

SAFETY DATA SHEET



Bacillus <5% (Licheniformis / Subtilis) Formulation

Version
2.0

Revision Date:
2025/04/14

SDS Number:
11508956-00002

Date of last issue: 2025/02/07
Date of first issue: 2025/02/07

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Bacillus <5% (Licheniformis / Subtilis) Formulation

Product code : Prevensa Probai A, Probai A

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : 1-13-12, Kudan-kita, Chiyoda-ku, Tokyo, Japan

Telephone : 03-6272-1099

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

Other hazards which do not result in classification

Important symptoms and outlines of the emergency assumed : Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin. May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Starch	9005-25-8	>= 20 - < 30	8-98

SAFETY DATA SHEET



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Bentonite	1302-78-9	$\geq 1 - < 10$	-
Bacillus licheniformis	68038-66-4	$\geq 1 - < 10$	-
Bacillus subtilis	68038-70-0	$\geq 1 - < 10$	-
2,6-Di-tert-butyl-p-cresol	128-37-0	$\geq 0.0025 - < 0.025$	3-540, 9-1805

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 if symptoms occur.

In case of skin contact : Wash with water and soap.
Get medical attention if symptoms occur.

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 if symptoms occur.
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.

Protection of first-aiders : No special precautions are necessary for first aid responders.

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
Nitrogen oxides (NO_x)
Metal oxides

Bacillus <5% (Licheniformis / Subtilis) FormulationVersion
2.0Revision Date:
2025/04/14SDS Number:
11508956-00002Date of last issue: 2025/02/07
Date of first issue: 2025/02/07

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 : Wear self-contained breathing apparatus for firefighting if necessary.
Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : 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**Handling**

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.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

SAFETY DATA SHEET



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Version
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Revision Date:
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SDS Number:
11508956-00002

Date of last issue: 2025/02/07
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Avoidance of contact
Hygiene measures

sessment
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.
: Oxidizing agents
: 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.

Storage

Conditions for safe storage : Keep in properly labelled containers.
Store in accordance with the particular national regulations.
Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Concentra- tion standard / Permissible con- centration	Basis
Starch	9005-25-8	TWA	10 mg/m3	ACGIH
Bentonite	1302-78-9	OEL-M (Respirable dust)	0.5 mg/m3	JP OEL JSOH
		OEL-M (Total dust)	2 mg/m3	JP OEL JSOH
2,6-Di-tert-butyl-p-cresol	128-37-0	8h-OEL-M	10 mg/m3	JP ISHL OEL 577-2(2)
		TWA (Inhal- able fraction and vapor)	2 mg/m3	ACGIH

Engineering measures

: All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

SAFETY DATA SHEET



Bacillus <5% (Licheniformis / Subtilis) Formulation

Version
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2025/04/14

SDS Number:
11508956-00002

Date of last issue: 2025/02/07
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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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	: powder
Colour	: white, grey
Odour	: No data available
Odour Threshold	: No data available
Melting point/freezing point	: No data available
Boiling point, initial boiling point and boiling range	: No data available
Flammability (solid, gas)	: May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	: Not applicable
Lower explosion limit and upper explosion limit / flammability limit	

SAFETY DATA SHEET



Bacillus <5% (Licheniformis / Subtilis) Formulation

Version
2.0

Revision Date:
2025/04/14

SDS Number:
11508956-00002

Date of last issue: 2025/02/07
Date of first issue: 2025/02/07

Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	Not applicable
Decomposition temperature	:	No data available
pH	:	No data available
Evaporation rate	:	Not applicable
Auto-ignition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Vapour pressure	:	Not applicable
Density and / or relative density		
Relative density	:	No data available
Density	:	No data available
Relative vapour density	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics		
Particle size	:	No data available

10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	May form explosive dust-air mixture during processing, han-

SAFETY DATA SHEET



Bacillus <5% (Licheniformis / Subtilis) Formulation

Version
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Revision Date:
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11508956-00002

Date of last issue: 2025/02/07
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tions

dling 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:

Starch:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Bentonite:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 425
Acute inhalation toxicity : LC50 (Rat): > 5.27 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 436

2,6-Di-tert-butyl-p-cresol:

Acute oral toxicity : LD50 (Rat): > 6,000 mg/kg
Method: OECD Test Guideline 401
Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation

Not classified based on available information.

SAFETY DATA SHEET



Bacillus <5% (Licheniformis / Subtilis) Formulation

Version
2.0

Revision Date:
2025/04/14

SDS Number:
11508956-00002

Date of last issue: 2025/02/07
Date of first issue: 2025/02/07

Components:

Bentonite:

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

2,6-Di-tert-butyl-p-cresol:

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

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Starch:

Species	:	Rabbit
Result	:	No eye irritation

Bentonite:

Species	:	Rabbit
Result	:	No eye irritation
Method	:	OECD Test Guideline 405

2,6-Di-tert-butyl-p-cresol:

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

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Starch:

Test Type	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig

SAFETY DATA SHEET



Bacillus <5% (Licheniformis / Subtilis) Formulation

Version
2.0

Revision Date:
2025/04/14

SDS Number:
11508956-00002

Date of last issue: 2025/02/07
Date of first issue: 2025/02/07

Result : negative

Bentonite:

Exposure routes : Skin contact
Species : Mouse
Result : negative

2,6-Di-tert-butyl-p-cresol:

Test Type : Human repeat insult patch test (HRIPT)
Exposure routes : Skin contact
Species : Humans
Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Starch:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Bentonite:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

2,6-Di-tert-butyl-p-cresol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative

SAFETY DATA SHEET



Bacillus <5% (Licheniformis / Subtilis) Formulation

Version
2.0

Revision Date:
2025/04/14

SDS Number:
11508956-00002

Date of last issue: 2025/02/07
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Carcinogenicity

Not classified based on available information.

Components:

2,6-Di-tert-butyl-p-cresol:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	22 Months
Result	:	negative

Reproductive toxicity

Not classified based on available information.

Components:

Bentonite:

Effects on fertility	:	Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials
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2,6-Di-tert-butyl-p-cresol:

Effects on fertility	:	Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:

2,6-Di-tert-butyl-p-cresol:

Assessment	:	No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.
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Repeated dose toxicity

Components:

Starch:

Bacillus <5% (Licheniformis / Subtilis) FormulationVersion
2.0Revision Date:
2025/04/14SDS Number:
11508956-00002Date of last issue: 2025/02/07
Date of first issue: 2025/02/07

Species	:	Rat
NOAEL	:	>= 2,000 mg/kg
Application Route	:	Skin contact
Exposure time	:	28 Days
Method	:	OECD Test Guideline 410

Bentonite:

Species	:	Mouse
NOAEL	:	500 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days

2,6-Di-tert-butyl-p-cresol:

Species	:	Rat
NOAEL	:	25 mg/kg
Application Route	:	Ingestion
Exposure time	:	22 Months

Aspiration toxicity

Not classified based on available information.

12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Bentonite:**

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 16,000 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	ErC50: > 100 mg/l Exposure time: 72 h

2,6-Di-tert-butyl-p-cresol:

Toxicity to fish	:	LC50 (Danio rerio (zebra fish)): > 0.57 mg/l Exposure time: 96 h Method: Directive 67/548/EEC, Annex V, C.1.
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 0.48 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0.24 mg/l

SAFETY DATA SHEET



Bacillus <5% (Licheniformis / Subtilis) Formulation

Version
2.0

Revision Date:
2025/04/14

SDS Number:
11508956-00002

Date of last issue: 2025/02/07
Date of first issue: 2025/02/07

Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.24 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity)	:	1
Toxicity to fish (Chronic toxicity)	:	NOEC (Oryzias latipes (Japanese medaka)): 0.053 mg/l Exposure time: 30 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0.316 mg/l Exposure time: 21 d
M-Factor (Chronic aquatic toxicity)	:	1
Toxicity to microorganisms	:	EC50: > 10,000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209

Persistence and degradability

Components:

2,6-Di-tert-butyl-p-cresol:

Biodegradability	:	Result: Not readily biodegradable. Biodegradation: 4.5 % Exposure time: 28 d Method: OECD Test Guideline 301C
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Bioaccumulative potential

Components:

2,6-Di-tert-butyl-p-cresol:

Bioaccumulation	:	Species: Cyprinus carpio (Carp) Bioconcentration factor (BCF): 330 - 1,800
Partition coefficient: n-octanol/water	:	log Pow: 5.1

Mobility in soil

No data available

Hazardous to the ozone layer

Not applicable

SAFETY DATA SHEET



Bacillus <5% (Licheniformis / Subtilis) Formulation

Version
2.0

Revision Date:
2025/04/14

SDS Number:
11508956-00002

Date of last issue: 2025/02/07
Date of first issue: 2025/02/07

Other adverse effects

No data available

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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Environmentally hazardous : no

IATA-DGR

UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo aircraft) : Not applicable
Packing instruction (passenger aircraft) : Not applicable

IMDG-Code

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable
Marine pollutant : Not applicable

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

Not applicable for product as supplied.

SAFETY DATA SHEET



Bacillus <5% (Licheniformis / Subtilis) Formulation

Version
2.0

Revision Date:
2025/04/14

SDS Number:
11508956-00002

Date of last issue: 2025/02/07
Date of first issue: 2025/02/07

National Regulations

Refer to section 15 for specific national regulation.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Priority Assessment Chemical Substance

Chemical name	Number
2,6-Di-tert-butyl-4-methylphenol	64

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Not applicable

Substances Subject to be Indicated Names

Not applicable

Skin and Eye Damage Substances (ISHL MO Art. 594-2)

Not applicable

Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

SAFETY DATA SHEET



Bacillus <5% (Licheniformis / Subtilis) Formulation

Version
2.0

Revision Date:
2025/04/14

SDS Number:
11508956-00002

Date of last issue: 2025/02/07
Date of first issue: 2025/02/07

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Not regulated as a dangerous good

Aviation Law

Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

Bacillus <5% (Licheniformis / Subtilis) FormulationVersion
2.0Revision Date:
2025/04/14SDS Number:
11508956-00002Date of last issue: 2025/02/07
Date of first issue: 2025/02/07

16. OTHER INFORMATION**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 : yyyy/mm/dd

Full text of other abbreviations

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
JP ISHL OEL 577-2(2)	: Concentration standard (Value set by the Minister of Health, Labour and Welfare stipulated under the Ministerial Ordinance Article 577-2(2))
JP OEL JSOH	: Japan. The Japan Society for Occupational Health. Recommendation of Occupational Exposure Limits
ACGIH / TWA	: 8-hour, time-weighted average
JP ISHL OEL 577-2(2) / 8h-OEL-M	: 8-hour Occupational Exposure Limit-Mean
JP OEL JSOH / OEL-M	: Occupational Exposure Limit-Mean

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 Tem-

SAFETY DATA SHEET



Bacillus <5% (Licheniformis / Subtilis) Formulation

Version
2.0

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SDS Number:
11508956-00002

Date of last issue: 2025/02/07
Date of first issue: 2025/02/07

perature; 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.

JP / EN