Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.1, 3.11 Application

Application Number: 2022-6336
Application: New End-Use Product Chemistry – Guarantee, Identity and Proportion of Formulants
New End-Use Product Label – Application Rate Increase and New Pests
Product: HUSKIE PRE
Registration Number: 35077
Active ingredients (a.i.): bromoxynil (present as mixed octanoate and heptanoate esters), pyrasulfotole
PMRA Document Number: 3544505

Purpose of Application

The purpose of this application was to register a new herbicide end-use product, HUSKIE PRE, for use as a pre-plant or post-plant but prior to crop emergence treatment on wheat (spring, durum, and winter), triticale, and barley.

Chemistry Assessment

HUSKIE PRE is formulated as an emulsifiable concentrate containing bromoxynil (present as mixed octanoate and heptanoate esters) at a concentration of 280 g/L and pyrasulfotole at a concentration of 25 g/L. This end-use product has a density of 1.12-1.16 g/mL and pH of 3.0-4.5. The required chemistry data for HUSKIE PRE have been provided, reviewed and found to be acceptable.

Health Assessments

HUSKIE PRE is of high oral acute toxicity and of low acute toxicity via the dermal and inhalation routes of exposure. It is minimally irritating to the eyes, mildly irritating to the skin and is considered a dermal sensitizer.

The registration of HUSKIE PRE for preplant or postplant, but preemergence application in spring, durum and winter wheat, triticale and barley is not expected to result in potential occupational or bystander exposure over the registered uses of pyrasulfotole and bromoxynil. No health risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

Canada

For bromoxynil, no new residue data were submitted to support the registration of HUSKIE PRE as a preplant or postplant, but preemergence, application on wheat (spring, durum and winter), barley and triticale. Previously reviewed residue data from field trials conducted in/on wheat and barley were reassessed in the framework of this application and found to be acceptable to support the uses.

For pyrasulfotole, new residue data from confirmatory field trials conducted in Canada on wheat and barley were submitted to support the registration of HUSKIE PRE. Pyrasulfotole was applied to wheat and barley at the proposed rate to compare the pre- and postemergence application timings, with samples harvested according to label directions. Additionally, previously reviewed residue data from field trials conducted in/on wheat and barley were reassessed in the framework of this application.

Based on this assessment, residues of bromoxynil and pyrasulfotole are not expected to be greater than those from the currently registered uses and will be covered by the established maximum residue limits (MRLs). Consequently, dietary exposure to residues of bromoxynil and pyrasulfotole is not expected to increase with the registration of HUSKIE PRE and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

After a scientific review of the available information, the environmental risks associated with the use of HUSKIE PRE are acceptable when used according to the label directions, which includes statements to mitigate risks to the environment.

Value Assessment

The registration of HUSKIE PRE provides users with another co-formulation of bromoxynil and pyrasulfotole for burndown control of a broad-spectrum of weeds when it is applied in tank mix with glyphosate herbicide in wheat, triticale, and barley. HUSKIE PRE contains active ingredients from two herbicide mode of action groups, providing users with a valuable tool that may help manage the development of herbicide-resistant weed biotypes.

Value information submitted for review consisted of scientific rationales, precedent registrations, and data from replicated field trials. This information collectively demonstrated that efficacy and crop tolerance of HUSKIE PRE applied in tank mix combination with glyphosate herbicide for control/suppression of the labeled weeds in wheat (spring, durum, and winter), triticale, and barley provide acceptable value.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the registration of HUSKIE PRE.

References

PMRA Document Number	Reference
3413029	2022, Product chemistry data to support the registration of Huskie Pre, an herbicide product (product identity and composition), DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.4.1 CBI
3405503	2022, Determination of bromoxynil-heptanoate, bromoxynil-octanoate and pyrasulfotole in EC-formulations, HPLC-UV, external standard, DACO: 3.4.1 CBI
3405504	2022, Validation of analytical method AM038622MF1 - Determination of bromoxynil-heptanoate, bromoxynil-octanoate and pyrasulfotole in the formulation bromoxynil-octanoate/heptanoate + pyrasulfotole EC 425 (400 + 25 g/L), DACO: 3.4.1 CBI
3405505	2022, Storage stability at elevated temperature and corrosion characteristics of bromoxynil-octanoate/heptanoate + pyrasulfotole EC 425 (400+25 g/L) - Packaging material: COEX/PA - Final report (14 days), DACO: 3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.9 CBI
3405506	2022, Bromoxynil-octanoate/heptanoate + pyrasulfotole EC 425 (400+25 g/L): The oxidation, reduction and chemical incompatibility properties, DACO: 3.5.4,3.5.5,3.5.8 CBI
3405507	2022, Safety relevant data of bromoxynil-octanoate/heptanoate + pyrasulfotole EC 425 (400+25 g/L), DACO: 3.5.11,3.5.12,3.5.8 CBI
3413031	2022, Waiver summary report for Huskie Pre, end use product, DACO: 3.5.13,3.5.15 CBI
3408883	2022, BXD+PYS EC 425 (400+25) G: Acute Oral Toxicity - Up-And-Down Procedure in Rats, DACO: 4.6.1
3408884	2022, BXD+PYS EC 425 (400+25) G: Acute Dermal Toxicity in Rats, DACO: 4.6.2
3405508	2022, BXD+PYS EC 425 (400+25) G: Acute Inhalation Toxicity in Rats, DACO: 4.6.3
3405509	2022, BXD+PYS EC 425 (400+25) G: Primary Eye Irritation in Rabbits, DACO: 4.6.4
3405510	2022, BXD+PYS EC 425 (400+25) G: Primary Skin Irritation in Rabbits, DACO: 4.6.5
3405511	2022, BXD+PYS EC 425 (400+25) G: Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6
3405542	2009, An analytical method for the determination of residues of AE 0317309 and AE 1073910 in wheat, corn, and soybean matrices using LC/MS/MS - Revised, DACO: 7.2.1
3413039	2020, RAAI0007: Magnitude of pyrasulfotole and metribuzin residues in barley after a pre-emergent and/or post-emergent application of Infinity (37.5 g/L) and Sencor (480 g/L) in North America., DACO: 7.4.1
3413040	2022, Magnitude of pyrasulfotole and metribuzin residues in wheat after a pre-emergent and/or post-emergent applications of Infinity (37.5 g/L) and Sencor (480 g/L) in North America, DACO: 7.4.1

3413025	2022, Part 10 - Value assessment of Huskie PRE Herbicide for pre-emergence weed control in wheat (spring, durum, winter), triticale, and barley, DACO: 10.1, 10.2.1, 10.2.2, 10.2.3.1, 10.3.1, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, and 10.5.5.
3413027	2022, Compilation of trial reports - Value assessment of Huskie Pre Herbicide for pre-emergence weed control in wheat (spring, durum, winter), triticale, and barley, DACO: 10.2.3.3 and 10.3.2.