Dossier According to Directive 91/414/EEC

Requiem® EC (QRD 452)

Terpenoid blend (α-terpinene, p-cymene, d-limonene) QRD 460

Product for insect pest control developed from plant extracts of *Chenopodium ambrosioides* near *ambrosioides*

DOCUMENT MIII, Section 4

METABOLISM AND RESIDUE DATA

Please refer to Document M-II Section 4.

No specific residue studies on the plant protection product are required in addition to those submitted in Annex II on the active substance. The summary from Document M-II Section 4 is reproduced below.

IIIA 8.1 Summary and evaluation of residue behaviour; Reasonable grounds in support of the petition

IIIA 8.1.1 Summary and evaluation of residue behaviour

Crop residue trials have not been conducted in Europe. However, data are available from two GLP compliant trials conducted in California, one on outdoor grown tomatoes, the second on outdoor grown mustard greens. In addition supporting data are presented from a study with primrose conducted according to the principles of GLP but unaudited. Further, it is well known that the active substance rapidly volatilises ([redacted], 2011) and breaks down in air, which makes analytical detection after spray application difficult.

Results of the primrose, tomato and mustard green studies demonstrate that multiple applications of QRD 452 or the original plant extract product resulted in no detectable residues even shortly after application and no accumulation of residues over multiple applications.

As a result of this data, and the fact that all three terpenes in the active substance are naturally occurring in many plant species, it was reasonable to conclude that plant metabolism studies with the active substance was not necessary. Data presented clearly show natural occurrence of the terpenes in QRD 452 is ubiquitous and the plant protection use does not appear to contribute in any meaningful way. In addition, the active substance is not expected to enter the plants after application to any significant degree, therefore, it is not available to be metabolised in plants from this proposed pesticide use.

Due to the fact that all three terpenes in the QRD 460 active substance are naturally occurring, have been shown to dissipate rapidly in the environment by volatilization (see Section 5, Environmental Fate), and that the available studies clearly demonstrate there is no meaningful residue on crops shortly after application, no residue definition is proposed and QRD 452 should be exempted from the need for MRLs.

An ADI is not appropriate due to the safe profile of QRD 452, so it is reasonable to conclude that the standard consumer risk model is not necessary. Values identified from the WHO/FAO assessment of the three terpene components of QRD 452 as food additives further support that exposure from the proposed plant protection use is negligible.

Future crops on which QRD 452 may be applied should also be exempted from the need for specific residue studies.

IIIA 8.1.2 Reasonable grounds in support of the petition

No metabolism studies or further residue studies are required to conclude that the consumer risk from the plant protection use of QRD 452 gives negligible concern and is acceptable.

Exposure to humans from natural and other sources of the three constituent terpenes has been a reality for centuries and no concern is raised about their toxicity or exposure effects from known studies or anecdotal evidence.

Due to the lack of residues detected after application of the QRD 452 product, it is proposed that QRD 452 be exempted from the need to set MRLs.

This is in line with EU Regulatory conclusions regarding essential oils and plant extracts and consistent with other regulatory bodies.

Annex 1 listing can be supported without a requirement for further consideration of consumer risk.