Health Canada Santé Canada

Evaluation Report for Category B, Subcategory B.4.1 Application

Application Number: 2008-1718
Application: B.4.1 (Conversion to full registration without consultation)
Product: Ranman 400SC Agricultural Fungicide
Registration Number: 27984
Active ingredients (a.i.): Cyazofamid (CYF)
PMRA Document Number: 1768839

Purpose of Application

The purpose of this application is to convert Ranman 400SC Agricultural Fungicide (Reg. No. 27984) from conditional to full registration.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

There were no toxicology data requirements for this application.

The end-use product, Ranman 400SC Agricultural Fungicide, was assessed for potential risk to workers handling and applying the product, as well as to individuals conducting post-application activities. No unacceptable risk is expected when workers follow the label directions and wear the personal protective equipment identified on the label.

To support the full registration of Ranman 400SC Agricultural Fungicide, additional data regarding the enforcement method for analysis of cyazofamid and the metabolites in animal matrices were submitted. The enforcement analytical method for determination of cyazofamid and the metabolites is considered acceptable. Based on the expectation that no quantifiable residues are anticipated in livestock matrices as a result of the consumption of treated feed commodities, maximum residue limits (MRLs) will be established at the method limit of quantification (LOQ) (0.02 ppm) for milk, fat, meat and meat by-products of cattle, goat, horse and sheep. Residues of cyazofamid in livestock will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

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Maximum Residue Limit(s)

No quantifiable residues of cyazofamid are anticipated in livestock matrices. Based on the analytical method for cyazofamid in livestock, the MRLs at method LOQ to cover residues of cyazofamid at 0.02 ppm in milk, fat, meat and meat by-products of cattle, goat, horse and sheep will be established.

Environmental Assessment

The following environmental deficiencies were noted during the registration of the subject products:

1. The n-octanol-water partition coefficient (log K_{OW}) for CTCA, a transformation product of cyazofamid (DACO 8.2.1)
2. Terrestrial field dissipation study in Prince Edward Island (DACO 8.3.2)
3. Freshwater sediment toxicity study with chironomids (DACO 9.3.4)
4. Freshwater algal toxicity study with *Selenastrum capricornutum* (DACO 9.8.2)

The n-octanol-water partition coefficient study, the chironomid study and freshwater algal study has been submitted as part of a previous application and the terrestrial field dissipation (TFD) study in Prince Edward Island (P.E.I.) was submitted as part of this application. It has been determined that the data requirements have been fulfilled. The PMRA does not require additional environmental data to support the full registration of Ranman 400SC Agricultural Fungicide for use on potato, carrot and cucurbit vegetables.

The risk assessment of the most sensitive species and buffer zones have been updated to the current PMRA standards. Based on the data submitted by the registrant, it has been concluded that the level of concern is exceeded for terrestrial plants, amphibian, freshwater species such as fathead minnow, and marine/estuarine species such as Easter oyster when applied at rates specified in the Ranman 400 SC Agriculture Fungicide product label. To mitigate the identified risk to aquatic organisms and terrestrial plants, a one meter buffer zones is required.

Value Assessment

A value assessment was not required for this application.

Conclusion

Following the review of all available data, a MRL of 0.02 ppm is recommended to cover residues of cyazofamid in milk, fat, meat and meat by-products of cattle, goat, horse and sheep. Residues of cyazofamid in these commodities at the recommended MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

After reviewing all available information, the PMRA is able to support the full registration of Ranman 400 SC Agricultural Fungicide.

References

1102828 2005 Determination of n-Octano/Water Partition Coefficient. Document Number: IB-2005-JLW-007-01.

1102829 1999. Effects of IKF-916 on the Development of Sediment Dwelling Larvae of *Chironomus riparius* in a Water-Sediment System. Study Project No. 732058.

1102830 1997. Algal Growth Inhibition Test of IKF-916 Technical with *Selenastrum capricornutum*. Project No. E95-1599.

1600474 2008 Terrestrial field dissipation of Ranman 400SC, Hunter River, Prince Edward Island – Canada 2005. Document Number: IB-2005-JLW-006-01-01.

1600472 2008, Development and Validation of Methodology for the Analysis of Residues of IKF-916, CCIM, CCIM-AM, CCBA, CCBA-AM and the Cysteine Conjugate of CCBA in Beef Matrices, 018343, DACO: 7.2.2

1600473 2008, Independent Laboratory Validation (ILV) of the Residue Analytical Method for Detection of Cyazofamid and Degradates in Milk and Liver, 021872-1, MRID: NA, DACO: 7.2.3

ISSN: 1911-8082