Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2019-5622
Application: New EP Product Chemistry-New Combination of Technical Grade Active Ingredients
Product: Smoulder
Registration Number: 33943
Active ingredients (a.i.): Saflufenacil and Metsulfuron-methyl
PMRA Document Number :3163419

Purpose of Application

The purpose of this application was to register a new end use product, Smoulder, for pre-seed and post-harvest treatment to wheat (spring, durum, and winter) and barley to control of several broadleaf weeds and to provide soil residual activity to suppress secondary flushes of volunteer canola.

Chemistry Assessment

Smoulder is formulated as a water dispersible granule containing saflufenacil at a concentration of 64.6% and metsulfuron-methyl at a concentration of 5.40%. This end-use product has a density of 0.537 g/mL and pH of 6.3-7.5. The required chemistry data for Smoulder have been provided, reviewed and found to be acceptable.

Health Assessments

Smoulder is of low acute toxicity via the oral, dermal, and inhalation routes of exposure in rats. It is mildly irritating to the eyes and slightly irritating to the skin in rabbits. Smoulder is negative for dermal sensitization in mice.

The use of Smoulder on barley and wheat (durum, spring and winter) to control various weeds is not expected to result in potential occupational or bystander exposure over the registered use of metsulfuron-methyl or saflufenacil. No health 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 metsulfuron-methyl or saflufenacil in wheat and barley were submitted to support the new combination of these active ingredients on the Smoulder label. Previously reviewed residue data from field trials and processing studies conducted in/on wheat and barley, as well as rotational crop data were reassessed in the framework of this petition. Based on this assessment, residues of metsulfuron-methyl and saflufenacil in/on treated wheat and barley commodities, and animal commodities, are not expected to increase and will be covered under the established maximum residue limits for metsulfuron-methyl and saflufenacil. Consequently, the dietary exposure to residues of metsulfuron-methyl and saflufenacil is not expected to increase and will not pose health risks of concern to any segment of the

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population, including infants, children, adults and seniors.

Environmental Assessment

Use of Smoulder is not expected to increase the environmental risks of metsulfuron-methyl or saflufenacil when used in accordance with label directions.

Value Assessment

The registration of Smoulder will provide farmers with an additional option for burndown control of certain broadleaf weeds in the early field season with soil residual activity to suppress secondary flushes of volunteer canola in Western Canada.

Value information submitted for review consisted of scientific rationales, precedent registrations, and data from field trials conducted in the Canadian Prairies between 2016 and 2019. This information demonstrated that Smoulder provided more consistent burndown control of weeds labelled for saflufenacil alone at the same rate and suppression of secondary flushes of volunteer canola labelled for saflufenacil alone at higher rates.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found it sufficient to support the registration of Smoulder.

References

PMRA Document Number	Reference
3038148	2019, BAS 807 00 H WG Group A - Product Identity, Composition and Analysis, DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1 CBI
3038149	2019, GLP Validation of Analytical Method AFR0153/01 and Certification of BAS 807 00 H Lot 1791-99, DACO: 3.4.1
3038150	2019, Method # AFR0153/01: Determination of Saflufenacil (BAS 800 H) and Metsulfuron-methyl (BAS 9108 H) Content in BAS 807 H WG Formulation by Reverse-Phase HPLC Using UV Detection, DACO: 3.4.1
3038151	2019, Determination of Physical/Chemical Properties of BAS 807 00 H: Accelerated Storage Stability and Corrosion Characteristics in Commercial Type Containers, DACO: 3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7
3038152	2019, Viscosity, DACO: 3.5.9
3038153	2019, Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008), DACO: 3.5.11, 3.5.12
3038154	2019, Miscibility of BAS 807 00 H, DACO: 3.5.13
3038155	2019, Dielectric Breakdown Voltage - BAS 807 00 H, DACO: 3.5.15
3038156	2019, Formulation Type of BAS 807 00 H, DACO: 3.5.4

3038157	2019, Container Material and Description, DACO: 3.5.5
3038158	2019, BAS 807 00 H: Determination of Oxidation/Reduction, Chemical Incompatibility, DACO: 3.5.8
3038160	4.6.1, Acute Oral LD_{50} Study in Rats, 2019
3038161	4.6.2, Acute Dermal LD_{50} Study in Rats, 2019
3038162	4.6.3, Acute Inhalation LC_{50} Study in Rats, 2019
3038163	4.6.4, Primary Eye Irritation Study in Rabbits, 2019
3038164	4.6.5, Primary Dermal Irritation Study in Rabbits, 2019
3038165	4.6.6, Dermal Sensitization Study in Mice (Local Lymph Node Assay), 2019
3038144	2019, Petition for application: Smoulder herbicide for burndown and residual weed control, DACO: 10.1,10.2,10.2.1,10.2.2,10.2.3,10.2.3.1,10.2.3.3(B),10.3,10.3.1, 10.3.2(A),10.3.3,10.4,10.5,10.5.1,10.5.2, and 10.5.4.
3038146	2019, Field trial reports – Smoulder herbicide, DACO: 10.2.3.3(B), 10.3.2(A), and 10.3.3.