

SAFETY DATA SHEET

Genentech
A Member of the Roche Group

EVRYSDI(Risdiplam) 0.75 mg/ml

Version
1.1

Revision Date:
08/05/2025

Date of last issue: 06/14/2025
Date of first issue: 06/14/2025

SECTION 1. IDENTIFICATION

Product name : EVRYSDI (Risdiplam) 0.75 mg/ml

Product code : RO703-4067Z13

Common name(s),
synonym(s) of the substance : Risdiplam and other inactive ingredients

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)

Not a hazardous substance or mixture.

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

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 : Do not leave the victim unattended.

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

In case of skin contact : Wash off with soap and water.

In case of eye contact : Remove contact lenses.
Protect unharmed eye.
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.

Most important symptoms and effects, both acute and delayed : None known.

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.

Unsuitable extinguishing media : High volume water jet

Specific hazards during fire fighting : No information available.

Hazardous combustion products : No hazardous combustion products are known

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, : Refer to protective measures listed in sections 7 and 8.

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emergency proceduresEnvironmental precautions : If the product contaminates rivers and lakes or drains inform
respective authorities.Methods and materials for
containment and cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).
Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGEAdvice on protection against
fire and explosion : Normal measures for preventive fire protection.Advice on safe handling : For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the
application area.Conditions for safe storage : Electrical installations / working materials must comply with
the technological safety standards.

Materials to avoid : No materials to be especially mentioned.

Storage temperature : Protect from heat and light

Further information on
storage stability : No decomposition if stored and applied as directed.

Packaging material : Suitable material: glass, Ampoules, Vials, Stainless steel

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)
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			

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Respiratory protection	: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where 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	<p>In case of contact through splashing:</p>
Material	: Nitrile rubber
Break through time	: > 30 min
Glove thickness	: > 0.11 mm
Material	<p>In case of full contact:</p>
Break through time	: butyl-rubber
Glove thickness	: > 480 min
Glove thickness	: > 0.4 mm
Remarks	: Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.
Eye protection	: Safety glasses
Skin and body protection	: Protective suit
Hygiene measures	: General industrial hygiene practice.

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

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Flash point	: 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
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
Explosive properties	: No data available
Oxidizing properties	: No data available
Particle characteristics	
Particle Size Distribution	: 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	: Stable under recommended storage conditions. No hazards to be specially mentioned.

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Conditions to avoid : No data available
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.

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

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 due to lack of data.

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Species	:	Mouse
Result	:	No skin irritation
Method	:	in silico model
Result	:	No skin irritation

L-Ascorbic acid:

Remarks	:	This information is not available.
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Serious eye damage/eye irritation

Not classified due to lack of data.

Components:**Risdiplam:**

Method	:	in vitro eye irritation test
Remarks	:	Eye effect

Respiratory or skin sensitization**Skin sensitization**

Not classified due to lack of data.

Respiratory sensitization

Not classified due to lack of data.

Components:**Risdiplam:**

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

Germ cell mutagenicity

Not classified due to lack of data.

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

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

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

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

Not classified due to lack of data.

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.

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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 due to lack of data.

Components:**D-Mannitol:**

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

Not classified due to lack of data.

Components:**D-Mannitol:**

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

Risdiplam:

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

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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

Aspiration toxicity

Not classified due to lack of data.

Components:**D-Mannitol:**

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.

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Test Type : OECD Test Guideline 432
Remarks : Not phototoxic (in vitro)

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

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

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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

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:****D-Mannitol:**

Biodegradability : Biodegradation: 68 %
Exposure time: 28 d

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

L-Ascorbic acid:

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

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Biodegradation: 100 %
Exposure time: 150 d
Method: OECD Test Guideline 302B

Bioaccumulative potential**Components:****D-Mannitol:**

Partition coefficient: n-octanol/water : log Pow: -3.10

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

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:**

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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 : No data available

Components:**Risdiplam:**

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

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

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

Special precautions for user

Remarks : No data available

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

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

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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	:	No SARA Hazards

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.

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**

Water

7732-18-5

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 : On the inventory, or in compliance with the inventory

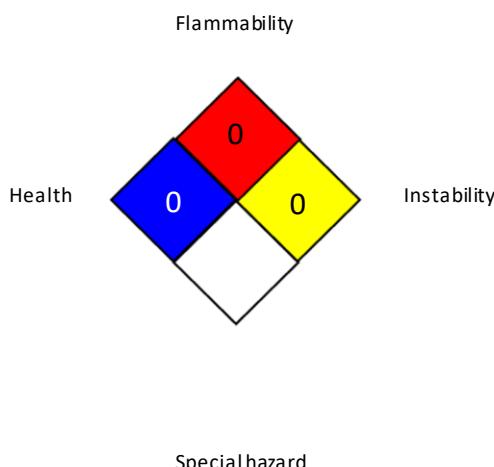
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ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
TCSI	:	Not in compliance with the inventory
TSCA	:	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

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 -

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

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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 / EN / 2404