

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.6 Application

Application Number: 2013-0660
Application: New End-use Product Chemistry-Guarantee, identity and proportion of formulants, new combination of technical grade active ingredients
Product: NUP 12003 Herbicide
Registration Number: 31434
Active ingredients (a.i.): Clodinafop-propargyl (CFP) and fluroxypyr (FLR)
PMRA Document Number : 2301958

Background

Fluroxypyr is currently registered for use in Western Canada as a post-emergent application on wheat (spring and durum) in the Prairie Provinces and Peace River Region of British Columbia in several end-use products.

Clodinafop-propargyl is currently registered for use in Western Canada as a post-emergent application on wheat (spring and durum) in the Prairie Provinces and Peace River, Okanagan and Creston Flats Regions of British Columbia in several end-use products.

Cloquintocet-mexyl is currently registered for use in Canada as a safener.

Purpose of Application

The purpose of this application was to register a new commercial class herbicide, NUP 12003 Herbicide containing the actives clodinafop-propargyl (guarantee 112 g/L) and fluroxypyr (guarantee 217 g/L present as 1-methylheptyl ester), for use on wheat (spring and durum) in the Prairie Provinces and the Peace River Region of British Columbia. This product also contains the herbicide safener cloquintocet-mexyl.

Chemistry Assessment

NUP 12003 Herbicide is formulated as an emulsifiable concentrate liquid containing fluroxypyr (present as 1-methylheptyl ester) and clodinafop-propargyl at nominal concentrations of 217 g/L and 112 g/L, respectively. This end-use product has a density of 1.090 g/cm³ and pH of 7.36 (1% dispersion). The chemistry requirements for this product have been fulfilled.

Health Assessments

NUP 12003 Herbicide is of low acute toxicity via the oral ($LD_{50} \text{ } \varnothing = 2661 \text{ mg/kg bw}$ [approximate 95% CI of 1750 mg/kg (lower) to 5000 mg/kg (upper)]), dermal ($LD_{50} \text{ } \varnothing/\varnothing > 5000 \text{ mg/kg}$) and inhalation ($LC_{50} \text{ } \varnothing/\varnothing > 5.06 \text{ mg/L}$) routes of exposure. It is minimally irritating to the eye (MAS (24-72 hours) = 2.07/110) and severely (MAS (24-72 hours) =

5.23/8.0) to the skin of the rabbit. It is not a dermal sensitizer in the mouse Local Lymph Node Assay.

Fluroxypyr, clodinafop-propargyl and cloquintocet-mexyl are currently registered in Canada for use on these crops. The use of NUP 12003 Herbicide is not expected to impact exposure to dietary residues of fluroxypyr, clodinafop-propargyl and cloquintocet-mexyl. Residues of fluroxypyr, clodinafop-propargyl and cloquintocet-mexyl will be covered by the existing maximum residue limits (MRLs) established for these commodities. Residues of fluroxypyr, clodinafop-propargyl and cloquintocet-mexyl in these commodities at the established MRLs will not pose an unacceptable health risk to any segment of the population, including infants, children, adults and seniors.

The uses of NUP 12003 Herbicide should not result in unacceptable exposure to the active ingredients, clodinafop-propargyl, fluroxypyr and cloquintocet-mexyl. No risks of concern are expected when workers follow the label directions and wear the personal protective equipment identified on the label.

Environmental Assessment

Based on data made available to the PMRA since the safener cloquintocet-mexyl was first registered for this use pattern, there is the potential that cloquintocet-mexyl can significantly increase the toxicity of certain herbicides to non-target organisms, and in order to bridge the combination of the actives fluroxypyr, clodinafop-propargyl and cloquintocet-mexyl, the applicant was asked to provide ecotoxicological studies conducted using the end use product NUP 12003 Herbicide.

In response to the request, the applicant submitted a *Rationale in Support of a Request for a Waiver from the Requirement to Submit Certain Environmental Toxicology Data for NUP 12003 Herbicide* (PMRA 2327529). On review, it was concluded that the rationale was not sufficient to waive the study requirements, which are required to complete the environmental risk assessment for NUP 12003 Herbicide. Data requirements remain for freshwater invertebrates/fish and freshwater plants and will be a condition of registration. Based on the results of the outstanding Tier I studies, additional data may be required.

Value Assessment

Value information submitted included data from 12 field trials conducted in Alberta, Saskatchewan, and Manitoba in 2012. The efficacy and crop safety of NUP 12003 Herbicide at the labeled rate of 164 g a.i./ha (equivalent to 108 g a.i./ha fluroxypyr plus 56 g a.i./ha clodinafop-propargyl) + Enhance Adjuvant at 0.25% v/v and in tank mixes with 2,4-D Ester or MCPA Ester at 560 g a.e./ha were reported.

The efficacy of NUP 12003 Herbicide at 164 g a.i./ha + Enhance Adjuvant at 0.25% v/v for control of grasses with 56 g a.i./ha of clodinafop-propargyl + Enhance Adjuvant at 0.25% v/v (i.e. wild oats and green and yellow foxtail) was shown to be acceptable. Therefore, all weed claims that are labeled for 56 g a.i./ha of clodinafop-propargyl + Enhance Adjuvant at 0.25% v/v are supported for the NUP 12003 Herbicide label. These weeds include wild oats, green and yellow foxtail, barnyard grass, volunteer (tame) oats, and volunteer canary seeds.

The efficacy of NUP 12003 Herbicide at 164 g a.i./ha + Enhance Adjuvant at 0.25% v/v for control of broadleaf weeds with 108 g a.e./ha of fluroxypyr or lower (i.e. cleavers, kochia, and volunteer flax) was shown to be acceptable. Therefore, all weed claims that are labeled for 108 g a.e./ha of fluroxypyr or lower are supported for the NUP 12003 Herbicide label. These weeds include cleavers, kochia (including Group 2 resistant biotypes), volunteer flax, and stork's bill. A claim of wild buckwheat suppression for 164 g a.i./ha of NUP 12003 Herbicide + 0.25% v/v of Enhance Adjuvant is also supported.

The efficacy of NUP 12003 Herbicide + Enhance Adjuvant in tank mixes with 2,4-D Ester or MCPA Ester for control of volunteer canola, redroot pigweed, lamb's-quarters, wild mustard, and flaxweed is acceptable and also comparable to that of the registered treatments of fluroxypyr + clodinafop-propargyl + 2,4-D Ester or MCPA Ester at their respective labeled rates. Therefore, all weed claims for the registered tank mixes of fluroxypyr + clodinafop-propargyl + 2,4-D Ester or MCPA Ester at the rates equivalent to the labeled rates for NUP 12003 Herbicide + 2,4-D Ester or MCPA Ester are supported to appear on the NUP 12003 Herbicide label.

As fluroxypyr (up to 144 g a.e./ha) and clodinafop-propargyl (up to 70 g a.i./ha) and the tank mixes of 144 g a.e./ha fluroxypyr plus up to 70 g a.i./ha clodinafop-propargyl + up to 560 g a.e./ha 2,4-D Ester or MCPA Ester are registered for use on spring wheat and durum wheat. Crop tolerance has been established. The submitted crop tolerance data further confirmed that spring and durum wheat exhibit an acceptable margin of crop safety to NUP 12003 Herbicide alone or in tank mixes when applied in accordance with label directions.

The registration of NUP 12003 Herbicide for post-emergent control of the labeled weeds on spring wheat and durum wheat in the Prairie Provinces and Peace River region of British Columbia and the labeled tank mixes have been found to have acceptable value. In addition, the registration of this herbicide provides wheat grower with an effective tool to manage both grasses and broadleaf weeds with one pass application.

Conclusion

The PMRA has completed an assessment of the information provided in support of the product, NUP 12003 Herbicide, and has found the information sufficient to support a conditional registration of this product.

Abbreviations

♀	female
♂	male
a.e.	acid equivalent
a.i.	active ingredient
bw	body weight
CI	confidence interval
cm ³	centimetre(s) cubed
g	gram(s)
ha	hectare(s)
kg	kilogram(s)

L	litre(s)
LC ₅₀	lethal concentration 50%
LD ₅₀	lethal dose 50%
MAS	maximum average score
mg	milligram(s)
MRL	maximum residue limit
PMRA	Pest Management Regulatory Agency
v/v	volume per volume dilution

References

A. List of Studies/Information Submitted by Registrant

PMRA Document Number	Reference
2270609	2012, NUP-12003 Acute Oral Toxicity Study in Rats, DACO: 4.6.1
2270610	2012, NUP-12003 Acute Dermal Toxicity Study in Rats, DACO: 4.6.2
2270611	2012, NUP-12003 Acute Inhalation Toxicity Study in Rats, DACO: 4.6.3
2270612	2012, NUP-12003 Primary Eye Irritation Study in Rabbits, DACO: 4.6.4
2270613	2012, NUP-12003 Primary Skin Irritation Study in Rabbits, DACO: 4.6.5
2270614	2012, NUP-12003 Local Lymph Node Assay in Mice, DACO: 4.6.6
2270615	2013, A rationale based on trial data to support the use of NUP 12003 (clodinafop/fluroxypyr) for grassy and broadleaf weed control in spring and durum wheat, DACO 10
2270604	2013, NUP 12003 Herbicide: Product Identification and Selected Chemical and Physical Properties, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.5.10, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.4, 3.5.5 CBI
2270606	2012, Final Report for: Physical and Chemical Characteristics of NUP-12003, DACO: 3.5.1, 3.5.11, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.8, 3.5.9
2270608	2012, Enforcement Method for the Analysis of Nufarm NUP-12003, DACO: 3.4.1 CBI
2300562	2012, Method 001 for pH, DACO: 3.5 CBI
2300564	2013, Method 004 for Specific Gravity, DACO: 3.5 CBI
2300565	2011, Method 036 for Descriptive Properties, DACO: 3.5 CBI
2300566	2013, Method 038 for Kinematic Viscosity, DACO: 3.5 CBI
2300567	2012, Method 114 for Flash Point, DACO: 3.5 CBI
2300568	2012, Method 146 for Chemical Incompatibility, DACO: 3.5 CBI
2402967	2014, Request for a Waiver from the Requirement to Provide an Analytical Method and Determination of the Chiral Stability of Clodinafop-propargyl in NUP-12003 Herbicide Formulation, DACO: 3.4.1
2327529	2013, Rationale in Support of a Request for a Waiver from the Requirement to Submit Certain Environmental Toxicology Data for NUP 12003 Herbicide, DACO: 9.9

B. Additional Information Considered

i) Published Information

Gerald R. Stephenson, Abraham Tal, Norman A. Vincent and J. Christopher Hall. 1993. Interactions of Fenoxaprop-ethyl with Fenchlorazole-ethyl in Annual Grasses. *Weed Technology* , Vol. 7, No. 1) pp. 163-168.

Kriton K. Hatzios 1997. Regulation of Enzymatic Systems Detoxifying Xenobiotics in Plants. Springer, 385 pp. [Information on page 297].

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