BASELINE DOSSIER

Bacillus subtilis QST 713

Microbial pest control agent against plant pathogenic fungi and bacteria

Dossier according to OECD guidance for industry data submissions for microbial pest control products and their microbial pest control agents – August 2006

Summary documentation, Tier II

Annex IIM, Section 6

Point IIM 9: Summary and evaluation of environmental impact

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Applicant

Bayer CropScience AG

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Introduction

This document summarizes all data submitted for the initial evaluation of *Bacillus subtilis* QST 713 as an active substance under Directive 91/414. Data provided in the initial dossier and in subsequent additional submissions are listed chronologically under the respective data point according to the OECD dossier guidance (2006).
This document is further named as **"Baseline Dossier"** since it presents all data previously submitted.

IIM 9 Summary and evaluation of environmental impact

IIM 9.1 Distribution and fate of MPCA

EU-Dossier: Doc M-IIB, Point 9

The fate and behaviour of *B. subtilis* introduced into the environment can be evaluated considering the reported characteristics of this species, as stated in the scientific literature, under consideration of the envisaged application and relevant properties of strain QST 713:

- *B. subtilis* is an autochthonous soil micro-organism, the strain QST 713 has originally been isolated from soil in a peach orchard. *B. subtilis* proliferates in response to fresh organic matter supply.
- *B. subtilis* is frequently occurring in different aquatic environments, and endospores have been detected in sediments and even in the open ocean. However, *B. subtilis* is not regarded an autochthonous inhabitant of aquatic environments and does not find optimal conditions for growth, e.g. in waters poor in organic carbon. Therefore, proliferation is not likely to occur and bacterial cells or endospores may survive in waters without exerting any environmental or health impact.
- Endospores are suitable for aerial distribution as they are easily blown up with the wind.
- Multiplication of *B. subtilis* in the air, aerosols or clouds can be excluded due to lack of organic matter supply, lack of mineral matrix to adhere to and due to exposure to desiccation and UV-radiation.

IIM 9.2 Identification of non-target species at risk and extent of their exposure

EU-Dossier: Doc M-IIB, Point 9

Due to the fact that the active ingredient is a viable micro-organism of ubiquitous occurrence and predominance in many environmental compartments, the terms residue and residue metabolism are not applicable to *B. subtilis* cells or spores which are introduced into the environment. Any dispersal of *B. subtilis* into the soil or to associated environments will not affect the natural micro-flora and is of minor concern.

The values summarised in the table below are based on the submitted study reports and the evaluation as outlined in the summary report on mammalian toxicity (see Doc. K-IIB, Sec. 3, P. 5.5).

Table IIM 9.2-1: Summary for non-target organism risk assessment

Organism group	Category/ genera (species)	PEC_i , PEC_{SW} resp.[1]	End-point
Bird	Small birds	1.5×10^6 mg a.i./ha	TER >100
	Bigger birds	1.5×10^6 mg a.i./ha	TER >100
Aquatic organisms	Freshwarer fish (rainbow trout)	1 mg a.i/L	TER >100
	Freshwater invertebrates (daphnids-acute)	1 mg a.i/L	TER >100
	Single cell green algae	1 mg a.i/L	TER >100
Arthropods	Honey bee	160 mg a.i./crown[2]	Safety factor > 3000
	Ladybird beetle	160 mg a.i./crown[2]	No hazardous effect
	Lacewing larvae	160 mg a.i./crown[2]	No hazardous effect
	Parasitic hymenoptera: *Nasonia*	160 mg a.i./crown[2]	No hazardous effect
	Parasitic hymenoptera: *Aphidius*	1.6×10^6 mg a.i./ha	Effect <30%
	Predatory mites: *Typhlodromus pyri*	1.6×10^6 mg a.i./ha	Effect 30.7%

[1] the calculation is based on maximum application rate of Serenade WP (15 kg/ha) – see Chapter 3.1

[2] theoretical a.i. load per tree crown calculated on the basis of 1000 L/ha at 1% Serenade™ WP, i.e. 10 kg product containing 1 kg a.i. and 3000 trees/ha

IIM 9.3 Identification of precautions necessary to minimize environmental contamination and to protect non-target species

EU-Dossier: Doc M-IIB, Point 9

The submitted study reports and the risk assessment prove that the active ingredient of Serenade™ WP, *Bacillus subtilis*, is non-toxic and considering the expected environmental concentration non-hazardous to the tested aquatic and terrestrial species. Therefore, no hazard classification or specific labelling according to EC directive 67/548/EEC is required.

The comparison of predicted and tolerable exposure comply with the limit values set by the EC directive 91/414/EEC. Finally, any significant hazard effects in invertebrates and fish can be excluded. Thus, no precautions or restrictions are necessary concerning the application of Serenade™ WP.

References

No references are submitted in this dossier part.