BASELINE DOSSIER

Bacillus subtilis QST 713

Bacillus subtilis QST 713

Microbial pest control agent against plant pathogenic fingi and bacteria

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

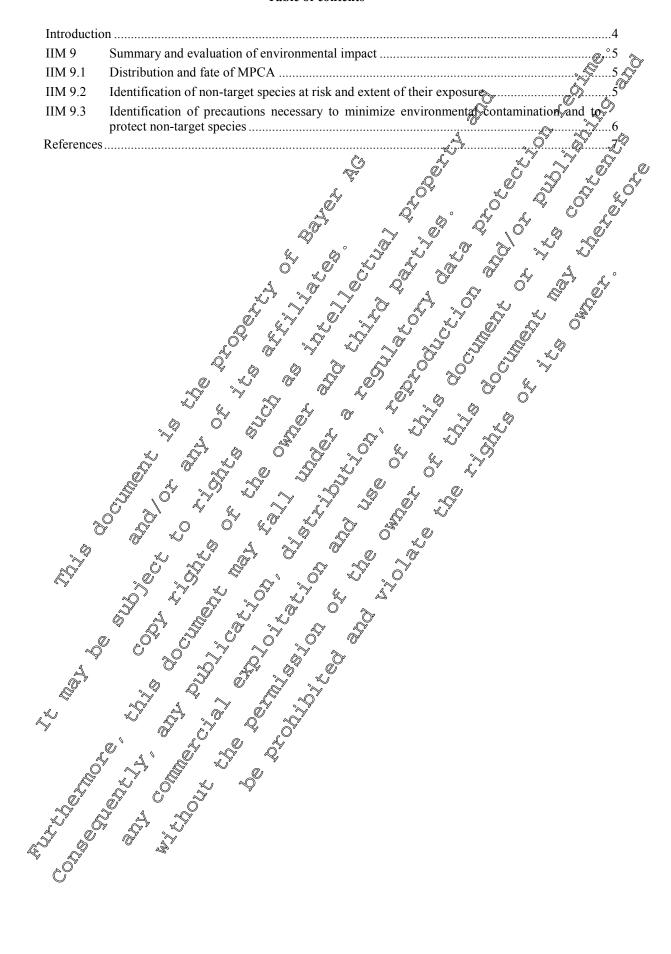
Summary documentation,

Point DM 9. Summary and evaluation of environmental impact

Applicant

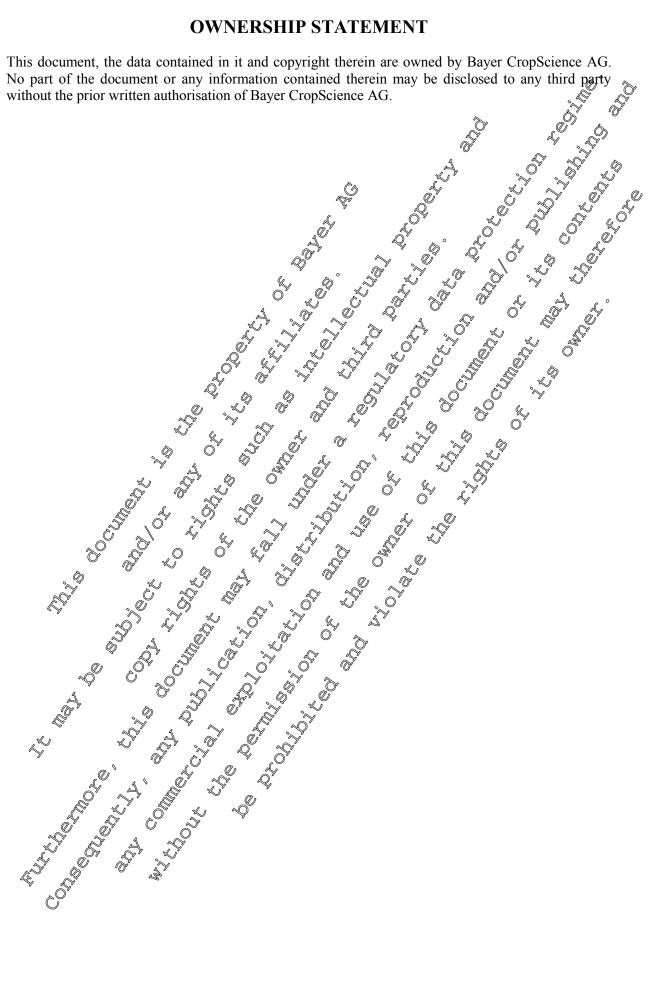
Bayer CropScience AG

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Introduction

as an active of submission (2006), and the submission of s tive essions of the second of THE STATE OF THE S

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 of fresh granic matter supply.
- B. subtilis is frequently occurring in different aquatic environments, and endespores have been detected in sediments and even in the open ocean However, B. Subtilism not reparted an autochthonous inhabitant of aquatic environments and does not find optimal conditions for growth, e.g. in waters poor in granic 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. substitus in the air, recrosols of clouds can be excluded due to law of organic matter supply lack of mineral matrix to adhere to and due to exposure to desiccation and UV-radiation.

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

EU-Dossier: Doc Malib, Point 9

is a viable anico compartment the temporary the temporary process which are introduced associated environments will at in the table below are based on the compartment of the compartmen Due to the fact that the active ingredient is a viable oricro-organism of up out our occurrence and predominance in many environmentancompartments the terms residue and residue metabolism are not applicable to B. Subtilis cells of spores which are introduced into the environment. Any dispersal of B. subtities into the soil of to associated environments will not affect the natural micro-flora and is

The values commarised in the table below are based on the submitted study reports and the evaluation as outlined in the summary report on prammation 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	ang a.i/L	TER NOO NOON O
Arthropods	Honey bee	160 mg a.i./crown ²	Safety factor > 3000
	Ladybird beetle	160 mg a.i. crowo?°	So hazafdous effect
	Lacewing larvae	o160 moa.i./crown ²	No hazardous effect
	Parasitic hymenoptera: Nasonia	160 ring a.i. Frown	No hazardous effect
	Parasitic hymenoptera, Aphidius	1.6 × 100° mg a 1.7 ha	Effects < 30%
	Predatory mites; Typhlogromus pyri	*Lo×10° mg a i Ana	Fiffect St. 7%, \$3

¹ the calculation is based on maximum application rate of Secondde W (15 kg) a) - see Chapter 3.1

IIM 9.3 Identification of precautions necessary to minimize environmental contamination and to protect not target species.

EU-Dossier: Doc M-LLB, Point S

The submitted study reports and the risk assessment prove that the active ingredient of SerenadeTM WP, *Bacillus subtilis*, is non-toxic and considering the expected environmental concentration non-pazardous to the tested aquate 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 directives 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 SerenadeTM WP.

² theoretical a.i. load per tree crown calculated on the basis of 2000 L/ba at 1% Serena T WP, i.e. 10 kg product containing 1 kg a.i. and 3000 trees/ha

References

