

VABYSMO 12% aqueous solutionVersion
1.4Revision Date:
07-28-2021Date of last issue: 06-10-2017
Date of first issue: 12-11-2015**SECTION 1. IDENTIFICATION**

Product name : VABYSMO 12% aqueous solution

Product code : RO686-7461/F06

Common name(s),
synonym(s) of the substance : Faricimab (RO6867461) 12 % aqueous solution with excipients
VEGF-Ang2 ophtha (RO6867461) 12 % aqueous solution with excipients
Bispecific antibody

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 : US Chemtrec phone (800)-424-9300

Emergency telephone 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)**

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Faricimab (RO6867461-000)	1607793-29-2	12.0
.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl	57-50-1	5.48
L-Histidine	71-00-1	0.31

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Sodium chloride (NaCl)	7647-14-5	0.15
Acetic acid	64-19-7	< 0.2
L-Methionine	63-68-3	0.1
Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs.	9005-64-5	0.04
Water	7732-18-5	> 81.0

SECTION 4. FIRST AID MEASURES

- General advice : 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.
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 : None known.
- 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.
- Specific hazards during fire fighting : No information available.
- Hazardous combustion products : In case of fire hazardous decomposition products may be produced such as:
Carbon monoxide
Nitrogen oxides (NOx)
- Further information : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Special protective equipment : Wear self-contained breathing apparatus for firefighting if

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for fire-fighters

necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Refer to protective measures listed in sections 7 and 8.
- Environmental precautions : Local authorities should be advised if significant spillages cannot be contained.
- 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 STORAGE

- Advice 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.
- Further information on storage conditions : See label, package insert or internal guidelines
- Materials to avoid : No materials to be especially mentioned.
- Storage temperature : Protected from heat and light
- Further information on storage stability : No decomposition if stored and applied as directed.
- Packaging material : Suitable material: Stainless steel, glass, Vials, Prefilled syringes

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Faricimab (RO6867461-000)	1607793-29-2	IOEL	0.020 mg/m3	Roche Industrial Hygiene Committee (RIHC)
.alpha.-D-	57-50-1	TWA	10 mg/m3	ACGIH

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Glucopyranoside, .beta.-D-fructofuranosyl				
		TWA (Respirable)	5 mg/m3	NIOSH REL
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0
Acetic acid	64-19-7	TWA	10 ppm	ACGIH
		STEL	15 ppm	ACGIH
		TWA	10 ppm 25 mg/m3	NIOSH REL
		ST	15 ppm 37 mg/m3	NIOSH REL
		TWA	10 ppm 25 mg/m3	OSHA Z-1
		TWA	10 ppm 25 mg/m3	OSHA P0

Engineering measures : No data available

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

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 : Safety glasses

Skin and body protection : Protective suit

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

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Appearance	:	liquid
Color	:	colorless, light brown
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	5.5
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	:	No data available
Relative density	:	No data available
Solubility(ies)		
Water solubility	:	completely miscible
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

SECTION 10. STABILITY AND REACTIVITY

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

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Chemical stability	:	Stable under normal conditions. Proteins are temperature-sensitive; the thermal denaturation has an impact on quality but does not affect Plant and Process Safety; during decomposition no flammable gas, no organic peroxide and no oxidising substances are created
Possibility of hazardous reactions	:	Stable under recommended storage conditions. No hazards to be specially mentioned.
Incompatible materials	:	No data available
Hazardous decomposition products	:	No data available

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified based on available information.

Components:**Faricimab (RO6867461-000):**

Acute oral toxicity : Remarks: Not bioavailable by oral administration

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

Acute oral toxicity : LD50 Oral (Rat): 29,700 mg/kg
LD50 Oral (Mouse): 14,000 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

Acetic acid:

Acute oral toxicity : LD50 Oral (Rat, male and female): 3,310 mg/kg
GLP: no

Acute inhalation toxicity : LC50 (Rat, male and female): 11.4 mg/l
Exposure time: 4 h
Test atmosphere: vapor
GLP: no
Assessment: The substance or mixture has no acute inhalation toxicity

Skin corrosion/irritation

Not classified based on available information.

Components:**Acetic acid:**

Species : Rabbit

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Exposure time : 4 h
 Method : OECD Test Guideline 404
 Result : Causes severe burns.
 GLP : No information available.

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Acetic acid:

Species : Rabbit
 Result : Risk of serious damage to eyes.
 Exposure time : 4 h
 Method : OECD Test Guideline 405
 GLP : No information available.

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Components:

Acetic acid:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
 Test system: Salmonella typhimurium
 Metabolic activation: Metabolic activation
 Method: OECD Test Guideline 471
 Result: negative
 GLP: No information available.
 Remarks: In vitro tests did not show mutagenic effects

Test Type: Chromosome aberration test in vitro
 Test system: Chinese hamster ovary cells
 Metabolic activation: with and without metabolic activation
 Method: OECD Test Guideline 473
 Result: negative
 GLP: no
 Remarks: In vitro tests did not show mutagenic effects

Genotoxicity in vivo : Test Type: Micronucleus test
 Species: Rat (male and female)
 Application Route: Inhalation
 Exposure time: 13 weeks
 Dose: 0, 1, 5, 20 ppm
 Method: Mutagenicity (micronucleus test)
 Result: negative
 GLP: yes

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Not classified based on available information.

Components:**.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**

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.

Acetic acid:

Species : Mouse, female
Application Route : dermal
Exposure time : 32 weeks
Result : negative
GLP : no
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 based on available information.

Components:**Faricimab (RO6867461-000):**

Effects on fetal development : Species: laboratory animal, female
Result: Based on its mechanism of action, effects on embryofetal development can be assumed

Acetic acid:

Effects on fetal development : Species: Mouse, female
Application Route: Oral
Dose: 10 ml/kg body weight
Duration of Single Treatment: 6 - 15 d
Developmental Toxicity: NOAEL: 345 mg/kg body weight
Method: Regulation (EC) No. 440/2008, Annex, B.31
GLP: No information available.

STOT-single exposure

Not classified based on available information.

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

STOT-repeated exposure

Not classified based on available information.

Components:**.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**

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

Repeated dose toxicity**Components:****Faricimab (RO6867461-000):**Species : cynomolgus monkey
NOAEL : ≥ 10 mg/kg/w
Application Route : i.v.
Exposure time : 2 Weeks**Aspiration toxicity**

Not classified based on available information.

Components:**.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**

No data available

Further information**Components:****Faricimab (RO6867461-000):**

Remarks : Globular proteins are generally well biodegradable

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

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

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**Toxicity to fish : LC50 (Fish): > 100 mg/l
Exposure time: 96 h

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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

Acetic acid:Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 300.82 mg/l
End point: mortality
Exposure time: 96 h
Test Type: semi-static test
Analytical monitoring: no
Method: OECD Test Guideline 203
GLP: yesToxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 300.82 mg/l
End point: Immobilization
Exposure time: 48 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 202
GLP: yesToxicity to algae/aquatic plants : EC50 (Skeletonema costatum (marine diatom)): > 300.82 mg/l
Exposure time: 72 h
Test Type: static test
Analytical monitoring: no
GLP: yes**Persistence and degradability****Components:****Faricimab (RO6867461-000):**

Biodegradability : Result: Globular proteins are generally well biodegradable

Acetic acid:Biodegradability : aerobic
Inoculum: activated sludge
Concentration: 3 mg/l
Result: Readily biodegradable.
Biodegradation: 96 %
Exposure time: 20 d
GLP: no**Bioaccumulative potential****Components:****Faricimab (RO6867461-000):**

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octanol/water : Remarks: No data available**.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**Partition coefficient: n-
octanol/water : log Pow: -3.67**Acetic acid:**

Bioaccumulation : Bioconcentration factor (BCF): 3.16

Partition coefficient: n-
octanol/water : log Pow: -0.17 (77 °F / 25 °C)
pH: 7
Method: No information available.
GLP: No information available.**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:****Faricimab (RO6867461-000):**Additional ecological
information : Protein with highly specific affinity to a certain antigen;
therefore, no appreciable ecotoxic potential is to be expected

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.
Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

Not regulated as a dangerous good

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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**CERCLA Reportable Quantity**

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Acetic acid	64-19-7	5000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

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 : No SARA Hazards**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 SOCM I Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

Acetic acid 64-19-7 >= 0.1 - < 1 %

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

Acetic acid 64-19-7 >= 0.1 - < 1 %

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

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US State Regulations

Massachusetts Right To Know

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl	57-50-1
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Pennsylvania Right To Know

Water	7732-18-5
Faricimab (RO6867461-000)	1607793-29-2
.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl	57-50-1
Acetic acid	64-19-7

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

California Permissible Exposure Limits for Chemical Contaminants

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl	57-50-1
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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.
Faricimab (RO6867461-000)
- AICS : Not in compliance with the inventory
- NZIoC : On the inventory, or 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 : Product contains 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

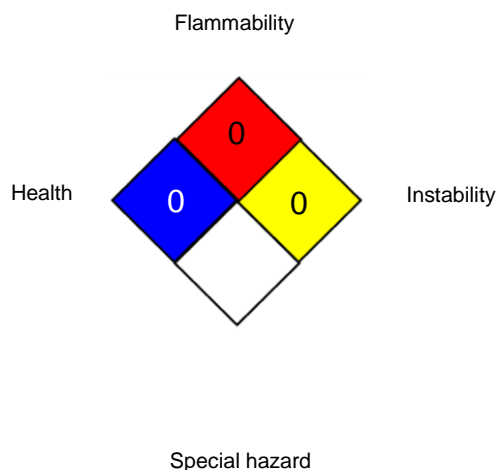
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NFPA 704:



HMIS® IV:

HEALTH	/	0
FLAMMABILITY		0
PHYSICAL HAZARD		0

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)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA P0	:	USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
ACGIH / STEL	:	Short-term exposure limit
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
NIOSH REL / ST	:	STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
OSHA P0 / TWA	:	8-hour time weighted average
OSHA Z-1 / TWA	:	8-hour time weighted average

AIIIC - 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

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Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances 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 / 2004