

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2021-5127
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data Policy - Equivalency/ Data Compensation
Product: FBN MCPA Ester 600 EC
Registration Number: 34973
Active ingredient (a.i.): MCPA (present as esters)
PMRA Document Number: **3414276**

Purpose of Application

The purpose of this application was to register FBN MCPA Ester 600 EC based on precedent registrations, for control of broadleaf weeds in wheat, barley, rye, oats, flax, pastures, roadside, and non-cropland areas.

Chemistry Assessment

FBN MCPA Ester 600 EC is formulated as an emulsifiable concentrate containing MCPA (present as 2-ethylhexyl ester) at a concentration of 600 g/L. This end-use product has a density of 1.06 – 1.07 g/mL and pH of 3.61 – 4.27. The required chemistry data for FBN MCPA Ester 600 EC have been provided, reviewed and found to be acceptable.

Health Assessments

FBN MCPA Ester 600 EC was considered toxicologically equivalent to the precedent products; therefore, no toxicology data were required. FBN MCPA Ester 600 EC is considered to be of moderate acute toxicity by the oral route, and low acute toxicity by the dermal and inhalation routes. It is considered to be minimally irritating to the eyes, slightly irritating to the skin and is not considered to be a dermal sensitizer.

The use pattern of FBN MCPA Ester 600 EC is comparable to the registered use pattern of the precedent products. Therefore, potential exposure for mixers, loaders, applicators, bystanders and postapplication workers is not expected to exceed the current exposure to the registered products of this active ingredient. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.

No new residue data for MCPA were submitted or are required to support the registration of FBN MCPA Ester 600 EC. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the FBN MCPA Ester 600 EC label, including the target crops, method (ground or aerial), rates and timing of application, geographic restrictions, preharvest intervals, feeding restrictions, and crop rotation restrictions are comparable to those on the label of the precedent end-use products.

Based on this assessment, residues are not expected to be greater than those from the currently registered uses and will be covered by the established maximum residue limits. Consequently, dietary exposure to residues of MCPA is not expected to increase with the registration of FBN MCPA Ester 600 EC 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 FBN MCPA Ester 600 EC will not pose any additional risks to the environment. The required environmental precautionary 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 FBN MCPA Ester 600 EC.

Value Assessment

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

The formulation of FBN MCPA 600 EC was compared to the formulation of the cited precedent products. The differences between the formulations were considered minor and are unlikely to result in any significant impact on product performance, in terms of efficacy and/or crop tolerance. Therefore, uses and claims found on the precedent product labels are supported for inclusion on the FBN MCPA Ester 600 EC label.

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 FBN MCPA Ester 600 EC.

References

PMRA Document Number	References
3271256	2021, Manufacturing Process Of MCPA Ester 600g/L EC, DACO: 3.2.1,3.2.2 CBI
3271257	2021, Manufacturing Process MCPA-2-ethylhexyl ester 600g/L EC, DACO: 3.2.1,3.2.2 CBI
3271261	2021, Validation of Analytical Method for MCPA-2-ethylhexyl ester, DACO: 3.4.1
3271262	2021, Determination of Physical State of MCPA-2-ethylhexyl ester 600 g/L EC, DACO: 3.5.2
3271263	2021, Determination of Colour of MCPA-2-ethylhexyl ester 600 g/L EC, DACO: 3.5.1
3271264	2021, Determination of Odour of MCPA-2-ethylhexyl ester 600g/L EC, DACO: 3.5.3
3271265	2021, Determination of Density and Specific Gravity of MCPA-2-ethylhexyl ester 600 g/L EC, DACO: 3.5.6
3271267	2021, Determination of Oxidizing/Reducing Properties of MCPA-2-ethylhexyl ester 600 g/L EC, DACO: 3.5.8
3271268	2021, Determination of Viscosity of MCPA-2-ethylhexyl ester 600 g/L EC, DACO: 3.5.9
3271269	2021, Determination of Accelerated Storage Stability of MCPA-2-ethylhexyl ester 600 g/L EC, DACO: 3.5.10
3271270	2021, Determination of Flash Point of MCPA-2-ethylhexyl ester 600 g/L EC, DACO: 3.5.11
3271271	2021, Determination of Explosive Properties of MCPA-2-ethylhexyl ester 600 g/L EC, DACO: 3.5.12
3271272	2021, Determination of Miscibility of MCPA-2-ethylhexyl ester 600 g/L EC in Water and Organic Solvents, DACO: 3.5.13
3271273	2021, Determination of Corrosion Characteristics of MCPA-2-ethylhexyl ester 600 g/L EC with Packaging Material, DACO: 3.5.14
3271274	2021, Physico-chemical Properties of MCPA Ester 600 EC, DACO: 3.4.1,3.5.1,3.5.10,3.5.11,3.5.12,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9
3405000	2022, Manufacturing Process Of MCPA Ester 600g/L EC, DACO: 3.2.1,3.2.2 CBI
3405001	2022, Manufacturing Process MCPA 2-ethylhexyl ester 600 g/L EC, DACO: 3.2.1,3.2.2 CBI

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