

Bacillus subtilis subsp. subtilis

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GENERAL INFORMATION

Bacillus subtilis subsp. subtilis

For further information on the current nomenclature of the species see [List of Prokaryotic Names with Standing in Nomenclature](#)

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Category:	Bacteria
Strain type:	NCIB 3610 = ATCC 6051 = DSM 10
	Further information: BacDive - The Bacterial Diversity Metadatabase (DSMZ)
Risk group:	1 Biological agents that are unlikely to cause human disease.
References:	Note +: Identified as or suspected of being pathogens in individual cases, mainly in individuals with considerably reduced immunity; identification of the type is often not reliable.
Consultant / Reference laboratory:	No consulting laboratory or reference laboratory exists for Bacillus subtilis. The Federal Institute for Risk Assessment (BfR) is responsible for matters of food safety.
	<u>Contact</u> Federal Institute for Risk Assessment, Dept. 5 (food safety) Dr T. Schwerdtle (acting) Max-Dohrn-Str. 8 - 10 D - 10589 Berlin, Tel.: +49 (0)30-18412-25000 Fax: +49 (0)30-18412-625000 E-mail: 5@bfr.bund.de



Microscopic image of Bacillus subtilis, Gram staining. CDC/ Dr W.A. Clark, 1977; Public Health Image Library (PHIL).

Medical significance

B. subtilis subsp. *subtilis* is considered to be non-pathogenic and has no infectious significance. In the few case reports on human infections in which *B. subtilis* was isolated, causal involvement in the infection process could not be proven.

Certain *B. subtilis* strains have gained importance as so-called probiotics (see below) and, in particular in the field of veterinary medicine, as feed additives for various animal species. To this end, the European Food Safety Authority (EFSA) has issued opinions on the safety and potential efficacy of several selected *B. subtilis* strains (mostly of strain PB6 and strains from the German Collection of Microorganisms and Cell Cultures (DSMZ)). In most cases, administration is considered harmless to the target organism, the consumer and the environment. In animals, if supported by studies, it is additionally considered to potentially promote weight gain and stabilise intestinal flora. A prerequisite for a strain to be classified as safe is proof that the strain is not toxic and does not exhibit resistance to antibiotics of importance to human and veterinary medicine. Such proof requires identification of the strain and qualified safety checks. Ideally, the identity check and taxonomic assignment should be carried out by means of whole genome analyses. *B. subtilis* is included by the EFSA in its QPS (qualified presumption of safety) list and is therefore, generally, considered safe.

Online retailers sell various *B. subtilis* preparations in the form of so-called probiotics. The WHO defines probiotics as “live microorganisms which when administered in adequate amounts confer a health benefit on the host”. Mostly, such probiotics are used to restore intestinal flora after diseases involving diarrhoea or to treat irritable bowel syndrome. These preparations chiefly consist of lactobacilli and bifidobacteria. The *B. subtilis* preparations available in online retail mostly contain live endospores of *B. subtilis*, as these are resistant to gastric acid and thus survive passage through the stomach and bowels. However, to date, no scientific proof has been demonstrated that *B. subtilis* has a positive effect on regenerating the human intestinal flora. The requisite clinical studies with expert statistical evaluation is not available in the case of *B. subtilis*.

Although the EFSA requires strain identity verification, a scientific study has shown that various products available in Europe incorrectly identify species. For instance, in five preparations labelled as containing *B. subtilis*, a different *Bacillus* species was identified. Not only that, some strains in the preparations exhibited antibiotic resistance. This raises questions about the safety of the available preparations.

The Consumers’ Office points out that you should consult a doctor before taking probiotics for therapeutic purposes. You should also consult a doctor before administering probiotics to immunocompromised individuals and young children.

Reference: [10378](#) [10401](#) [25326](#) [25327](#) [25328](#)

Transmission routes

Transmission does not occur.

Reference: 99999

For further information on transmission routes see chapter EPIDEMIOLOGY.

OCCUPATIONAL SAFETY AND HEALTH

Sector | Activity | Protective measures | Inactivation/Decontamination | Immediate measures/First aid | Occupational health care

SECTORS

- Laboratories
- Industry

Reference: 10401 99999

ACTIVITIES

- Laboratory activities
- Feed manufacturing
- Fermentation

Reference: 10401 99999

PROTECTIVE MEASURES

General protective measures

Ensure compliance with general hygiene regulations.

The following protective measures apply to specific activities in laboratories, the husbandry of laboratory animals and biotechnological activities. For further information see [TRBA 100](#), [TRBA 120](#), [TRBA 500](#).



Technical measures

Where tasks intentionally involve biomaterials, their identity must be verified and documented routinely.

For biological agents of the risk group 1 the basic rules of good microbiological practice are to be followed in the intended laboratory operations. For biomaterials exhibiting sensitising or toxic properties, the risk assessment may indicate that additional precautions are necessary.

The doors of the protection level area must be equipped with an inspection window.

Wash basins, disposable towels and hand detergents must be available.

Surfaces (worktops, floors) must be easy to clean and resistant to the materials and detergents used.

Work areas are to be maintained in a clean and tidy state. Only tools and devices that are actually needed may remain on the benches.

Pipettors must be provided and used. Mouth pipetting is not permitted.

If the use of pointed or sharp instruments cannot be avoided, they must be disposed of in suitable containers after use.

Suitable containers must be available for the collection of waste that constitutes biological agents.

Organisational measures

Injuries must be reported immediately to the person in charge.

Personal protection - body protection

Lab coats are mandatory.
Used lab coats must be kept separate from normal clothing.

Personal protection - hand protection

Use protective gloves as required.
The skin protection plan must be observed.

Personal protection - respiratory protection

Respiratory protection (at the least an FFP1 mask) must be worn during activities in which dry aerosols (dusts of spores, enzymes) are generated, e.g. during industrial processes such as feed production.

Occupational hygiene

The consumption and storage of food and alcohol/tobacco in the protection level area is forbidden.
The hands are to be thoroughly cleaned and treated according to the hand protection plan following completion of the activities or contamination processes.

Vaccination

Vaccination is not necessary, and a vaccine is not available.

Reference: 00001 99999

INACTIVATION / DECONTAMINATION

All solid and liquid wastes can be disposed of without pre-treatment if not otherwise stipulated by legal regulations (such as water, waste or genetic engineering legislation).
Inactivating resistant spores requires the use of sporicidal disinfectants.

Reference: 00001 99999

IMMEDIATE MEASURES / FIRST AID / POST-EXPOSURE PROPHYLAXIS

Accidental release measures

No special measures are required.

First aid: eyes and mucous membranes

Rinse eyes with eye wash or employ an eye wash bottle for 10 - 15 minutes while keeping your eyes open.

First aid: skin

Skin disinfection as per the hygiene plan.

First aid: respiratory tract

If necessary, perform nasal lavage.

First aid: swallowing

Rinse your mouth, then spit out.

Information for physicians

B. subtilis is non-pathogenic, and thus no further action is required.

Reference: 99999

OCCUPATIONAL HEALTH CARE according to ArbMedVV

In the case of activities with the biological agent no health care is required. An indication on restrictions for immunosuppressed workers should be made.

MORPHOLOGY AND PHYSIOLOGY

MORPHOLOGY

B. subtilis is a Gram-positive rod bacterium with a diameter of approximately 0.5 - 1.0 µm and a length of approximately 1.0 - 5.0 µm. Its cells can form long filaments. Generally, its cells are motile and possess peritrichous flagella. It develops endospores. The morphology of its colonies on solid media is highly diverse; they are often irregular and can appear to be mixed colonies. Their consistency ranges from moist to buttery, or mucilaginous to membranous, with an underlying mucilaginous matrix (with or without mucilaginous deposits on the surface), and they become rough and crusty as they dry.

Reference: [10377](#)

PHYSIOLOGY

It was long believed that *Bacillus subtilis* was a strictly aerobic bacterium. However, recent studies have shown that *B. subtilis* also grows anaerobically, either by using nitrate or nitrite as a terminal electron acceptor or by fermentation. Catalase positive, oxidase variable. Production of various extracellular proteases. Growth at temperatures of 25 - 37 °C on culture media for cultivation of undemanding bacteria.

Reference: [10377](#) [25329](#) [25330](#)

INFORMATION ON MOLECULAR BIOLOGY

Genome

The genome of the type strain DSM10T consists of a chromosome 4.166 million base pairs long, which codes for 4341 genes. The NCBI GenBank assigns it the accession number JAEPVU0000000. The accession number for the 16S rRNA gene is LN681568.

Reference: [04711](#)

OCCURRENCE / NATURAL HABITAT

FREE-LIVING / HOST BOUND

This biological agent is free-living.

B. subtilis is mainly found free-living in the soil (upper soil layers), but it can also colonise the bowels of humans and animals and the roots of plants. *B. subtilis* often forms a symbiotic relationship with plants, promoting plant growth.

Reference: [25331](#) [25334](#) [25335](#)

HOSTS

Humans, animals, plants.

Reference: [25331](#) [25334](#) [25335](#)

VECTORS

No vector is known.

Reference: [99999](#)

GEOGRAPHIC DISTRIBUTION

B. subtilis is distributed worldwide.

Reference: [10377](#) [25331](#) [25334](#) [25335](#)

PATHOGENICITY / PATHOGENIC PROPERTIES

CHARACTERISTIC OF PATHOGENICITY

Not human-pathogenic (it does not cause diseases in humans).
Not animal-pathogenic (it does not cause diseases in animals).

B. subtilis has no known pathogenic properties.

Reference: [10377 99999](#)

MINIMUM INFECTIOUS DOSE (MID)

Infection with *B. subtilis* does not occur.

Reference: [99999](#)

CARCINOGENICITY / MUTAGENICITY / REPRODUCTIVE TOXICITY

Such properties have never been described for this organism.

Reference: [99999](#)

ALLERGENICITY / SENSITISING EFFECT

An allergic / sensitising potential is not known.

B. subtilis produces the extracellular enzyme subtilisin, which has been reported to cause allergic or hypersensitivity reactions in individuals after repeated exposure (e.g. in industrial processes).

Reference: [25336 25337](#)

TOXIGENICITY / TOXIN FORMATION

The organism has never been shown to generate medically relevant toxins.

Reference: [99999](#)

DISEASE

DESCRIPTION

B. subtilis is non-pathogenic.

Reference: [99999](#)

ZOONOSIS

Zoonosis (transmission between animals and humans): No

Not applicable

Reference: [99999](#)

INFECTIOUS STAGES

No stage is infectious.

Reference: [99999](#)

INCUBATION PERIOD

Not applicable

Reference: [99999](#)

SYMPTOMS AND COURSE OF DISEASE

B. subtilis has no known pathogenic properties.

Reference: [99999](#)

LETHALITY

Not applicable.

Reference: 99999

THERAPY

Not applicable.

Reference: 99999

PROPHYLAXIS

Not applicable.

Reference: 99999

EPIDEMIOLOGY

TRANSMISSION ROUTES / PORTALS OF ENTRY

Transmission does not occur.

Reference: 99999

PATHOGEN RESERVOIR

The primary reservoir is the soil.

Reference: 10377

INCIDENCE

Not applicable.

Reference: 99999

RESISTANCE / TENACITY

SPORULATION

Forms spores.

Bacillus subtilis forms heat- and acid-resistant endospores.

Reference: 10377 25332

CONIDIA FORMATION

Does not form conidia.

Reference: 99999

RESISTANCES

B. subtilis endospores are highly resistant to harmful environmental factors and common non-sporicidal disinfectants.

Some strains of *B. subtilis* have been observed to be resistant to different classes of antibiotics.

Reference: 25332 25333

LEGAL PRINCIPLES / REGULATIONS

LAWS AND ORDINANCES

Ordinance on Safety and Health Protection at Workplaces Involving Biological Agents
(Biological Agents Ordinance - [BioStoffV](#))

Law for the regulation of genetic engineering (Genetic Engineering Act - [GenTG](#)) and associated regulations (only in German).

Public notice of the list risk-rated donor organisms and recipient organisms for genetic engineering of 5. July 2013

TECHNICAL RULES AND OTHER REGULATIONS

[TRBA 100](#)

Protective measures for activities involving biological agents in laboratories

[TRBA 213](#)

Waste collection: Protective measures (only in German)

[TRBA 214](#)

Plants for the treatment and recovery of waste (only in German)

[TRBA 220](#)

Safety and health for activities involving biological agents in sewage plants

[TRBA 230](#)

Protective measures for activities involving biological agents in agriculture and forestry and comparable activities

[TRBA 400](#)

Guideline for risk assessment and for the instruction of employees in relation to activities with biological agents

[TRBA / TRGS 406](#)

Sensitising substances for the respiratory tract (only in German)

[TRBA 450](#)

Criteria for the classification of biological agents

[TRBA 466](#)

Classification of prokaryotes (bacteria and archaea) into risk groups (only in German)

[TRBA 500](#)

Basic measures to be taken for activities involving biological agents

LINKS

Further Links:

[European Food Safety Authority \(EFSA\)](#)

REFERENCES

[General information](#) | [Occupational and health protection](#) | [Morphology and physiology](#) | [Occurrence/natural habitat](#) | [Pathogenicity/pathogenic properties](#) | [Disease](#) | [Epidemiology](#) | [Resistance/Tenacity](#) | [Legal basics](#) | [Links](#) | [References](#)

Quelle: 00001

Informationen aus den Technischen Regeln für Biologische Arbeitsstoffe, insbesondere aus:
Information from the technical rules for biological substances, in particular from:

- [TRBA 100](#)

Schutzmaßnahmen für Tätigkeiten mit biologischen Arbeitsstoffen in Laboratorien; Ausgabe:
Oktober 2013, geändert 2014

Protective measures for activities involving biological agents in laboratories; Edition: October 2013,
amended 2014

- [TRBA 120](#)

Versuchstierhaltung; Ausgabe: Juli 2012, geändert 2017

Experimental animal husbandry; Edition July 2012, amended 2017

- [TRBA 500](#)

Grundlegende Maßnahmen bei Tätigkeiten mit biologischen Arbeitsstoffen; Ausgabe: April 2012

Basic measures to be taken for activities involving biological agents; Edition April 2012

Quelle: 01466

[TRBA 466](#)

Einstufung von Prokaryonten (Bacteria und Archaea) in Risikogruppen; Ausgabe: August 2015,
zuletzt geändert: GMBL Nr. 25-31 vom 14. August 2019, S. 478

Classification of prokaryotes (bacteria and archaea) in risk groups; Edition August 2015, last
amended August 2019

Quelle: 02014

Verordnung zur arbeitsmedizinischen Vorsorge ([ArbMedVV](#))

Ordinance on Occupational Health Care ([ArbMedVV](#))

Quelle: 04711

Lilge L, Hertel R, Morabbi Heravi K, Henkel M, Commichau FM, Hausmann R. Draft Genome Sequence of the Type Strain *Bacillus subtilis* subsp. *subtilis* DSM10. *Microbiol Resour Announc.* 2021 Mar 11; 10(10):e00158-21.

Quelle: 10377

Logan N. A., De Vos P. The firmicutes. IN: *Bergey's Manual of Systematic Bacteriology* 2015

<https://doi.org/10.1002/9781118960608.gbm00530>

Quelle: 10378

Verbraucherzentrale: Lebensmittel mit speziellen Bakterienkulturen (früher: "Probiotika"). Stand 22.12.2020

<https://www.verbraucherzentrale.de/wissen/lebensmittel/kennzeichnung-und-inhaltsstoffe/lebensmittel-mit-spezialen-bakterienkulturen-frueher-probiotika-13937>

Quelle: 10401

Europäische Behörde für Lebensmittelsicherheit (EFSA)

<https://www.efsa.europa.eu/de/search?s=bacillus+subtilis>

Quelle: 25326

Saif Ul Islam, *Clinical Uses of Probiotics.* *Medicine (Baltimore)* .2016 Feb;95(5):e2658.

Quelle: 25327

Lee N.-K., Kim W.-S., Paik H.-D. *Bacillus* strains as human probiotics: characterization, safety, microbiome, and probiotic carrier. *Food Sci Biotechnol.* 2019 Oct 8;28(5):1297-1305.

Quelle: 25328

Hoa N. T., Baccigalupi L., Huxham A., Smertenko A., Van P. H., Ammendola S., Ricca E., et al. (2000). Characterization of *Bacillus* species used for oral bacteriotherapy and bacterioprophyllaxis of gastrointestinal disorders. *Appl. Environ. Microbiol.* 66 5241–5247

Quelle: 25329

Härtig E, Jahn D. Regulation of the anaerobic metabolism in *Bacillus subtilis*. *Adv Microb Physiol.* 2012;61:195-216.

Quelle: 25330

Cruz Ramos H, et al. Fermentative metabolism of *Bacillus subtilis*: physiology and regulation of gene expression. J Bacteriol. 2000 Jun; 182(11):3072-80.

Quelle: 25331

Posada LF, Álvarez JC, Romero-Tabarez M, de-Bashan L, Villegas-Escobar: Enhanced molecular visualization of root colonization and growth promotion by *Bacillus subtilis* EA-CB0575 in different growth systems. Microbiol Res. 2018 Dec; Vol. 217:69-80.

Quelle: 25332

Setlow P.: Spores of *Bacillus subtilis*: their resistance to and killing by radiation, heat and chemicals J Appl Microbiol. 2006 Sep; 101(3):514-25.

Quelle: 25333

Andrews J. M., Wise R.: Susceptibility testing of Bacillus species. Journal of Antimicrobial Chemotherapy, Volume 49, Issue 6, June 2002, Pages 1040–1042,

Quelle: 25334

Hong HA, et al. *Bacillus subtilis* isolated from the human gastrointestinal tract. Res Microbiol. 2009 Mar; 160(2): 134-43

Quelle: 25335

Penaloza-Vazquez A, et al. Isolation and characterization of *Bacillus* spp. strains as potential probiotics for poultry. Can J Microbiol. 2019 Oct; 65(10): 762-774.

Quelle: 25336

Pepys J. Allergic asthma to *Bacillus subtilis* enzyme: a model for the effects of inhalable proteins Am J Ind Med. 1992; 21(4):587-93.

Quelle: 25337

Wüthrich B, Ott F: Occupational asthma due to proteases in the detergent industry. Schweiz Med Wochenschr 1969 Nov 1; 99(44): 1584-1586

Quelle: 99999

Angabe des Bearbeiters

Indication of the author

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