

XOFLUZA(TM) (Baloxavir Marboxil) Tablets 40mg

Version 2.0 Revision Date: 12-08-2020 Date of last issue: 02-20-2020
Date of first issue: 02-20-2020

SECTION 1. IDENTIFICATION

Product name : XOFLUZA(TM) (Baloxavir Marboxil) Tablets 40mg
Product code : RO719-1686/F13
Common name(s),
synonym(s) of the substance : XOFLUZA Film Coated Tablets 40 mg
XOFLUZA F.C. Tablets 40 mg
BS11564, BS11395

Manufacturer or supplier's details

Company name of supplier : Genentech, Inc.
Address : DNA Way 1
94080 South San Francisco
CA
USA
Telephone : 001-(650) 225-1000
E-mail address : info.sds@roche.com
Emergency telephone
Emergency telephone : US Chemtrec phone (800)-424-9300
number


Recommended use of the chemical and restrictions on use

Recommended use : Formulated pharmaceutical active substance
Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION**GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Carcinogenicity : Category 1A

GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H350 May cause cancer.

Precautionary Statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

XOFLUZA(TM) (Baloxavir Marboxil) Tablets 40mg
Version
2.0Revision Date:
12-08-2020Date of last issue: 02-20-2020
Date of first issue: 02-20-2020**Response:**

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

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)
Baloxavir Marboxil	1985606-14-1	15.9
Lactose-1-Hydrate	64044-51-5	61.9
Cellulose	9004-34-6	9.0
Croscarmellose sodium	74811-65-7	4.4
2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8	4.4
sodium octadecyl fumarate	4070-80-8	1.3
Titanium oxide (TiO ₂)	13463-67-7	< 0.9
Talc (Mg ₃ H ₂ (SiO ₃) ₄)	14807-96-6	0.1
non hazardous compounds	Not Assigned	2.1

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.

XOFLUZA(TM) (Baloxavir Marboxil) Tablets 40mg

Version
2.0

Revision Date:
12-08-2020

Date of last issue: 02-20-2020
Date of first issue: 02-20-2020

Rinse mouth with water.

Most important symptoms and effects, both acute and delayed : May cause 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.

Specific hazards during fire fighting : Do not allow run-off from fire fighting to enter drains or water courses.

Hazardous combustion products : In case of fire hazardous decomposition products may be produced such as:
Hydrogen fluoride
Sulfur oxides
Nitrogen oxides (NOx)
Carbon oxides

Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

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 : Avoid dust formation.

Environmental precautions : Prevent product from entering drains.

Methods and materials for containment and cleaning up : Pick up and arrange disposal without creating dust.
Sweep up and shovel.
Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

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

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 : Containers which are opened must be carefully resealed and

XOFLUZA(TM) (Baloxavir Marboxil) Tablets 40mg
Version
2.0Revision Date:
12-08-2020Date of last issue: 02-20-2020
Date of first issue: 02-20-2020

kept upright to prevent leakage.
 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: Blister packages, Stainless steel, glass bottles

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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Baloxavir Marboxil	1985606-14-1	IOEL	0.0025 mg/m3	Roche Industrial Hygiene Committee (RIHC)
Cellulose	9004-34-6	TWA	10 mg/m3	ACGIH
		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
Titanium oxide (TiO ₂)	13463-67-7	TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (Total dust)	10 mg/m3	OSHA P0
		TWA	10 mg/m3 (Titanium dioxide)	ACGIH
Talc (Mg ₃ H ₂ (SiO ₃) ₄)	14807-96-6	TWA (Dust)	20 Million particles per cubic foot	OSHA Z-3
		TWA	2 mg/m3	ACGIH

XOFLUZA(TM) (Baloxavir Marboxil) Tablets 40mg

Version
2.0

Revision Date:
12-08-2020

Date of last issue: 02-20-2020
Date of first issue: 02-20-2020

		(Respirable particulate matter)		
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Engineering measures : No data available

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

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 : tablet
- Color : white, light yellow
- Odor : Not applicable
- Odor Threshold : Not applicable
- pH : Not applicable
- 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 : Not applicable

XOFLUZA(TM) (Baloxavir Marboxil) Tablets 40mg

Version 2.0	Revision Date: 12-08-2020	Date of last issue: 02-20-2020 Date of first issue: 02-20-2020
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Relative density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	Not applicable
Viscosity, kinematic	:	Not applicable
Explosive properties	:	No data available
Oxidizing properties	:	No data available

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.
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 oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
		Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: 95.26 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method
		Acute toxicity estimate: 118.18 mg/l

XOFLUZA(TM) (Baloxavir Marboxil) Tablets 40mg

Version
2.0

Revision Date:
12-08-2020

Date of last issue: 02-20-2020
Date of first issue: 02-20-2020

Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

Baloxavir Marboxil:

Acute oral toxicity : LD50 Oral (Rat): > 2,000 mg/kg

Cellulose:

Acute oral toxicity : LD50 Oral (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 Dermal (Rabbit): > 2,000 mg/kg

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.

Components:

Talc (Mg3H2(SiO3)4):

Remarks : This information is not available.

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Talc (Mg3H2(SiO3)4):

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.

XOFLUZA(TM) (Baloxavir Marboxil) Tablets 40mg

Version
2.0

Revision Date:
12-08-2020

Date of last issue: 02-20-2020
Date of first issue: 02-20-2020

STOT-single exposure

Not classified based on available information.

Components:

Talc (Mg₃H₂(SiO₃)₄):

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:

Baloxavir Marboxil:

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

Talc (Mg₃H₂(SiO₃)₄):

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

Repeated dose toxicity

Components:

Baloxavir Marboxil:

Species : Rat
NOAEL : mg/kg bw/day, 2000
Application Route : Oral
Exposure time : 2 Weeks
Remarks : Subacute toxicity

Aspiration toxicity

Not classified based on available information.

Components:

Talc (Mg₃H₂(SiO₃)₄):

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Baloxavir Marboxil:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 10.6 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
GLP: yes
Remarks: average measured concentration

XOFLUZA(TM) (Baloxavir Marboxil) Tablets 40mg

 Version
 2.0

 Revision Date:
 12-08-2020

 Date of last issue: 02-20-2020
 Date of first issue: 02-20-2020

- NOEC (Danio rerio (zebra fish)): 10.6 mg/l
 Exposure time: 96 h
 Method: OECD Test Guideline 203
 GLP: yes
 Remarks: average measured concentration
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 17.4 mg/l
 Exposure time: 48 h
 Method: OECD Test Guideline 202
 GLP: yes
 Remarks: measured initial concentration
- NOEC (Daphnia magna (Water flea)): 17.4 mg/l
 Exposure time: 48 h
 Method: OECD Test Guideline 202
 Remarks: measured initial concentration
- Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 9.28 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201
 GLP: yes
 Remarks: average measured concentration
- NOErC (Desmodesmus subspicatus (green algae)): 1.75 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201
 GLP: yes
 Remarks: average measured concentration
- EyC50 (Desmodesmus subspicatus (green algae)): 4.76 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201
 GLP: yes
 Remarks: average measured concentration
- Toxicity to microorganisms : (activated sludge): Exposure time: 14 d
 Method: OECD Test Guideline 301F
 GLP: yes
 Remarks: no adverse influence on substrate biodegradation

Cellulose:
Ecotoxicology Assessment

- Acute aquatic toxicity : This product has no known ecotoxicological effects.
- Chronic aquatic toxicity : This product has no known ecotoxicological effects.

Titanium oxide (TiO₂):

- Toxicity to fish : LC0 (Leuciscus idus (Golden orfe)): > 1,000 mg/l
 Exposure time: 48 h
- Toxicity to daphnia and other aquatic invertebrates : EC0 (Daphnia magna (Water flea)): 3 mg/l
 Exposure time: 720 h

XOFLUZA(TM) (Baloxavir Marboxil) Tablets 40mgVersion
2.0Revision Date:
12-08-2020Date of last issue: 02-20-2020
Date of first issue: 02-20-2020**Ecotoxicology Assessment**

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

Other organisms relevant to
the environment : No data available**Talc (Mg₃H₂(SiO₃)₄):**Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100,000 mg/l
Exposure time: 24 h**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**Persistence and degradability****Components:****Baloxavir Marboxil:**Biodegradability : Result: Not readily biodegradable.
Biodegradation: < 10 %
Exposure time: 28 d
Method: OECD Test Guideline 301F
GLP: yesPhysico-chemical
removability : Method: OECD Test Guideline 301F
Remarks: Not abiotically degradable**Bioaccumulative potential****Components:****Baloxavir Marboxil:**Partition coefficient: n-
octanol/water : log Pow: 2.24
Method: calculated, consensus of various QSARslog Pow: 2.46 (77 °F / 25 °C)
pH: 5
Method: OECD Test Guideline 117
GLP: yeslog Pow: 2.45 (77 °F / 25 °C)
pH: 7
Method: OECD Test Guideline 117
GLP: yes

log Pow: 2.46 (77 °F / 25 °C)

XOFLUZA(TM) (Baloxavir Marboxil) Tablets 40mgVersion
2.0Revision Date:
12-08-2020Date of last issue: 02-20-2020
Date of first issue: 02-20-2020pH: 9
Method: OECD Test Guideline 117
GLP: yes**Cellulose:**

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

Titanium oxide (TiO₂):

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

Talc (Mg₃H₂(SiO₃)₄):

Partition coefficient: n-octanol/water : Remarks: No data 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).Additional ecological information : An environmental hazard cannot be excluded in the event of
unprofessional handling or disposal.
Harmful to aquatic life with long lasting effects.**Components:****Talc (Mg₃H₂(SiO₃)₄):**

Adsorbed organic bound halogens (AOX) : Remarks: Not applicable

Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**Waste from residues : The product should not be allowed to enter drains, water
courses or the soil.
Can be disposed as waste water, when in compliance with
local regulations.

XOFLUZA(TM) (Baloxavir Marboxil) Tablets 40mgVersion
2.0Revision Date:
12-08-2020Date of last issue: 02-20-2020
Date of first issue: 02-20-2020

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

SECTION 15. REGULATORY INFORMATION**EPCRA - Emergency Planning and Community Right-to-Know****CERCLA Reportable Quantity**

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

SARA 304 Extremely Hazardous Substances Reportable Quantity

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

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

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

SARA 311/312 Hazards : Carcinogenicity**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 SOCOMI Intermediate or Final VOC's (40 CFR 60.489).

XOFLUZA(TM) (Baloxavir Marboxil) Tablets 40mgVersion
2.0Revision Date:
12-08-2020Date of last issue: 02-20-2020
Date of first issue: 02-20-2020**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**

Cellulose	9004-34-6
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Pennsylvania Right To Know

Lactose-1-Hydrate	64044-51-5
Baloxavir Marboxil	1985606-14-1
Cellulose	9004-34-6
Croscarmellose sodium	74811-65-7
2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8

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 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 List of Hazardous Substances

2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8
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California Permissible Exposure Limits for Chemical Contaminants

Cellulose	9004-34-6
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California Regulated Carcinogens

Talc (Mg ₃ H ₂ (SiO ₃) ₄)	14807-96-6
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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.

Baloxavir Marboxil

Croscarmellose sodium

non hazardous compounds

sodium octadecyl fumarate

AICS : Not in compliance with the inventory

XOFLUZA(TM) (Baloxavir Marboxil) Tablets 40mg

Version 2.0 Revision Date: 12-08-2020 Date of last issue: 02-20-2020
 Date of first issue: 02-20-2020

- 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 : Product contains substance(s) not listed on TSCA inventory.

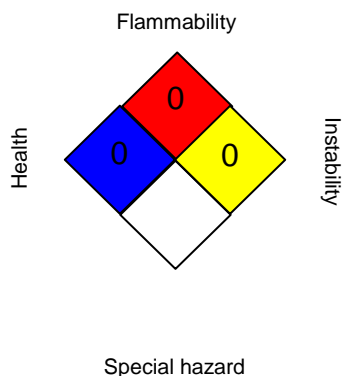
TSCA list

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

NFPA:



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
- OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
- ACGIH / TWA : 8-hour, time-weighted average
- NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour

XOFLUZA(TM) (Baloxavir Marboxil) Tablets 40mgVersion
2.0Revision Date:
12-08-2020Date of last issue: 02-20-2020
Date of first issue: 02-20-2020

workday during a 40-hour workweek

OSHA P0 / TWA : 8-hour time weighted average
OSHA Z-1 / TWA : 8-hour time weighted average
OSHA Z-3 / TWA : 8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund 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 : 12-08-2020

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / Z8 / 1810