

EVRYSDI Powder for Oral Solution 60 mgVersion
1.2Revision Date:
08/05/2025Date of last issue: 08/05/2025
Date of first issue: 06/20/2025**SECTION 1. IDENTIFICATION**

Product name : EVRYSDI Powder for Oral Solution 60 mg

Product code : RO703-4067/F13-00

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

In case of emergencies: : US CHEMTREC PHONE (800)-424-9300

Recommended use of the chemical and restrictions on use

Recommended use : Formulated pharmaceutical active substance

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

Combustible dust

Serious eye damage : Category 1

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 : May form combustible dust concentrations in air.
H317 May cause an allergic skin reaction.

EVRYSDI Powder for Oral Solution 60 mg
Version
1.2Revision Date:
08/05/2025Date of last issue: 08/05/2025
Date of first issue: 06/20/2025

H318 Causes serious eye damage.
 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.
 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 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.
 P333 + P313 If skin irritation or rash occurs: 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
Poly(oxy-1,2-ethanediyl), .alpha.-	25322-68-3	1

EVRYSDI Powder for Oral Solution 60 mg
Version
1.2Revision Date:
08/05/2025Date of last issue: 08/05/2025
Date of first issue: 06/20/2025

hydro-.omega.-hydroxy-		
Sucralose	56038-13-2	0.8
L-Ascorbic acid	50-81-7	0.7
Ethylenediaminetetraacetic acid disodium salt dihydrate	6381-92-6	0.4

SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.
Consult a physician.
Show this material safety data sheet to the doctor in attendance.
Do not leave the victim unattended.

If inhaled : If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.

In case of skin contact : If on skin, rinse well with water.

In case of eye contact : Small amounts splashed into eyes can cause irreversible tissue damage and blindness.
In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Continue rinsing eyes during transport to hospital.
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 induce vomiting.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Take victim immediately to hospital.

Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.
Causes serious eye damage.
Suspected of causing genetic defects.
May damage fertility. May damage the unborn child.
May cause damage to organs through prolonged or repeated exposure.

Protection of first-aiders : First Aid responders should pay attention to self-protection and use the recommended protective clothing

Notes to physician : Treat symptomatically.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

EVRYSDI Powder for Oral Solution 60 mgVersion
1.2Revision Date:
08/05/2025Date of last issue: 08/05/2025
Date of first issue: 06/20/2025

Unsuitable extinguishing media : High volume water jet

Specific hazards during fire fighting : Do not allow run-off from fire fighting to enter drains or water courses.

Hazardous combustion products : Carbon oxides
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.
Refer to protective measures listed in sections 7 and 8.

Environmental precautions : Prevent product from entering drains.
Prevent further leakage or spillage if safe to do so.
If the product contaminates rivers and lakes or drains inform respective authorities.

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

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Avoid dust formation.
Provide appropriate exhaust ventilation at places where dust is formed.

Advice on safe handling : Avoid formation of respirable particles.
Do not breathe vapors/dust.
Avoid exposure - obtain special instructions before use.
Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Dispose of rinse water in accordance with local and national

EVRYSDI Powder for Oral Solution 60 mg
Version
1.2Revision Date:
08/05/2025Date of last issue: 08/05/2025
Date of first issue: 06/20/2025

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 the technological safety standards.

Storage temperature : Protect 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)
Benzoic acid, sodium salt (1:1)	532-32-1	TWA (Inhalable particulate matter)	2.5 mg/m3	ACGIH
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)
Substance name	Environmental Compartment			Value
Risdiplam	Surface waters			0.73 µg/l
	Remarks:Based on acute data			

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where

EVRYSDI Powder for Oral Solution 60 mg
Version
1.2Revision Date:
08/05/2025Date of last issue: 08/05/2025
Date of first issue: 06/20/2025

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

Hand protection

In case of contact through splashing:

- : Nitrile rubber
- : > 30 min
- : > 0.11 mm

In case of full contact:

- : butyl-rubber
- : > 480 min
- : > 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

SAFETY DATA SHEET

Genentech
A Member of the Roche Group

EVRYSDI Powder for Oral Solution 60 mg

Version 1.2 Revision Date: 08/05/2025 Date of last issue: 08/05/2025
Date of first issue: 06/20/2025

Melting point/ range : No data available

Boiling point/boiling range : No data available

Flash point : Not applicable

Evaporation rate : No data available

Self-ignition : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Solubility in other solvents : No data available

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

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : Not applicable

Viscosity, kinematic : Not applicable

Explosive properties : No data available

Oxidizing properties : No data available

Particle characteristics

Particle Size Distribution : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

EVRYSDI Powder for Oral Solution 60 mg

Version 1.2 Revision Date: 08/05/2025 Date of last issue: 08/05/2025
Date of first issue: 06/20/2025

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. No data available
Incompatible materials	: No data available Not applicable
Hazardous decomposition products	: No data available No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified due to lack of data.

Product:

Acute oral toxicity : Acute toxicity estimate: 3,256 mg/kg
Method: Calculation method

Components:**D-Mannitol:**

Acute oral toxicity : LD50 Oral (Rat): 13,500 mg/kg
LD50 Oral (Mouse): 22,000 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: > 30 mg/l
Test atmosphere: dust/mist
Method: Expert judgment

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Expert judgment

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

EVRYSDI Powder for Oral Solution 60 mgVersion
1.2Revision Date:
08/05/2025Date of last issue: 08/05/2025
Date of first issue: 06/20/2025**Benzoic acid, sodium salt (1:1):**

Acute oral toxicity : LD50 (Rat): 2,100 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

3(2H)-Furanone, 4-hydroxy-2,5-dimethyl-:Acute oral toxicity : LD50 Oral (Rat, female): 1,660 mg/kg
Method: OECD Test Guideline 401
GLP: no**Skin corrosion/irritation**

Not classified due to lack of data.

Product:

Remarks : Extremely corrosive and destructive to tissue.

Components:**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

EVRYSDI Powder for Oral Solution 60 mgVersion
1.2Revision Date:
08/05/2025Date of last issue: 08/05/2025
Date of first issue: 06/20/2025**Benzoic acid, sodium salt (1:1):**

Species : Rabbit
Exposure time : 4 h
Assessment : No skin irritation
Method : Draize Test
Result : No skin irritation
GLP : yes
Remarks : Not classified

L-Ascorbic acid:

Remarks : This information is not available.

3(2H)-Furanone, 4-hydroxy-2,5-dimethyl-:

Species : reconstructed human epidermis (RhE)
Method : OECD Test Guideline 431
Result : Corrosive after 3 minutes to 1 hour of exposure
GLP : yes

Serious eye damage/eye irritation

Causes serious eye damage.

Product:

Remarks : May cause irreversible eye damage.

Components:**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

Benzoic acid, sodium salt (1:1):

Species : Rabbit

EVRYSDI Powder for Oral Solution 60 mg

Version 1.2 Revision Date: 08/05/2025 Date of last issue: 08/05/2025
 Date of first issue: 06/20/2025

Exposure time : 24 h
 Assessment : Irritating to eyes.
 Method : Draize Test
 GLP : yes
 Remarks : slight irritation

3(2H)-Furanone, 4-hydroxy-2,5-dimethyl-:

Species : Chicken eye
 Result : Risk of serious damage to eyes.
 Method : OECD Test Guideline 438
 GLP : yes

Respiratory or skin sensitization
Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified due to lack of data.

Product:

Remarks : Causes sensitization.

Components:
Risdiplam:

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

3(2H)-Furanone, 4-hydroxy-2,5-dimethyl-:

Test Type : Local lymph node assay (LLNA)
 Species : Mouse
 Method : OECD Test Guideline 429
 Result : The product is a skin sensitizer, sub-category 1A.
 GLP : yes

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

EVRYSDI Powder for Oral Solution 60 mgVersion
1.2Revision Date:
08/05/2025Date of last issue: 08/05/2025
Date of first issue: 06/20/2025

Result: positive

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

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

3(2H)-Furanone, 4-hydroxy-2,5-dimethyl-:

Genotoxicity in vivo : Remarks: Not classified due to data which are conclusive although insufficient for classification.

Carcinogenicity

Not classified due to lack of data.

Components:**D-Mannitol:**

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.

Risdiplam:

Result : negative

Benzoic acid, sodium salt (1:1):

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.

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.

EVRYSDI Powder for Oral Solution 60 mg
Version
1.2Revision Date:
08/05/2025Date of last issue: 08/05/2025
Date of first issue: 06/20/2025
3(2H)-Furanone, 4-hydroxy-2,5-dimethyl-:

Species : Rat
 Application Route : Oral
 Exposure time : 24 month(s)
 Dose : 100, 200, 400 mg/kg bw/day
 NOAEL : 200 mg/kg bw/day
 LOAEL : 400 mg/kg bw/day
 Method : OECD Test Guideline 451
 GLP : yes
 Remarks : No significant adverse effects were reported

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 - : Presumed human reproductive toxicant, May damage fertility.

EVRYSDI Powder for Oral Solution 60 mgVersion
1.2Revision Date:
08/05/2025Date of last issue: 08/05/2025
Date of first issue: 06/20/2025

Assessment May damage the unborn child.

3(2H)-Furanone, 4-hydroxy-2,5-dimethyl-:**STOT-single exposure**

Not classified due to lack of data.

Components:**D-Mannitol:**

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

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

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

Benzoic acid, sodium salt (1:1):

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:**D-Mannitol:**

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

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

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

EVRYSDI Powder for Oral Solution 60 mgVersion
1.2Revision Date:
08/05/2025Date of last issue: 08/05/2025
Date of first issue: 06/20/2025**Risdiplam:**

Target Organs : Eyes, Skin, Testes, digestive system
Assessment : May cause damage to organs through prolonged or repeated exposure.

Benzoic acid, sodium salt (1:1):

Assessment : The substance or mixture is not classified as specific target organ toxicant, 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 : 7.5 mg/kg bw/day
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

3(2H)-Furanone, 4-hydroxy-2,5-dimethyl-:

Species : Rat, male and female
NOAEL : 400 mg/kg

EVRYSDI Powder for Oral Solution 60 mgVersion
1.2Revision Date:
08/05/2025Date of last issue: 08/05/2025
Date of first issue: 06/20/2025

Application Route : Oral
Exposure time : 12w
Dose : 50, 100, 200, 400 mg/kg bw/day
Method : OECD Test Guideline 408
GLP : yes

Aspiration toxicity

Not classified due to lack of data.

Components:**D-Mannitol:**

No data available

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

No data available

Benzoic acid, sodium salt (1:1):

No data available

L-Ascorbic acid:

No data available

Further information**Product:**

Remarks : No data available

Components:**D-Mannitol:**

Remarks : Health injuries are not known or expected under normal use.

Risdiplam:

Test Type : OECD Test Guideline 432

Remarks : Not phototoxic (in vitro)

EVRYSDI Powder for Oral Solution 60 mgVersion
1.2Revision Date:
08/05/2025Date of last issue: 08/05/2025
Date of first issue: 06/20/2025**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****D-Mannitol:**

Toxicity to fish : LC50 (Fish): > 100 mg/l
Exposure time: 96 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

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

EVRYSDI Powder for Oral Solution 60 mg
Version
1.2Revision Date:
08/05/2025Date of last issue: 08/05/2025
Date of first issue: 06/20/2025

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

Benzoic acid, sodium salt (1:1):

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 460 mg/l
 LC0 (Oncorhynchus mykiss (rainbow trout)): 5,000 mg/l

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 7,000 mg/l
 Method: OECD Test Guideline 202

Toxicity to microorganisms : EC50 (Bacteria): > 500 mg/l
 Exposure time: 24 h

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

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

EVRYSDI Powder for Oral Solution 60 mg

Version 1.2 Revision Date: 08/05/2025 Date of last issue: 08/05/2025
Date of first issue: 06/20/2025

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

3(2H)-Furanone, 4-hydroxy-2,5-dimethyl-:

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 6.8 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202
GLP: yes

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 194.03 mg/l
Exposure time: 72 h
Test Type: static test
Method: OECD Test Guideline 201
GLP: yes

Persistence and degradability**Components:****D-Mannitol:**

Biodegradability : Biodegradation: 68 %
Exposure time: 28 d

Risdiplam:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d

EVRYSDI Powder for Oral Solution 60 mg
Version
1.2Revision Date:
08/05/2025Date of last issue: 08/05/2025
Date of first issue: 06/20/2025Method: OECD Test Guideline 301F
GLP: yesPhysico-chemical
removability : Method: OECD Test Guideline 301F
Remarks: Not abiotically degradable**Benzoic acid, sodium salt (1:1):**Biodegradability : Biodegradation: 90 %
Exposure time: 7 d
Method: OECD Test Guideline 301
Remarks: Readily biodegradable, according to appropriate
OECD test.**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**3(2H)-Furanone, 4-hydroxy-2,5-dimethyl-:**

Biodegradability : Result: Readily biodegradable.

Bioaccumulative potential**Components:****D-Mannitol:**Partition coefficient: n-
octanol/water : log Pow: -3.10**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

EVRYSDI Powder for Oral Solution 60 mgVersion
1.2Revision Date:
08/05/2025Date of last issue: 08/05/2025
Date of first issue: 06/20/2025

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

Benzoic acid, sodium salt (1:1):

Partition coefficient: n-octanol/water : log Pow: -2.13

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)

3(2H)-Furanone, 4-hydroxy-2,5-dimethyl-:

Partition coefficient: n-octanol/water : log Pow: 0.95 (68 °F / 20 °C)
pH: 2.5
Method: OECD Test Guideline 107

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).

EVRYSDI Powder for Oral Solution 60 mg
Version
1.2Revision Date:
08/05/2025Date of last issue: 08/05/2025
Date of first issue: 06/20/2025

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.
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)

Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : no

IATA-DGR

UN/ID No. : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
(Risdiplam)

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

EVRYSDI Powder for Oral Solution 60 mg
Version
1.2Revision Date:
08/05/2025Date of last issue: 08/05/2025
Date of first issue: 06/20/2025

Environmentally hazardous : yes

IMDG-Code

UN number

: UN 3077

Proper shipping name

: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
N.O.S.
(Risdiplam)

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)

Class

: 9

Packing group

: III

Labels

: Class 9 - Miscellaneous dangerous substances and articles

ERG Code

: 171

Marine pollutant

: no

Special precautions for user

Remarks : No data available

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION**CERCLA Reportable Quantity**

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

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

Components	CAS-No.	Component TPQ (lbs)
SARA 311/312 Hazards	: Combustible dust Respiratory or skin sensitization Germ cell mutagenicity Reproductive toxicity Specific target organ toxicity (single or repeated exposure) Serious eye damage or eye irritation	

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).

EVRYSDI Powder for Oral Solution 60 mg
Version
1.2Revision Date:
08/05/2025Date of last issue: 08/05/2025
Date of first issue: 06/20/2025

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 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

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

US State Regulations
Massachusetts Right To Know
Pennsylvania Right To Know

D-Mannitol	69-65-8
Isomalt	64519-82-0
NOTUPDATED_non hazardous compounds	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:

AIIC	: Not in compliance with the inventory
DSL	: This product contains the following components that are not on the Canadian DSL nor NDSL.
	Isomalt
	NOTUPDATED_non hazardous compounds
	Risdiplam
	Sucralose
	Butyric acid ethyl ester
NZIoC	: Not in compliance with the inventory
ENCS	: Not in compliance with the inventory

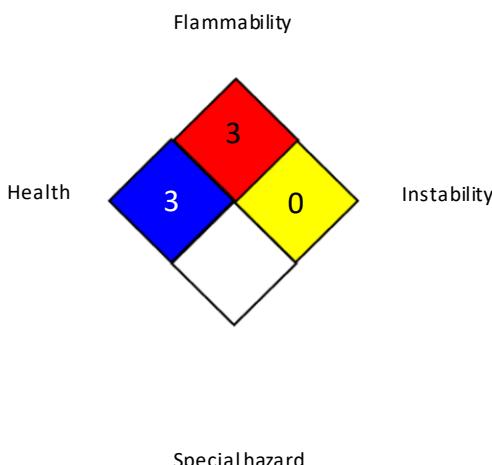
EVRYSDI Powder for Oral Solution 60 mg
Version
1.2Revision Date:
08/05/2025Date of last issue: 08/05/2025
Date of first issue: 06/20/2025

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	:	Product contains substance(s) not listed on TSCA inventory.
TECI	:	Not in compliance with the inventory

TSCA list

No substances are subject to a Significant New Use Rule.

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

SECTION 16. OTHER INFORMATION
Further information**NFPA 704:****HMIS® IV:**

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

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
US WEEL	:	USA. Workplace Environmental Exposure Levels (WEEL)
ACGIH / TWA	:	8-hour, time-weighted average
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,

EVRYSDI Powder for Oral Solution 60 mgVersion
1.2Revision Date:
08/05/2025Date of last issue: 08/05/2025
Date of first issue: 06/20/2025

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; KECL - 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; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 08/05/2025

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 / EN / 2404