

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.1 Application

Application Number: 2013-0311
Application: New End Use Product
Product: Clethodim 360EC Herbicide
Registration Number: 31496
Active ingredients (a.i.): Clethodim
PMRA Document Number: 2359306

Purpose of Application

The purpose of this application was to register the end use product Clethodim 360EC Herbicide. The use pattern for the new end use product falls within the currently registered use pattern for the active ingredient, clethodim.

Chemistry Assessment

Clethodim 360EC Herbicide is formulated as an emulsifiable concentrate containing clethodim at a nominal concentration of 360 g/L. This end-use product has a density of 0.9800-0.9871 g/mL and pH of 3.96. The chemistry data requirements for this product have been fulfilled.

Health Assessments

Clethodim 360EC Herbicide is of low acute toxicity to rats via the oral ($LD_{50\text{♀}} = 3129 \text{ mg/kg bw}$), dermal ($LD_{50\text{♂♀}} = 5050 \text{ mg/kg bw}$) and inhalation ($LC_{50\text{♂♀}} = 2.23 \text{ mg/L}$) routes. It is mildly irritating to the eyes and minimally irritating to the skin of rabbits. It is not a dermal sensitizer in guinea pigs.

The use of Clethodim 360EC Herbicide on canola, flax, field pea, lentil, chickpea, dry onions, potato, yellow mustard, oriental mustard, soybean, seedling alfalfa, sunflower, dry bean, highbush blueberry, fenugreek, coriander, spinach and prairie carnation is not expected to result in potential occupational or bystander exposure over the currently registered use pattern of clethodim. No risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

Clethodim is currently registered for use on seedling alfalfa, dry common beans, highbush blueberry, canola, chickpeas, coriander, fenugreek, flax, field peas, lentils, oriental (brown) mustard (condiment and oilseed types), yellow mustard, dry onions, potatoes, prairie carnation, soybeans, spinach and sunflowers with a similar use pattern and restrictions as on the Clethodim 360EC Herbicide label. No increase in dietary exposure to clethodim is expected. The resulting residues will be covered under the established MRLs for clethodim, including metabolites containing the 2-cyclohex-1-enone moiety, and will not pose an unacceptable health risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

Additional environmental data were not required to support Clethodim 360EC Herbicide. Environmental exposure to clethodim as a result of the registration is expected to be similar to that associated with the currently registered use pattern.

Value Assessment

To support the application, information was provided on the precedent product, Select Herbicide, and also provided twenty-one (21) bridging trials that were conducted in the Prairie Provinces (Alberta, Saskatchewan and Alberta) and in North Dakota in 2009 and 2012 to demonstrate equivalency between Clethodim 360EC Herbicide and the Select Herbicide (Reg. No. 28891) formulation of clethodim. All trials were conducted post-emergence in various broadleaf crops and in all trials, Clethodim 360EC Herbicide was applied and directly compared to the registered Select Herbicide formulation. Results indicate a comparable performance and a comparable level of injury among all formulations.

The information provided indicates that Clethodim 360EC Herbicide is agronomically equivalent to the Select Herbicide formulation of clethodim. Therefore, all the uses and claims that are currently registered on the Select Herbicide are supported for Clethodim 360EC Herbicide. It has been determined that the registration of Clethodim 360EC Herbicide is supported from a value perspective and would provide growers with a higher concentrated formulation of clethodim that reduces the amount of volume that needs to be transported to treat equivalent number of hectares when compared to Select Herbicide formulated at 240 g ai/L.

Conclusion

PMRA has reviewed information provided in support of the new end use product as described above. Based on this review, the new end use product, Clethodim 360EC Herbicide, is acceptable for full registration.

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