Safety Data Sheet according to Regulation (EC) 1907/2006/EC, and its amendments

Date of Revision: **January**, 2023

Country: Not applicable (EU Master SDS)

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name: Agree® WP, Agree® 50 WP, Turex® WP, Turex® 50 WP

Active substance: *Bacillus thuringiensis* subspecies *aizawai* GC-91

REACH Registration No.: Not relevant (Mixture).

UFI code: [Voluntary and Country-specific. To be added in national SDS.]

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses: Bioinsecticide

1.3. Details of the supplier of the safety data sheet

Name: Certis U.S.A., LLC

Address: 9145 Guilford Road, Suite 175
Columbia, Maryland 21046
U.S.A.

Phone Number: +1 (800) 255-3924

Email: sds@certisbio.com

1.4. Emergency telephone number

General medical emergency number: 112

Local toxicological center(s):

[Country-specific. To be added in national SDS.]

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) No 1272/2008 (CLP)

CLP Classification: None.

This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

2.1.2 Additional information:

For full text of Hazard- and EU Hazard-statements: see SECTION 16.

2.2. Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]

Hazard Pictogram(s): None

Signal Word: None

Hazard Statements: None

Precautionary Statements: P102 Keep out of reach of children.

P501 Dispose of the container/contents in accordance with municipal rules for disposal of waste.

Additional label elements (refer to section 16 for further information), according to Part 4 Annex II to Regulation (EC) No. 1272/2008 (CLP):

EUH401: To avoid risks to human health and the environment, comply with the instructions for use.

Microorganisms may have the potential to provoke sensitizing reactions.

2.3. Other hazards

The mixture does not contain PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII.

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties nor it is identified as having endocrine disturbing properties in accordance with the criteria set out Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0.1% by weight.

This mixture does not contain nanoforms.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

None of the ingredients of the mixture meets the criteria for classification in any hazard class according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

SECTION 4: First aid measures

4.1. Description of first aid measures

General notes: Move away from the dangerous area. Lay the victim down and place him in the lying position to rest, keep him warm by covering him with clothing.

Following eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Following skin contact: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. Do not apply any medication agent except on the advice of a physician.

Following inhalation: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If signs/symptoms persist, get medical advice/attention.

Following ingestion:	Call a POISON CENTER or doctor/physician if you feel unwell. Do NOT induce vomiting unless directed to do so by medical personnel. Rinse your mouth.

4.2. Most important symptoms and effects, both acute and delayed

May cause sensitization in some individuals.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians: Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:	Dry chemical, alcohol foam, carbon dioxide.
Unsuitable extinguishing media:	Not available.

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products:	Carbon monoxide. Carbon dioxide. Oxides of Sulphur.

5.3. Advice for firefighters

Protection of firefighters:	Keep upwind of fire. Wear protective clothing and self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel:	Avoid generation of dusts. Do not inhale dust. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area and observe emergency procedures.
6.1.2. For emergency responders:	Use personal protection recommended in Section 8. Isolate the hazard area and deny entry to unnecessary and unprotected personnel.

6.2. Environmental precautions

Keep out of drains, sewers, ditches, and waterways.

6.3. Methods and material for containment and cleaning up

6.3.1. For containment:	Contain spill.
6.3.2. For cleaning Up:	Collect mechanically. Sweep, vacuum, or shovel material and transfer the product to containers properly labelled and hermetically sealed. Avoid generation of dust. Thoroughly wash objects and dirty floors observing environmental standards. Clean with disinfectants.
6.3.3. Other Information:	Dispose of in accordance with local regulations for disposal of non-hazardous waste.

6.4. Reference to other sections

See Section 8 for occupational exposure limits and risk management measures. Refer to Section 13 for disposal considerations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Keep integrity of the package up to the moment of use as biopesticide. For the use as biopesticide, the user should follow the instructions on the packaging label.
Wash hands before and after use.

7.2. Conditions for safe storage, including any incompatibilities

Store in a dry place. Store in a closed container. Protect from sunlight.

Do not to eat, drink and smoke in work areas.

7.3. Specific end use(s)

Follow application instructions on product label.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Not applicable.

8.2. Exposure controls

Under normal conditions of use and handling, the end user should refer to the indication recommended on the packaging label and Good Agronomic Practices. In all other cases, the user should follow the following recommendations:

8.2.1. Engineering controls:	Ensure ventilation is adequate to keep airborne dust levels low.
8.2.2. Personal protective equipment:	Not required.
Eye/Face protection:	Not required.
Skin protection	Not required.
Hand protection:	Wear protective gloves. (Glove thickness > 0.4 mm. Directive: protective gloves according to EN 374.)
Body protection:	Wear suitable protective clothing. For brief contact, no precautions other than clean body-covering clothing should be needed. In case of risk of significant exposure, wear high-quality clothing.
Respiratory protection:	Not required.
Thermal hazards:	Not applicable.
General hygiene considerations:	Handle according to established industrial hygiene and safety practices.
8.2.3. Environmental exposure controls:	Follow all applicable environmental protection legislation.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Solid.
Colour:	Grey-beige homogeneous powder. RAL.1019.
Odour:	Characteristic odour.
Odour threshold:	Not available.
Melting point / Freezing point:	Not applicable (a microorganism will not melt/re-solidify).
Initial boiling point:	Not relevant (used as a solid at normal conditions, product is mainly constituted by a microorganism).
Flammability (solid):	The product is not flammable
Flash point:	Not applicable (solid).
Auto-ignition temperature:	The relative self-ignition temperature is 210ºC, at atmospheric pressure.
Decomposition temperature:	Not applicable.
pH:	6.54 (1% dispersion at 25ºC).
Evaporation rate:	Not applicable (product is a solid).
Viscosity:	Not applicable (product is a solid at normal conditions).
Solubility:	Not applicable for microorganisms.
Partition coefficient (n-octanol/water):	Not applicable (product is a solid).
Vapour pressure:	Not applicable (product is a solid).
Bulk density:	Tap density: 0.51 g/mL.
Particle characteristics:	Powder. Dry sieve analysis (particle size distribution): 6.27 µm, 32.93 µm, 76.82 µm
Lower & Upper Flammability Limits:	Not applicable (product is a solid).
Explosive properties:	Not explosive (test method according to European Commission Regulation (EC) 440/2008).
Oxidising properties:	Not oxidising (test method according to European Commission Regulation (EC) 440/2008).

9.2. Other information

No additional relevant information available

SECTION 10: Stability and reactivity

10.1. Reactivity	No known hazardous reactions when handled and stored according to stated provisions.
10.2. Chemical stability	Stable when handled and stored according to stated provisions.
10.3. Possibility of hazardous reactions	No known hazardous reactions.
10.4. Conditions to avoid	Avoid exposure to moisture and to excessive heat, as it may compromise shelf-life.

10.5. Incompatible materials — No known incompatible materials.

10.6. Hazardous decomposition products — No known hazardous decomposition products in designated use.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute Toxicity	Not classified for acute oral, inhalation and dermal toxicity, based on the information available for the formulation.
- **Acute oral toxicity**	LD_{50} (oral): > 5050 mg/kg bw (rat). Test with formulated product (Agree WP)
- **Acute dermal toxicity**	LD_{50} (dermal): > 2020 mg/kg bw (rabbit). Test with formulated product (Agree WP)
- **Acute inhalation toxicity**	LC_{50} (inhalation): > 5.78 mg/L (maximum attainable concentration in air) no observed effect in rats. Test with formulated product (Agree WP)
Skin corrosion/irritation:	Not classified for skin corrosion/irritation based on the information available for individual substances in the mixture and tests with the formulated product (Agree WP) in rabbits.
Serious eye damage/irritation:	Not classified for irritation to the eye based on the information available for individual substances in the mixture and test with the formulated product (Agree WP) in rabbits.
Respiratory or skin sensitization:	No suitable methods available for microbials, as per Regulation 284/2013. The following precautionary labelling phrase is currently required for all microorganisms in EU: "Contains *B. thuringiensis* subsp. *aizawai.* Microorganisms may have the potential to provoke sensitizing reactions"
Germ cell mutagenicity:	Not classified based on the information available for individual substances in the mixture.
Carcinogenicity:	Not classified based on the information available for individual substances in the mixture.
Reproductive toxicity:	Not classified based on the information available for individual substances in the mixture.
STOT-single exposure:	Not classified based on the information available for individual substances in the mixture
STOT-repeated exposure:	Not classified based on the information available for individual substances in the mixture.
Aspiration hazard:	Not classified based on the information available for individual substances in the mixture.

11.2. Information on other hazards

The mixture does not contain components identified as having endocrine disrupting properties in accordance with the criteria set out in Delegated Regulation (EU) 2017/2100 or Regulation (EU) 2018/605 at levels of 0,1% (w/w) or higher.

11.2.2. Other information

Not known any adverse health effect.

SECTION 12: Ecological information

12.1. Toxicity: Low toxicity and no pathogenicity was observed in tested aquatic species (fish, daphnia, algae), bees, non-target arthropods and earthworms.

Test species	Test method	Test substance	LC50
Fish *(Oncorhynchus mykiss)*	32 days (semi-static)	Bacillus thuringiensis aizawai (GC-91)	LC_{50} > $2x10^{10}$ CFU/L
Aquatic invertebrate *(Daphnia magna)*	48-hour, static	Similar formulation with the same active substance (Agree 50® WG)	EC_{50} > 25 mg/L
Aquatic invertebrate *(Daphnia magna)*	21 days, semi-static	Bacillus thuringiensis aizawai (GC-91)	NOEC = $1.57x10^{8}$ CFU/L
Algae *(Scenedesmus subspicatus)*	72 hours, static	Bacillus thuringiensis aizawai (GC-91)	EC_{50} > 3.6×10^{9} CFU/L
Honey bee *(Apis mellifera)*	Oral, respiratory, direct and indirect contact (72 h)	Agree 50® WP	LD_{50} is > 2 g a.s./L. No behavioural anomaly was observed
Bumblebee *(Bombus terrestris)*	Oral and direct contact (68 days)	Similar formulation with the same active substance (Agree 50® WG)	No effects on queens, workers, hive weight.
Parasitoid *(Aphidius Rhopalosiphi)*	Acute, laboratory (Adults)	Agree 50® WP	LR_{50} > 4.5 kg product/ha
Predatory mite *(Typhlodromus pyri)*	Acute, laboratory (protonymphs)	Agree 50® WP	LR_{50} > 4.5 kg product/ha
Eisenia fetida	Laboratory (acute test)	Agree 50® WP	LC_{50} > 1000 mg/kg soil

12.2. Persistence and degradability

Soil: Available information indicates that Bacillus thuringiensis spores may persist from days to years in soil under natural field conditions. Information specific to strain GC-91 was unavailable. The low potential for spore germination, growth and re-sporulation in bulk soils minimises multiplication. Germination in the rhizosphere may occur.

Water: multiplication in water is not expected. When reaching aquatic environments, Bt comes across unfavourable conditions (e.g. lack of nutrients, temperature) leading to a rapid decline of the population size. Thus, proliferation of this bacterial species in natural water bodies is not expected to occur, and population size will decline upon hostile environmental conditions.

Air: re-aerolisation of applied spores is possible but spores rapidly drop in viability following release to air. Fate and transport via air after application is unlikely to play a role in environmental exposure to B. thuringiensis subsp. aizawai including Bta GC-91 spores and endotoxins.

12.3. Bioaccumulative potential Evaluation of bioaccumulation is not relevant for micro-organisms.

12.4. Mobility in soil The mobility of *B. thuringiensis* and the spores can be considered limited.

12.5. Results of PBT and vPvB assessment	Not relevant for micro-organisms.
12.6. Endocrine disrupting Properties	The mixture does not contain components identified as having endocrine disrupting properties in accordance with the criteria set out in Delegated Regulation (EU) 2017/2100 or Regulation (EU) 2018/605 at levels of 0,1% (w/w) or higher.
12.7. Other adverse effects	No other effects to report.
12.8. Additional information	No additional information.

SECTION 13: Disposal considerations

13.1.Waste treatment methods

Waste material must be disposed of in accordance with the Framework Directive on waste 2008/98/EC and Directive 94/62/EC on packaging and packaging waste, as well as other national and local regulations. No mixing with other waste. Handle un-cleaned containers like the product itself. Do not reuse empty packaging.

European List of Waste (LoW) code:
02 01 09 – Agrochemical waste other than those mentioned in 02 01 08

Dispose content/ container in accordance with licensed collectors sorting instructions.

SECTION 14: Transportation information

14.1. UN number
Not regulated.

14.2. UN proper shipping name
Not regulated.

14.3. Transport hazard class(es)
Not regulated.

14.4. Packing group
Not regulated.

14.5. Environmental hazards
Not regulated.

14.6. Special precautions for user
Not regulated.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
Not regulated.

SECTION 15: Regulatory information

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

Regulation (EC) No. 1107/2009:	The active ingredient *B. thuringiensis* subspecies *aizawai* strain GC-91 is approved in EU under Regulation (EC) No 1107/2009. Agree 50® WP is a bioinsecticide authorized in several EU Member States. Registration number: *[add from corresponding Member State authorization database for plant protection products]*
Regulation (EU) No. 2021/283:	All co-formulants comply with Regulation (EU) 2021/283
Regulation (EU) No. 547/2011:	SP 1: Do not contaminate water with the product or its container. (Do not clean application equipment near surface water./Avoid contamination via drains from farmyards and roads.)

[Additional labelling information may apply according to national provisions and requirements in certain EU Member States]

Further information: The strain Bta GC-91 is deposited in the Northern Collection of Type Cultures (NCTC) under the reference number NCTC 11821.

15.2. Chemical safety assessment

Chemical Safety Assessment: Not required.

SECTION 16: Other information

Disclaimer:
The information in this Safety Data Sheet is based on the present state of knowledge and legislation. This SDS provides guidance on health, safety and environmental aspects of the product and should not be construed as any guarantee of technical performance. The product should not be used for any other purposes than those in Section 1.

16.1. SDS Authoring Information:

Revision date:	January, 2023.
Version number:	4.0
Previous version:	1.0 (January 2012), 2.0 (February 2014), 3.0 (September 2016)
SDS Prepared by:	Certis U.S.A., LLC

Indication of changes:

SDS EU format according to Commission Regulation (EU) 2020/878.

Description of hazard statements set out in section 3:

Not applicable.

Main Data Source:

EFSA: European Food Safety Authority.
ECHA: European Chemicals Agency.
Draft Renewal Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009 for the approval renewal of *Bacillus thuringiensis* subsp. *aizawai* GC-91.

Training advice:

No specific training is required. Handle in accordance with good industrial hygiene and safety procedures.

Abbreviations and acronyms

CLP	Classification Labelling and Packaging
EC50	Median effective concentration
ErC50	The concentration of test substance which results in a 50 percent reduction in growth rate, acute endpoint
EbC50	The concentration of test substance which results in a 50 percent reduction in biomass growth, acute endpoint.
LC50	Median lethal concentration
LD50	Median lethal dose
PBT	Persistent Bioaccumulating and Toxic
SDS	Safety Data Sheet
CAS No	Chemical Abstract Service number
vPvB	Very Persistent and Very Bioaccumulating
EU/UE	European Union