ERIVEDGE Capsules 150 mg

Version	Revision Date:	Date of last issue: 01/21/2026
3.0	09/02/2026	Date of first issue: 06/13/2025

SECTION 1. IDENTIFICATION

Product name	:	ERIVEDGE Capsules 150 mg
Product code	:	RO545-0815/F03-00
Common name(s), synonym(s) of the substance	:	ERIVEDGE Capsules 150 mg

Manufacturer or supplier's details

Company name of supplier	:	Genentech, Inc.
Address	:	1 DNA Way South San Francisco, CA 94080 USA
Telephone	:	001-(650) 225-1000
E-mail address	:	info.sds@roche.com
Emergency telephone		
In case of emergencies:	:	US CHEMTREC PHONE (800)-424-9300

Recommended use of the chemical and restrictions on use

Recommended use	:	Formulated pharmaceutical active substance

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Hazards for the product as supplied

Reproductive toxicity	:	Category 1B
Specific target organ toxicity - repeated exposure	:	Category 2

Other hazards
None known.

GHS label elements

Hazard pictograms	:	
Signal Word	:	Danger
Hazard Statements	:	H360FD May damage fertility. May damage the unborn child. H373 May cause damage to organs through prolonged or repeated exposure.
Precautionary Statements	:	**Prevention:** P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P260 Do not breathe dust. P280 Wear protective gloves, protective clothing, eye protection and face protection. **Response:** P308 + P313 IF exposed or concerned: Get medical advice/ attention. **Storage:** P405 Store locked up. **Disposal:** P501 Dispose of contents/ container to an approved waste disposal plant.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture	:	Mixture

Components

Chemical name	CAS No./Unique ID	Concentration (% w/w)	Trade secret
Vismodegib	879085-55-9*	35.29	-
Cellulose	9004-34-6*	20.54	-
Gelatins	9000-70-8*	17.51	-
Lactose-1-Hydrate	64044-51-5*	16.82	-
Starch, carboxymethyl ether, sodium salt	9063-38-1*	4.12	-
2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8*	2.47	-
Sulfuric acid monododecyl ester sodium salt (1:1)	151-21-3*	1.65	-
Talc (Mg3H2(SiO3)4)	14807-96-6*	0.82	-
Octadecanoic acid, magnesium salt (2:1)	557-04-0*	0.4	-
Titanium oxide (TiO2)	13463-67-7*	0.35	-
Iron oxide (Fe3O4)	1317-61-9*	0.02	-
Iron oxide (Fe2O3)	1309-37-1*	0.01	-

* Indicates that the identifier is a CAS No.

SECTION 4. FIRST AID MEASURES

General advice	:	Move out of dangerous area. Show this material safety data sheet to the doctor in attendance. Do not leave the victim unattended.
If inhaled	:	If unconscious, place in recovery position and seek medical advice. If symptoms persist, call a physician.
In case of skin contact	:	If skin irritation persists, call a physician. If on skin, rinse well with water. If on clothes, remove clothes.
In case of eye contact	:	Flush eyes with water as a precaution. Remove contact lenses. Protect unharmed eye. Keep eye wide open while rinsing. If eye irritation persists, consult a specialist.
If swallowed	:	Induce vomiting immediately and call a physician. Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician. Take victim immediately to hospital.
Most important symptoms and effects, both acute and delayed	:	May damage fertility. May damage the unborn child. May cause damage to organs through prolonged or repeated exposure.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection and use the recommended protective clothing
Notes to physician	:	Treat symptomatically.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	:	High volume water jet
Specific hazards during fire fighting	:	Do not allow run-off from fire fighting to enter drains or water courses.
Hazardous combustion products	:	Gaseous hydrogen chloride (HCl). Sulfur oxides Nitrogen oxides (NOx) Carbon oxides Sodium oxides
Further information	:	Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
Special protective equipment for fire-fighters	:	Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Prevent any exposure Use personal protective equipment. Avoid dust formation.

Avoid breathing dust.

Refer to protective measures listed in sections 7 and 8.

Environmental precautions : Prevent product from entering drains.

Prevent further leakage or spillage if safe to do so.

If the product contaminates rivers and lakes or drains inform respective authorities.

Methods and materials for containment and cleaning up : Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Avoid dust formation.

Provide appropriate exhaust ventilation at places where dust is formed.

Advice on safe handling : Avoid formation of respirable particles.

Do not breathe vapors/dust.

Avoid exposure - obtain special instructions before use.

Avoid contact with skin and eyes.

For personal protection see section 8.

Smoking, eating and drinking should be prohibited in the application area.

Dispose of rinse water in accordance with local and national regulations.

Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.

Containers which are opened must be carefully resealed and kept upright to prevent leakage.

Electrical installations / working materials must comply with the technological safety standards.

Storage temperature	:	15 °C to 30 °C Protect against light. Protect from moisture.
Further information on storage stability	:	No decomposition if stored and applied as directed.
Packaging material	:	Suitable material: Plastic container of HDPE, Polyethylene bag in metal drum, Stainless steel, glass

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Vismodegib	879085-55-9	IOEL	0.0003 mg/m3	Roche Industrial Hygiene Committee (RIHC)
Cellulose	9004-34-6	TWA	10 mg/m3	ACGIH
		TWA (Respirable)	5 mg/m3	NIOSH REL
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0
Talc (Mg3H2(SiO3)4)	14807-96-6	TWA (Dust)	20 Million particles per cubic foot	OSHA Z-3
		TWA	2 mg/m3	OSHA P0

		(respirable dust fraction)		
		TWA (Respirable)	2 mg/m3	NIOSH REL
		TWA (Respirable particulate matter)	2 mg/m3	ACGIH
Titanium oxide (TiO2)	13463-67-7	TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (Total dust)	10 mg/m3	OSHA P0
		TWA (Respirable particulate matter)	0.2 mg/m3 (Titanium dioxide)	ACGIH
		TWA (Respirable particulate matter)	2.5 mg/m3 (Titanium dioxide)	ACGIH

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Vismodegib	Surface waters	9.2 µg/l
	Remarks:Based on acute data	
sodium dodecyl sulphate	Fresh water	0.176 mg/l
	Sea water	0.0176 mg/l
	Fresh water sediment	6.97 mg/kg
	Sea sediment	0.697 mg/kg
	Soil	1.29 mg/kg
Vismodegib	Surface waters	9.2 µg/l
	Remarks:Based on acute data	
sodium dodecyl sulphate	Fresh water	0.176 mg/l

	Sea water	0.0176 mg/l
	Fresh water sediment	6.97 mg/kg
	Sea sediment	0.697 mg/kg
	Soil	1.29 mg/kg

Engineering measures : No data available

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

In case of contact through splashing:

Material : Nitrile rubber

Break through time : > 30 min

Glove thickness : > 0.11 mm

In case of full contact:

Material : butyl-rubber

Break through time : > 480 min

Glove thickness : > 0.4 mm

Remarks	:	Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.
Eye protection	:	Eye wash bottle with pure water Tightly fitting safety goggles
Skin and body protection	:	Choose body protection according to the amount and concentration of the dangerous substance at the work place.
Protective measures	:	Instruction of employees mandatory
Hygiene measures	:	When using do not eat or drink. When using do not smoke. Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	capsules
Color	:	gray
Color		pink
Odor	:	Not applicable
Odor Threshold	:	Not applicable

pH	:	Not applicable
Melting point/ range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	No data available
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available

Solubility(ies)

Water solubility	:	No data available
Solubility in other solvents	:	No data available

Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available

Viscosity

Viscosity, dynamic	:	Not applicable
Viscosity, kinematic	:	Not applicable
Explosive properties	:	No data available
Oxidizing properties	:	No data available

Particle characteristics

Particle Size Distribution	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	No decomposition if stored and applied as directed.
Conditions to avoid	:	No data available
Incompatible materials	:	Not applicable

Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity
Not classified due to lack of data.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: 63.49 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method
Acute dermal toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method

Components:

Vismodegib:

Acute oral toxicity	:	LD50 Oral (Rat): > 2,000 mg/kg Method: OECD Test Guideline 423 GLP: yes

Cellulose:

Acute oral toxicity	:	LD50 Oral (Rat): > 5,000 mg/kg
Acute dermal toxicity	:	LD50 Dermal (Rabbit): > 2,000 mg/kg

Sulfuric acid monododecyl ester sodium salt (1:1):

Acute oral toxicity : LD50 Oral (Rat, male and female): 1,200 mg/kg

Method: OECD Test Guideline 401

Acute inhalation toxicity : Assessment: The component/mixture is moderately toxic after short term inhalation.

Acute dermal toxicity : LD50 Dermal (Rat, male and female): > 2,000 mg/kg

Method: OECD Test Guideline 402

GLP: yes

Remarks: No mortality observed at this dose.

Titanium oxide (TiO2):

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

Method: OECD Test Guideline 425

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

Skin corrosion/irritation

Not classified due to lack of data.

Product:

Remarks : May cause skin irritation and/or dermatitis.

Components:

Vismodegib:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

GLP : yes

Sulfuric acid monododecyl ester sodium salt (1:1):

Species : Rabbit

Method : OECD Test Guideline 404

Result	:	Irritating to skin.
GLP	:	no

Talc (Mg3H2(SiO3)4):

Remarks	:	This information is not available.

Titanium oxide (TiO2):

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	No skin irritation

Serious eye damage/eye irritation

Not classified due to lack of data.

Product:

Remarks	:	Product dust may be irritating to eyes, skin and respiratory system.

Components:

Sulfuric acid monododecyl ester sodium salt (1:1):

Species	:	Rabbit
Result	:	Risk of serious damage to eyes.
Method	:	OECD Test Guideline 405
GLP	:	no

Talc (Mg3H2(SiO3)4):

Remarks	:	This information is not available.

Titanium oxide (TiO2):

Species	:	Rabbit
Result	:	No eye irritation
Method	:	OECD Test Guideline 405

Respiratory or skin sensitization

Skin sensitization

Not classified due to lack of data.

Respiratory sensitization
Not classified due to lack of data.

Components:

Sulfuric acid monododecyl ester sodium salt (1:1):

Result	:	Did not cause sensitization on laboratory animals.

Titanium oxide (TiO2):

Species	:	Guinea pig
Assessment	:	Does not cause skin sensitization.
Method	:	OECD Test Guideline 406

Germ cell mutagenicity
Not classified due to lack of data.

Components:

Vismodegib:

Genotoxicity in vitro	:	Test Type: Ames test Method: Mutagenicity (Salmonella typhimurium - reverse mutation assay) Result: negative GLP: yes Test Type: Chromosome aberration test in vitro Result: negative
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Rat Application Route: Oral Result: negative

Sulfuric acid monododecyl ester sodium salt (1:1):

Genotoxicity in vitro	:	Test Type: Microbial mutagenesis assay (Ames test) Method: OECD Test Guideline 471 Result: negative

Genotoxicity in vivo	:	Test Type: Micronucleus test Method: OECD Test Guideline 474 Result: negative

Carcinogenicity
Not classified due to lack of data.

Components:

Cellulose:

Remarks	:	No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

IARC

Group 2A: Probably carcinogenic to humans

Talc (Mg3H2(SiO3)4)	14807-96-6

Group 2B: Possibly carcinogenic to humans

Titanium oxide (TiO2)	13463-67-7

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
May damage fertility. May damage the unborn child.

Components:

Vismodegib:

Effects on fetal development	:	Test Type: Embryo-fetal development Species: Rat Application Route: Oral Embryo-fetal toxicity.: LOEL: 10 mg/kg bw/day Result: Teratogenicity and developmental toxicity GLP: yes
Reproductive toxicity -	:	Presumed human reproductive toxicant, May damage fertility.

Assessment	May damage the unborn child.

STOT-single exposure
Not classified due to lack of data.

Components:

Sulfuric acid monododecyl ester sodium salt (1:1):

Routes of exposure	:	Inhalation
Target Organs	:	Respiratory Tract
Assessment	:	May cause respiratory irritation.

Talc (Mg3H2(SiO3)4):

Assessment	:	The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT-repeated exposure
May cause damage to organs through prolonged or repeated exposure.

Components:

Vismodegib:

Assessment	:	May cause damage to organs through prolonged or repeated exposure.

Talc (Mg3H2(SiO3)4):

Assessment	:	The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Repeated dose toxicity

Components:

Vismodegib:

Species	:	Rat
NOAEL	:	<5 mg/kg/w
Application Route	:	Oral
Exposure time	:	26 Weeks
Species	:	Mouse
NOAEL	:	50 mg/kg bw/day

Application Route	:	Oral
Exposure time	:	84 d
Remarks	:	Subchronic toxicity

Aspiration toxicity
Not classified due to lack of data.

Components:

Talc (Mg3H2(SiO3)4):
No data available

Further information

Product:

Remarks	:	No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Vismodegib:

Toxicity to fish	:	LC50 (Danio rerio (zebra fish)): > 1.5 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 GLP: yes NOEC (Danio rerio (zebra fish)): 1.5 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 GLP: yes
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Test Type: Immobilization Analytical monitoring: yes Method: OECD Test Guideline 202

GLP: yes

Remarks: nominal concentration

NOEC (Daphnia magna (Water flea)): 0.85 mg/l

Exposure time: 48 h

Test Type: Immobilization

Analytical monitoring: yes

Method: OECD Test Guideline 202

GLP: yes

Remarks: average measured concentration

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (algae)): 0.118 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

GLP: yes

EyC50 (Pseudokirchneriella subcapitata (algae)): 0.099 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

GLP: yes

NOEC (Pseudokirchneriella subcapitata (algae)): 0.069 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

GLP: yes

Remarks: nominal concentration

ErC50 (Desmodesmus subspicatus (green algae)): 0.95 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

GLP: yes

Remarks: nominal concentration

EyC50 (Desmodesmus subspicatus (green algae)): 0.52 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

GLP: yes

Remarks: nominal concentration

NOEC (Desmodesmus subspicatus (green algae)): 0.32 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

GLP: yes

Remarks: nominal concentration

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 1.5 mg/l

Exposure time: 21 d

Analytical monitoring: yes

Method: OECD Test Guideline 211

GLP: yes

Remarks: nominal concentration

Lowest Observed Effect Concentration (Daphnia magna (Water flea)): 1.5 mg/l

Exposure time: 21 d

Analytical monitoring: yes

Method: OECD Test Guideline 211

GLP: yes

Remarks: nominal concentration

Toxicity to microorganisms : (activated sludge): 54 mg/l

Exposure time: 14 d

Remarks: no adverse influence on substrate biodegradation nominal concentration

Cellulose:

Ecotoxicology Assessment

Acute aquatic toxicity	:	This product has no known ecotoxicological effects.
Chronic aquatic toxicity	:	This product has no known ecotoxicological effects.

Sulfuric acid monododecyl ester sodium salt (1:1):

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 3.6 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Ceriodaphnia dubia (water flea)): 5.55 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to fish (Chronic toxicity)	:	NOEC (Pimephales promelas (fathead minnow)): > 1.36 mg/l Exposure time: 42 d
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Ceriodaphnia dubia (water flea)): 0.88 mg/l Exposure time: 7 d
Toxicity to microorganisms	:	EC0 (Pseudomonas putida): > 100 mg/l Method: OECD Test Guideline 209

Talc (Mg3H2(SiO3)4):

Toxicity to fish	:	LC50 (Danio rerio (zebra fish)): > 100,000 mg/l Exposure time: 24 h

Ecotoxicology Assessment

Acute aquatic toxicity	:	This product has no known ecotoxicological effects.
Chronic aquatic toxicity	:	This product has no known ecotoxicological effects.

Toxicity Data on Soil	:	Not expected to adsorb on soil.
Other organisms relevant to the environment	:	No data available

Titanium oxide (TiO2):

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l Exposure time: 96 h Test Type: static test
		LC50 (Cyprinodon variegatus (sheepshead minnow)): > 10,000 mg/l Exposure time: 96 h Test Type: semi-static test Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	LC50 (Daphnia magna (Water flea)): > 1,000 mg/l Exposure time: 48 h Test Type: static test Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h Test Type: static test Method: OECD Test Guideline 201
		EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l Exposure time: 72 h Method: ISO 10253
		NOEC (Skeletonema costatum (marine diatom)): 5,600 mg/l Exposure time: 72 h

Method: ISO 10253

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

Persistence and degradability

Components:

Vismodegib:

Biodegradability : aerobic
Inoculum: activated sludge, non-adapted
Theoretical oxygen demand
Result: Not readily biodegradable.
Exposure time: 28 d
Method: OECD Test Guideline 301F
GLP: yes

Sulfuric acid monododecyl ester sodium salt (1:1):

Biodegradability : aerobic
Inoculum: activated sludge, non-adapted
Result: Readily biodegradable.
Biodegradation: 95 %
Exposure time: 28 d
Method: OECD Test Guideline 301B
GLP: yes

Titanium oxide (TiO2):

Biodegradability : Remarks: Not applicable

Bioaccumulative potential

Components:

Vismodegib:

Partition coefficient: n-octanol/water	:	log Pow: 1.59 Method: OECD Test Guideline 117 GLP: yes

Cellulose:

Partition coefficient: n-octanol/water	:	Remarks: No data available

Sulfuric acid monododecyl ester sodium salt (1:1):

Bioaccumulation	:	Species: Cyprinus carpio (Carp) Bioconcentration factor (BCF): 3.9 - 5.3 Exposure time: 3 d
Partition coefficient: n-octanol/water	:	log Pow: -2.03 (68 °F / 20 °C) Method: OECD Test Guideline 107

Talc (Mg3H2(SiO3)4):

Partition coefficient: n-octanol/water	:	Remarks: No data available

Titanium oxide (TiO2):

Partition coefficient: n-octanol/water	:	Remarks: No data available

Mobility in soil

Components:

Vismodegib:

Distribution among environmental compartments	:	Koc method Medium: Soil Koc: 2129 - 5001 ml/g

Method: OECD Test Guideline 106

Remarks: Slightly mobile in soils

Koc method

Medium: Sludge

Koc: 684 - 895 ml/g

Method: OECD Test Guideline 106

Other adverse effects

Product:

Ozone-Depletion Potential	:	Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
Additional ecological information	:	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Very toxic to aquatic life with long lasting effects.

Components:

Vismodegib:

Results of PBT and vPvB assessment	:	Non-classified PBT substance

Talc (Mg3H2(SiO3)4):

Adsorbed organic bound halogens (AOX)	:	Remarks: Not applicable
Additional ecological information	:	No data available

Endocrine disrupting properties

Components:

Vismodegib:

Assessment : Does not have endocrine disrupting properties.

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : The product should not be allowed to enter drains, water courses or the soil.

Do not contaminate ponds, waterways or ditches with chemical or used container.

Send to a licensed waste management company.

Contaminated packaging : Empty remaining contents.

Dispose of as unused product.

Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (2-Chloro-N-[4-chloro-3-(2-pyridinyl)phenyl]-4-(methylsulfonyl)-benzamide)
Class	:	9
Packing group	:	III
Labels	:	9
Environmentally hazardous	:	no

IATA-DGR

UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (2-Chloro-N-[4-chloro-3-(2-pyridinyl)phenyl]-4-(methylsulfonyl)-benzamide)

Class	:	9
Packing group	:	III
Labels	:	Class 9 - Miscellaneous dangerous substances and articles
Packing instruction (cargo aircraft)	:	956
Packing instruction (passenger aircraft)	:	956
Environmentally hazardous	:	yes

IMDG-Code

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (2-Chloro-N-[4-chloro-3-(2-pyridinyl)phenyl]-4-(methylsulfonyl)-benzamide)
Class	:	9
Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

Transport in bulk according to IMO instruments
Not applicable

Domestic regulation

49 CFR

UN/ID/NA number	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (2-Chloro-N-[4-chloro-3-(2-pyridinyl)phenyl]-4-(methylsulfonyl)-benzamide)
Class	:	9
Packing group	:	III
Labels	:	Class 9 - Miscellaneous dangerous substances and articles
ERG Code	:	171
Marine pollutant	:	no

Special precautions for user

Remarks : No data available

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.

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Reproductive toxicity

Specific target organ toxicity (single or repeated exposure)

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act
This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act
This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

Cellulose	9004-34-6

Pennsylvania Right To Know

Vismodegib	879085-55-9
Cellulose	9004-34-6
Gelatins	9000-70-8
Lactose-1-Hydrate	64044-51-5
Starch, carboxymethyl ether, sodium salt	9063-38-1

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California Prop. 65

WARNING: This product can expose you to chemicals including Titanium oxide (TiO2), which is/are known to the State of California to cause cancer, and Vismodegib, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances

2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8

California Permissible Exposure Limits for Chemical Contaminants

Cellulose	9004-34-6

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

AU AIIC	:	Not in compliance with the inventory
CA. DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. Vismodegib
NZ NZIoC	:	Not in compliance with the inventory

JP ENCS	:	Not in compliance with the inventory
JP ISHL	:	Not in compliance with the inventory
KR KECI	:	Not in compliance with the inventory
PH PICCS	:	Not in compliance with the inventory
CN IECSC	:	Not in compliance with the inventory
TW TCSI	:	Not in compliance with the inventory
US TSCA	:	Product contains substance(s) not listed on TSCA inventory.
TH TECI	:	Not in compliance with the inventory

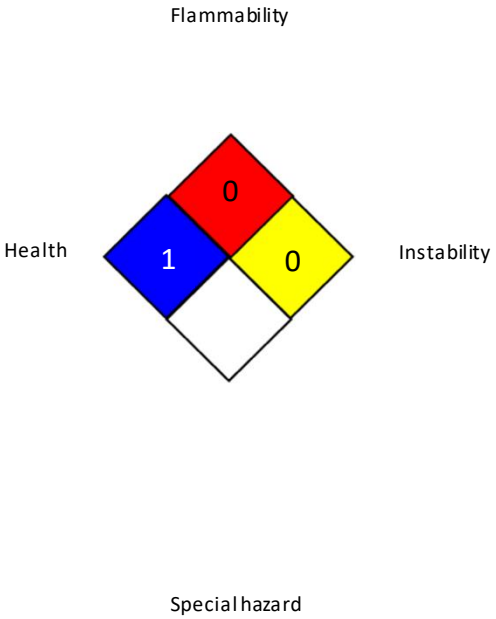
TSCA list
No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

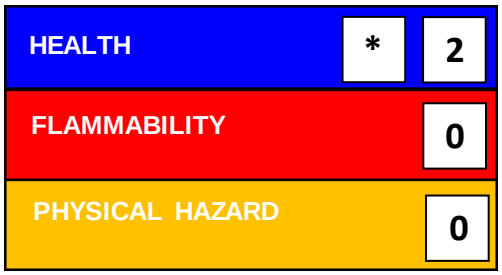
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV / CED:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA P0	:	USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
OSHA Z-3	:	USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
ACGIH / TWA	:	8-hour, time-weighted average
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA P0 / TWA	:	8-hour time weighted average
OSHA Z-1 / TWA	:	8-hour time weighted average
OSHA Z-3 / TWA	:	8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response,

Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardization; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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 Organization 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; 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

The GHS classification for skin irritation and/or sensitization of the pure ingredients causes a corresponding GHS classification for the whole formulation. In view of the nature of the formulatedproduct (film-coated tablet, capsule, etc.), an over-interpretation of the potential hazard is possible.

Revision Date : 09/02/2026

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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.