

SAFETY DATA SHEET



C.f.a.s. DAT Qualitative Plus

Version
1.8

Revision Date:
04-13-2022

Date of last issue: 10-21-2021
Date of first issue: 11-26-2015

SECTION 1. IDENTIFICATION

Product name : C.f.a.s. DAT Qualitative Plus

Product code : 03304698190

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics
-

Address : 9115 Hague Road
Indianapolis, IN 46250
USA

Telephone : 1-800-428-5074

Emergency telephone

In case of emergencies: : CHEMTREC

1-800-424-9300 (U.S. or Canada)
1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

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

Chemical nature : Handle as potentially infectious.

Components

Chemical name	CAS-No.	Concentration (% w/w)
glycerol	56-81-5	$\geq 1 - < 5$
Morphinan - 3,6 - diol, 7,8 - didehydro - 4,5 - epoxy - 17 - methyl - (5 - alpha,6 - alpha) - ,sulfate (2:1) (salt) , pentahydrate	6211-15-0	< 0.1

Actual concentration is withheld as a trade secret

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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	: 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	: Refer to protective measures listed in sections 7 and 8.
Environmental precautions	: Local authorities should be advised if significant spillages

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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.

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION
Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
glycerol	56-81-5	TWA (mist, respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (mist, total dust)	15 mg/m ³	OSHA Z-1
		TWA (Mist - total dust)	10 mg/m ³	OSHA P0
		TWA (Mist - respirable fraction)	5 mg/m ³	OSHA P0
Morphinan - 3,6 - diol, 7,8 - didehydro - 4,5 - epoxy - 17 - methyl - (5 - alpha,6 - alpha) - ,sulfate (2:1) (salt) , pentahydrate	6211-15-0	IOEL	0.005 mg/m ³	Roche Industrial Hygiene Committee (RIHC)
		STEL	0.01 mg/m ³	

Engineering measures : No data available

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

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Hand protection

Material : Protective gloves

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

Appearance : liquid

Color : yellow

Odor : characteristic

Odor Threshold : No data available

pH : 5 - 9

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

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

Density : 1.013 g/cm³

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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
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

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.
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:**glycerol:**

Acute oral toxicity	: LC50 (Mouse): 11,500 mg/kg
Acute inhalation toxicity	: LC50 (Rat, male): 275000 mg/m3 Exposure time: 7 h Test atmosphere: vapor GLP: no Assessment: The component/mixture is minimally toxic after short term inhalation.
Acute dermal toxicity	: LD50 (Guinea pig, male and female): 56,750 mg/kg GLP: no

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Acute oral toxicity : LD50 Oral (Rat): 973 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:**glycerol:**

Species	: Rabbit
Exposure time	: 24 h
Result	: No skin irritation
GLP	: no

Morphinan - 3,6 - diol, 7,8 - didehydro - 4,5 - epoxy - 17 - methyl - (5 - alpha,6 - alpha) - ,sulfate (2:1) (salt) , pentahdrate:

Remarks : This information is not available.

Serious eye damage/eye irritation

Not classified based on available information.

Components:**glycerol:**

Species	: Rabbit
Result	: No eye irritation
Exposure time	: 7 d
GLP	: no

Morphinan - 3,6 - diol, 7,8 - didehydro - 4,5 - epoxy - 17 - methyl - (5 - alpha,6 - alpha) - ,sulfate (2:1) (salt) , pentahdrate:

Remarks : This information is not available.

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:**glycerol:**

Assessment : Mild eye irritant, Mild respiratory irritant, No skin irritation

Germ cell mutagenicity

Not classified based on available information.

Components:**glycerol:**

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Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Result: negative
GLP: No information available.

Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster ovary cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: negative
GLP: No information available.

Carcinogenicity

Not classified based on available information.

Components:**glycerol:**

Species : Rat, male and female
Application Route : Oral
Exposure time : 2 Years
GLP : No information available.
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:**glycerol:**

Effects on fertility : Test Type: Two-generation study
Species: Rat, male and female
Application Route: Oral
Dose: 2000 mg/kg bw/day
Fertility: NOAEL: 2,000 mg/kg body weight
GLP: no

Effects on fetal development : Species: Rabbit, female
Application Route: Oral
Dose: 11.8, 54.8, 254.5, 1180 mg/kg bw/day
Duration of Single Treatment: 29 d
Developmental Toxicity: NOAEL: 1,180 mg/kg bw/day
GLP: no

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Not classified based on available information.

Components:**Morphinan - 3,6 - diol, 7,8 - didehydro - 4,5 - epoxy - 17 - methyl - (5 - alpha,6 - alpha) - ,sulfate (2:1) (salt) , pentahdrate:**

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

STOT-repeated exposure

Not classified based on available information.

Repeated dose toxicity**Components:****glycerol:**

Species : Rat, male and female
NOAEL : 4580 mg/kg
NOAEL : 4,580 mg/kg
Application Route : Oral
Exposure time : 90 d
Number of exposures : daily
Dose : 4580 - 25,800 mg/kg/day
GLP : no

Species : Rat, male and female
Application Route : Inhalation
Test atmosphere : dust/mist
Exposure time : 13 Weeks
Number of exposures : 6 hours/day, 5 days/week
Dose : 33, 165 and 660 mg/m3
GLP : No information available.

Species : Rat
NOAEL : 5040 mg/kg
NOAEL : 5,040 mg/kg
Application Route : dermal
Exposure time : 45 Weeks
Number of exposures : 8 hours/day, 5 days/week
Dose : 0.5-4.0 ml/kg
GLP : no

Repeated dose toxicity - Assessment : Mild eye irritant, Mild respiratory irritant, No skin irritation

Aspiration toxicity

Not classified based on available information.

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SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****glycerol:**

- Toxicity to fish : LC50 (*Oncorhynchus mykiss* (rainbow trout)): 54,000 mg/l
End point: mortality
Exposure time: 96 h
Test Type: static test
GLP: no
- Toxicity to daphnia and other aquatic invertebrates : LC50 (*Daphnia magna* (Water flea)): 1,955 mg/l
End point: mortality
Exposure time: 48 h
Test Type: static test
Analytical monitoring: no
GLP: no
- Toxicity to algae/aquatic plants : (*Scenedesmus quadricauda* (Green algae)): > 10,000 mg/l
End point: Growth rate
Exposure time: 8 d
Test Type: static test
GLP: no
- Toxicity to microorganisms : EC50 (*Pseudomonas putida*): > 10,000 mg/l
End point: Growth rate
Exposure time: 16 h
Test Type: static test
GLP: No information available.

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

Morphinan - 3,6 - diol, 7,8 - didehydro - 4,5 - epoxy - 17 - methyl - (5 - alpha,6 - alpha) - ,sulfate (2:1) (salt) , pentahdrate:

Ecotoxicology Assessment

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

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Biodegradability : aerobic
Inoculum: activated sludge
Concentration: 226 mg/l
Result: Readily biodegradable.
Biodegradation: 94 %
Exposure time: 24 h
GLP: no

Morphinan - 3,6 - diol, 7,8 - didehydro - 4,5 - epoxy - 17 - methyl - (5 - alpha,6 - alpha) - ,sulfate (2:1) (salt) , pentahdrate:

Biodegradability : Remarks: No data available

Bioaccumulative potential**Components:****glycerol:**

Partition coefficient: n- : log Pow: -1.75 (77 °F / 25 °C)
octanol/water pH: 7.4
Method: OECD Test Guideline 107
GLP: no

Morphinan - 3,6 - diol, 7,8 - didehydro - 4,5 - epoxy - 17 - methyl - (5 - alpha,6 - alpha) - ,sulfate (2:1) (salt) , pentahdrate:

Bioaccumulation : Remarks: No data available

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

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:**Morphinan - 3,6 - diol, 7,8 - didehydro - 4,5 - epoxy - 17 - methyl - (5 - alpha,6 - alpha) - ,sulfate (2:1) (salt) , pentahdrate:**

Additional ecological information : No data available

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SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

- Waste from residues : Special treatment as infectious material is mandatory in compliance with local regulations (disinfection and incineration). 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

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 : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

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

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

SARA 304 Extremely Hazardous Substances Reportable Quantity

Listed substances in the product are at low enough levels to not be expected to exceed the 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

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SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

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

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

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

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489):

glycerol	56-81-5	>= 1 - < 5 %
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Clean Water Act

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

Hydrochloric acid	7647-01-0	>= 0 - < 0.1 %
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The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

Hydrochloric acid	7647-01-0	>= 0 - < 0.1 %
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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

glycerol	56-81-5
Sodium azide (Na(N3))	26628-22-8

Pennsylvania Right To Know

Water	7732-18-5
glycerol	56-81-5
Sodium azide (Na(N3))	26628-22-8

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 Prop. 65

WARNING: This product can expose you to chemicals including Secobarbital sodium, Nordazepam, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

California Permissible Exposure Limits for Chemical Contaminants

glycerol	56-81-5
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The ingredients of this product are reported in the following inventories:

AIIC : Not in compliance with the inventory

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DSL	: This product contains the following components that are not on the Canadian DSL nor NDSL.
	Protein
	Morphinan - 3,6 - diol, 7,8 - didehydro - 4,5 - epoxy - 17 - methyl - (5 - alpha,6 - alpha) - ,sulfate (2:1) (salt) , pentahdrate
	Methadone hydrochloride
	Methaqualone hydrochloride
	Piperidine-1-(1-phenylcyclohexyl)-hydrochloride
	Nordazepam
	3-(benzoyloxy)-8-methyl-8-azabicyclo(3.2.1)octane-2-carboxylic acid
	11-Nor-9-Carboxy-Tetrahydrocannabinol
	Benzeneethanamine, N,.alpha.-dimethyl-, hydrochloride (1:1), (.alpha.S)-
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 active and not listed on TSCA inventory.
TECI	: Not in compliance with the inventory

TSCA list

No substances are subject to a Significant New Use Rule.

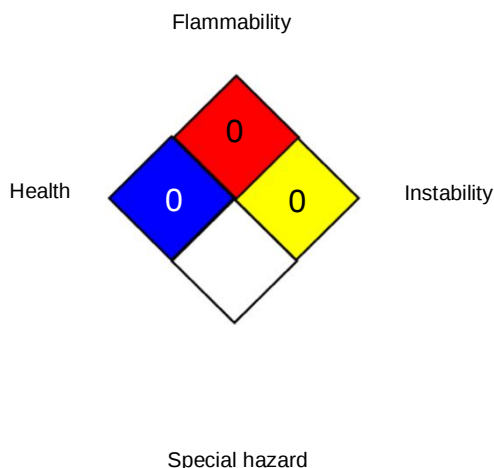
No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

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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

OSHA P0	:	USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
OSHA P0 / TWA	:	8-hour time weighted average
OSHA Z-1 / TWA	:	8-hour time weighted average

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

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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 / Z8 / 2104