SAFETY DATA SHEET

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), synonym(s) of the substance : BS10965, BS10966 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 number : US Chemtrec phone (800)-424-9300

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 - repeated exposure : Category 2 (Eyes, Skin, Testes, digestive system)

GHS label elements
Hazard pictograms :

Signal Word : Danger
Hazard Statements : H317 May cause an allergic skin reaction.
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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Components</strong></td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>Risdipram</td>
<td>1825352-65-5</td>
</tr>
<tr>
<td>D-Mannitol</td>
<td>69-65-8</td>
</tr>
<tr>
<td>Isomalt</td>
<td>64519-82-0</td>
</tr>
<tr>
<td>Strawberry Flavour</td>
<td>Not Assigned</td>
</tr>
<tr>
<td>Butanedioic acid, 2,3-dihydroxy-(2R,3R)-</td>
<td>87-69-4</td>
</tr>
<tr>
<td>Benzoic acid, sodium salt (1:1)</td>
<td>532-32-1</td>
</tr>
</tbody>
</table>
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
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

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

Predicted No Effect Concentration (PNEC):

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
<th>Remarks: Based on acute data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risdiplam</td>
<td>Surface waters</td>
<td>0.73 µg/l</td>
<td></td>
</tr>
</tbody>
</table>

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
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
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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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
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: 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: negative

Genotoxicity in vivo: 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:
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.

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 toxicity

Species: Rat
NOEL: 2.5 mg/kg bw/day
Application Route: Oral
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 aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 135 mg/l  
Exposure time: 48 h  

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

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 concentration  

NOEC (Brachydanio rerio (zebrafish)): 0.821 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 203  
GLP: yes  
Remarks: average measured concentration  

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:
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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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:**
Partition coefficient: n-octanol/water : log Pow: 0.69 (72.5 °F / 22.5 °C)
ph: 5
Method: OECD Test Guideline 107
GLP: yes

 log Pow: 2.37 (72.5 °F / 22.5 °C)
ph: 7
Method: OECD Test Guideline 107
GLP: yes

 log Pow: 2.63 (72.5 °F / 22.5 °C)
ph: 9
Method: OECD Test Guideline 107
GLP: yes

 log Pow: <= -1.08 (77 °F / 25 °C)
ph: 5
Method: OECD Test Guideline 117
GLP: yes

 log Pow: 0.58 (77 °F / 25 °C)
ph: 7
Method: OECD Test Guideline 117
GLP: yes

 log 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)
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).

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.
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
- 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 SOCMI Intermedi ate or Final VOC's (40 CFR 60.489):
- Benzoic acid, sodium salt 532-32-1 >= 1 - < 5 %
- Poly(oxy-1,2-ethanediyl). alpha.-hydroxy.-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
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**
SAFETY DATA SHEET

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

NFPA 704:

<table>
<thead>
<tr>
<th>Flammability</th>
<th>Health</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>2</td>
</tr>
</tbody>
</table>

HMIS® IV:

<table>
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<tr>
<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
</tr>
</thead>
<tbody>
<tr>
<td>*</td>
<td>2</td>
<td>0</td>
</tr>
</tbody>
</table>

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; 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; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act

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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.

US / Z8 / 2204