SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Belzutifan Formulation

Version: 4.2  Revision Date: 09/30/2023  SDS Number: 5276390-00014  Date of last issue: 04/27/2023  Date of first issue: 11/14/2019

SECTION 1. IDENTIFICATION

Product name: Belzutifan Formulation

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)

Combustible dust

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

GHS label elements

Hazard pictograms: 

Signal Word: Warning

Hazard Statements: If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.

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:
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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>: Mixture</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
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</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>35</td>
</tr>
<tr>
<td>Belzutifan</td>
<td>1672668-24-4</td>
<td>8</td>
</tr>
</tbody>
</table>

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.
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**: 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 spills 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: 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

- inert or nuisance dust: 50 Million particles per cubic foot
  Value type (Form of exposure): TWA (total dust)
  Basis: OSHA Z-3
  15 mg/m³
  Value type (Form of exposure): TWA (total dust)
  Basis: OSHA Z-3
  5 mg/m³
  Value type (Form of exposure): TWA (respirable fraction)
  Basis: OSHA Z-3
  15 Million particles per cubic foot
  Value type (Form of exposure): TWA (respirable fraction)
  Basis: OSHA Z-3

- Dust, nuisance dust and particulates: 10 mg/m³
  Value type (Form of exposure): PEL (Total dust)
  Basis: CAL PEL
  5 mg/m³
  Value type (Form of exposure): PEL (respirable dust fraction)
  Basis: CAL PEL
Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
--- | --- | --- | --- | --- |
Cellulose | 9004-34-6 | TWA | 10 mg/m³ | ACGIH |
 |  |  | TWA (Respirable) | 5 mg/m³ | NIOSH REL |
 |  |  | TWA (total) | 10 mg/m³ | NIOSH REL |
 |  |  | TWA (total dust) | 15 mg/m³ | OSHA Z-1 |
 |  |  | TWA (respirable fraction) | 5 mg/m³ | OSHA Z-1 |
Belzutifan | 1672668-24-4 | TWA | 70 µg/m³ (OEB 3) | Internal |
 |  |  | Wipe limit | 70 µg/100 cm² | 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 containment devices).

Minimize open handling.

**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. 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
- **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

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

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.

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.

**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.

**IARC**
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

**NTP**
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
Reproductive toxicity
Suspected of damaging 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

Effects on fetal development : Test Type: Fertility/early embryonic development
                               Species: Rat
                               Application Route: Ingestion
                               Result: negative

Belzutifan:
Effects on fertility : Remarks: Information taken from reference works and the
                     literature.

Effects on fetal development : Remarks: Information taken from reference works and the
                              literature.

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

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
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 : >= 9,000 mg/kg
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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

- **NOAEL** : 200 mg/kg
- **LOAEL** : 6 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.

**Components:**

**Belzutifan:**

Not applicable

**Experience with human exposure**

**Components:**

**Belzutifan:**

- **General Information** : Symptoms: Fatigue, flu-like symptoms, fluid retention, Headache, 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 (Oryzias latipes (Japanese medaka)): > 100 mg/l
  - Exposure time: 48 h
  - Remarks: Based on data from similar materials

**Belzutifan:**
- **Toxicity to algae/aquatic plants**: EC50 (Raphidocelis subcapitata (freshwater green alga)): > 10 mg/l
  - End point: Growth rate
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
  - EC10 (Raphidocelis subcapitata (freshwater green alga)): > 10 mg/l
    - End point: Growth rate
    - Exposure time: 72 h
    - Method: OECD Test Guideline 201

- **Toxicity to fish (Chronic toxicity)**: NOEC (Pimephales promelas (fathead minnow)): 0.52 mg/l
  - Exposure time: 32 d
  - Method: OECD Test Guideline 210

- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**: EC10 (Daphnia magna (Water flea)): 3.9 mg/l
  - Exposure time: 21 d
  - Method: OECD Test Guideline 211

- **Toxicity to microorganisms**: EC50: > 1,000 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition of activated sludge
  - Method: OECD Test Guideline 209
  - NOEC: 1,000 mg/l
  - 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 : 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
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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:
- Combustible dust
- 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
Cellulose 9004-34-6
D-mannitol 69-65-8
Cellulose, 2-hydroxypropyl methyl ether, acetate hydrogen butanedioate 71138-97-1
Belzutifan 1672668-24-4
Croscarmellose sodium 74811-65-7

California Permissible Exposure Limits for Chemical Contaminants
Cellulose 9004-34-6

The ingredients of this product are reported in the following inventories:
CEPA: not determined
AICS: not determined
IECSC: not determined

SECTION 16. OTHER INFORMATION

Further information
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NFPA 704:

HMIS® IV:

<table>
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<tr>
<th>Health</th>
<th>Flammability</th>
<th>Instability</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>*</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Special hazard</td>
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</tbody>
</table>

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)
CAL PEL : California permissible exposure limits for chemical contaminants (Title 8, Article 107)
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
ACGIH / TWA : 8-hour, time-weighted average
CAL PEL / PEL : Permissible exposure limit
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA : 8-hour time weighted average
OSHA Z-3 / TWA : 8-hour time weighted average

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 Pre-
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Belzutifan Formulation

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Date of first issue: 11/14/2019

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