

**EVRYSDI® Powder for Oral Solution(60mg)**

Version 1.0                      Revision Date: 08-17-2020                      Date of last issue: -  
Date of first issue: 08-17-2020

**SECTION 1. IDENTIFICATION**

Product name                      : EVRYSDI® 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                              : DNA Way 1  
    94080 South San Francisco  
    CA  
    USA  
Telephone                          : 001-(650) 225-1000  
E-mail address                    : info.sds@roche.com  
Emergency telephone            : US Chemtrec phone                      (800)-424-9300  
Emergency telephone num-      :  
ber

**Recommended use of the chemical and restrictions on use**

Recommended use                : Formulated pharmaceutical active substance  
Restrictions on use               : For professional users only.

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**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.

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**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Risdiplam	1825352-65-5	3.0
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	6.0
Benzoic acid, sodium salt (1:1)	532-32-1	1.5
Poly(oxy-1,2-ethanediyl), .alpha.-	25322-68-3	1.0

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hydro-.omega.-hydroxy-		
Sucralose	56038-13-2	0.8
L-Ascorbic acid	50-81-7	0.7
Edetic acid disodium salt dihydrate (EDTA-2Na-2H <sub>2</sub> O)	6381-92-6	0.4

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**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.

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**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.

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- 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.

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**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.

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**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.  
Electrical installations / working materials must comply with

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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.
- Packaging material : Suitable material: Stainless steel, Polyethylene bag in metal drum, glass, glass bottles

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**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/m <sup>3</sup>	Roche Industrial Hygiene Committee (RIHC)
Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-	25322-68-3	TWA (aerosol)	10 mg/m <sup>3</sup>	US WEEL
L-Ascorbic acid	50-81-7	IOEL	10 mg/m <sup>3</sup>	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

Material : Protective gloves

Remarks : Wear appropriate protective gloves to prevent skin contact.

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- Eye protection : Replace torn or punctured gloves promptly.  
: 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.

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**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
- 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

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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

**Components:****Risdiplam:**

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

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Acute inhalation toxicity : Acute toxicity estimate: 5.1 mg/l  
Test atmosphere: dust/mist  
Method: Expert judgment

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.

**Components:****Strawberry Flavour:**

Result : Irritating to eyes.

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

Result : Irritating to eyes.  
Remarks : May cause irreversible eye damage.



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### **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: negative

Method: OECD Test Guideline 487  
Result: positive

Genotoxicity in vivo : Method: OECD Test Guideline 474  
Result: negative

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

### **Carcinogenicity**

Not classified based on available information.

### **Components:**

#### **Risdiplam:**

Result : negative

### **L-Ascorbic acid:**

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**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  
Duration of Single Treatment: 12 d  
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.

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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  
Exposure time : 14 d  
Remarks : Subacute toxicitySpecies : Mouse  
MTD : 20 mg/kg bw/day  
Application Route : Oral  
Exposure time : 7 Days  
Remarks : Subacute toxicity

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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)

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**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 hToxicity 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  
Method: OECD Test Guideline 203  
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 concentration

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- Toxicity 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: yes
- NOEC (Daphnia magna (Water flea)): 0.28 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
GLP: yes
- Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): > 0.344 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
GLP: yes
- NOErC (Desmodesmus subspicatus (green algae)): 0.344 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
GLP: yes
- Toxicity 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 203
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l  
Exposure time: 72 h
- Toxicity to fish (Chronic toxicity) : > 1 mg/l

**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

**L-Ascorbic acid:**

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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

**Bioaccumulative potential****Components:****Strawberry Flavour:**

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

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

Partition coefficient: n-octanol/water : log Pow: < 1

**Risdiplam:**

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Partition coefficient: n-octanol/water	:	log Pow: <= -1.08 pH: 5 Method: OECD Test Guideline 117 GLP: yes
		log Pow: 0.58 pH: 7 Method: OECD Test Guideline 117 GLP: yes
		log Pow: 0.81 pH: 9 Method: OECD Test Guideline 117 GLP: yes
		log Pow: 1.3 Method: calculated, consensus of various QSARs

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

Partition coefficient: n-octanol/water	:	Remarks: No data available
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**L-Ascorbic acid:**

Partition coefficient: n-octanol/water	:	log Pow: -2.15 (73 °F / 23 °C)
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**Mobility in soil**

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).
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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.
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**Components:**

**Risdiplam:**

Results of PBT and vPvB assessment	:	Non-classified vPvB substance Non-classified PBT substance
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**Poly(oxy-1,2-ethanediyl), .alpha.-hydro.-omega.-hydroxy-:**

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



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**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**

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**

**EPCRA - Emergency Planning and Community Right-to-Know**

**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**

Components	CAS-No.	Component TPQ (lbs)
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**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)

**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.

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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**

**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**

**Vermont Chemicals of High Concern**

**Washington Chemicals of High Concern**

**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.

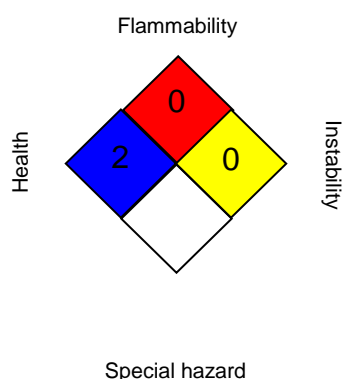
- Isomalt
- Strawberry Flavour
- Risdiplam
- Sucralose

- 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.

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Date of first issue: 08-17-2020**SECTION 16. OTHER INFORMATION****NFPA:****HMIS® IV:**

<b>HEALTH</b>	*	<b>2</b>
<b>FLAMMABILITY</b>		<b>0</b>
<b>PHYSICAL HAZARD</b>		<b>0</b>

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

AICS - Australian Inventory of Chemical Substances; 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); EC<sub>x</sub> - Concentration associated with x% response; EHS - Extremely Hazardous Substance; EL<sub>x</sub> - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErC<sub>x</sub> - 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; IC<sub>50</sub> - 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; LC<sub>50</sub> - Lethal Concentration to 50 % of a test population; LD<sub>50</sub> - 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; TSCA - Toxic Substances

# SAFETY DATA SHEET

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

Revision Date : 08-17-2020

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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