

# SAFETY DATA SHEET



## Belzutifan Formulation

Version 4.0      Revision Date: 14.04.2025      SDS Number: 5276386-00012      Date of last issue: 30.09.2023  
Date of first issue: 14.11.2019

### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Belzutifan Formulation

#### Manufacturer or supplier's details

Company name of supplier : MSD  
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@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

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 : 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/ face protection.

#### Response:

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

#### Storage:

P405 Store locked up.

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### Disposal:

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

### Other hazards

Dust contact with the eyes can lead to mechanical irritation.

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

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	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	>= 30 -< 50
Belzutifan	1672668-24-4	>= 5 -< 10

## 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 : Contact with dust can cause mechanical irritation or drying of the skin.  
Dust contact with the eyes can lead to mechanical irritation.  
Suspected of damaging fertility. Suspected of damaging the unborn child.  
May cause 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

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Carbon dioxide (CO<sub>2</sub>)  
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.

## SECTION 7. HANDLING AND STORAGE

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Technical measures	<ul style="list-style-type: none"><li>Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.</li></ul>		
Local/Total ventilation Advice on safe handling	<ul style="list-style-type: none"><li>Use only with adequate ventilation.</li><li>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.</li></ul>		
Hygiene measures	<ul style="list-style-type: none"><li>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.</li></ul>		
Conditions for safe storage	<ul style="list-style-type: none"><li>Keep in properly labeled containers. Store locked up. Store in accordance with the particular national regulations.</li></ul>		
Materials to avoid	<ul style="list-style-type: none"><li>Do not store with the following product types: Strong oxidizing agents</li></ul>		

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Cellulose	9004-34-6	VLE-PPT	10 mg/m <sup>3</sup>	NOM-010-STPS-2014
		TWA	10 mg/m <sup>3</sup>	ACGIH
Belzutifan	1672668-24-4	TWA	70 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	70 µg/100 cm <sup>2</sup>	Internal

Engineering measures	<ul style="list-style-type: none"><li>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</li></ul>
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the compound to uncontrolled areas (e.g., open-face 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.

## 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

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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 characteristics	:	
Particle size	:	26.13 µm

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## 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



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### 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

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||Result : negative

**Belzutifan:**

||Remarks : Not classified due to lack of data.

**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.

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### Repeated dose toxicity

#### Components:

##### **Cellulose:**

Species	:	Rat
NOAEL	:	>= 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.

#### Components:

##### **Belzutifan:**

Not applicable
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### 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
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##### **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

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### 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

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## 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.

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## 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

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

Not applicable for product as supplied.

### Domestic regulation

#### NOM-002-SCT

Not regulated as a dangerous good

### Special precautions for user

Not applicable

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## SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, : Not applicable  
essential chemical products and machinery for  
producing capsules, tablets and pills.

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

CEPA : not determined

AICS : not determined

IECSC : not determined

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## SECTION 16. OTHER INFORMATION

Revision Date : 14.04.2025  
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### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting  
the Work Environment - Identification, Assessment and Con-  
trol - Appendix 1 Occupational Exposure Limits  
ACGIH / TWA : 8-hour, time-weighted average  
NOM-010-STPS-2014 / VLE- : Time weighted average limit value  
PPT

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 Or-

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ganisation 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/>

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

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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