

Contans WG
(1×10^{12} CFU *Coniothyrium minitans*/kg)
Microbial pest control product against *Sclerotinia* spp.

Dossier according to OECD dossier guidance for microbial pest control agents and microbial pest control products – August 2006

Summary documentation, Tier II

Annex IIM, Section 4

Point IIM 8 – Rationale to waive residue studies on MPCP

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IIM 8 Residues in/on food and feed products for the Microbial Pest Control Product (rationale to waive residue studies on MPCP)

The applicants apply for a waiver for performing residue studies with Contans WG, based on the following considerations.

- *Coniothyrium minitans* strain CON/M/91-08 is of natural origin. Therefore, its application in control of *Sclerotinia spp.* means only a fluctuation of the population size in the biotope.
- The experience that contact of *C. minitans* with man or animals does not impose any risk for their health has been confirmed by acute toxicity studies (refer to Doc. M, Annex IIM, Section 3, Point 5).
- *Coniothyrium minitans* does not produce and accumulate toxins or secondary metabolites of toxicological concern (see Annex II, Section 1, Point IIM 2.6).
- Colonization of humans or warm-blooded animals does not occur as the strain does not grow at 33°C and above (see Annex II, Point IIM 2.8). No irritation or allergy associated to *C. minitans* strain CON/M/91-08 is known. Only single cases of *Coniothyrium* infections not related to *C. minitans* strain CON/M/91-08 have been reported for immune-suppressed patients. *C. minitans* is not regarded to have genotoxic potential.
- Due to the intended use as soil directed application with subsequent incorporation, drench or introduction via overhead irrigation into the soil, no deposit is likely to occur. As *C. minitans* is a poor survivor on the phylloplane, residues from accidental contamination of above-ground plant parts by splashes of soil drench solution are not relevant. *C. minitans* does hardly survive on plant tissue longer than two weeks and does not represent a health risk.
- *C. minitans* is unable to enter plant tissues, to infest them, or to multiply outside from *Sclerotinia spp.* sclerotia.
- The formulants present in Contans WG do not have any negative impact on the environment and will be rapidly degraded.

In conclusion, due to the lack of any toxicity potential to mammals and the low environmental concentration in soil predicted from maximum field use of Contans WG, residue data on Contans WG are considered not relevant.

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References

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