

EVRYSDI(R) Powder for Oral Solution 60mg

Version 1.1 Revision Date: 06-06-2023 Date of last issue: 08-17-2020
Date of first issue: 08-17-2020

SECTION 1. IDENTIFICATION

Product name : EVRYSDI(R) Powder for Oral Solution 60mg

Product code : RO703-4067/F13

Common name(s), syno- : BS10965, BS10966
nym(s) of the substance Risdiplam Powder for Oral Solution

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

Emergency telephone num- : US Chemtrec phone (800)-424-9300
ber

Recommended use of the chemical and restrictions on use

Recommended use : Formulated pharmaceutical active substance

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION**GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Eye irritation : Category 2A

Skin sensitization : Category 1

Germ cell mutagenicity : Category 2

Reproductive toxicity : Category 1B

Specific target organ toxicity : Category 2 (Eyes, Skin, Testes, digestive system)
- repeated exposure

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H317 May cause an allergic skin reaction.

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H319 Causes serious eye irritation.
 H341 Suspected of causing genetic defects.
 H360FD May damage fertility. May damage the unborn child.
 H373 May cause damage to organs (Eyes, Skin, Testes, digestive system) 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/ fume/ gas/ mist/ vapors/ spray.
 P264 Wash skin thoroughly after handling.
 P272 Contaminated work clothing must not be allowed out of the workplace.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
 P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.
 P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
 P337 + P313 If eye irritation persists: Get medical advice/ attention.
 P363 Wash contaminated clothing before reuse.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Risdiplam	1825352-65-5	3
D-Mannitol	69-65-8	67.2
Isomalt	64519-82-0	11.9
Strawberry Flavour	Not Assigned	7.5
Butanedioic acid, 2,3-dihydroxy-(2R,3R)-	87-69-4	6
Benzoic acid, sodium salt (1:1)	532-32-1	1.5

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Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-	25322-68-3	1
Sucralose	56038-13-2	0.8
L-Ascorbic acid	50-81-7	0.7
Edetic acid disodium salt dihydrate (EDTA-2Na-2H ₂ O)	6381-92-6	0.4

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 : Move to fresh air.
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 : Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.
- If swallowed : 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.
Rinse mouth with water.
- Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.
Causes serious eye irritation.
Suspected of causing genetic defects.
May damage fertility. May damage the unborn child.
May cause damage to organs through prolonged or repeated exposure.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

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 : Do not allow run-off from fire fighting to enter drains or water

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- fighting : courses.
- Hazardous combustion products : Carbon oxides
In case of fire hazardous decomposition products may be produced such as:
Nitrogen oxides (NOx)
- 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 : Avoid exposure
Use personal protective equipment.
Avoid dust formation.
Avoid breathing dust.
- 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.
Persons susceptible to skin sensitization problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.
- 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.

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

- Further information on storage conditions : See label, package insert or internal guidelines
- Storage temperature : Protected from heat and light
Protect from moisture.
- Further information on storage stability : Keep in a dry place.
No decomposition if stored and applied as directed.
- Packaging material : Suitable material: Stainless steel, Polyethylene bag in metal drum, glass, glass bottles

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Risdiplam	1825352-65-5	IOEL	0.002 mg/m3	Roche Industrial Hygiene Committee (RIHC)
Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-	25322-68-3	TWA (aerosol)	10 mg/m3	US WEEL
L-Ascorbic acid	50-81-7	IOEL	10 mg/m3	Roche Industrial Hygiene Committee (RIHC)

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Risdiplam	Surface waters	0.73 µg/l
	Remarks: Based on acute data	

Engineering measures : No data available

Personal protective equipment

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.
Effective dust mask

Hand protection

In case of contact through splashing:
 Material : Nitrile rubber
 Break through time : > 30 min

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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 Wear face-shield and protective suit for abnormal processing problems.
Skin and body protection	:	Dust impervious protective suit 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	:	powder
Color	:	country-specific
Odor	:	Not applicable
Odor Threshold	:	Not applicable
pH	:	Not applicable
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
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

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Relative vapor density	:	Not applicable
Relative 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

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. Dust may form explosive mixture in air.
Conditions to avoid	:	Do not expose to temperatures above: 80 °C Exposure to light.
Incompatible materials	:	No data available
Hazardous decomposition products	:	No data available

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: 3,256 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: > 200 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method

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Acute oral toxicity : LD50 (Rat): > 50 - 300 mg/kg
 Method: OECD Test Guideline 420
 GLP: yes

No-observed-effect level (Rat): 10 mg/kg

Poly(oxy-1,2-ethanediyl), .alpha.-hydro.-omega.-hydroxy-:

Acute oral toxicity : LD50 Oral (Rat): 28,000 mg/kg

Acute dermal toxicity : LD50 Dermal (Rabbit): 20,000 mg/kg

L-Ascorbic acid:

Acute oral toxicity : LD50 Oral (Rat): 11,900 mg/kg

LD50 Oral (Mouse): 8,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks : May cause skin irritation and/or dermatitis.

Components:**Strawberry Flavour:**

Result : Irritating to skin.

Butanedioic acid, 2,3-dihydroxy- (2R,3R)-:

Remarks : Extremely corrosive and destructive to tissue.

Risdiplam:

Species : Mouse
 Result : No skin irritation

Method : in silico model
 Result : No skin irritation

L-Ascorbic acid:

Remarks : This information is not available.

Serious eye damage/eye irritation

Causes serious eye irritation.

Product:

Remarks : May cause irreversible eye damage.

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Result : Irritating to eyes.

Butanedioic acid, 2,3-dihydroxy- (2R,3R)-:Result : Risk of serious damage to eyes.
Remarks : May cause irreversible eye damage.**Risdiplam:**Method : in vitro eye irritation test
Remarks : Eye effect**Respiratory or skin sensitization****Skin sensitization**

May cause an allergic skin reaction.

Respiratory sensitization

Not classified based on available information.

Product:

Remarks : Causes sensitization.

Components:**Strawberry Flavour:**

Assessment : May cause sensitization by skin contact.

Risdiplam:Test Type : Local lymph node assay (LLNA)
Species : Mouse
Method : OECD Test Guideline 429
Result : Not a skin sensitizer.**Germ cell mutagenicity**

Suspected of causing genetic defects.

Components:**Risdiplam:**Genotoxicity in vitro : Method: OECD Test Guideline 471
Result: negativeMethod: OECD Test Guideline 487
Result: positiveGenotoxicity in vivo : Method: OECD Test Guideline 474
Result: negative

Germ cell mutagenicity - Assessment : In vitro tests showed mutagenic effects

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Carcinogenicity

Not classified based on available information.

Components:

Risdiplam:

Result : negative

L-Ascorbic acid:

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 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.

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:

Risdiplam:

Effects on fertility : Species: Rat, females
Application Route: Oral
Dose: 7,5 mg/kg bw/day
Duration of Single Treatment: 12 d
Result: Effects on fetal development.

Species: Rabbit, females
Application Route: Oral
Dose: 12 mg/kg bw/day
Duration of Single Treatment: 14 d
Symptoms: Fetal mortality.

Species: Rabbit, females
Application Route: Oral
Dose: 4 mg/kg bw/day
Duration of Single Treatment: 14 d

Species: Rabbit, females
Application Route: Oral
Dose: 4 mg/kg bw/day
Duration of Single Treatment: 14 d

Species: Rat, females
Application Route: Oral
Dose: 3 mg/kg bw/day

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Symptoms: No adverse effects.

Reproductive toxicity - Assessment : Presumed human reproductive toxicant, May damage fertility. May damage the unborn child.

STOT-single exposure

Not classified based on available information.

Components:**Butanedioic acid, 2,3-dihydroxy- (2R,3R)-:**

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

L-Ascorbic acid:

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

STOT-repeated exposure

May cause damage to organs (Eyes, Skin, Testes, digestive system) through prolonged or repeated exposure.

Components:**Butanedioic acid, 2,3-dihydroxy- (2R,3R)-:**

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

Risdiplam:Target Organs : Eyes, Skin, Testes, digestive system
Assessment : May cause damage to organs through prolonged or repeated exposure.**L-Ascorbic acid:**

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

Repeated dose toxicity**Components:****Risdiplam:**Species : Rat
NOAEL : mg/kg bw/day, 7,5
Application Route : Oral
Exposure time : 14 d
Remarks : Subacute toxicitySpecies : Rat
NOEL : 2.5 mg/kg bw/day
Application Route : Oral

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Exposure time : 14 d
Remarks : Subacute toxicity

Species : Mouse
MTD : 20 mg/kg bw/day
Application Route : Oral
Exposure time : 7 Days
Remarks : Subacute toxicity

Aspiration toxicity

Not classified based on available information.

Components:**Butanedioic acid, 2,3-dihydroxy- (2R,3R)-:**

No data available

L-Ascorbic acid:

No data available

Further information**Components:****Risdiplam:**

Test Type : OECD Test Guideline 432

Remarks : Not phototoxic (in vitro)

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Butanedioic acid, 2,3-dihydroxy- (2R,3R)-:**

Toxicity to fish : LC50 (Carassius auratus (goldfish)): 1,000 mg/l
Exposure time: 72 h

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 135 mg/l
aquatic invertebrates Exposure time: 48 h

Ecotoxicology Assessment

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

Other organisms relevant to : No data available
the environment

Risdiplam:

Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 0.821 mg/l
Exposure time: 72 h

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GLP: yes
Remarks: average measured concentrationNOEC (Brachydanio rerio (zebrafish)): 0.821 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 203
GLP: yes
Remarks: average measured concentrationToxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.732 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
GLP: yesNOEC (Daphnia magna (Water flea)): 0.28 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
GLP: yesToxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): > 0.344 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yesNOErC (Desmodesmus subspicatus (green algae)): 0.344 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yesToxicity to microorganisms : (activated sludge): 35 mg/l
Exposure time: 14 d
Method: OECD Test Guideline 301F
GLP: yes
Remarks: no adverse influence on substrate biodegradation**Poly(oxy-1,2-ethanediyl), .alpha.-hydro.-omega.-hydroxy-:**Toxicity to fish : LC50 (Cyprinus carpio (Carp)): > 100 mg/l
Exposure time: 4 d
Method: OECD Test Guideline 203Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
Exposure time: 72 h

Toxicity to fish (Chronic toxicity) : > 1 mg/l

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- 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

L-Ascorbic acid:

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 1,020 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

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:****Risdiplam:**

- Biodegradability : Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301F
GLP: yes
- Physico-chemical removability : Method: OECD Test Guideline 301F
Remarks: Not abiotically degradable

Poly(oxy-1,2-ethanediyl), .alpha.-hydro.-omega.-hydroxy-:

- Biodegradability : Biodegradation: > 90 %
Exposure time: 28 d
Method: OECD Test Guideline 301

L-Ascorbic acid:

- Biodegradability : Biodegradation: 97 %
Exposure time: 5 d
Method: OECD Test Guideline 302B
- Biodegradation: 100 %
Exposure time: 150 d
Method: OECD Test Guideline 302B

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octanol/water : Remarks: No data available**Butanedioic acid, 2,3-dihydroxy- (2R,3R)-:**Partition coefficient: n-
octanol/water : log Pow: < 1**Risdiplam:**Partition coefficient: n-
octanol/water : log Pow: 0.69 (72.5 °F / 22.5 °C)
pH: 5
Method: OECD Test Guideline 107
GLP: yeslog Pow: 2.37 (72.5 °F / 22.5 °C)
pH: 7
Method: OECD Test Guideline 107
GLP: yeslog Pow: 2.63 (72.5 °F / 22.5 °C)
pH: 9
Method: OECD Test Guideline 107
GLP: yeslog Pow: <= -1.08 (77 °F / 25 °C)
pH: 5
Method: OECD Test Guideline 117
GLP: yeslog Pow: 0.58 (77 °F / 25 °C)
pH: 7
Method: OECD Test Guideline 117
GLP: yeslog Pow: 0.81 (77 °F / 25 °C)
pH: 9
Method: OECD Test Guideline 117
GLP: yes**Poly(oxy-1,2-ethanediyl), .alpha.-hydro.-omega.-hydroxy-:**Partition coefficient: n-
octanol/water : Remarks: No data available**L-Ascorbic acid:**Partition coefficient: n-
octanol/water : log Pow: -2.15 (73 °F / 23 °C)

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No data available

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.
Toxic to aquatic life with long lasting effects.

Components:**Risdiplam:**

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

Poly(oxy-1,2-ethanediyl), .alpha.-hydro.-omega.-hydroxy-:

Adsorbed organic bound halogens (AOX) : Remarks: Not applicable

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.
Empty containers should be taken to an approved waste handling site for recycling or disposal.
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.
(Risdiplam mixture)
Class : 9

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Packing group : III
Labels : 9

IATA-DGR

UN/ID No. : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
(Risdiplam mixture)
Class : 9
Packing group : III
Labels : Miscellaneous
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.
(Risdiplam mixture)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

Domestic regulation**49 CFR**

UN/ID/NA number : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
(Risdiplam mixture)
Class : 9
Packing group : III
Labels : CLASS 9
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.

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This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Serious eye damage or eye irritation
Respiratory or skin sensitization
Germ cell mutagenicity
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).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489):

Benzoic acid, sodium salt (1:1)	532-32-1	>= 1 - < 5 %
Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-	25322-68-3	>= 1 - < 5 %

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

US State Regulations**Massachusetts Right To Know**

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

D-Mannitol	69-65-8
Isomalt	64519-82-0
Strawberry Flavour	Not Assigned
Butanedioic acid, 2,3-dihydroxy- (2R,3R)-	87-69-4
Risdiplam	1825352-65-5

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

EVRYSIDI(R) Powder for Oral Solution 60mg

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

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Isomalt

Strawberry Flavour

Risdiplam

Sucralose

AICS : Not in compliance with the inventory

NZIoC : Not in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

TCSI : Not in compliance with the inventory

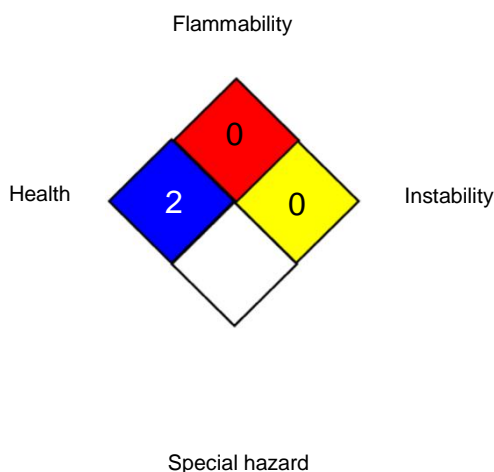
TSCA : Substance(s) not listed on TSCA inventory

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

EVRYSDI(R) Powder for Oral Solution 60mgVersion
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HEALTH	*	2
FLAMMABILITY		0
PHYSICAL HAZARD		0

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

US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)
US WEEL / TWA : 8-hr TWA

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 Standardisation; 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 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; 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, Authorisation 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; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act

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(United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 06-06-2023

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.

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