

Evaluation Report for Category B, Subcategory 2.6, 3.11 and 3.12 Application

Application Number:	2008-1295
Application:	New end-use product – new combination of technical grade active ingredients, pests, site or host.
Product:	Isomate CM/OFM TT
Registration Number:	29352
Active ingredients (a.i.):	E,E-8, 10-Dodecadien-1-ol 1-Dodecanol 1-Tetradecanol Z-8-Dodecen-1-yl Acetate E-8 Dodecen-1-yl Acetate Z-8-Dodecen-1-ol
PMRA Document Number:	1771411

Purpose of Application

This is an application for the registration of the end-use product Isomate-CM/OFM TT (96.89 % guarantee), which contains a grouping of six separate straight-chained lepidopteran pheromones (SCLPs), for commercial use as a mating disruptant for the control of codling moth, oriental fruit moth and lesser appleworm in pome fruits, stone fruit, walnut and butternut.

Chemistry Assessment

Isomate CM/OFM TT contains six active ingredients, (*E,E*)-8,10-Dodecadien-1-ol (62.76%), 1-Dodecanol (9.92%), 1-Tetradecanol (2.00%), Z-8-Dodecen-1-yl Acetate (15.92%), *E*-8-Dodecen-1-yl Acetate (1.16%) and Z-8-Dodecen-1-ol (0.22%). This product has a specific gravity of 0.8702 at 25 °C and pH of 6.0. The chemistry requirements for Isomate CM/OFM TT are complete.

Health Assessments

Waivers were granted for the acute oral, dermal, and inhalation toxicities, primary eye irritation, primary skin irritation, and dermal sensitization for this group of SCLPs, which have been well characterized in the past. It is expected that all acute toxicities will be low, regardless of the route of administration, that the primary eye irritation will be minimal, the primary skin irritation will be slight to moderate, and that there will not be any dermal sensitization associated with the active ingredients.

Isomate-CM/OFM TT is contained in a slow release dispenser and positioned on a branch in the upper canopy of the tree, ensuring that risk due to exposure to the applicator, worker, and bystander is negligible. Therefore, occupational, bystander, and/or post-application exposure assessments were not considered necessary.

Based on the low toxicity of SCLPs in general, a food residue exposure assessment was not performed and a Maximum Residue Limit (MRL) not proposed.

Environmental Assessment

The environmental risk associated with the use of Isomate CM/OFM TT is expected to be minimal based on the following information: (i) Active ingredients in Isomate CM/OFM TT are part of the group of lepidopteran pheromones defined as SCLPs. SCLP is a well defined chemical group and available information has demonstrated that SCLPs pose minimal risk to the environment at volumes similar to naturally occurring concentrations (refer to PRO2002-02). (ii) Previous environmental review of some of the active ingredients in Isomate CM/OFM TT has indicated minimal risk to mammals, birds, and aquatic organisms (refer to the Decision Document for Isomate-C Plus Codling Moth Pheromone, E94-01). (iii) The active ingredients in Isomate CM/OFM TT are contained in polyethylene tubes, and therefore, minimal environmental exposure is expected.

Value Assessment

Efficacy was expected to be acceptable because the active ingredients in Isomate-CM/OFM TT were already registered in Canada for mating disruption of codling moth and oriental fruit moth, although they were not combined in a single product previously. Submitted efficacy data from operational trials in southern Ontario confirmed that Isomate-CM/OFM TT can effectively disrupt mating of codling moth and oriental fruit moth and limit fruit damage by these pests to negligible levels when used as part of an integrated pest management program. Isomate-CM/OFM TT is also expected to be effective for mating disruption of lesser appleworm because two of the compounds used as sex pheromones by the oriental fruit moth are also used as sex pheromones by the lesser appleworm.

Conclusion

The PMRA has completed an assessment of available information for Isomate CM/OFM TT and has found the information sufficient to a full registration.

References

PMRA Document Number	Reference
1579194	2008, Part 10, Value of an EP, DACO: 10.1, 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.3, 10.3.1, 10.5.1, 10.5.2, 10.5.3, 10.5.4
1632919	2004, Trap Catches – OFM Trials, DACO: 10.2.3.3(C)
1579192	2008, MSDS-Material Safety Data Sheets-Product, DACO: 0.9
1579210	2008, Part 3, Product Chemistry for Registration of an EP, DACO: 3.0 CBI
1579211	2008, CBI Reference to Parent Document, Part 3, Product Chemistry for Registration of an EP, DACO:3.0, 3.1.1, 3.1.2, 3.1.3, 3.1.4,3.2.1, 3.2.2,3.3.1, 3.3.2, 3.4.1,3.5.1, 3.5.10,3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.9 CBI
1704094	2009, MSDS - Material Safety Data Sheets - Components, DACO: 0.9.1
1704095	2009, MSDS - Material Safety Data Sheets - components, DACO: 0.9.1
1704096	2009, Name And Address of Formulation Plant, DACO: 3.1.2
1704097	2009, Manufacturers of Formulants; Description of Formulation Process, DACO: 3.2.1, 3.2.2 CBI
1579243	2008, Part 4, Acute Toxicology Studies of an EP, DACO: 4.6
1579275	2008, MSDS-Product, DACO: 0.9
1704094	2009, MSDS - MATERIAL SAFETY DATA SHEETS - COMPONENTS, DACO: 0.9.1
1704095	2009, MSDS - MATERIAL SAFETY DATA SHEETS - COMPONENTS, DACO: 0.9.1
1579209	2008, Comprehensive Data Summary of an EP, DACO: 12.7

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