

Renewal Assessment Report

***Bacillus thuringiensis*
subsp. *aizawai* strain GC-
91**

Volume 3 – B.4 Further information

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Rapporteur Member State: The Netherlands

Co-Rapporteur Member State: Germany

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Introduction

Bacillus thuringiensis subsp. *aizawai* GC-91 (in the following abbreviated as Bta GC-91) is a transconjugant strain originating from a Bta and a Bt subsp. *kurstaki* strain. Bta in general occurs ubiquitous in soils on plants as well as in infested insects. Bta acts highly specific against insect species of the order Lepidoptera and is not expected to have any harmful effects on beneficials and other non-target species of other insect orders. The insecticidal activity of Bta is mainly attributed to spore bound insecticidal pro-toxins (Cry toxins) which are ingested by the target pests and activated under alkaline conditions in the midgut of the larvae.

As the manufacturing process of Bta GC-91 has not been changed since original approval, all data submitted for the original approval of the strain are considered fully applicable for the current evaluation.

Besides new information, the submitted dossier includes all data, which have been presented in the DAR (Jan 2007) and DAR addendum (Nov 2012). This information is marked grey with a clear indication where the information is originating from.

B.4 Further information on the micro-organism

B.4.1 Recommended methods and precautions concerning handling, storage, transport or fire

Information from DAR

Handling of Bta strain GC-91 does not require special precautionary measures or protective clothing, as indicated by the submitted toxicological studies. However, exposure to the strain may result in eye, skin and respiratory tract irritation, therefore appropriate protection clothing and a breathing mask should be used.

The following general precautionary measures in handling are stated in the Material Safety Data Sheet.

To avoid any direct contact with the product.

Prevent eating, drinking, tobacco usage, and cosmetic application in areas where there is a potential for exposure to the material.

To wash hands after contamination with the product.

Individuals with allergic history or pre-existing dermatitis should use extra care when handling this product.

Wear protective clothing during handling.

Recommended storage conditions are:

Store the material in well-ventilated, secure area away from children and domestic animals.

Do not store food, beverages or tobacco products in the storage area.

Prevent eating, drinking, tobacco usage and cosmetic application in areas where there is a potential exposure to the product.

Always wash thoroughly after handling.

There are no restrictions regarding transport on land or sea.

In case of fire the following information and instructions are given:

Extinguishing media:	Dry chemical, foam or CO2 extinguishing media
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NFPA Hazard Classification	HEALTH HAZARD 1, FIRE HAZARD 0, REACTIVITY 0
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Measures unsuitable for safety reasons:	None
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Special hazard properties (products or vapours from thermal combustion):	This product presents a possible dust explosion hazard.
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Protective equipment:	Wear full protective clothing and self-breathing apparatus. Evacuate nonessential personnel from the area to prevent exposure to fire, smoke, fumes, or products of combustion. Prevent use of contaminated buildings, area, and equipment until decontamination
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Other advices:	none
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New information

The following information is provided in the Material safety data Sheet for the Technical material of Bta GC-91 (submitted in Doc J, Point MP 1.4).

Precautions for safe handling

Avoid breathing dust. Avoid contact with skin and eyes. Avoid contact with open wounds. Wash hands thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Keep away from excessive heat and open flames. After handling, wash hands before eating, drinking, or smoking.

Conditions for safe storage, including any incompatibilities

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

Transport hazard class: not applicable

Firefighting measures:

Suitable Extinguishing Media:	Dry chemical, water fog, alcohol foam, carbon dioxide.
Unsuitable Extinguishing Media:	Not available.
Special hazards arising from the substance or mixture	Dust may form explosive mixtures in air.
Hazardous combustion products:	Carbon monoxide. Carbon dioxide.
Protection of Firefighters:	Keep upwind of fire. Wear protective clothing and self-contained breathing apparatus.

B.4.2 Procedures for destruction or decontamination

Information from DAR

Specific measures in case of an accident are not required since Bta strain GC-91 is not expected to impose any risk for environment or health.

The standard protection measures for workers are adequately protecting their health in case Bta strain GC-91 containing material is released or spilled accidentally at the manufacturing facilities.

The contaminated area may be cleaned by sweeping up spill, keeping dust to a minimum and placing spill in an approved chemical container. The spill should be washed with water containing a strong detergent, absorbed with pet litter or other absorbent material, swept up and placed in a chemical container. Spillage can be safely disposed off in a sealed container in accordance with all applicable federal, state, and local environmental regulations.

New information

Methods for Containment:	Contain spill. Reclaim material if possible.
Methods for Clean-Up:	Collect mechanically. Sweep, vacuum, or shovel material into a container for disposal. Clean up affected area with plenty of water. Avoid generation of dusts.
Other Information:	Dispose of in accordance with local regulations for disposal of non-hazardous waste.
Disposal Instructions:	Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations. No mixing with other waste. Handle un-cleaned containers like the product itself. Waste should not be disposed of by release to sewers.

B.4.3 Measures in case of an accident

Information from DAR

No specific treatment after contact with the strain contaminated material is required since the strain is not infective for humans. As a general precautionary measure in case of direct contact to the Bta strain the applicant states the below listed first aid instructions. In addition, persons who may want to seek medical attention upon accidental contact with Bta strain GC-91 should inform the physician about the identity of *Bacillus thuringiensis* ssp. *aizawai* on species level, and may show the label of the packaging as supporting information.

First aid measures:

General advice:	If poisoning is suspected, immediately contact a physician, the nearest hospital, or the nearest Poison Control Centre. Tell the person contacted the complete product name, and the type and amount of exposure. Describe any symptoms and follow any advice given.
Skin contact	Wash with plenty of soap and water, including hair and under fingernails. Do not apply any medicating agent except on the advice of a physician. Remove contaminated clothing and decontaminate prior to use
Eye contact:	Immediately wash eyes with a large amount of running water. Hold eyelids apart to rinse the entire surface of the eyes and lids. Do not apply any medicating agent except on the advice of a physician
Ingestion	If victim is fully conscious, immediately give large amounts of water to drink and induce vomiting. Never give anything by mouth to an unconscious person. The active ingredient of this product has a high affinity for activated charcoal. In case of ingestion of large amounts, 5 mg/kg activated charcoal suspension (50g/400mL water) can be given to absorb the remaining toxicant.
Inhalation:	Move victim from contaminated area to fresh air. Apply artificial respiration if necessary
Other information:	none
Advice to Physician	Exposure may result in eye, skin and respiratory tract irritation.

New information

Description of first aid measures

Eye Contact:	IF IN EYES: 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.
Skin Contact:	IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
Inhalation:	IF INHALED: 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.
Ingestion:	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

Personal precautions, protective equipment and emergency procedures

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

Environmental precautions

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

Methods and material for containment and cleaning up

Methods for Containment:	Contain spill. Reclaim material if possible.
Methods for Clean-Up:	Collect mechanically. Sweep, vacuum, or shovel material into a container for disposal. Clean up affected area with plenty of water. Avoid generation of dusts.
Other Information:	Dispose of in accordance with local regulations for disposal of non-hazardous waste.

B.4.4 References relied on

No references submitted.