

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number:	2019-3338
Application:	Submission subject to the Protection of Proprietary Interests in
	Pesticide Data (PPIP) policy
Product:	MEDIA MCPA Ester 600
Registration Number:	34293
Active ingredient (a.i.):	MCPA (present as esters)
PMRA Document Number: 3145335	

Purpose of Application

The purpose of this application was to register the new end-use product MEDIA MCPA Ester 600 based on a registered precedent.

Chemistry Assessment

MEDIA MCPA Ester 600 is formulated as an emulsifiable concentrate containing MCPA, present as 2-ethylhexyl ester at a concentration of 600 g a.e./L. This end-use product has a density of 1.06 g/mL and pH of 3 - 4. The required chemistry data for MEDIA MCPA Ester 600 have been provided, reviewed and found to be acceptable.

Health Assessments

MEDIA MCPA Ester 600 was considered toxicologically equivalent to the precedent product; therefore, no toxicology data are required. MEDIA MCPA Ester 600 is considered to be of moderate acute toxicity via the oral route, and of low acute toxicity via 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 of MEDIA MCPA Ester 600 on wheat, barley, rye, oats, flax, pastures, roadside and non-cropland areas is not expected to result in potential occupational or bystander exposure over the registered uses of MCPA. No risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

No new residue data for MCPA were submitted to support the registration of MEDIA MCPA Ester 600. Previously reviewed residue data on MCPA were reassessed in the framework of this petition. The dietary exposure assessments on file are considered adequate to cover the residues of MCPA expected from the use of this new product. No health risks of concern have been identified for any segment of the population including infants, children, adults and seniors.



Environmental Assessment

The uses are within the currently registered use pattern of the active ingredient MCPA present as esters. The label includes the required environmental precautions and hazards statements. Therefore, the risks to the environment from the registration of MEDIA MCPA Ester 600 are acceptable when it is used according to label directions.

Value Assessment

The availability of MEDIA MCPA Ester 600 will provide users with another option to control broadleaf weeds in small grain cereals, flax, pastures, roadside, and non-cropland areas. Registration of a generic product may increase product competition, which may in turn reduce purchasing costs of similar products.

The formulation of MEDIA MCPA Ester 600 was compared to the formulations of the cited precedent product. The differences between the formulations are unlikely to result in any significant impact on product performance, in terms of both efficacy and crop tolerance. The agronomic equivalence between MEDIA MCPA Ester 600 and the cited precedent product can be established. Therefore, all uses and claims found on the precedent product label are supported for inclusion on the MEDIA MCPA Ester 600 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 MEDIA MCPA Ester 600.

References

PMRA Document	Reference
Number	
3011756	2019, Product identity, DACO: 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2.3, 3.5.12,
	3.5.15 CBI
3011757	2019, Formulation Process, DACO: 3.2, 3.2.1, 3.2.2 CBI
3011758	2018, MCPA Acid 600 g/L EC Method Validation for determination of
	the active substance content and relevant impurity [CBI Removed],
	DACO: 3.4, 3.4.1 CBI
3011759	2018, MCPA Acid 600 g/L EC Part I: Physicochemical properties
	evaluation of the initial preparation and after accelerated storage [CBI
	Removed], DACO: 3.5, 3.5.10, 3.5.14, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6,
	3.5.7, 3.5.9

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