Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.6, 3.1 and 3.2 Application

Application Number: 2008-1728
Application: New combination of technical active grade ingredients, an increase in application rate and change in application timing.
Product: 18284 Herbicide
Registration Number: 29367
Active ingredients (a.i.): Pyrasulfotole, Bromoxynil and Fenoxaprop-p-ethyl
PMRA Document Number: 1773416

Purpose of Application

The purpose of this application is to register a new end-use product, 18284 Herbicide, a co-formulation of the registered active ingredients Bromoxynil Mixed Ester Solution 60% Manufacturing Concentrate (Registration Number 24404) and Fenoxaprop-p-ethyl Technical Herbicide (Registration Number 21903), and the conditionally registered active ingredient Pyrasulfotole Technical Herbicide (Registration Number 28737). 18284 Herbicide is proposed for post-emergent use on spring wheat, durum wheat and spring barley to be applied once a season via ground or aerial application.

Chemistry Assessment

18284 Herbicide is formulated as an emulsifiable concentrate containing pyrasulfotole, bromoxynil (present as mixed octanoate and heptanoate esters), and fenoxaprop-p-ethyl at the nominal concentrations of 15.5 g/L, 87.5 g/L and 46 g/L, respectively. This end-use product has a density of 1.0356 g/mL and a pH of 6.35 (10% suspension). With the exception of the storage stability study (and corrosion characteristics) that is currently in progress, the chemistry requirements for 18284 Herbicide are complete.

Health Assessments

18284 Herbicide exhibits slight acute oral (LD_{50}♀ = 1105 mg/kg) and low acute dermal (LD_{50} ♂♀> 2000 mg/kg) and inhalation (LC_{50}♂♀ >2.02mg/L) toxicity in rats. It is corrosive to the eye with a persistence up to 21 days (MAS = 63.32/110), and moderately irritating (MAS= 4.1/8.0) to the skin of the rabbit. It is a dermal sensitizer in the guinea pig using the Ritz and Buehler method.

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No new residue data were required to support the registration of 18284 Herbicide on spring wheat, durum wheat and spring barley, since all three active ingredients in this co-formulation, pyrasulfotole, bromoxynil and fenoxaprop-p-ethyl, are currently registered for use in Canada as a tank-mix with similar application rates and conditions of use as 18284 Herbicide. Residues of pyrasulfotole resulting from the use of 18284 Herbicide are expected to be covered by the established maximum residue limits (MRLs) on wheat and barley. Residues of bromoxynil and fenoxaprop-p-ethyl are expected to remain covered by the 0.1 ppm as specified in subsection B.15.002(1) of Division 15 of the Food and Drugs Regulations. The increased application rate of the safener mefenpyr-diethyl in the 18284 Herbicide formulation is not expected to affect the residues of the active ingredients on treated crops.

Since there is no expansion of the registered use patterns of the active ingredients, and the most restrictive directions for use are respected, the use of 18284 Herbicide on spring and durum wheat and spring barley is not expected to impact the magnitude of the residues of pyrasulfotole, bromoxynil and fenoxaprop-p-ethyl in/on these commodities. Therefore, no increase in dietary exposure is anticipated.

The proposed use pattern of 18284 Herbicide fits within the existing use pattern for bromoxynil, fenoxaprop-P-ethyl, and pyrasulfotole, with the exception of the regional application restrictions for some proposed crops. Exposure to workers handling the product, are not expected to increase over the currently registered use pattern for the active ingredients when all label precautions are adhered to.

Environmental Assessment

The use pattern for 18284 Herbicide is comparable to that of the conditionally registered end-use product Infinity Herbicide (Registration Number 28738) when used in a tank mix with Puma 120 Super (Registration Number 25864), in that the use is for similar crops, same application rate and application method. It is therefore not expected that the use of 18284 Herbicide will pose an additional environmental risk. Buffer zones and environmental label statements were reviewed.

Value Assessment

The data from 17 small plot field trials were submitted in support of the new end-use product, 18284 Herbicide. These efficacy and crop tolerance trials were all conducted in 2007 in Alberta, Saskatchewan and Manitoba, on spring wheat, durum wheat, and spring barley. The data submitted for review support the registration of 18284 Herbicide from a value perspective.

Conclusion

The PMRA has completed an assessment of available information for 18284 Herbicide and, based on the conditional status of the active ingredient Pyrasulfotole Technical Herbicide (Registration Number 28737), has found the information sufficient to support a conditional registration for 18284 Herbicide.

References

PMRA Document Number	Reference
1600832	2008, 18284 Herbicide Part 3, 08030DC, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.3.1, 3.5.1, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15 CBI
1600834	2008, Product Chemistry of Wolverine Total, M-297890-01-1, DACO: 0.9.1, 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.4.1 CBI
1722304	2009, Statement of Product Specification Form (SPSF) – Basic formulation dated 2009-02-12, DACO 0.1.6003 CBI
1722305	2009, Statement of Product Specification Form (SPSF) – Alternate formulation dated 2009-02-12, DACO 0.1.6003 CBI
1600827	2007, 18284 Herbicide – Part 10 Value. DACO 10.1, 10.2.3.1, 10.2.3.3(B), 10.3.1, 10.3.2(A)
1600838	2008, Acute Oral Toxicity Up and Down Procedure in Rats, DACO: 4.6.1
1600841	2008, Acute Dermal Toxicity Study in Rats - Limit Test, DACO: 4.6.2
1600843	2008, Acute Inhalation Toxicity Study in Rats - Limit Test, DACO: 4.6.3
1600845	2008, Primary Eye Irritation Study in Rabbits, DACO: 4.6.4
1600848	2008, Primary Skin Irritation Study in Rabbits, DACO: 4.6.5
1600849	2008, Dermal Sensitization Study in Guinea Pigs (Buehler Method), DACO: 4.6.6

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