

TAMIFLU(R) Powder for Oral SuspensionVersion
1.5Revision Date:
02-27-2020Date of last issue: 06-05-2019
Date of first issue: 12-10-2015**SECTION 1. IDENTIFICATION**

Product name : TAMIFLU(R) Powder for Oral Suspension

Product code : 00010158710

Common name(s), syno- : TAMIFLU DRY SYRUP
nym(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 num- : US Chemtrec phone (800)-424-9300
ber**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 29 CFR 1910.1200**

Skin sensitization : Category 1

Carcinogenicity : Category 2

GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.
H351 Suspected of causing cancer.

Precautionary Statements :

Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read
and understood.

P261 Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.

TAMIFLU(R) Powder for Oral Suspension

 Version
 1.5

 Revision Date:
 02-27-2020

 Date of last issue: 06-05-2019
 Date of first issue: 12-10-2015

P272 Contaminated work clothing must not be allowed out of the workplace.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

P363 Wash contaminated clothing before reuse.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Oseltamivir phosphate	204255-11-8	3.9
D-Glucitol	50-70-4	86.0
1,2,3-Propanetricarboxylic acid, 2-hydroxy-, sodium salt (1:1)	18996-35-5	5.5
Titanium oxide (TiO ₂)	13463-67-7	1.5
Xanthan gum	11138-66-2	1.5
non hazardous compounds	Not Assigned	1.34
Benzoic acid, sodium salt (1:1)	532-32-1	0.25
1,2-Benzisothiazol-3(2H)-one, 1,1-dioxide, sodium salt (1:1)	128-44-9	0.01

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.

TAMIFLU(R) Powder for Oral Suspension

Version 1.5	Revision Date: 02-27-2020	Date of last issue: 06-05-2019 Date of first issue: 12-10-2015
----------------	------------------------------	---

- 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.
Suspected of causing cancer.
- 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.
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during fire fighting : No information available.
- Hazardous combustion products : In case of fire hazardous decomposition products may be produced such as:
Nitrogen oxides (NO_x)
Oxides of phosphorus
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.
Avoid dust formation.
Avoid breathing dust.
- Environmental precautions : Prevent product from entering drains.
Prevent further leakage or spillage if safe to do so.
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for : Keep in suitable, closed containers for disposal.

TAMIFLU(R) Powder for Oral Suspension

Version
1.5

Revision Date:
02-27-2020

Date of last issue: 06-05-2019
Date of first issue: 12-10-2015

containment and cleaning up

SECTION 7. HANDLING AND STORAGE

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

- Advice on safe handling : Avoid formation of respirable particles.
Do not breathe vapors/dust.
Avoid exposure - obtain special instructions before use.
Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Dispose of rinse water in accordance with local and national 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.
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 : to 25 °C
Protect against light.

- Further information on storage stability : Keep in a dry place.

- Packaging material : Suitable material: glass

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Oseltamivir phosphate	204255-11-8	IOEL	0.2 mg/m ³	Roche Industrial Hygiene Committee (RIHC)
Titanium oxide (TiO ₂)	13463-67-7	TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (Total dust)	10 mg/m ³	OSHA P0

TAMIFLU(R) Powder for Oral Suspension

Version
1.5

Revision Date:
02-27-2020

Date of last issue: 06-05-2019
Date of first issue: 12-10-2015

		TWA	10 mg/m3 (Titanium dioxide)	ACGIH
--	--	-----	--------------------------------	-------

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

Skin and body protection : Dust impervious protective suit
Choose body protection according to the amount and concentration of the dangerous substance at the work place.

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

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : powder
- Color : white, light yellow
- Odor : odorless
- Odor Threshold : Not applicable
- pH : 3.0 - 5.0 (68 °F / 20 °C)
suspension
- Melting point/range : No data available
- Boiling point/boiling range : No data available
- Evaporation rate : No data available
- Flammability (solid, gas) : Does not sustain combustion.
- Flammability (liquids) : Does not sustain combustion.
- 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

TAMIFLU(R) Powder for Oral SuspensionVersion
1.5Revision Date:
02-27-2020Date of last issue: 06-05-2019
Date of first issue: 12-10-2015

Relative vapor density	:	Not applicable
Relative density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	log Pow: 0.36 pH: 7.4 The value is given in analogy to the following substances: Oseltamivir phosphate
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	Not applicable
Viscosity, kinematic	:	Not applicable
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	:	No decomposition if stored and applied as directed. Dust may form explosive mixture in air.
Conditions to avoid	:	Exposure to light.
Incompatible materials	:	No data available
Hazardous decomposition products	:	No data available

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified based on available information.

Product:

Acute inhalation toxicity	:	Acute toxicity estimate: > 200 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method
---------------------------	---	---

TAMIFLU(R) Powder for Oral Suspension

Version
1.5

Revision Date:
02-27-2020

Date of last issue: 06-05-2019
Date of first issue: 12-10-2015

Components:

Oseltamivir phosphate:

Acute oral toxicity : MNLD (Maximum No Lethal Dose) (Rat): > 2,000 mg/kg
Assessment: The component/mixture is minimally toxic after single ingestion.

Titanium oxide (TiO₂):

Acute oral toxicity : LD50 (Rat): > 7,500 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 10,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks : May cause skin irritation and/or dermatitis.

Serious eye damage/eye irritation

Not classified based on available information.

Product:

Remarks : Product dust may be irritating to eyes, skin and respiratory system.

Components:

Oseltamivir phosphate:

Species : Rabbit
Result : Eye irritation
Method : OECD Test Guideline 405
GLP : yes
Remarks : May cause irreversible eye damage.

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:

Oseltamivir phosphate:

Species : Guinea pig

TAMIFLU(R) Powder for Oral SuspensionVersion
1.5Revision Date:
02-27-2020Date of last issue: 06-05-2019
Date of first issue: 12-10-2015

Assessment : May cause sensitization by skin contact.
Method : OECD Test Guideline 406
GLP : yes

Germ cell mutagenicity

Not classified based on available information.

Components:**Oseltamivir phosphate:**

Genotoxicity in vitro : Result: negative
Remarks: In vitro tests did not show mutagenic effects

Carcinogenicity

Suspected of causing cancer.

IARC Group 2B: Possibly carcinogenic to humans
Titanium oxide (TiO₂) 13463-67-7

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:**Oseltamivir phosphate:**

Effects on fertility : Species: laboratory animal
Result: Animal testing did not show any effects on fertility.

Effects on fetal development : Species: laboratory animal
Result: No teratogenic effects.

STOT-single exposure

Not classified based on available information.

Components:**Oseltamivir phosphate:**

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:**Oseltamivir phosphate:**

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

TAMIFLU(R) Powder for Oral SuspensionVersion
1.5Revision Date:
02-27-2020Date of last issue: 06-05-2019
Date of first issue: 12-10-2015**Repeated dose toxicity****Components:****Oseltamivir phosphate:**

Species : Rat
 NOAEL : 250 mg/kg
 Application Route : Oral
 Exposure time : 4 Weeks
 GLP : yes
 Remarks : Subchronic toxicity

Aspiration toxicity

Not classified based on available information.

Components:**Oseltamivir phosphate:**

No data available

Further information**Components:****Oseltamivir phosphate:**

Remarks : Not phototoxic (in vitro)

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Oseltamivir phosphate:**

Toxicity to fish : LC50 (Cyprinus carpio (Carp)): > 100 mg/l
 Exposure time: 96 h
 Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 33 mg/l
 Exposure time: 48 h
 Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Selenastrum capricornutum (green algae)): 463 mg/l
 Exposure time: 96 h
 Method: OECD Test Guideline 201

EyC50 (Selenastrum capricornutum (green algae)): 59 mg/l
 Exposure time: 96 h
 Method: OECD Test Guideline 201

NOErC (Selenastrum capricornutum (green algae)): 46 mg/l
 Exposure time: 96 h
 Method: OECD Test Guideline 201

TAMIFLU(R) Powder for Oral SuspensionVersion
1.5Revision Date:
02-27-2020Date of last issue: 06-05-2019
Date of first issue: 12-10-2015NOEC (Selenastrum capricornutum (green algae)): 10 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 201Toxicity to microorganisms : (activated sludge): 30 mg/l
Exposure time: 14 d
Method: OECD Test Guideline 302C
GLP: no
Remarks: no adverse influence on substrate biodegradation**Titanium oxide (TiO₂):**Toxicity to fish : LC₀ (Leuciscus idus (Golden orfe)): > 1,000 mg/l
Exposure time: 48 hToxicity to daphnia and other : EC₀ (Daphnia magna (Water flea)): 3 mg/l
aquatic invertebrates Exposure time: 720 h**Ecotoxicology Assessment**

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

Other organisms relevant to : No data available
the environment**Persistence and degradability****Components:****Oseltamivir phosphate:**Biodegradability : Biodegradation: 3.0 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Biodegradation: 2.8 %
Exposure time: 14 d
Method: OECD Test Guideline 301B**Bioaccumulative potential****Components:****Oseltamivir phosphate:**Partition coefficient: n- : log Pow: 0.36
octanol/water pH: 7.4**Titanium oxide (TiO₂):**Partition coefficient: n- : Remarks: No data available
octanol/water**Mobility in soil**

No data available

TAMIFLU(R) Powder for Oral Suspension

Version
1.5

Revision Date:
02-27-2020

Date of last issue: 06-05-2019
Date of first issue: 12-10-2015

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).

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.
Can be disposed as waste water, when in compliance with local regulations.

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.
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.

TAMIFLU(R) Powder for Oral Suspension

Version
1.5

Revision Date:
02-27-2020

Date of last issue: 06-05-2019
Date of first issue: 12-10-2015

SARA 304 Extremely Hazardous Substances Reportable Quantity

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

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

Components	CAS-No.	Component TPQ (lbs)
SARA 311/312 Hazards	:	Respiratory or skin sensitization Carcinogenicity

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 SOCOMI 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

US State Regulations

Massachusetts Right To Know

Titanium oxide (TiO ₂)	13463-67-7
1,2-Benzisothiazol-3(2H)-one, 1,1-dioxide, sodium salt (1:1)	128-44-9

Pennsylvania Right To Know

D-Glucitol	50-70-4
1,2,3-Propanetricarboxylic acid, 2-hydroxy-, sodium salt (1:1)	18996-35-5
Oseltamivir phosphate	204255-11-8
Titanium oxide (TiO ₂)	13463-67-7
1,2-Benzisothiazol-3(2H)-one, 1,1-dioxide, sodium salt (1:1)	128-44-9

Maine Chemicals of High Concern

Vermont Chemicals of High Concern

Washington Chemicals of High Concern

California Prop. 65

WARNING: This product can expose you to chemicals including Titanium oxide (TiO₂), which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California Permissible Exposure Limits for Chemical Contaminants

Titanium oxide (TiO ₂)	13463-67-7
------------------------------------	------------

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.

TAMIFLU(R) Powder for Oral Suspension

Version
1.5

Revision Date:
02-27-2020

Date of last issue: 06-05-2019
Date of first issue: 12-10-2015

Oseltamivir phosphate
non hazardous compounds

- 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

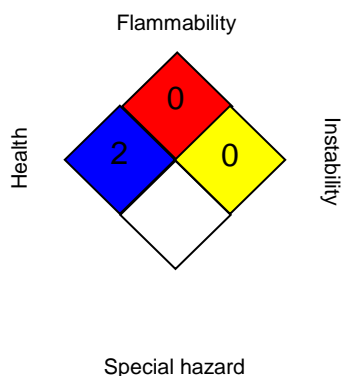
TSCA list

No substances are subject to a Significant New Use Rule.

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

SECTION 16. OTHER INFORMATION

NFPA:



HMIS® IV:

HEALTH	*	2
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)
- 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

TAMIFLU(R) Powder for Oral SuspensionVersion
1.5Revision Date:
02-27-2020Date of last issue: 06-05-2019
Date of first issue: 12-10-2015

ACGIH / TWA : 8-hour, time-weighted average
OSHA P0 / TWA : 8-hour time weighted average
OSHA Z-1 / TWA : 8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; 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 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

Revision Date : 02-27-2020

The information provided in this Material 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