

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Proligestone Formulation

Version 2.11 Revision Date: 11/30/2023 SDS Number: 3068525-00013 Date of last issue: 09/30/2023
Date of first issue: 08/07/2018

SECTION 1. IDENTIFICATION

Product name : Proligestone Formulation
Other means of identification : Delvosteron (A004103)

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
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
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Carcinogenicity : Category 2
Reproductive toxicity : Category 1B
Specific target organ toxicity : Category 2 (Adrenal gland, Ovary, Uterus (including cervix))
- repeated exposure

GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H351 Suspected of causing cancer.
H360D May damage the unborn child.
H373 May cause damage to organs (Adrenal gland, Ovary, Uterus (including cervix)) 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.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Proligestone Formulation

Version 2.11 Revision Date: 11/30/2023 SDS Number: 3068525-00013 Date of last issue: 09/30/2023
Date of first issue: 08/07/2018

Response:

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

Storage:

P405 Store locked up.

Disposal:

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)
Proligestone	23873-85-0	$\geq 5 - < 10$
Polyethylene glycol	25322-68-3	$\geq 1 - < 5$

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 causing cancer.
May damage the unborn child.
May cause 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.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Proligestone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
2.11	11/30/2023	3068525-00013	Date of first issue: 08/07/2018

SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon 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.

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.

SECTION 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Proligestone Formulation

Version 2.11 Revision Date: 11/30/2023 SDS Number: 3068525-00013 Date of last issue: 09/30/2023
Date of first issue: 08/07/2018

- Local/Total ventilation : CONTROLS/PERSONAL PROTECTION section.
: If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.
: Do not breathe mist or vapors.
: 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.
: 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
: 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
Proligestone	23873-85-0	TWA	5 ug/m3 (OEB 4)	Internal
		Wipe limit	50 ug/100cm2	Internal
Polyethylene glycol	25322-68-3	TWA (aerosol)	10 mg/m ³	US WEEL

- Engineering measures** : 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.
If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

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

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Proligestone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
2.11	11/30/2023	3068525-00013	Date of first issue: 08/07/2018

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. 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 : 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. 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 : Aqueous solution

Color : white to off-white

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

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Proligestone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
2.11	11/30/2023	3068525-00013	Date of first issue: 08/07/2018

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
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	1.035 g/cm ³
Solubility(ies)	:	
Water solubility	:	soluble
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
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.
Particle size	:	Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Proligestone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
2.11	11/30/2023	3068525-00013	Date of first issue: 08/07/2018

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:

Proligestone:

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

Polyethylene glycol:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 423
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

Components:

Polyethylene glycol:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation
Remarks : Based on data from similar materials

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Polyethylene glycol:

Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405
Remarks : Based on data from similar materials

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Proligestone Formulation

Version 2.11 Revision Date: 11/30/2023 SDS Number: 3068525-00013 Date of last issue: 09/30/2023
Date of first issue: 08/07/2018

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Polyethylene glycol:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative
Remarks : Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:

Polyethylene glycol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials

Carcinogenicity

Suspected of causing cancer.

Components:

Proligestone:

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in animal studies

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

May damage the unborn child.

Components:

Proligestone:

Effects on fertility : Test Type: Fertility
Species: Rat
Application Route: Subcutaneous
Fertility: NOAEL: 10 mg/kg body weight

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Proligestone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
2.11	11/30/2023	3068525-00013	Date of first issue: 08/07/2018

Result: No effects on fertility.

Test Type: Fertility
Species: Rabbit
Application Route: Subcutaneous
Fertility: LOAEL: 10 mg/kg body weight
Result: Postimplantation loss.

Reproductive toxicity - Assessment : May damage the unborn child. Suspected of damaging fertility.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

May cause damage to organs (Adrenal gland, Ovary, Uterus (including cervix)) through prolonged or repeated exposure.

Components:

Proligestone:

Target Organs : Adrenal gland, Ovary, Uterus (including cervix)
Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Proligestone:

Species : Dog
LOAEL : 25 mg/kg
Application Route : Subcutaneous
Exposure time : 90 d
Target Organs : Adrenal gland, Uterus (including cervix), Ovary

Species : Rat
LOAEL : 50 mg/kg
Application Route : Subcutaneous
Exposure time : 90 d
Target Organs : Adrenal gland, Uterus (including cervix), Ovary

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Proligestone:

General Information : Remarks: May cause cancer based on animal data.
Inhalation : Symptoms: Jaundice, Headache, Dizziness, menstrual irregularities, changes in libido, bleeding, breast changes

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Proligestone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
2.11	11/30/2023	3068525-00013	Date of first issue: 08/07/2018

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Proligestone:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 0.5 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: No toxicity at the limit of solubility.

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 0.5 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility.

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility.

NOEC (Pseudokirchneriella subcapitata (green algae)): 1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility.

Toxicity to microorganisms : EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility.

NOEC: 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility.

Polyethylene glycol:

Toxicity to fish : LC50 (Poecilia reticulata (guppy)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Persistence and degradability

Components:

Proligestone:

Biodegradability : Result: Not readily biodegradable.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Proligestone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
2.11	11/30/2023	3068525-00013	Date of first issue: 08/07/2018

Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Polyethylene glycol:

Biodegradability : Result: rapidly degradable
Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

Polyethylene glycol:

Partition coefficient: n-octanol/water : log Pow: < 3

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.
Do not dispose of waste into sewer.
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

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

Special precautions for user

Not applicable

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Proligestone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
2.11	11/30/2023	3068525-00013	Date of first issue: 08/07/2018

SECTION 15. REGULATORY INFORMATION

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
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
Proligestone	23873-85-0
Polyethylene glycol	25322-68-3
Sodium citrate, dihydrate	6132-04-3

California Prop. 65

WARNING: This product can expose you to chemicals including Proligestone, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances

Proligestone	23873-85-0
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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

SAFETY DATA SHEET

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Proligestone Formulation

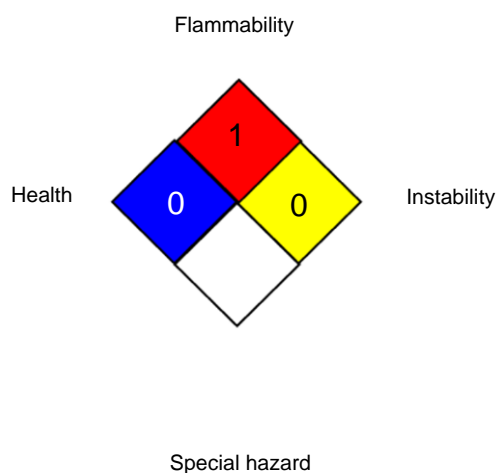
Version
2.11

Revision Date:
11/30/2023

SDS Number:
3068525-00013

Date of last issue: 09/30/2023
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NFPA 704:



HMIS® IV:

HEALTH	*	2
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

US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)
US WEEL / TWA : 8-hr TWA

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

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Proligestone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
2.11	11/30/2023	3068525-00013	Date of first issue: 08/07/2018

Inventory; 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

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 : 11/30/2023

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