

Belzutifan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/27/2023
2.2	09/30/2023	5276359-00012	Date of first issue: 11/14/2019

SECTION 1. IDENTIFICATION

Product name : Belzutifan Formulation
Other means of identification : No data available

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 Hazardous Products Regulations

Reproductive toxicity : Category 2

Specific target organ toxicity : Category 2 (Blood, epididymis, Testis)
- repeated exposure (Oral)

GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
H373 May cause damage to organs (Blood, epididymis, Testis) through prolonged or repeated exposure if swallowed.

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.
P280 Wear protective gloves, protective clothing, eye protection and face protection.
Response:
P308 + P313 IF exposed or concerned: Get medical attention.
Storage:

Belzutifan Formulation

Version 2.2 Revision Date: 09/30/2023 SDS Number: 5276359-00012 Date of last issue: 04/27/2023
Date of first issue: 11/14/2019

P405 Store locked up.

Disposal:

P501 Dispose of contents and 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.
May form combustible dust concentrations in air during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Cellulose	No data available	9004-34-6	35
Belzutifan	No data available	1672668-24-4	8

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.
Get medical attention.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : Suspected of damaging fertility. Suspected of damaging the unborn child.
May cause damage to organs through prolonged or repeated exposure if swallowed.
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 (see section 8).

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Belzutifan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/27/2023
2.2	09/30/2023	5276359-00012	Date of first issue: 11/14/2019

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 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. 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.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Belzutifan Formulation

Version 2.2 Revision Date: 09/30/2023 SDS Number: 5276359-00012 Date of last issue: 04/27/2023
Date of first issue: 11/14/2019

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 only with adequate ventilation.
- Advice on safe handling : Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
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.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m ³	CA AB OEL
		TWA (Total dust)	10 mg/m ³	CA BC OEL
		TWA (respirable dust fraction)	3 mg/m ³	CA BC OEL
		TWAEV (total dust)	10 mg/m ³	CA QC OEL
		TWA	10 mg/m ³	ACGIH
Belzutifan	1672668-24-4	TWA	70 µg/m ³ (OEB 3)	Internal
		Wipe limit	70 µg/100 cm ²	Internal

- 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.
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face

Belzutifan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/27/2023
2.2	09/30/2023	5276359-00012	Date of first issue: 11/14/2019

containment devices).
Minimize open handling.

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 | : | |
| 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 | : | powder |
| Color | : | No data available |
| 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 |

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Belzutifan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/27/2023
2.2	09/30/2023	5276359-00012	Date of first issue: 11/14/2019

Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form combustible dust concentrations in air during processing, handling or other means.
Flammability (liquids)	:	Not applicable
Burning number	:	5
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
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Minimum ignition energy	:	3 - 10 mJ Method: With inductance 10 - 30 mJ Method: Without inductance
Particle size	:	26.13 µm

SECTION 10. STABILITY AND REACTIVITY

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Belzutifan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/27/2023
2.2	09/30/2023	5276359-00012	Date of first issue: 11/14/2019

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form combustible dust concentrations in air 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

Acute toxicity

Not classified based on available information.

Components:

Cellulose:

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 5.8 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg

Belzutifan:

Acute oral toxicity	:	LD0 (Rat): 200 mg/kg LD0 (Dog): 30 mg/kg
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Skin corrosion/irritation

Not classified based on available information.

Components:

Belzutifan:

Species	:	human skin
Method	:	EpiDerm
Result	:	No skin irritation
Remarks	:	Not classified due to lack of data.

Serious eye damage/eye irritation

Not classified based on available information.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Belzutifan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/27/2023
2.2	09/30/2023	5276359-00012	Date of first issue: 11/14/2019

Components:

Belzutifan:

Result	:	No eye irritation
Method	:	Bovine cornea (BCOP)
Remarks	:	Not classified due to lack of data.

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Belzutifan:

Test Type	:	Local lymph node assay (LLNA)
Routes of exposure	:	Dermal
Species	:	Mouse
Result	:	Not a skin sensitizer.
Remarks	:	Not classified due to lack of data.

Germ cell mutagenicity

Not classified based on available information.

Components:

Cellulose:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: In vitro mammalian cell gene mutation test Result: negative
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Result: negative

Belzutifan:

Genotoxicity in vitro	:	Test Type: Ames test Result: negative Test Type: Micronucleus test Test system: mammalian cells Result: negative
Genotoxicity in vivo	:	Remarks: Not classified due to lack of data.

Belzutifan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/27/2023
2.2	09/30/2023	5276359-00012	Date of first issue: 11/14/2019

Carcinogenicity

Not classified based on available information.

Components:

Cellulose:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	72 weeks
Result	:	negative

Belzutifan:

Remarks	:	Not classified due to lack of data.
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Reproductive toxicity

Suspected of damaging fertility. Suspected of damaging the unborn child.

Components:

Cellulose:

Effects on fertility	:	Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative
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Effects on fetal development	:	Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative
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Belzutifan:

Effects on fertility	:	Remarks: Information taken from reference works and the literature.
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Effects on fetal development	:	Remarks: Information taken from reference works and the literature.
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Reproductive toxicity - Assessment	:	Suspected of damaging fertility. Suspected of damaging the unborn child.
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STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

May cause damage to organs (Blood, epididymis, Testis) through prolonged or repeated exposure if swallowed.

Components:

Belzutifan:

Routes of exposure	:	Ingestion
Target Organs	:	Blood, epididymis, Testis

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Belzutifan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/27/2023
2.2	09/30/2023	5276359-00012	Date of first issue: 11/14/2019

Assessment : Shown to produce significant health effects in animals at concentrations of >10 to 100 mg/kg bw.

Routes of exposure : Oral
Target Organs : Blood, epididymis, Testis
Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Cellulose:

Species : Rat
NOAEL : $\geq 9,000$ mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Belzutifan:

Species : Rat
LOAEL : 6 mg/kg
Application Route : Oral
Exposure time : 28 d
Target Organs : Blood, Testis, epididymis

Species : Rat, male
NOAEL : 2 mg/kg
LOAEL : 6 mg/kg
Application Route : Oral
Exposure time : 13 Weeks
Target Organs : Blood, Central nervous system, epididymis, Liver, Testis

Species : Rat, female
LOAEL : 200 mg/kg
Application Route : Oral
Exposure time : 13 Weeks
Target Organs : Blood, Central nervous system, Liver

Species : Dog
LOAEL : 1 mg/kg
Application Route : Oral
Exposure time : 28 d
Target Organs : Blood

Species : Dog
LOAEL : 1 mg/kg
Application Route : Oral
Exposure time : 13 Weeks
Target Organs : Blood

Aspiration toxicity

Not classified based on available information.

Belzutifan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/27/2023
2.2	09/30/2023	5276359-00012	Date of first issue: 11/14/2019

Components:

Belzutifan:

Not applicable

Experience with human exposure

Components:

Belzutifan:

General Information	:	Symptoms: Fatigue, flu-like symptoms, fluid retention, Head-ache, musculoskeletal pain, Nausea
Ingestion	:	Target Organs: Blood Symptoms: anemia, Changes in the blood count

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Cellulose:

Toxicity to fish	:	LC50 (<i>Oryzias latipes</i> (Japanese medaka)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
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Belzutifan:

Toxicity to algae/aquatic plants	:	EC50 (<i>Raphidocelis subcapitata</i> (freshwater green alga)): > 10 mg/l End point: Growth rate Exposure time: 72 h Method: OECD Test Guideline 201
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	:	EC10 (<i>Raphidocelis subcapitata</i> (freshwater green alga)): > 10 mg/l End point: Growth rate Exposure time: 72 h Method: OECD Test Guideline 201
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Toxicity to fish (Chronic toxicity)	:	NOEC (<i>Pimephales promelas</i> (fathead minnow)): 0.52 mg/l Exposure time: 32 d Method: OECD Test Guideline 210
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Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	EC10 (<i>Daphnia magna</i> (Water flea)): 3.9 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
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Toxicity to microorganisms	:	EC50: > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition of activated sludge Method: OECD Test Guideline 209
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NOEC: 1,000 mg/l

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Belzutifan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/27/2023
2.2	09/30/2023	5276359-00012	Date of first issue: 11/14/2019

Exposure time: 3 h
Test Type: Respiration inhibition of activated sludge
Method: OECD Test Guideline 209

Persistence and degradability

Components:

Cellulose:

Biodegradability : Result: Readily biodegradable.

Belzutifan:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 50 %
Exposure time: 18.1 d
Method: OECD Test Guideline 314

Bioaccumulative potential

Components:

Belzutifan:

Partition coefficient: n-octanol/water : log Pow: 1.11
pH: 7

Mobility in soil

Components:

Belzutifan:

Distribution among environmental compartments : log Koc: 2.52
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

Not regulated as a dangerous good

Belzutifan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/27/2023
2.2	09/30/2023	5276359-00012	Date of first issue: 11/14/2019

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

TDG

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

CEPA : not determined

AICS : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CA AB OEL	:	Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL	:	Canada. British Columbia OEL
CA QC OEL	:	Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA	:	8-hour, time-weighted average
CA AB OEL / TWA	:	8-hour Occupational exposure limit
CA BC OEL / TWA	:	8-hour time weighted average
CA QC OEL / TWA EV	:	Time-weighted average exposure 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 Chemi-

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Belzutifan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/27/2023
2.2	09/30/2023	5276359-00012	Date of first issue: 11/14/2019

cal 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; 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

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 : 09/30/2023
Date format : mm/dd/yyyy

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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