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



Vorinostat Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.3 28.09.2024 9371557-00008 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 : Vorinostat 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)

Germ cell mutagenicity, Category 2 H341: Suspected of causing genetic defects. Reproductive toxicity, Category 1B H360FD: May damage fertility. May damage the

Specific target organ toxicity - repeated

exposure, Category 1

Short-term (acute) aquatic hazard, Cate-

Long-term (chronic) aquatic hazard, Cat-

egory 1

unborn child.

H372: Causes damage to organs through pro-

longed or repeated exposure. H400: Very toxic to aquatic life.

H410: Very toxic to aquatic life with long lasting

effects.

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



Vorinostat Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.3
 28.09.2024
 9371557-00008
 Date of first issue: 27.08.2021

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)

Hazard pictograms :





Signal word : Danger

Hazard 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.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P260 Do not breathe dust.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye

protection/ face protection.

Response:

P308 + P313 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.

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

CI	hemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Vo	orinostat	149647-78-9	Muta. 2; H341	>= 50 - < 70

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



Vorinostat Formulation

ersion I.3	Revision Date: 28.09.2024	SDS Number: 9371557-00008	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021		
			Repr. 1B; H360FD STOT RE 1; H372 (Blood, thymus gland, Bone mar- row, spleen, Gas- trointestinal tract) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1		
Substances with a workplace exposure limit :					
Cellul	ose	9004-34-6 232-674-9	>= 20 - < 3	0	

For explanation of abbreviations see section 16.

SECTION 4: 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, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

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



Vorinostat Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.3
 28.09.2024
 9371557-00008
 Date of first issue: 27.08.2021

Risks : Suspected of causing genetic defects.

May damage fertility. May damage the unborn child. Causes damage to organs through prolonged or repeated

exposure.

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 (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 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-

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



Vorinostat Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.3
 28.09.2024
 9371557-00008
 Date of first issue: 27.08.2021

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.

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 con-

tainer 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 deter-

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



Vorinostat Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.3
 28.09.2024
 9371557-00008
 Date of first issue: 27.08.2021

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.

7.2 Conditions for safe storage, including 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

dust of any kind 10 mg/m3

Value type (Form of exposure): TWA (Inhalable)

Basis: GB EH40

4 mg/m3

Value type (Form of exposure): TWA (Respirable fraction)

Basis: GB EH40

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Vorinostat	149647-78- 9	TWA	5 μg/m3	Internal
	3	14.0	- 0 // 00 0	1
		Wipe limit	50 μg/100 cm ²	Internal
Cellulose	9004-34-6	TWA (inhalable	10 mg/m3	GB EH40
		dust)		
		TWA (Respirable	4 mg/m3	GB EH40
		dust)	_	
		STEL (inhalable	20 mg/m3	GB EH40
		dust)		

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



Vorinostat Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.3
 28.09.2024
 9371557-00008
 Date of first issue: 27.08.2021

8.2 Exposure controls

Engineering measures

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

Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

If sufficient ventilation is unavailable, use with local exhaust ventilation.

Personal protective equipment

Eye/face protection : Wear the following personal protective equipment:

Safety goggles

Equipment should conform to BS EN 166

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending

on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the

end of workday.

Skin and body protection : Select appropriate protective clothing based on chemical re-

sistance data and an assessment of the local exposure poten-

tıaı.

Skin contact must be avoided by using impervious protective

clothing (gloves, aprons, boots, etc).

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended 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 : No data available

Odour : odourless

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

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



Vorinostat Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.3 28.09.2024 9371557-00008 Date of first issue: 27.08.2021

Flash point No data available

No data available Evaporation rate

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 No data available

No data available Relative vapour density

No data available Density

Solubility(ies)

Water solubility Partition coefficient: n-

octanol/water

No data available No data available

Auto-ignition temperature No data available

Decomposition temperature No data available

Viscosity

No data available Viscosity, dynamic

Viscosity, kinematic No data available

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.

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



Vorinostat Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.3 28.09.2024 9371557-00008 Date of first issue: 27.08.2021

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 toxicological effects

Information on likely routes of :

exposure

Inhalation

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

administration)

Acute toxicity (other routes of : LDLo (Mouse): 1,250 mg/kg

Application Route: Intravenous

Exposure time: 4 h

Cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

: LC50 (Rat): > 5.8 mg/l Acute inhalation toxicity

Exposure time: 4 h

Test atmosphere: dust/mist

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

Skin corrosion/irritation

Not classified based on available information.

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



Vorinostat Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.3 28.09.2024 9371557-00008 Date of first issue: 27.08.2021

Components:

Vorinostat:

Species : Rabbit

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Vorinostat:

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

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



Vorinostat Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.3
 28.09.2024
 9371557-00008
 Date of first issue: 27.08.2021

Germ cell mutagenicity- As-

sessment

Positive result(s) from in vivo mammalian somatic cell muta-

genicity tests.

Cellulose:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Ingestion

Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Cellulose:

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

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

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



Vorinostat Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.3
 28.09.2024
 9371557-00008
 Date of first issue: 27.08.2021

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-

sessment

Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of adverse

effects on development, based on animal experiments.

Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Components:

Vorinostat:

Exposure routes : Ingestion

Target Organs : Blood, thymus gland, Bone marrow, spleen, Gastrointestinal

tract

Assessment : Causes damage to organs through prolonged or repeated

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



Vorinostat Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.3
 28.09.2024
 9371557-00008
 Date of first issue: 27.08.2021

exposure.

Repeated dose toxicity

Components:

Vorinostat:

Species : Rat
LOAEL : 20 mg/kg
Application Route : Oral
Exposure time : 6 Months

Target Organs : Blood, thymus gland, Bone marrow, spleen

Species : Dog
NOAEL : 60 mg/kg
LOAEL : 160 mg/kg
Application Route : Oral
Exposure time : 6 Months

Target Organs : Gastrointestinal tract

Species : Dog
NOAEL : 40 mg/kg
LOAEL : 100 mg/kg
Application Route : Oral
Exposure time : 4 Weeks
Target Organs : Blood

Cellulose:

Species : Rat

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

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Vorinostat:

Ingestion : Symptoms: Diarrhoea, Fatigue, Nausea, anorexia

SECTION 12: Ecological information

12.1 Toxicity

Components:

Vorinostat:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 10 mg/l

Exposure time: 96 h

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



Vorinostat Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.3
 28.09.2024
 9371557-00008
 Date of first issue: 27.08.2021

LC50 (Cyprinodon variegatus (sheepshead minnow)): > 10

mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 10 mg/l

Exposure time: 48 h

EC50 (Americamysis): 7.4 mg/l

Exposure time: 96 h

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 0.183

mg/l

Exposure time: 96 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.011

mg/l

Exposure time: 96 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox-

icity)

1

Toxicity to microorganisms : EC50 : > 1,000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition

Toxicity to fish (Chronic tox-

icity)

NOEC: 1.5 mg/l

Exposure time: 33 d

Species: Pimephales promelas (fathead minnow)

Method: OECD Test Guideline 210

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0.15 mg/l Exposure time: 21 d

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

M-Factor (Chronic aquatic

toxicity)

: 1

Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l

Exposure time: 48 h

Remarks: Based on data from similar materials

12.2 Persistence and degradability

Components:

Vorinostat:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 39.5 %

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



Vorinostat Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.3
 28.09.2024
 9371557-00008
 Date of first issue: 27.08.2021

Exposure time: 28 d

Method: OECD Test Guideline 314

Cellulose:

Biodegradability : Result: Readily biodegradable.

12.3 Bioaccumulative potential

Components:

Vorinostat:

Partition coefficient: n-

octanol/water

: log Pow: 1.42

12.4 Mobility in soil

Components:

Vorinostat:

Distribution among environmental compartments

: log Koc: 3.37

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

This substance/mixture does not contain components considered to have endocrine disrupting properties for environment

according to UK REACH Article 57(f).

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.

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



Vorinostat Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.3
 28.09.2024
 9371557-00008
 Date of first issue: 27.08.2021

SECTION 14: Transport information

14.1 UN number

ADN : UN 3077
ADR : UN 3077
RID : UN 3077
IMDG : UN 3077
IATA : UN 3077

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Vorinostat)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Vorinostat)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Vorinostat)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Vorinostat)

IATA : Environmentally hazardous substance, solid, n.o.s.

(Vorinostat)

14.3 Transport hazard class(es)

Class Subsidiary risks

ADN : 9
ADR : 9
RID : 9
IMDG : 9
IATA : 9

14.4 Packing group

ADN

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

ADR

Packing group : III
Classification Code : M7
Hazard Identification Number : 90

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



Vorinostat Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.3
 28.09.2024
 9371557-00008
 Date of first issue: 27.08.2021

956

Labels : 9 Tunnel restriction code : (-)

RID

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

IMDG

Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo

aircraft)

Packing instruction (LQ) : Y956 Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen- : 956

ger aircraft)

Packing instruction (LQ) : Y956
Packing group : III

Labels : Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

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

Remarks : Not applicable for product as supplied.

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



Vorinostat Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.3
 28.09.2024
 9371557-00008
 Date of first issue: 27.08.2021

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 : Not applicable

concern (SVHC) for Authorisation

The Persistent Organic Pollutants Regulations (retained : Not applicable

Regulation (EU) 2019/1021 as amended for Great Brit-

ain)

Regulation (EC) on substances that deplete the ozone : Not applicable

layer

UK REACH List of substances subject to authorisation : Not applicable

(Annex XIV)

GB Export and import of hazardous chemicals - Prior : Not applicable

Informed Consent (PIC) Regulation

Control of Major Accident Hazards Regulations 2015 (COMAH)

Quantity 1 Quantity 2

E1 ENVIRONMENTAL 100 t 200 t

HAZARDS

Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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.

Full text of H-Statements

H341 : Suspected of causing genetic defects.

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



Vorinostat Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.3
 28.09.2024
 9371557-00008
 Date of first issue: 27.08.2021

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

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 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 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

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/

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



Vorinostat Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.3
 28.09.2024
 9371557-00008
 Date of first issue: 27.08.2021

Classification of the mixture: Classification procedure:

Muta. 2 H341 Calculation method
Repr. 1B H360FD Calculation method
STOT RE 1 H372 Calculation method
Aquatic Acute 1 H400 Calculation method
Aquatic Chronic 1 H410 Calculation method

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