

SAFETY DATA SHEET



Lufenuron Premix Formulation

Version 2.1 Revision Date: 09.05.2025 SDS Number: 11441527-00004 Date of last issue: 14.04.2025
Date of first issue: 23.09.2024

SECTION 1. IDENTIFICATION

Product name : Lufenuron Premix Formulation

Product code : IMVIXA Premix

Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Skin sensitization : Category 1

Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure (Oral) : Category 1 (Central nervous system, Lungs, Liver, Stomach)

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Hazard pictograms :

Signal Word : Danger

Hazard Statements : H317 May cause an allergic skin reaction.
H360D May damage the unborn child.

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H372 Causes damage to organs (Central nervous system, Lungs, Liver, Stomach) through prolonged or repeated exposure if swallowed.

H410 Very toxic to aquatic life with long lasting effects.

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 dust.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

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

P273 Avoid release to the environment.

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

: Response:

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

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

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

P362 + P364 Take off contaminated clothing and wash it before reuse.

P391 Collect spillage.

: Storage:

P405 Store locked up.

: Disposal:

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

Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Starch	9005-25-8	>= 70 -< 90
Lufenuron (ISO)	103055-07-8	>= 10 -< 20

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.

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	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. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	: Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation. May cause an allergic skin reaction. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure if swallowed.
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 ₂) Dry chemical
Unsuitable extinguishing media	: None known.
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. Exposure to combustion products may be a hazard to health.
Hazardous combustion products	: Carbon oxides Nitrogen oxides (NO _x)
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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11441527-00004Date of last issue: 14.04.2025
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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. 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.

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 : If sufficient ventilation is unavailable, 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. Wash skin thoroughly after handling. 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. 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 locked up. Keep tightly closed.

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Materials to avoid : Store in accordance with the particular national regulations.
Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
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	
Starch	9005-25-8	CMP	10 mg/m ³	AR OEL	
		Further information: A4 - Not classifiable as a human carcinogen			
Lufenuron (ISO)	103055-07-8	TWA	10 mg/m ³	ACGIH	
		200 µg/m ³ (OEB 2)			
		Further information: DSEN			
		Wipe limit	100 µg/100 cm ²	Internal	

Engineering measures : Use feasible engineering controls to minimize exposure to compound.
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection : Chemical-resistant gloves

Material

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

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.
Contaminated work clothing should not be allowed out of the workplace.
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,

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industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	White to light 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	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable

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Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics	:	
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 explosive dust-air mixture during processing, handling or other means. 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.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
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Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 5.000 mg/kg Method: Calculation method
Acute dermal toxicity	:	Acute toxicity estimate: > 5.000 mg/kg Method: Calculation method

Components:

Starch:

Acute oral toxicity	:	LD50 (Rat): > 5.000 mg/kg
Acute dermal toxicity	:	LD50 (Rabbit): > 2.000 mg/kg

Lufenuron (ISO):

Acute oral toxicity	:	LD50 (Rat): > 2.000 mg/kg LD50 (Mouse): > 2.000 mg/kg
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Acute inhalation toxicity	:	LC50 (Rat): 2.350 mg/m ³ Test atmosphere: dust/mist
Acute dermal toxicity	:	LD50 (Rabbit): > 2.000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Lufenuron (ISO):

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

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Starch:

Species	:	Rabbit
Result	:	No eye irritation

Lufenuron (ISO):

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

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified based on available information.

Components:

Starch:

Test Type	:	Maximization Test
Routes of exposure	:	Skin contact
Species	:	Guinea pig
Result	:	negative

Lufenuron (ISO):

Test Type	:	Maximization Test
Species	:	Guinea pig
Assessment	:	May cause sensitization by skin contact.
Result	:	Sensitizer

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Germ cell mutagenicity

Not classified based on available information.

Components:

Starch:

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

Lufenuron (ISO):

Genotoxicity in vitro : Test Type: Ames test
Result: negative

Test Type: Mouse Lymphoma
Test system: Chinese hamster cells
Result: negative

Test Type: Cytogenetic assay
Test system: Chinese hamster ovary cells
Result: negative

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

Test system: Human lymphocytes
Result: negative

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

Test Type: Unscheduled DNA synthesis test (UDS) in testicular cells
Species: Rat
Result: negative

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity

Not classified based on available information.

Components:

Lufenuron (ISO):

Species : Rat
Application Route : Ingestion
Exposure time : 18 month(s)
Result : negative

Carcinogenicity - Assess- : Weight of evidence does not support classification as a car-

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ment cinogen

Reproductive toxicity

May damage the unborn child.

Components:**Lufenuron (ISO):**

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Oral
General Toxicity Parent: NOAEL: 8,3 mg/kg wet weight
Early Embryonic Development: NOAEL: 20,9 mg/kg body weight
Result: Animal testing did not show any effects on fertility.

Effects on fetal development : Test Type: Development
Species: Rat
Application Route: Oral
General Toxicity Maternal: NOAEL: 500 mg/kg body weight
Developmental Toxicity: NOAEL: 1.000 mg/kg body weight
Symptoms: No adverse effects.
Remarks: No significant adverse effects were reported

Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
General Toxicity Maternal: NOAEL: 20,9 mg/kg body weight
Embryo-fetal toxicity: 8,3 mg/kg body weight
Result: Fetal abnormalities.

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

STOT-single exposure

Not classified based on available information.

Components:**Lufenuron (ISO):**

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

STOT-repeated exposure

Causes damage to organs (Central nervous system, Lungs, Liver, Stomach) through prolonged or repeated exposure if swallowed.

Components:**Lufenuron (ISO):**

Routes of exposure : Oral
Target Organs : Central nervous system, Lungs, Liver, Stomach
Assessment : Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.

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Repeated dose toxicity

Components:

Starch:

Species : Rat
NOAEL : >= 2.000 mg/kg
Application Route : Skin contact
Exposure time : 28 Days
Method : OECD Test Guideline 410

Lufenuron (ISO):

Species : Rat
NOAEL : 5,34 mg/kg
Application Route : oral (feed)
Exposure time : 4 Months
Target Organs : Central nervous system, digestive system
Symptoms : central nervous system effects

Species : Rat
NOAEL : 1,93 mg/kg
Application Route : oral (feed)
Exposure time : 2 y
Symptoms : central nervous system effects, Convulsions

Species : Mouse
NOAEL : 2,12 mg/kg
Application Route : oral (feed)
Exposure time : 18 Months
Target Organs : Central nervous system, Liver, Prostate
Symptoms : central nervous system effects, Convulsions

Species : Dog
NOAEL : 7,02 mg/kg
Application Route : oral (feed)
Exposure time : 1 y
Target Organs : Central nervous system, Liver, Lungs
Symptoms : Convulsions, Fatality, Irregularities

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Lufenuron (ISO):

General Information : Remarks: May be harmful if swallowed.
May cause neurotoxic effects.

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SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Lufenuron (ISO):**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 73.100 µg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

LC50 (Oncorhynchus mykiss (rainbow trout)): > 29.000 µg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

LC50 (Oncorhynchus mykiss (rainbow trout)): 370 µg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Americamysis): 0,042 µg/l
Exposure time: 96 h
Method: US-EPA OPPTS 850.1035

EC50 (Daphnia magna (Water flea)): 0,41 µg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Raphidocelis subcapitata (freshwater green alga)): 209 µg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

EC50 (Scenedesmus subspicatus): 17 µg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 10.000

Toxicity to fish (Chronic toxicity) : NOEC (Oncorhynchus mykiss (rainbow trout)): 80 µg/l
Exposure time: 33 d
Method: OECD Test Guideline 210

NOEC (Oncorhynchus mykiss (rainbow trout)): 20 µg/l
Exposure time: 359 d
Method: OECD Test Guideline 229

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 8,38 µg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

NOEC (Daphnia magna (Water flea)): 90 µg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

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NOEC (Chironomus riparius (harlequin fly)): 2 µg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 10

Persistence and degradability

No data available

Bioaccumulative potential

Components:

Lufenuron (ISO):

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 28
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : log Pow: 5,12

Mobility in soil

Components:

Lufenuron (ISO):

Distribution among environmental compartments : log Koc: 5,38
Method: OECD Test Guideline 106

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.
Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Lufenuron (ISO))
Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes

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IATA-DGR

UN/ID No. : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
(Lufenuron (ISO))
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 956
Packing instruction (passenger aircraft) : 956
Environmentally hazardous : yes

IMDG-Code

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
N.O.S.
(Lufenuron (ISO))
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Argentina. Carcinogenic Substances and Agents : Not applicable
Registry.

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

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

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

SECTION 16. OTHER INFORMATION

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Date format : dd.mm.yyyy

Further information

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/>

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AR OEL : Argentina. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average
AR OEL / CMP : TLV (Threshold Limit Value)

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; 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; KECL - 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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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