

Evaluation Report for Category B, Subcategory 2.3, 2.4 Application

Application Number: 2006-2402
Application: Change in the identity and proportion of formulants
Product: Aatrex Liquid 480 Agricultural Herbicide
Registration Number: 18450
Active ingredients (a.i.): Atrazine and related triazines at 480 g/L
PMRA Document Number: 1424068

Background

Aatrex Liquid 480 Herbicide is currently registered for pre-plant incorporated, pre-emergence and post-emergence control of weeds in corn. Refer to the product label for specific details of use, including registered tank mix partners, application rates and methods, precautions, restrictions, and protective equipment requirements.

All end-use products containing atrazine are currently under re-evaluation.

Purpose of Application

The purpose of this submission is to amend the proportion and identity of formulants for Aatrex Liquid 480 Agricultural Herbicide.

Chemistry Assessment

Aatrex Liquid 480 Herbicide is a solution containing the active ingredient atrazine plus related triazines at a nominal concentration of 480 g/L. This product has a density of 1.104 g/mL and pH of 5.0. The chemistry requirements for Aatrex Liquid 480 Herbicide are complete.

Health Assessments

Residues of atrazine on corn resulting from the alteration of the formulation of Aatrex Liquid 480 Agricultural Herbicide are expected to be covered by the 0.1 ppm General Regulations (Table II, Division 15 of the Food and Drugs Act and Regulations), since the changes do not affect the application rates or use pattern. The change in the identity and proportion of formulants in this product is not expected to result in an increase in dietary exposure and, therefore, will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

The formulation changes are minor and are not expected to significantly change the toxicity profile of this product.

Also, minor formulation changes will not result in a change in handler or post application exposure of risk compared to the previously registered formulation.

Environmental Assessment

The formulation changes are minor and do not affect the guarantee of the active ingredient or the application rate, and therefore, will not result in an increase in environmental risk compared to the previously registered formulation.

Value Assessment

The applicant submitted a waiver request for Part 10 data stating that the changes in the formulation will not impact the efficacy of or crop tolerance to Aatrex Liquid 480 Herbicide. The PMRA agrees that the formulation changes are minor and would not likely lead to a change in agronomic performance.

Conclusion

The PMRA has completed an evaluation of this application and has found the information sufficient to support the changes in the identity and proportion of formulants in Aatrex Liquid 480 Herbicide.

References

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

METHOD OF ANALYSIS

- PMRA 1184403 Aatrex Liquid 480 Herbicide (A8566A) - Product Identification, DACO 3.1.1, 3.1.2, 3.1.3, and 3.1.4.
- PMRA 1184405 Manufacturing Process, DACO 3.2.2.
- PMRA 1184406 Discussion of Formation of Impurities and Quality Control Statement, DACO 3.2.3.
- PMRA 1184407 Aatrex Liquid 48- Herbicide (A8556A) - Establishing Certain Limits, DACO 3.3.1.
- PMRA 1184409 Analytical Method SF-76-1 - Atrazine (G30027) in Formulation A8566A, DACO 3.4.1.
- PMRA 1184410 Final Report: A8566A - Validation of Analytical Method SF-76/1, DACO 3.4.1.
- PMRA 1184411 A8566A: Color, Physical State and Odor, DACO 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, and 3.5.9.
- PMRA 1184413 Final Report - Density, DACO 3.5.6.
- PMRA 1184414 Final Report - pH, DACO 3.5.7.
- PMRA 1184415 Oxidizing Properties, DACO 3.5.8.
- PMRA 1184416 Final Report - Viscosity, DACO 3.5.9.
- PMRA 1184417 Final Report - Storage Stability, DACO 3.5.10.
- PMRA 1184418 Flash Point, DACO 3.5.11.
- PMRA 1184419 Explosive Properties, DACO 3.5.12.
- PMRA 1184420 Corrosion Characteristics after Storage for 1 Year at 20°C, DACO 3.5.14.
- PMRA 1303065 Aatrex Liquid 480 Herbicide Response to Sept. 8, 2006 Clarifax - Manufacturing Method Information, DACO 3.2.2.

PMRA 1303066 Aatrex Liquid 480 Herbicide Response to Sept. 8, 2006 Clarifax - Storage Stability, DACO 3.5.10.

PMRA 1184404 Aatrex Liquid 480 Herbicide (A8566A) Starting Materials, DACO 0.9 and 3.2.1.

VALUE

PMRA 1262004 AATREX® Liquid 480 Herbicide Rationale in Support of a Request for a Waiver from the Provision of Part 10 Data, 1pp. DACO 10.2.3.1, 10.2.3.2, 10.2.3.3, and 10.2.3.4.

B. ADDITIONAL INFORMATION CONSIDERED

None.

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