

Evaluation Report for Category B, Subcategory 2.3, 2.4 Application

Application Number: 2016-1464
Application: New End-Use Product Chemistry – Identify and Proportion of Formulants
Product: Mester 480SC Herbicide
Registration Number: 33632
Active ingredients (a.i.): Mesotrione
PMRA Document Number : 2788805

Purpose of Application

The purpose of this application was to register Mester 480SC Herbicide based on a precedent product.

Chemistry Assessment

Mester 480SC Herbicide is formulated as a suspension concentrate containing mesotrione at a nominal concentration of 480 g/L. This end-use product has a density of 1.16 g/cm³ and pH of 3.26. The required chemistry data for Mester 480SC Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

The product is considered toxicologically equivalent to the precedent product. No toxicological data were submitted or are required.

The use of Mester 480SC Herbicide on field, seed, and sweet corn, MGI tolerant soybeans, mesotrione tolerant soybeans, flax, cranberry, asparagus (established), blueberry, rhubarb, pearl millet, sorghum and turf is not expected to result in potential occupational or bystander exposure over the registered use of mesotrione. No health risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

No residue data for mesotrione were submitted to support the registration of Mester 480SC Herbicide. The use pattern on the Mester 480SC Herbicide label (including the target crops, application rates, timing and number of application, pre-harvest intervals and tank-mix partners) is identical to the registered use pattern on the label of the precedent product. The minor changes in the formulation of Mester 480SC Herbicide are not expected to significantly impact the residues in/on the treated crops. Therefore, residues of mesotrione in/on treated crops are not expected to increase and will be covered under the maximum residue limits (MRLs) established for mesotrione. Consequently, the dietary exposure to residues of mesotrione is not expected to increase with the registration of the end-use product and will not pose health risk of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

Mester 480SC Herbicide is an end-use product containing mesotrione as the technical active. As the crops, application rates and method of application for Mester 480SC Herbicide are identical as those currently registered for the precedent product, the use of Mester 480SC Herbicide is not expected to pose additional environmental concerns.

Value Assessment

The availability of Mester 480SC Herbicide would provide users an alternative option to control broadleaf weeds in an array of crops. Registration of a generic product may increase product competition in the marketplace thereby potentially reducing purchasing costs of similar products.

The formulation of Mester 480SC Herbicide was compared to the formulation of the cited precedent product. It was concluded that differences in the formulations were unlikely to result in any significant impact on product performance, in terms of both efficacy and crop tolerance.

Conclusion

The PMRA completed an assessment of the available information and found it sufficient to support the registration of Mester 480SC Herbicide.

References

| PMRA Document Number | References |
|----------------------|--|
| 2630913 | 2015, Accelerated Storage Stability and Corrosion Characteristics of Mesotrione 40% (w/w) SC, DACO: 3.5.10,3.5.14 |
| 2630914 | 2015, Physical and Chemical Characteristics of Mesotrione 40% (w/w) SC, DACO: 3.5.1,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9 |
| 2630915 | 2016, Additional Product Chemistry for Mester Herbicide, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.4.1,3.4.2,3.5.11,3.5.12,3.5.13,3.5.15,3.5.4,3.5.5 |
| 2630916 | 2016, Additional Product Chemistry for Mester Herbicide, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.4.1,3.4.2,3.5.11,3.5.12,3.5.13,3.5.15,3.5.4,3.5.5 CBI |
| 2630907 | 2016, Description of Process Formulation to Mester Herbicide (Mesotrione 480 g/L SC), DACO: 3.2.1,3.2.2,3.2.3,3.3.1 CBI |
| 2672178 | 2016, Mesotrione 480 g/L SC: Validation of the Analytical Method for the Determination of the Active Ingredient Content, DACO: 3.4.1 |

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