

Evaluation Report for Category B, Subcategory 3.11 & 3.12 Application

Application Number: 2013-7116

Application: New or Changes to Product Labels-New Pests; New Site or Host

Product: Isomate OFM TT

Registration Number:

Active ingredients (a.i.): (E)-8-Dodecen-1-yl acetate, (Z)-8-Dodecen-1-ol, and (Z)-8-Dodecen-1-yl acetate

PMRA Document Number : 2419990

Purpose of Application

The purpose of this application was to register a new end-use product, Isomate OFM TT based on precedent products owned by the same applicant. Isomate OFM TT is an insect mating disruption pheromone intended for use on stone fruits and pome fruits to control the oriental fruit moth (*Grapholita molesta*) and the lesser apple worm (*Grapholita prunivora*).

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

Isomate OFM TT, a mixture of three straight chain lepidopteran pheromones (SCLPs), is considered to be of low acute toxicity by the oral, dermal, and inhalation routes, slightly irritating to the skin, minimally irritating to the eyes, and not a dermal sensitizer.

Isomate OFM TT contains formulants which are in currently registered end-use products for use on food crops at concentrations similar to those for Isomate OFM TT. Therefore, their inclusion in Isomate OFM TT is considered to be acceptable.

There were no contaminants of toxicological concern to human health identified in Isomate OFM TT.

The method of application is by attaching a slow release dispenser to the lateral branches of the trees. The amount of the active ingredient to be handled by an individual is calculated to be 62.96 to 125.91 g a.i./ha. Isomate OFM TT is applied once per year.

The label statements for Isomate OFM TT, coupled with the end-use product's low toxicity and negligible exposure, is considered adequate to address any potential risk due to exposure of the applicator.

The application of Isomate OFM TT near residential areas may result in the exposure of

residents to low levels of the pheromone by inhalation. It is not expected that the airborne concentration of the pheromone will pose a significant risk due to bystander exposure.

Neither a restricted entry interval (REI) nor a preharvest interval (PHI) was required for the application of Isomate OFM TT.

Since the method of application (retrievable, slow-release dispensers) is unlikely to contact crops and the released pheromone is not expected to result in significant concentrations above background concentrations, residues of toxicological concern in the diet or in drinking water are not expected.

Maximum Residue Limit

Oriental Fruit Moth Pheromone Technical, a mixture of three SCLPs, is currently registered in Canada but an established maximum residue limit (MRL) has not been assigned for the parent compounds and related metabolites, nor is one required.

Environmental Assessment

It is not expected that the use of Isomate OFM TT would result in any additional environmental risk given that the use pattern is the same as for currently registered precedent products. Environmental concerns have been mitigated through adequate statements on the product label.

Value Assessment

Two field trials demonstrated that Isomate OFM TT has value in disrupting male moths' response to pheromones and reducing subsequent larval damage. In addition, the new dispenser type is easier to apply and fewer dispensers per hectare are required compared to similar products already registered, thus reducing labour costs.

Conclusion

The PMRA has conducted a review of the available information in support of this new end-use product and has determined that full registration can be supported for Isomate OFM TT.

References

- 2376752 2013, Part 10, Value for Registration of an EP, DACO: 10.1, 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.3, 10.3.1, 10.3.2, 10.5.1, 10.5.2, 10.5.3, 10.5.4
- 2376772 2013, Comprehensive Data Summary Registration of an EP, DACO: 12.7
- 2376798 2013, Acute Toxicology Studies for Registration of an EP, DACO: 4.6,4.6.1,4.6.2,4.6.3,4.6.4,4.6.5,4.6.6
- 2376800 2013, Acute Toxicology Studies for Registration of an EP (CBI), DACO: 4.6, CBI
- 2376802 2013, Exposure Summaries (EP), DACO: 5.1, 5.2

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