Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2009-3122
Application: Changes to Product Labels - New Host
Product: Velpar DF Herbicide Water Dispersible Granule
Registration Number: 25225
Active ingredients (a.i.): hexazinone [VPR]
PMRA Document Number : 2239701

Purpose of Application

The purpose of this application was to extend the current use of Velpar DF Herbicide Water Dispersible Granule to include established forage alfalfa for control of dandelion, quack grass, sow thistle, narrow-leaved hawk's beard and scentless chamomile.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

The use on established forage alfalfa is identical to that currently registered for established seed alfalfa, which is the same crop with a different portion of the plant that is harvested. There is no increase in exposure potential to handlers, applicators, or to field workers re-entering treated areas. Plant metabolism, livestock metabolism and residue data for hexazinone were submitted to support the use expansion to forage alfalfa on the Velpar DF Herbicide Water Dispersible Granule label. Based on the dietary burden and residue data, maximum residue limits (MRLs) of 0.04 ppm in fat, meat and meat byproducts of cattle, goats, hogs, horses and sheep to cover the sum of hexazinone and metabolite B; and of 0.09 ppm in milk to cover the sum of hexazinone and metabolites B and C-2 will be established.

Following the review of all available data for hexazinone, MRLs for livestock commodities are recommended. Residues in these commodities at the established MRLs will not pose an unacceptable risk to any segment of the population, including infants, children and seniors.

Environmental Assessment

Since the proposed use expansion follows the same registered use pattern, application rates, frequency, and methods of application, the impact of Velpar DF Herbicide Water Dispersible Granule on the environment remains the same. Environmental concerns have been mitigated through environmental statements and buffer zones on the product label.

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Value Assessment

A rationale to address the value data requirements was submitted. As the proposed use on established forage alfalfa is identical to that currently registered on the product label for established seed alfalfa, and as seed alfalfa and forage alfalfa are the same crop, differing only in the portion of the plant harvested, the applicant's rationale to support the proposed amendment is acceptable from a value perspective.

Conclusion

The PMRA has completed an evaluation of the subject application and found the information sufficient to include established forage alfalfa for control of dandelion, quack grass, sow thistle, narrow-leaved hawk's beard and scentless chamomile on the product label.

References

PMRA Document Number	Reference
1791598	1995, Magnitude of residues of Hexazinone in edible tissues and milk of lactating dairy cows, DACO: 7.5,7.5.1,7.6
1791602	1995, Magnitude of residues of Hexazinone in edible tissues and milk of lactating dairy cows, DACO: 7.5,7.5.1,7.6
1791603	2000, Magnitude of residues of Hexazinone in rotational crops following application of Velpar Herbicide at maximum label rates to alfalfa, DACO: 7.4.4
1791607	1996, Confined accumulation study of [4-carbonyl-14C] Hexazinone (DPX-A3674) in rotational crops, DACO: 7.4.3
1791611	1993, Magnitude of residues of Hexazinone in alfalfa forage, hay and seed grown in the Western United States following application of Velpar Herbicide, DACO: 7.4,7.4.1,7.4.6
1791612	1993, Magnitude of residues of Hexazinone in alfalfa forage and hay grown in the Eastern United States following application of Velpar Herbicide, DACO: 7.4,7.4.1,7.4.6
1791624	2005, Analytical method for the determination of Hexazinone and metabolites in pasture grass, sugarcane and pineapples using LC/MS/MS., DACO: 7.1,7.2,7.2.1,7.2.2,7.2.4,7.2.5

1791626 1993, A comparison of ^{14}C-hexazinone metabolites in hen tissues and eggs and goat tissues and milk with synthesised metabolite standards, DACO: 6.4

1791627 1994, A comparison of ^{14}C-hexazinone metabolites in hen tissues and eggs and goat tissues and milk with synthesised metabolite standards - examples of calculations and chromatographic raw data, DACO: 6.4

1791628 1979, Metabolism of ^{14}C-labeled hexazinone in Alfalfa, DACO: 6.1,6.3

1791629 1992, The metabolism of ^{14}C-Hexazinone in the goat, DACO: 6.1,6.2

1791631 1992, The metabolism of ^{14}C-Hexazinone in the goat - the freezer storage stability of ^{14}C-residues in tissues and milk from a lactating goat dosed with ^{14}C-Hexazinone, DACO: 6.1,6.2

1791632 1990, The metabolism of ^{14}C-Hexazinone in laying hens, DACO: 6.1,6.2

1791633 1992, The metabolism of ^{14}C-Hexazinone in laying hens - the freezer storage stability of tissues, eggs and excreta from laying hens dosed with 14C-Hexazinone, DACO: 6.1,6.2

1791634 1993, The metabolism of ^{14}C-Hexazinone in laying hens - comparison of ^{14}C-Hexazinone metabolites in excreta, tissues and eggs of hens with reference compounds metabolites A-1,C-1 and E-1, DACO: 6.1,6.2

1928696 1980, Rotational Crop Studies With 14C-labelled Hexazinone, DACO: 7.4.4

1928697 1993, Rotational Crop Studies With 14C-labelled Hexazinone, DACO: 7.4.4

1928700 1997, Enforcement analytical method for the determination of hexazinone and metabolites of interest in animal tissues and milk using ESI-LC/MS, DACO: 7.2.1,7.2.2

1928701 1997, Independent laboratory validation of a proposed enforcement analytical method for the determination of hexazinone and its metabolites of interest in Animal tissue and milk using ESI-LC/MS, DACO: 7.2.3

1928703 1996, Magnitude of residues in alfalfa forage, hay, and seed grown in the western United States following application of Velpar herbicide, DACO: 7.3

1928705 1999, Analytical method for the determination of hexazinone and metabolites of interest in lettuce, wheat, and corn using ESI-LC/MS, DACO: 7.4.4

1944961 2010, Rationale to waive requirement for rotational vegetable study, DACO: 7.4.3

1791638 2009, DACO 10 Value for Velpar DF on Forage Alfalfa, DACO: 10.1,10.2,10.2.1,10.2.2,10.2.3,10.2.3.1,10.2.3.3,10.3,10.3.1,10.3.2(A)

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