

EVRYSDI(R) (Risdiplam) 0.75 mg/ml

Version Revision Date: Date of last issue: -

1.0 09-25-2020 Date of first issue: 09-25-2020

SECTION 1. IDENTIFICATION

Product name : EVRYSDI(R) (Risdiplam) 0.75 mg/ml

Product code : RO703-4067/Z13

Common name(s), : Risdiplam and other inactive ingredients

synonym(s) of the substance

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

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

number

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)

Skin sensitization : Category 1

GHS label elements

Hazard pictograms :

Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.

Precautionary Statements : Prevention:

P261 Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.
P272 Contaminated work clothing must not be allowed out of

the workplace.

P280 Wear protective gloves.

Response:



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P302 + P352 IF ON SKIN: Wash with plenty of soap and water. P333 + P313 If skin irritation or rash occurs: Get medical advice/

attention.

P363 Wash contaminated clothing before reuse.

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	0.075
Strawberry Flavour	Not Assigned	0.19

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 on skin, rinse well with water.

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.

Rinse mouth with water.

Most important symptoms and effects, both acute and

delayed

May cause an allergic skin reaction.

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

No information available.

Hazardous combustion

products

Carbon oxides

Further information : Standard procedure for chemical fires.

Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

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 Use personal protective equipment.

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.

Methods and materials for

containment and cleaning up

Soak up with inert absorbent material (e.g. sand, silica gel,

acid binder, universal binder, sawdust).

Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against :

fire and explosion

Normal measures for preventive fire protection.

Advice on safe handling : 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.



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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

Further information on

storage stability

No decomposition if stored and applied as directed.

Packaging material Suitable material: glass, Ampoules, Vials

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

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

Predicted No Effect Concentration (PNEC):

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

Engineering measures No data available

Personal protective equipment

Hand protection

Material Protective gloves

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



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Skin and body protection : Impervious clothing

Choose body protection according to the amount and

concentration of the dangerous substance at the work place.

Hygiene measures : Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Clear liquid

Color : country-specific

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/range : No data available

Boiling point/boiling range : No data available

Evaporation rate : No data available

Self-ignition : Not applicable

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 : No data available

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 : No data available

Viscosity, kinematic : No data available



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SECTION 10. STABILITY AND REACTIVITY

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

Chemical stability : Stable under normal conditions.

Possibility of hazardous

reactions

: No decomposition if stored and applied as directed.

Conditions to avoid : No data available

Incompatible materials : No data available

Hazardous decomposition

products

No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified based on available information.

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 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:



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Result : Irritating to skin.

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

Not classified based on available information.

Product:

Remarks : Vapors may cause irritation to the eyes, respiratory system

and the skin.

Components:

Strawberry Flavour:

Result : Irritating to eyes.

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.



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Germ cell mutagenicity

Not classified based on available information.

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:

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.

OSHANo 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

Not classified based on available information.

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



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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:

L-Ascorbic acid:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, single exposure.

STOT-repeated exposure

Not classified based on available information.

Components:

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



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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:

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:

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



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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

Exposure time: 72 h

Method: OECD Test Guideline 201

GLP: yes

NOErC (Desmodesmus subspicatus (green algae)): 0.344

Exposure time: 72 h

Method: OECD Test Guideline 201

GLP: ves

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-:

LC50 (Cyprinus carpio (Carp)): > 100 mg/l Toxicity to fish

Exposure time: 4 d

Method: OECD Test Guideline 203

aquatic invertebrates

Toxicity to daphnia and other : 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



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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

Risdiplam:

Partition coefficient: n-

pH: 5

octanol/water

Method: OECD Test Guideline 117

GLP: yes

log Pow: 0.58

log Pow: <= -1.08

pH: 7

Method: OECD Test Guideline 117

GLP: yes



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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

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).

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 : 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.



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Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable

Domestic regulation

49 CFR

Not regulated as a dangerous good

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

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

SARA 311/312 Hazards : Respiratory or skin sensitization

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

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

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

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

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

Clean Water Act

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



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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

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

Pennsylvania Right To Know

Water 7732-18-5

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.



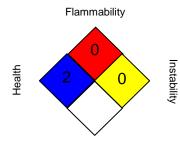
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SECTION 16. OTHER INFORMATION

NFPA:



Special hazard

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

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); ECx -Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx -Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC -International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. -Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ -Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund



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Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance 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

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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 / 1810