Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.6, 3.11, 3.12 Application

Application Number: 2014-5171
Application: New End-Use Product Chemistry – New Combination of TGAIs
New Product Labels – New Pests and New Site
Product: Focus Herbicide
Registration Number: 32292
Active ingredients (a.i.): Carfentrazone-ethyl and Pyroxasulfone
PMRA Document Number : 2630748

Purpose of Application

The purpose of this application was to register an end-use product, Focus Herbicide, containing a new combination of active ingredients, carfentrazone-ethyl and pyroxasulfone, for controlling annual grasses and broadleaf weeds in spring/winter wheat, field corn and soybeans.

Chemistry Assessment

Focus Herbicide is formulated as a suspension containing carfentrazone-ethyl and pyroxasulfone at nominal concentrations of 53 g/L and 447 g/L respectively. This end-use product has a density of 1.21 g/mL and pH of 5.83. All the required chemistry data for Focus Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Focus Herbicide was of low acute toxicity via the oral, dermal and inhalation routes in the rat. It was minimally irritating to the eye and slightly irritating to the skin of rabbits. It was not a dermal sensitizer in mice.

Focus Herbicide, for use on field corn, soybeans, and spring and winter wheat to control annual grasses and broadleaf weeds, fits within the registered use pattern for carfentrazone-ethyl. For pyroxasulfone, the use pattern does not fit within the registered use pattern as there are differences in the formulation type and the level of recommended personal protective equipment, and therefore a mixer/loader/applicator quantitative risk assessment was conducted, with calculated Margins of Exposure (MOEs) all above the target of 1000. A postapplication risk assessment was not required as the product is for preplant or pre-emergent application. No health risks of concern are expected provided workers follow label directions and wear personal protective equipment as stated on the label.

No residue data for pyroxasulfone and carfentrazone-ethyl were submitted to support the registration of the end-use product Focus Herbicide, containing these active ingredients, for preplant/pre-emergent use on field corn, soybeans and wheat (spring and winter). The use pattern for Focus Herbicide is the same as the use pattern of currently registered end-

use products containing carfentrazone-ethyl and pyroxasulfone. The maximum residue limits (MRLs) currently established for residues of carfentrazone-ethyl, including the metabolite α, 2-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]-4-fluorobenzenepropanoic acid, in/on field corn, soybean and wheat commodities, the MRLs currently established for residues of pyroxasulfone, including the metabolite M-3, in/on field corn and wheat commodities, and the MRLs currently under promulgation for residues of pyroxasulfone, including the metabolite M-28, in/on soybean commodities are considered adequate to cover the expected residue levels generated by the use of Focus Herbicide. Dietary exposure to carfentrazone-ethyl and pyroxasulfone is not expected to increase and will not pose an unacceptable health risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

No environmental data for carfentrazone-ethyl and pyroxasulfone were submitted for the registration of the end-use product, Focus Herbicide. Environmental exposure and risk are not expected to increase as the uses and application rates for the subject product are less than the registered uses for both active ingredients.

Value Assessment

Focus Herbicide, with two distinct herbicide modes of action including carfentrazone-ethyl (Group 14) and pyroxasulfone (Group 15), and tank mix compatibility with atrazine (Group 5) and/or glyphosate (Group 9) provides farmers with a useful pesticide solution against a broad spectrum of annual broadleaf and grassy weeds with both contact and residual activities.

Value information submitted demonstrated that efficacy and crop safety of Focus Herbicide were comparable to the precedent products at the same active ingredient rate per hectare. Labelled efficacy claims and host claims are supported for Focus Herbicide. Since carfentrazone-ethyl is a contact herbicide without soil residual activity, the labelled Rotational Crop Restriction for the precedent product is applicable to Focus Herbicide.

Information also supported (1) new weed claims, including control of green pigweed and wormseed mustard and suppression of foxtail barley, wild buckwheat, and wild mustard and (2) tank mixtures with atrazine or glyphosate in field corn and glyphosate in soybean and wheat. The information included data from 21 combined efficacy and crop tolerance trials and scientific rationales.

Conclusion

The Pest Management Regulatory Agency has reviewed the available information and is able to support the registration of Focus Herbicide, containing a new combination of active ingredients, carfentrazone-ethyl and pyroxasulfone, for controlling annual grasses and broadleaf weeds in spring/winter wheat, field corn and soybeans.

References

PMRA Document Number	References
2525006	2014, Determination of Physical & Chemical Characteristics of F9312-4: pH, Physical State, Flammability, Viscosity and Density, DACO: 3.0, 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2, 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.4, 3.4.1, 3.4.2, 3.5, 3.5.1, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.16, 3.5.2, 3.5.3, 3.5.4, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI
2471921	2014, Determination of Physical & Chemical Characteristics of F9312-4: pH, Physical State, Flammability, Viscosity and Density, DACO: 3.0, 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2, 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.4, 3.4.1, 3.4.2, 3.5, 3.5.1, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.16, 3.5.2, 3.5.3, 3.5.4, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI
2589492	2015, 0.8 - Correspondence - FOCUS - Clarification, DACO: 0.8
2619381	2016, Analytical Test Method Validation and Purity Determination of Active Ingredients in F9312, DACO: 3.4.1 CBI
2589493	2014, Storage Stability and Container Corrosion Evaluation of F9312-4, DACO: 3.5.10,3.5.14 CBI
2471924	2014, F9312-4: Acute Oral Toxicity Up and Down Procedure in Rats, DACO: 4.6.1
2471925	2014, F9312-4: Acute Dermal Toxicity in Rats, DACO: 4.6.2
2471928	2014, F9312-4: Acute Inhalation Toxicity Study in Rats, DACO: 4.6.3
2471929	2014, F9312-4: Primary Eye Irritation Study in Rabbits, DACO: 4.6.4
2471930	2014, F9312-4: Primary Skin Irritation Study in Rabbits, DACO: 4.6.5
2471931	2014, F9312-4: Skin Sensitization: Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6
2501521	2015, Focus Herbicide Use Scenario Summary, DACO: 5.2
2486224	2014, Application to register SOLO ADV, a formulation replacement for SOLO WDG Herbicide, 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, 10.3.3, 10.4, 10.5, 10.5.1, 10.5.2, 10.5.3, and 10.5.4.

ISSN: 1911-8082