SAFETY DATA SHEET
according to the Globally Harmonized System

Belzutifan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	14.04.2025	5276384-00012	Date of first issue: 14.11.2019

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Belzutifan Formulation

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number : +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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification

Reproductive toxicity : Category 2

Long-term (chronic) aquatic hazard : Category 3

GHS label elements

Hazard pictograms :

Signal word : Warning

Hazard statements : H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
P203 Obtain, read and follow all safety instructions before use.

P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P318 IF exposed or concerned, get medical advice.

Storage:

P405 Store locked up.

Disposal:

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

Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form combustible dust concentrations in air during processing, handling or other means.

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

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.

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.

5. FIREFIGHTING 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 firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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.

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 labelled 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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m3	ACGIH
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	:	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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Colour	:	No data available
Odour	:	No data available
Odour 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
Vapour pressure	:	Not applicable
Relative vapour 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
Auto-ignition 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

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.

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:

Method	:	Bovine cornea (BCOP)

Result	:	No eye irritation
Remarks	:	Not classified due to lack of data.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Belzutifan:

Test Type	:	Local lymph node assay (LLNA)
Exposure routes	:	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.

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 foetal 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 foetal 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

Not classified based on available information.

Components:

Belzutifan:

Exposure routes	:	Ingestion
Target Organs	:	Blood, epididymis, Testis
Assessment	:	Shown to produce significant health effects in animals at concentrations of >10 to 100 mg/kg bw.

Exposure routes	:	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
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

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

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

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

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

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.

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 IMO instruments
Not applicable for product as supplied.

Special precautions for user
Not applicable

15. REGULATORY INFORMATION

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

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

CEPA	:	not determined
AICS	:	not determined
IECSC	:	not determined

16. OTHER INFORMATION

Revision Date	:	14.04.2025

Further information

Sources of key data used to compile the 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.

Date format	:	dd.mm.yyyy

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA	:	8-hour, time-weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA

- International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; 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

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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