

## Timolol Formulation

Version 5.4      Revision Date: 10/10/2020      SDS Number: 1598341-00010      Date of last issue: 03/23/2020  
Date of first issue: 05/01/2017

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**SECTION 1. IDENTIFICATION**

Product name : Timolol Formulation

**Manufacturer or supplier's details**

Company name of supplier : Merck & Co., Inc  
Address : 2000 Galloping Hill Road  
Kenilworth - New Jersey - U.S.A. 07033  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Pharmaceutical

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

Reproductive toxicity : Category 2  
Specific target organ toxicity : Category 1 (Cardio-vascular system, Lungs)  
- repeated exposure

**GHS label elements**

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H361d Suspected of damaging the unborn child.  
H372 Causes damage to organs (Cardio-vascular system, Lungs) through prolonged or repeated exposure.

Precautionary Statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P260 Do not breathe mist or vapors.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P280 Wear protective gloves, protective clothing, eye protection and face protection.

**Response:**

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

**Storage:**

P405 Store locked up.

**Disposal:**

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P501 Dispose of contents and 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)
(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate	26921-17-5	$\geq 0.1 - < 1$

Actual concentration is withheld as a trade secret

**SECTION 4. FIRST AID MEASURES**

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
 When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.  
 Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
 Remove contaminated clothing and shoes.  
 Get medical attention.  
 Wash clothing before reuse.  
 Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.  
 Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
 Get medical attention.  
 Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : Suspected of damaging the unborn child.  
 Causes damage to organs through prolonged or repeated exposure.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

**SECTION 5. FIRE-FIGHTING MEASURES**

- Suitable extinguishing media : Water spray  
 Alcohol-resistant foam  
 Carbon dioxide (CO<sub>2</sub>)  
 Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire : Exposure to combustion products may be a hazard to health.

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fighting  
 Hazardous combustion products : Carbon oxides  
 Metal oxides  
 Phosphorus compounds

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
 Use water spray to cool unopened containers.  
 Remove undamaged containers from fire area if it is safe to do so.  
 Evacuate area.

Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus.  
 Use personal protective equipment.

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### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
 Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.  
 Prevent further leakage or spillage if safe to do so.  
 Prevent spreading over a wide area (e.g., by containment or oil barriers).  
 Retain and dispose of contaminated wash water.  
 Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Soak up with inert absorbent material.  
 For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.  
 Clean up remaining materials from spill with suitable absorbent.  
 Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
 Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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### SECTION 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not breathe mist or vapors.  
 Do not swallow.  
 Avoid contact with eyes.  
 Avoid prolonged or repeated contact with skin.  
 Wash skin thoroughly after handling.  
 Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure

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- assessment  
 Do not eat, drink or smoke when using this product.  
 Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.  
 Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
 Strong oxidizing agents  
 Organic peroxides  
 Explosives  
 Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate	26921-17-5	TWA	10 µg/m <sup>3</sup> (OEB 3)	Internal
Further information: Eye, Skin				
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal

- Engineering measures** : Ensure adequate ventilation, especially in confined areas.  
 Minimize workplace exposure concentrations.  
 Dust formation may be relevant in the processing of this product. In addition to substance-specific OELs, general limitations of concentrations of particulates in the air at workplaces have to be considered in workplace risk assessment. Relevant limits include: OSHA PEL for Particulates Not Otherwise Regulated of 15 mg/m<sup>3</sup> - total dust, 5 mg/m<sup>3</sup> - respirable fraction; and ACGIH TWA for Particles (insoluble or poorly soluble) Not Otherwise Specified of 3 mg/m<sup>3</sup> - respirable particles, 10 mg/m<sup>3</sup> - inhalable particles.

#### Personal protective equipment

- Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.
- Hand protection

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Material	:	Chemical-resistant gloves
Remarks	:	Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.
Eye protection	:	Wear the following personal protective equipment: Safety glasses
Skin and body protection	:	Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	Aqueous solution
Color	:	Colorless to pale yellow
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	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

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Relative vapor density            : No data available

Density                                : No data available

Solubility(ies)  
  Water solubility                 : soluble

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

Autoignition temperature        : No data available

Decomposition temperature       : No data available

Viscosity  
  Viscosity, kinematic            : No data available

Explosive properties              : Not explosive

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

Molecular weight                 : Not applicable

Particle size                        : Not applicable

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**SECTION 10. STABILITY AND REACTIVITY**

Reactivity                         : Not classified as a reactivity hazard.

Chemical stability                 : Stable under normal conditions.

Possibility of hazardous reac-  
  tions                               : Can react with strong oxidizing agents.

Conditions to avoid                : None known.

Incompatible materials            : Oxidizing agents

Hazardous decomposition         : No hazardous decomposition products are known.  
  products

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**SECTION 11. TOXICOLOGICAL INFORMATION****Information on likely routes of exposure**

Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Components:****(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:**

Acute oral toxicity                : LD50 (Rat): 1,000 mg/kg

LD50 (Mouse): 1,140 mg/kg

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Acute toxicity (other routes of administration) : LD50 (Mouse): 300 mg/kg  
Application Route: Intraperitoneal

LD50 (Mouse): 800 mg/kg  
Application Route: Subcutaneous

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:**

Species : Rabbit  
Method : Draize Test  
Result : No skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:**

Species : Rabbit  
Result : Mild eye irritation

Species : Dog  
Result : No eye irritation

**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:****(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test  
Species: Mouse  
Method: OECD Test Guideline 474  
Result: negative

**Carcinogenicity**

Not classified based on available information.

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### Components:

#### **(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:**

Species : Rat  
 Application Route : Oral  
 Exposure time : 2 Years  
 LOAEL : 300 mg/kg body weight  
 Result : negative  
 Target Organs : Adrenal gland  
 Remarks : The significance of these findings for humans is not certain.

Species : Mouse, female  
 Application Route : Oral  
 Exposure time : 18 Months  
 LOAEL : 500 mg/kg body weight  
 Result : negative  
 Target Organs : Lungs, Mammary gland, Uterus (including cervix)  
 Remarks : The significance of these findings for humans is not certain.

Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen

**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**

Suspected of damaging the unborn child.

### Components:

#### **(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:**

Effects on fertility : Test Type: Fertility/early embryonic development  
 Species: Rat  
 Application Route: Oral  
 Fertility: NOAEL Mating/Fertility: 150 mg/kg body weight  
 Early Embryonic Development: NOAEL F1: 150 mg/kg body weight

Effects on fetal development : Test Type: Embryo-fetal development  
 Species: Rabbit  
 Developmental Toxicity: LOAEL F1: 50 mg/kg body weight  
 Result: Some evidence of adverse effects on development, based on animal experiments.

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.



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**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

Causes damage to organs (Cardio-vascular system, Lungs) through prolonged or repeated exposure.

**Product:**

Target Organs : Cardio-vascular system, Lungs  
Assessment : Causes damage to organs through prolonged or repeated exposure.

**Components:****(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:**

Target Organs : Lungs, Cardio-vascular system  
Assessment : Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:**

Species : Rat  
NOAEL : 25 mg/kg  
Application Route : Oral  
Exposure time : 67 Weeks

Species : Dog  
NOAEL : 10 mg/kg  
Application Route : Oral  
Exposure time : 54 Weeks  
Target Organs : Kidney

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Product:**

General Information : May cause  
Stomach/intestinal disorders  
Respiratory disorders  
Symptoms: Irregular cardiac activity, central nervous system effects  
Eye contact : Symptoms: burning or stinging of the eye

**Components:****(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:**

Eye contact : Symptoms: burning or stinging of the eye, dryness of the eyes, Headache, Nausea, Dizziness, dry mouth, changes in libido, hair loss, Allergic reactions  
Ingestion : Symptoms: Headache, Fatigue, Respiratory disorders, Gas-

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trointestinal discomfort, Allergic reactions, Rash, hair loss, altered mental status, Dizziness, changes in libido

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 411 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 161 mg/l  
aquatic invertebrates : Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to microorganisms : EC50: > 1,000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition

EC50 (Photobacterium phosphoreum): > 1,800 mg/l

**Persistence and degradability****Components:****(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 0 %  
Exposure time: 30 d

Stability in water : Hydrolysis: 0 %(61 d)  
Method: FDA 3.09

**Bioaccumulative potential****Components:****(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:**

Partition coefficient: n- : log Pow: 1.48  
octanol/water

**Mobility in soil**

No data available

**Other adverse effects**

No data available

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**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.  
Contaminated packaging : Empty containers should be taken to an approved waste

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handling site for recycling or disposal.  
 If not otherwise specified: Dispose of as unused product.

**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 for product as supplied.

**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)
Disodium hydrogenorthophosphate	7558-79-4	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** : Reproductive toxicity  
 Specific target organ toxicity (single or repeated exposure)

**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.

**US State Regulations****Pennsylvania Right To Know**

Water 7732-18-5  
 Disodium hydrogenorthophosphate 7558-79-4

**California List of Hazardous Substances**

Disodium hydrogenorthophosphate 7558-79-4

**The ingredients of this product are reported in the following inventories:**

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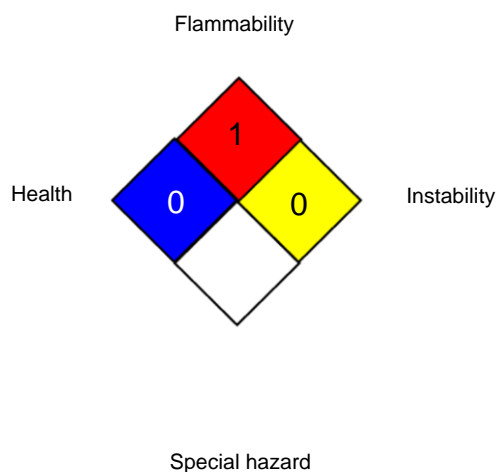
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AICS : not determined  
 DSL : not determined  
 IECSC : not determined

### SECTION 16. OTHER INFORMATION

#### Further information

##### NFPA 704:



##### HMIS® IV:

HEALTH	*	3
FLAMMABILITY		1
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

AICC - 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

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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

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 10/10/2020

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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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