Health Canada Santé Canada

Evaluation Report for Category B, subcategories B.2.3, B.2.4, C.8.1, C.8.2 (Identity/Proportion of Formulants, Initial/Master Product Status) Application

Application Number: 2005-1011
Application: Evaluation Report for Category B, subcategories B.2.3, B.2.4, C.8.1, C.8.2 (Identity/Proportion of Formulants, Initial/Master Product Status)
Product: Release EC Silvicultural Herbicide
Registration Number: 28431
Active ingredients (a.i.): Triclopyr
PMRA Document Number: 1364555

Purpose of Application

The purpose of this submission is to register a new commercial herbicide, Release EC Silvicultural Herbicide, with an altered formulation from that of Release Silvicultural Herbicide (PCP# 22093), and a Master/Initial Product Status. Release Silvicultural Herbicide and Release EC Silvicultural Herbicide have the same use pattern: For the control of undesirable woody plants and annual and perennial broadleaved weeds in forest and woodland management areas. Release Silvicultural Herbicide is intended to be replaced by Release EC Silvicultural Herbicide. For specific details of uses, application rates and methods, precautions, restrictions, and personal protective equipment, refer to product label.

Chemistry Assessment

Release EC Silviculture Herbicide is formulated as an emulsifiable concentrate containing triclopyr, present as butoxyethyl ester, at a nominal concentration of 480 g/L. This end-use product has a density of 1.1116 g/mL and a pH of 3.36 for a 1% solution. With the exception of the storage stability study that is currently in progress, the chemistry requirements for Release EC Silviculture Herbicide are complete.

Health Assessment

The data for an identical product was reviewed to support Release Sivliculture Herbicide. The results indicate that Release Sivliculture Herbicide is of low acute toxicity by the dermal (LD_{50} > 5000 mg/kg bw) and by oral routes (LD_{50} = 3200 mg/kg bw) in rats. It is of low toxicity via inhalation with an LC_{50} greater than 5.05 mg/L in rats. Release Sivliculture Herbicide is a moderate irritant to the skin of rabbits. It is mildly irritating to rabbit eyes. This product is a dermal sensitizer in guinea pigs.

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The personal protective equipment recommended on the label (Where frequent inhalation of spray mist cannot be avoided, occupational exposure to pesticides can be reduced by use of an air-purifying respirator equipped with an organic-vapour-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a cannister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapour (OV) cartridge or cannister with any N, R, P or HE prefilter. When handling concentrate, wear goggles or faceshield, chemical resistant gloves (nitrile or neoprene), clean coveralls over long-sleeved shirt and long pants, impermeable head covering and chemical resistant boots (rubber) during all mixing/loading activities. When spraying dilute solution and during equipment maintenance and repair, wear clean coveralls over long-sleeved shirt and long pants, impermeable head covering, chemical resistant gloves (nitrile or neoprene) and chemical resistant footwear such as rubber boots.) is considered adequate to address acute and short term risk associated with Triclopyr.

To support the new formulation of Release EC Silvicultural Herbicide, no new residue data were submitted. Following the comparison of the new formulation to the original formulation of Release Silvicultural Herbicide (PCP# 22093), there is no indication that any formulants will have an impact on the magnitude of the residues of triclopyr when the new formulation will be used according to the label, since the use directions are identical. Therefore, no increase in dietary exposure is anticipated.

Maximum Residue Limit(s)

Based on the maximum residues observed in crops treated according to label directions, residues triclopyr and the metabolite 3,5,6-trichloro-2-pyridinol in liver and kidney of cattle, goats, hogs, horses and sheep are covered under the established MRL of 0.5 ppm. An MRL of 0.1 ppm was now recommended to cover residues of triclopyr and the metabolite 3,5,6-trichloro-2-pyridinol in meat, fat and meat by-products (except liver and kidney) of cattle, goats, hogs, horses and sheep and an MRL of 0.01 ppm was now recommended to cover residues of triclopyr only in milk.

Environmental Assessment

No environmental studies were required to support registration of Release EC Silviculture Herbicide since it has the same active concentration and use pattern as Release Silviculture Herbicide but different formulants. The formulants in Release EC Silviculture Herbicide were determined to be of equal or decreased risk to the environment than those found in Release Silviculture Herbicide, therefore no additional impact to the environment is expected from use of Release EC Silviculture Herbicide, and overall risk to the environment is expected to decrease.

Value Assessment

The data package submitted in support of the registration of Garlon 4 EC under application number 2005-1003 is applicable to Release EC Silvicultural Herbicide. Reports of 11 field trials conducted in the U.S. were submitted. The trials were conducted in California, Georgia, Kansas, Oregon, and Virginia in 2003 and 2004. Efficacy and crop safety of Garlon 4 EC was directly compared to that of the registered Garlon 4 in these trials. Control of maple, ground ivy, lespedeza, yellow poplar, sweet clover, loblolly pine, oak, common goldenrod, dandelion, and clover were visually assessed from 1 to 3 times during the growing season. Mean control of these weeds following the application of Garlon 4 EC was comparable to that of Garlon 4. The tolerance of conifer species, including douglas fir, balsam fir, white pine, eastern hemlock, and spruce, and one grass species, tall fescue, to Garlon 4 EC was visually assessed from 1 to 4 times during the growing season. Mean crop injury following the application of Garlon 4 EC was comparable to that of Garlon 4 over all the tested conifer and grass species. As the performance of Garlon 4 EC Herbicide was concluded to be similar to that of Garlon 4 Herbicide, it was concluded that the performance of Release EC Silvicultural Herbicide was similar to that of Release Silvicultural Herbicide (Reg. No. 22093).

Conclusions

The Agency has completed an assessment of available information for Release EC Sivicultural Herbicide and has found the information sufficient to allow for conditional registration, with registration being contingent upon fulfilling the following requirements: DACO 3.5.10 Submission of storage stability study.

MRLs

Following the review of all available data, a MRL of 0.1 ppm for meat, fat and meat by-products (except liver and kidney) of cattle, goats, hogs, horses and sheep is recommended to cover residues of triclopyr and the metabolite 3,5,6-trichloro-2-pyridinol and a MRL of 0.01 ppm for milk is recommended to cover residues of triclopyr only. The currently established MRL of 0.5 ppm for residues of triclopyr and the metabolite 3,5,6-trichloro-2-pyridinol in liver and kidney (cattle, goat, hog, horse and sheep) is considered adequate to cover residues of triclopyr and the metabolite 3,5,6-trichloro-2-pyridinol in/on these livestock commodities. Residues of triclopyr and the metabolite 3,5,6-trichloro-2-pyridinol in these livestock commodities at the established MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Reference List

PMRA 1047051. Determination of color, physical state, odor, oxidizing and reducing action, flammability, explodability, pH, viscosity and density of GF-1529, an end use product containing triclopyr BEE. Dow AgroSciences LLC. Laboratory Study ID FAPC043368. Study report date: 10-Nov-2004. 17 pp. DACO 3.5.

PMRA 1047052. Accelerated storage stability study of GF-1529: a triclopyr butoxyethyl ester emulsifiable concentrate formulation, in glass for 2 weeks at 54˚C. Dow AgroSciences LLC Laboratory Study ID FOR-05-010. Study report date: 03-Jun-2005. 19 pp. DACO 3.5.10.

PMRA 1047050. Group A - Product identity, composition, and analysis for GF-1529; an end use product containing triclopyr butoxyethyl ester. Dow AgroSciences LLC. Laboratory Study ID NAFST-04-882. Study report date: 20-Dec-2004. 70 pp.

PMRA 1303474. Pest Management Regulatory Agency (2006). Re-evaluation Decision Document. RRD2006-02. http://www.pmra-arla.gc.ca/english/pdf/rrd/rrd2006-02-e.pdf pp 5.

PMRA 1047048. Garlon 4 formulation project biology review, November 2004. Dow AgroSciences. DACO 10.1. pp. 31

PMRA 1073213. Garlon 4 formulation: Weed trials, woody plant (brush) trials, and conifer tolerance trials. September, 2005. Dow AgroSciences. DACO 10.2.3.3 and DACO 10.3.2. pp. 118.

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