Health Canada Santé Canada

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2021-0933
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data (PPIP) Policy – Equivalency/Data Compensation Assessment
Product: OSIM Plus
Registration Number: 34712
Active ingredients (a.i.): 2,4-D (present as 2-ethylhexyl ester) and Fluroxypyr (present as 1-methylheptyl ester)
PMRA Document Number: 3333784

Purpose of Application

The purpose of this application was to register OSIM Plus, a new herbicide end-use product to control post-emergence broadleaf weeds in spring wheat, durum wheat, winter wheat, and spring barley, based on a registered precedent product.

Chemistry Assessment

OSIM Plus is formulated as an emulsifiable concentrate containing fluroxypyr, present as 1-methylheptyl ester and 2,4-D, present as 2-ethylhexyl ester at concentrations of 90 g/L and 360 g/L, respectively. This end-use product has a density of 1.059 – 1.062 g/mL and pH of 3.68 (1% solution). The required chemistry data for OSIM Plus have been provided, reviewed and found to be acceptable.

Health Assessments

OSIM Plus was considered toxicologically equivalent to the precedent product; therefore, no toxiciology data were required. OSIM Plus is considered slightly acutely toxic via the oral route and of low acute dermal and inhalation toxicity. It is considered mildly irritating to the eyes and skin and is not considered a dermal sensitizer.

The requested use pattern of OSIM Plus, containing active ingredients 2,4-D, present as 2-ethylhexyl ester, and fluroxypyr, present as 1-methylheptyl ester, is comparable to the registered use pattern of the precedent product.

Therefore, potential exposure for mixers, loaders, applicators, bystanders and postapplication workers is not expected to exceed the current exposure to the registered products of these active ingredients. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.

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No new residue data for 2,4-D (present as 2-ethylhexyl ester) and fluroxypyr (present as 1-methylheptyl ester) were submitted or are required to support the registration of OSIM Plus. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the OSIM Plus label, including the target crops, method, rates and timing of application, geographic restrictions, preharvest intervals, feeding restrictions, and crop rotation restrictions are comparable to the precedent end-use product.

Based on this assessment, 2,4-D and fluroxypyr residues are not expected to be greater than that for the currently registered uses and will be covered by their respective established maximum residue limits (MRLs). Consequently, dietary exposure to residues of 2,4-D (present as 2-ethylhexyl ester) and fluroxypyr (present as 1-methylheptyl ester) is not expected to increase with the registration of OSIM Plus and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use of OSIM Plus will not pose any additional risks to the environment. The required environmental precautions statements and spray buffer zones to mitigate risks to the environment are included in the label. When used according to label directions, the environmental risks are acceptable for OSIM Plus.

Value Assessment

Registration of a generic product may increase product competition, which may in turn reduce purchasing costs of similar products.

The formulation of OSIM Plus was compared to the formulation of the cited precedent product. The differences between the two formulations were considered minor, which are unlikely to result in any significant impact on product performance, in terms of efficacy and/or crop tolerance. Data from the replicated field trials corroborated the conclusion from the formulation comparison. The agronomic equivalence between OSIM Plus and the cited precedent product was established. Therefore, all uses and claims found on the precedent product label are supported for inclusion on the OSIM Plus label subject to the required label amendments/updates.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of OSIM Plus.

References

PMRA Document Number	Reference
3206994	2021, Description of Process Formulation to 2,4-D 2-ethylhexyl ester 360 g/L (as acid) and Fluroxypyr 1-methylheptyl ester 90 g/L (as acid) EC Sharda, DACO: 3.2,3.2.1,3.2.2,3.2.3 CBI
3206997	2021, Product Identification OSIM Plus, DACO: 3.0,3.1,3.1.1,3.1.2,3.1.3,3.1.4,3.2.3,3.5.13,3.5.15,3.5.16,3.5.4,3.5.5, CBI
3206998	2018, Determination of Flash Point of Fluroxypyr 90 g a.e./L (as Meptyl Ester) + 2,4-D 360 g.a.e./L (as EHE) EC, DACO: 3.5.11 CBI
3206999	2018, Determination of Auto Ignition Temperature of Fluroxypyr 90 g a.e./L (as Meptyl Ester) + 2,4-D 360 g.a.e./L (as EHE) EC, DACO: 3.5.11 CBI
3207000	2018, Determination of Explosive Properties of Fluroxypyr 90 g a.e./L (as Meptyl Ester) + 2,4-D 360 g.a.e./L (as EHE) EC, DACO: 3.5.12 CBI
3207001	2018, Determination of Relative Density of Fluroxypyr 90 g a.e./L (as Meptyl Ester) + 2,4-D 360 g.a.e./L (as EHE) EC, DACO: 3.5.6 CBI
3207002	2018, Oxidation/Reduction: Chemical Incompatibility of Fluroxypyr 90 g a.e./L (as Meptyl Ester) + 2,4-D 360 g.a.e./L (as EHE) EC, DACO: 3.5.8 CBI
3207003	2019, Determination of Viscosity of Fluroxypyr 90 g a.e./L (as Meptyl Ester) + 2,4-D 360 g.a.e./L (as EHE) EC, DACO: 3.5.9 CBI
3207005	2021, Accelerated Storage Stability Test by Heating at Elevated Temperature of Fluroxypyr 90 g a.e./L (as Meptyl Ester) + 2,4-D 360 g.a.e./L (as EHE) EC, DACO: 3.4,3.4.1,3.5,3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.7,3.7 CBI
3207006	2016, Efficacy, Phytotoxicity andYield Protocol for Sharda Cropchem Ltd. Generic Herbicides on Barley, DACO: 10.2.3, 10.2.3.2(B), 10.3.
3207007	2016, Efficacy, Phytotoxicity and Yield Protocol for Sharda Cropchem Ltd. Generic Herbicides on Barley, DACO: 10.2.3, 10.2.3.2(B), 10.3.