

SAFETY DATA SHEETS

This SDS packet was issued with item:

078408577

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078249030

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078072765

Zeranol Formulation

Version 4.0 Revision Date: 04/12/2018 SDS Number: 682073-00005 Date of last issue: 10/30/2017
Date of first issue: 05/19/2016

SECTION 1. IDENTIFICATION

Product name : Zeranol 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

Telefax : 908-735-1496

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

SECTION 2. HAZARDS IDENTIFICATION**GHS classification in accordance with 29 CFR 1910.1200**

Combustible dust

Carcinogenicity : Category 2

Reproductive toxicity : Category 1B

Specific target organ systemic toxicity - repeated exposure : Category 1 (Endocrine system, Liver)

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : May form combustible dust concentrations in air.
H351 Suspected of causing cancer.
H360FD May damage fertility. May damage the unborn child.
H372 Causes damage to organs (Endocrine system, Liver) through prolonged or repeated exposure.

Precautionary Statements : **Prevention:**
P201 Obtain special instructions before use.

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P202 Do not handle until all safety precautions have been read and understood.
 P260 Do not breathe dust.
 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/ face protection.

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

Dust contact with the eyes can lead to mechanical irritation.
 Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous ingredients

Chemical name	CAS-No.	Concentration (% w/w)
Zeranol	26538-44-3	>= 70 - < 90
Boric acid	10043-35-3	>= 10 - < 20
Magnesium stearate	557-04-0	>= 10 - < 20

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 : If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.

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- Get medical attention.
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : Suspected of causing cancer.
May damage fertility. May damage the unborn child.
Causes damage to organs through prolonged or repeated exposure.
Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.
- 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.
- Notes to physician : Treat symptomatically and supportively.
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SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during fire fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Do not use a solid water stream as it may scatter and spread fire.
Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides
Boron oxides
Metal oxides
- 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 and personal protective equipment recommendations.

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- Environmental precautions : Discharge into the environment must be avoided.
Prevent further leakage or spillage if safe to do so.
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 : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
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 : Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : Use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.
Store locked up.
Keep tightly closed.
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

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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Zeranol	26538-44-3	TWA	2 µg/m ³ (OEB 4)	Internal
		Wipe limit	20 µg/100 cm ²	Internal
Boric acid	10043-35-3	TWA (Inhalable fraction)	2 mg/m ³ (Borate)	ACGIH
		STEL (Inhalable fraction)	6 mg/m ³ (Borate)	ACGIH
Magnesium stearate	557-04-0	TWA (Inhalable fraction)	10 mg/m ³	ACGIH
		TWA (Respirable fraction)	3 mg/m ³	ACGIH

Engineering measures : Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies.

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

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.

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If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

- Skin and body protection : Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.
- Hygiene measures : Ensure that eye flushing systems and safety showers are located close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : powder
- Color : yellow
- Odor : odorless
- 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 : Not applicable
- Evaporation rate : No data available
- Flammability (solid, gas) : May form combustible dust concentrations in air.
- Flammability (liquids) : No data available
- Upper explosion limit / Upper flammability limit : No data available
- Lower explosion limit / Lower flammability limit : No data available

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Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	insoluble
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	:	No data available
Dust deflagration index (Kst)	:	180 m.b_/s
Minimum ignition energy	:	5 - 10 mJ
Particle size	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form combustible dust concentrations in air. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

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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.

Product:

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

Components:**Zeranol:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : Remarks: No data available
Acute dermal toxicity : Remarks: No data available

Boric acid:

Acute oral toxicity : LD50 (Rat): 3,500 - 4,100 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 2.03 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: The substance or mixture has no acute inhalation toxicity
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

Magnesium stearate:

Acute oral toxicity : LD50 (Rat): > 2,500 mg/kg
Assessment: The substance or mixture has no acute oral toxicity

Skin corrosion/irritation

Not classified based on available information.

Components:**Zeranol:**

Remarks : No data available

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Boric acid:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Zeranol:**

Remarks : No data available

Boric acid:

Species : Rabbit
Result : No eye irritation

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:**Zeranol:**

Remarks : No data available

Boric acid:

Routes of exposure : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

Magnesium stearate:

Routes of exposure : Skin contact
Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:**Zeranol:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Test system: rat hepatocytes
Result: negative

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Genotoxicity in vivo : Test Type: Cytogenetic assay
 Species: Mouse
 Cell type: Bone marrow
 Result: negative

Boric acid:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
 Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo
 cytogenetic assay)
 Species: Mouse
 Application Route: Ingestion
 Result: negative

Carcinogenicity

Suspected of causing cancer.

Components:**Zeranol:**

Species : Mouse
 Application Route : Oral
 Exposure time : 2 Years
 Result : positive
 Target Organs : female reproductive organs, Pituitary gland

Species : Rat
 Application Route : Oral
 Exposure time : 2 Years
 Result : negative

Species : Dog
 Application Route : Oral
 Exposure time : 2 Years
 Result : negative

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in animal studies

Boric acid:

Species : Mouse
 Application Route : Ingestion
 Exposure time : 103 weeks
 Method : OECD Test Guideline 451
 Result : negative

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.

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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

May damage fertility. May damage the unborn child.

Components:

Zeranol:

Effects on fertility	: Test Type: Three-generation reproduction toxicity study Species: Rat Application Route: Oral Result: No significant adverse effects were reported
	Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Oral General Toxicity F1: LOAEL: 3 mg/kg body weight Symptoms: Reduced body weight Result: Effects on reproduction parameters.
	Test Type: Fertility Species: Rat, males Application Route: Oral Fertility: LOAEL: 1.25 mg/kg body weight Symptoms: Reduced fertility
Effects on fetal development	: Test Type: Embryo-fetal development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 2 mg/kg body weight Symptoms: Reduced number of viable fetuses. Result: Embryolethal effects., No teratogenic effects.
	Test Type: Embryo-fetal development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: >= 5 mg/kg body weight Result: No significant adverse effects were reported
Reproductive toxicity - Assessment	: Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of adverse effects on development, based on animal experiments.

Boric acid:

Effects on fertility	: Test Type: Three-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: positive
Effects on fetal development	: Test Type: Embryo-fetal development Species: Rabbit

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Application Route: Ingestion
 Result: positive

Reproductive toxicity - Assessment : Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of adverse effects on development, based on animal experiments.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Causes damage to organs (Endocrine system, Liver) through prolonged or repeated exposure.

Components:

Zeranol:

Target Organs Assessment : Endocrine system, Liver
 : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Zeranol:

Species : Rat
 NOAEL : 0.175 mg/kg
 LOAEL : 1.225 mg/kg
 Application Route : Oral
 Exposure time : 13 Weeks
 Target Organs : Liver

Species : Dog
 NOAEL : 0.25 mg/kg
 LOAEL : 1.25 mg/kg
 Application Route : Oral
 Exposure time : 14 Weeks
 Target Organs : male reproductive organs

Species : Rat
 NOAEL : 0.1 mg/kg
 LOAEL : 0.8 mg/kg
 Application Route : Oral
 Exposure time : 26 Weeks
 Symptoms : Liver disorders

Species : Dog
 NOAEL : 0.025 mg/kg
 LOAEL : 2.5 mg/kg
 Application Route : Oral
 Exposure time : 29 Weeks
 Target Organs : Reproductive organs, Bone marrow, Bladder
 Symptoms : hair loss

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Species : Dog, female
 LOAEL : 15 mg/kg
 Application Route : Oral
 Exposure time : 7 y
 Target Organs : female reproductive organs
 Symptoms : Changes in the blood count

Species : Monkey, female
 Application Route : Oral
 Exposure time : 10 y
 Target Organs : female reproductive organs

Boric acid:

Species : Rat
 NOAEL : 100 mg/kg
 LOAEL : 334 mg/kg
 Application Route : Ingestion
 Exposure time : 2 y

Magnesium stearate:

Species : Rat
 NOAEL : 5,000 mg/kg
 Application Route : Ingestion
 Exposure time : 3 Months

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****Zeranol:**

Ingestion : Remarks: May cause adverse reproductive effects.

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Boric acid:**

Toxicity to fish : LC50 (Oncorhynchus kisutch (coho salmon)): 600 mg/l
 Exposure time: 96 h
 Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 133 mg/l
 Exposure time: 48 h
 Toxicity to algae : EC50 (Selenastrum capricornutum (green algae)): 52.4 mg/l
 Exposure time: 72 h
 NOEC (Selenastrum capricornutum (green algae)): 17.5 mg/l

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	Exposure time: 72 h
Toxicity to fish (Chronic toxicity)	: NOEC (Pimephales promelas (fathead minnow)): 11.2 mg/l Exposure time: 32 d
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Chironomus riparius (harlequin fly)): 32 mg/l Exposure time: 28 d
Toxicity to microorganisms	: EC50: > 175 mg/l Exposure time: 3 h Method: OECD Test Guideline 209

Persistence and degradability

Components:

Zeranol:

Biodegradability	: Result: Not readily biodegradable. Biodegradation: 50 % Exposure time: 91 d
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Magnesium stearate:

Biodegradability	: Result: Not biodegradable.
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Bioaccumulative potential

Components:

Zeranol:

Partition coefficient: n-octanol/water	: log Pow: 3.13
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Boric acid:

Bioaccumulation	: Species: Oysters Bioconcentration factor (BCF): 0.7 - 1.4
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Partition coefficient: n-octanol/water	: log Pow: -1.09
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Mobility in soil

Components:

Zeranol:

Distribution among environmental compartments	: log Koc: 2.95
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Other adverse effects

No data available

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US State Regulations**Pennsylvania Right To Know**

Zeranol	26538-44-3
D-Glucose, 4-O-.beta.-D-galactopyranosyl-, monohydrate	64044-51-5
Magnesium stearate	557-04-0
Boric acid	10043-35-3

California Prop. 65

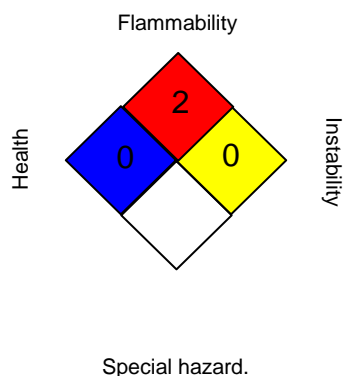
This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

California Permissible Exposure Limits for Chemical Contaminants

Magnesium stearate	557-04-0
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The ingredients of this product are reported in the following inventories:

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

SECTION 16. OTHER INFORMATION**Further information****NFPA 704:****HMIS® IV:**

HEALTH	*	3
FLAMMABILITY		2
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)
ACGIH / TWA	:	8-hour, time-weighted average
ACGIH / STEL	:	Short-term exposure limit

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 Haz-

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ardous 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

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 : 04/12/2018

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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.

US / Z8