Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.5, 3.12 Application

Application Number: 2013-3560
Application: New Product and New Site
Product: Heat LQ
Registration Number: 31468
Active ingredients (a.i.): Saflufenacil
PMRA Document Number: 2445457

Purpose of Application

The purpose of this application was to register a new end use product, Heat LQ, containing the active ingredient, saflufenacil, for pre-seed or pre-emergence control of broadleaf weeds in selective crops and chemfallow and for desiccation of dry common beans, red lentil varieties, dry field peas, soybeans, sunflowers, wheat, barley, and triticale in the Prairie Provinces and Peace River region of BC.

Chemistry Assessment

Heat LQ is formulated as a suspension concentrate containing saflufenacil at a nominal concentration of 342 g/L. This end-use product has a density of 1.140 – 1.160 g/mL and pH of 4.0 – 6.0. The chemistry requirements for Heat LQ have been fulfilled.

Health Assessments

Heat LQ Herbicide is of low acute toxicity by the oral route in female rats; it is of low acute toxicity by the dermal and inhalation routes in rats. It is minimally irritating to the rabbit eye and skin and is a skin sensitizer in guinea pigs.

Heat LQ as a harvest aid or to control broadleaf weeds fits within the registered use pattern for saflufenacil. The potential exposures of mixers, loaders, applicators, post-application re-entry workers, and bystanders are not expected to exceed the current exposures to registered products. No risks of concern are expected when following label instructions and precautions, including wearing the personal protective equipment identified on the label.

To support Heat LQ, previously reviewed residue data were reassessed in the framework of these petitions:

- pre-plant or pre-emergent applications: barley, corn (sweet, field), rice, sorghum, wheat, pea (succulent, dry), dry bean, soybean (succulent, dry);
- late season applications for harvest aid/dessicant use : dry bean, dry pea, dry soybean, sunflower and canola.

To support the domestic use of Heat LQ as a pre-harvest weed management treatment on wheat

(spring, winter, and durum), barley (spring, winter, malting) and triticale, residue data from field trials conducted in Canada and the United States were submitted. Saflufenacil was applied to wheat and barley at one- to 1.6-fold approved rates, and harvested according to label directions. Data on wheat were extended to triticale. In addition, processing studies in treated wheat and barley were reviewed to determine the potential for concentration of residues of saflufenacil and metabolites M800H11 and M800H35 into processed commodities.

Maximum Residue Limit(s)

The recommendation for maximum residue limits (MRLs) for total residues of saflufenacil was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. MRLs to cover residues of saflufenacil and metabolites M800H11 and M800H35 (all expressed in parent equivalents) in/on crops and processed commodities are proposed as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the proposed MRLs for the raw agricultural commodities (RACs). The MRLs to cover residues of saflufenacil in/on livestock matrices are proposed as shown in Table 2.

TABLE 1. Summary of Field Trial and Processing Data Used to Support Maximum Residue Limit(s) (MRLs)

Commodity	Application Method/Total Application Rate (g ai/ha)	PHI (days)	Combined Residues[1] (ppm)		Currently Established MRL (ppm)	Recommended MRL (ppm)
			Min	Max		
Wheat (grain) extended to triticale (grain)	Broadcast foliar application/48-52	2-3	<0.03	0.68	0.03[2]	1.0 (barley) 0.6 (wheat, triticale) 1.5 (barley bran)
Barley (grain)	Broadcast foliar application/48.1-81.1	2-3	0.06	0.58		

[1] Combined residues are the sum of saflufenacil, M800H11 and M800H35 (expressed in parent equivalents). [2] The currently established MRL of 0.03 ppm in/on cereal grains (CG 15) is based on a pre-seed or pre-emergent use pattern.

TABLE 2. Maximum Residue Limit(s) (MRLs) in Livestock Matrices.

Commodity	Currently Established MRL (ppm)	Recommended MRL (ppm)
Meat byproducts of cattle, goat, horses, and sheep	None	20
Meat byproducts of hogs		1.0
Fat of cattle, goat, horses, and sheep		0.02
Eggs; fat of hog, and poultry; meat of cattle, goat, hog, sheep, horses, and poultry; meat byproducts of poultry; milk		0.01

Following the review of all available data, MRLs are recommended to cover total residues of

saflufenacil, M800H11 and M80H35 (expressed in parent equivalents) in food commodities, and to cover residues of saflufenacil in livestock commodities, as proposed in Tables 1 and 2. Residues in these crops and livestock commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

Heat LQ is not expected to increase the environmental exposure relative to other registered water soluble granular formulations. Therefore, limited risk is expected. Environmental concerns have been mitigated through adequate statements on the product label.

Value Assessment

Value information submitted included data from 26 field trials, scientific rationale, and history of use information in the US. Efficacy (i.e., weed control and crop desiccation) and crop safety of pre-seeding and pre-harvest applications of Heat LQ alone at the labeled one x rate or in tank mix with glyphosate herbicide at 450 or 900 g a.e./ha were directly compared to Heat WG alone or in tank mix with glyphosate at the same a.i. rate per hectare in the submitted trials.

The efficacy of Heat LQ plus glyphosate for control of redroot pigweed, volunteer canola, lamb's-quarters, round-leaved mallow, wild buckwheat, and kochia was comparable to that of Heat WG plus glyphosate in five trials. Therefore, all weed claims that are labeled for Heat WG are supported for inclusion on the Heat LQ label.

The efficacy of Heat LQ for desiccation of soybean and lentils was comparable to that of Heat WG in six trials. Therefore, all crop desiccant claims that are labeled for Heat WG are supported for inclusion on the Heat LQ label.

The crop safety of Heat LQ alone or plus glyphosate for soybeans, barley, lentils, spring wheat, and durum wheat was comparable to that of Heat WG alone or plus glyphosate in 18 trials. Therefore, all host claims that are labeled for Heat WG are supported for inclusion on the Heat LQ label.

Considering data from 11 field trials and the mode of action of saflufenacil, crop desiccant claims for small grain cereals, including wheat, barley and triticale, were not supported. However, it was demonstrated in the field trials that a pre-harvest application of Heat LQ improved dry down of volunteer canola, common ragweed, and Canada fleabane in winter wheat. Therefore, pre-harvest dry down of these weeds in small grain cereals is supported for inclusion on the Heat LQ label.

Rotational crop tolerance claims for Heat WG can be extrapolated to Heat LQ because application rate on a.i. per hectare basis are the same for both formulations (products).

In addition, the applicant indicated that the value of water-based suspension concentrate is ease of use. Farmers prefer suspension concentrate formulation above water soluble granular formulation.

Based on the weight of evidence, the registration of Heat LQ for pre-seeding and pre-emergent broadleaf weed control, pre-harvest weed management, and crop desiccation are supported from a value standpoint.

Conclusion

PMRA has reviewed information provided in support of Heat LQ as described above. Based on this review, Heat LQ is acceptable for registration.

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