ponents:			
Distri	nostat: bution among environ- al compartments	:	log Koc: 3.37	
12.5 Resu	ılts of PBT and vPvB a	sse	ssment	
Prod Asse	<u>uct:</u> ssment	:	to be either persi	nixture contains no components considered stent, bioaccumulative and toxic (PBT), or nd very bioaccumulative (vPvB) at levels of
12.6 Endo	ocrine disrupting prope	ertie	es	
Prod	uct:			
Asse	ssment	:	ered to have end REACH Article 5	hixture does not contain components consid- locrine disrupting properties according to 7(f) or Commission Delegated regulation or Commission Regulation (EU) 2018/605 at higher.
	e r adverse effects ata available			



Vorinostat Formulation

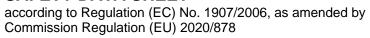
Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	44853-00024	Date of first issue: 06.01.2015

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 or ID number			
	ADN	:	UN 3077	
	ADR	:	UN 3077	
	RID	:	UN 3077	
	IMDG	:	UN 3077	
	ΙΑΤΑ	:	UN 3077	
14.2	2 UN proper shipping name			
	ADN	:	ENVIRONMENTALLY N.O.S. (Vorinostat)	Y HAZARDOUS SUBSTANCE, SOLID,
	ADR	:	ENVIRONMENTALLY N.O.S. (Vorinostat)	(HAZARDOUS SUBSTANCE, SOLID,
	RID	:	ENVIRONMENTALLY N.O.S. (Vorinostat)	(HAZARDOUS SUBSTANCE, SOLID,
	IMDG	:	ENVIRONMENTALLY N.O.S. (Vorinostat)	(HAZARDOUS SUBSTANCE, SOLID,
	ΙΑΤΑ	:	Environmentally hazardous substance, solid, n.o.s. (Vorinostat)	
14.3	B Transport hazard class(es)			
			Class	Subsidiary risks
	ADN	:	9	
	ADR	:	9	
	RID	:	9	
	IMDG	:	9	





Vers 4.3	sion	Revision Date: 28.09.2024		9S Number: 853-00024	Date of last issue: 06.04.2024 Date of first issue: 06.01.2015
14.4	IATA Packir	ng group	:	9	
	ADN Packing Classifi	g group ication Code I Identification Number	:	III M7 90 9	
	Classifi Hazard Labels	g group ication Code I Identification Number restriction code	:	III M7 90 9 (-)	
	Classifi	g group ication Code I Identification Number	: : : : : : : : : : : : : : : : : : : :	III M7 90 9	
	IMDG Packing Labels EmS C	g group ode	:	III 9 F-A, S-F	
	aircraft Packin	g instruction (cargo	:	956 Y956 III Miscellaneous	
	Packing ger airc Packing	Passenger) g instruction (passen- craft) g instruction (LQ) g group	:	956 Y956 III Miscellaneous	
14.5	Enviro	nmental hazards			
	ADN Enviror	nmentally hazardous	:	yes	
	ADR Enviror	nmentally hazardous	:	yes	
	RID Enviror	nmentally hazardous	:	yes	
	IMDG Marine	pollutant	:	yes	
		Passenger) nmentally hazardous	:	yes	



Vorinostat Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	44853-00024	Date of first issue: 06.01.2015

IATA (Cargo)

Environmentally hazardous : yes

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

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

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 Concern for Authorisation (Article 59).	:	Not applicable
Regulation (EC) on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollu- tants (recast)	:	Not applicable
Regulation (EU) No 649/2012 of the European Parlia- ment and the Council concerning the export and import of dangerous chemicals	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable

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

		Quantity 1	Quantity 2
E1	ENVIRONMENTAL	100 t	200 t
	HAZARDS		

Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AICS	: not determined
DSL	: not determined

IECSC : not determined

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



Vorinostat Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	44853-00024	Date of first issue: 06.01.2015

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 H-Statements				
H341 :	Suspected of causing genetic defects.			
H360FD :	May damage fertility. May damage the unborn child.			
H372 :	Causes damage to organs through prolonged or repeated exposure if swallowed.			
H400 :	Very toxic to aquatic life.			
H410 :	Very toxic to aquatic life with long lasting effects.			
Full text of other abbreviations	5			
Aquatic Acute :	Short-term (acute) aquatic hazard			
Aquatic Chronic	Long-term (chronic) aquatic hazard			
Muta.	Germ cell mutagenicity			
Repr. :	Reproductive toxicity			
STOT RE :	Specific target organ toxicity - repeated exposure			
IE OEL :	Ireland. List of Chemical Agents and Carcinogens with Occu- pational 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 - (Quanti-



Vorinostat Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	44853-00024	Date of first issue: 06.01.2015

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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to	:	Internal technical data, data from raw material SDSs, OECD
compile the Safety Data Sheet		eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/
Choot		oy; mp.//oona.ou/opa.ou/

Classification of the mixture:				
H341	Calculation method			
H360FD	Calculation method			
H372	Calculation method			
H400	Calculation method			
H410	Calculation method			
	H341 H360FD H372 H400			

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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