

Evaluation Report for Category B, Subcategory 2.2,2.3, and 2.4 Application

Application Number: 2006-3760
Application: Category B.2.2 (Form of Active), B.2.3 (Identity of Formulants),
and B.2.4 (Proportion of Formulants)
Product: Vantage Plus MAX II Herbicide Solution
Registration Number: 28840
Active ingredients (a.i.): glyphosate, as dimethylamine salt
PMRA Document Number: 1518559

Purpose of Application

The purpose of this application was to register Vantage Plus MAX II Herbicide Solution, an end-use herbicide product containing a new form of glyphosate (present as dimethylamine salt). The product is intended for nonselective weed control in cropland systems and in non-cropland areas. The requested use pattern for this product is similar to that of Vantage Plus Max Herbicide Solution (Reg. No. 27615). For specific details of uses, application rates and methods, precautions, restrictions and personal protective equipment requirements, refer to the product label.

Chemistry Assessment

Vantage Plus MAX II Herbicide Solution is a solution containing the active ingredient glyphosate present as dimethylamine salt at a nominal concentration of 480 g/L. This product has a density of 1.2114 g/ml at 20°C and a pH of 4.59. The chemistry requirements for Vantage Plus MAX II Herbicide have been completed.

Health Assessments

To support the new salt form of glyphosate, the dimethylamine salt, on the Vantage Plus MAX II Herbicide Solution label, no new residue data were submitted. The food residue risk profile of the new salt form of glyphosate is expected to be similar to that of the other registered glyphosate salt forms. Therefore, no increase in dietary exposure is anticipated. The change in the salt form of glyphosate will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Vantage Plus MAX II Herbicide Solution is of low toxicity to rats via the oral ($LD_{50} > 5000$ mg/kg), dermal ($LD_{50} > 2000$ mg/kg) and inhalation ($LC_{50} > 5.63$ mg/L) routes. It is moderately irritating to the eye and mildly irritating to the skin of rabbits. It was found to be a skin sensitizer in mice.

No increase in exposure is expected from the use of Vantage Plus MAX II Herbicide Solution, containing glyphosate as the dimethylamine salt, over existing uses of glyphosate-containing products.

Environmental Assessment

No environmental studies were required to support the registration of Vantage Plus MAX II Herbicide Solution. The properties of glyphosate as the dimethylamine salt are expected to be similar to those of currently registered glyphosate products. The use pattern (application rate, volume, equipment, timing, etc.) is the same as for Vantage Plus MAX Herbicide Solution. Thus, no increase in environmental risk is expected from the use of Vantage Plus MAX II Herbicide Solution.

Value Assessment

Value data were submitted to establish whether Vantage Plus MAX II Herbicide Solution, the first herbicide to contain glyphosate as the dimethylamine salt, was agronomically equivalent to several other glyphosate herbicides, including Vantage Plus Max Herbicide Solution (Reg. No. 27615), containing glyphosate as the isopropylamine salt, Roundup WeatherMax with Transorb II Technology (Reg. No. 27487), containing glyphosate as the potassium salt, and Touchdown IQ (Reg. No. 27192), containing glyphosate as the diammonium salt. Application rates (on an acid equivalent basis) and timings for Vantage Plus MAX II Herbicide Solution are similar to those for these other products.

Efficacy data were submitted from two field trials conducted in Manitoba. Each trial included treatments of Vantage Plus MAX II Herbicide Solution at 450 and 900 g a.e./ha, which, respectively, correspond to 0.5x and 1x of the minimum rate required for control of certain perennial weeds, including dandelion, perennial sowthistle and Canada thistle. The efficacy of Vantage Plus MAX II Herbicide Solution for control of Canada thistle, perennial sowthistle and dandelion was similar to that observed in treatments of the other glyphosate products.

Crop safety data were submitted from eight field trials conducted on glyphosate tolerant canola (5 trials), glyphosate tolerant soybean (2 trials), and glyphosate tolerant corn (1 trial) in 2006 in Alberta and Manitoba. Treatments of Vantage Plus MAX II Herbicide Solution at 900 g a.e./ha were included in all trials and a rate of 1800 g a.e./ha was included in four trials conducted on glyphosate tolerant canola and glyphosate tolerant soybean (2 trials each). The rate of 900 g a.e./ha corresponds to the single application rate in glyphosate tolerant corn, 1.3x the maximum single application rate in glyphosate tolerant canola, and the lower single application rate in glyphosate tolerant soybean. Visually assessed injury in treatments of Vantage Plus MAX II Herbicide Solution for each glyphosate tolerant crop was comparable to that observed in treatments of the other glyphosate products. Injury was either not detectable or slight in the early season, and no injury was evident at the mid season evaluation.

Vantage Plus MAX II Herbicide Solution was concluded to be agronomically equivalent to other glyphosate products.

Conclusion

The PMRA has completed an evaluation of the subject application and has determined that Vantage Plus MAX II Herbicide Solution is eligible for full registration.

References

Studies/Information Provided by Applicant/Registrant

Chemistry Assessment

1261916	2006, Product Identity, N/A, DACO: 3.1.1,3.1.2
1261917	2005, Group A - Product Identity, Composition and Analysis for GF-1280; an End-use Product containing N-(phosphonomethyl)glycine, NASFT-05-127, MRID: N/A, DACO: 3.1.3,3.1.4,3.2.1,3.2.2,3.2.3,3.3.1,3.4.1
1261918	2005, Determination of Colour, Physical State, Odour, Oxidizing and Reducing Action, Flammability, Explodability, pH, Viscosity and Density of GF-1280, a Liquid End-Use Product Containing Glyphosate, FAPC053279, MRID: N/A, DACO: 3.5.1,3.5.11,3.5.12,3.5.13
1261919	2005, Group B - Physical/Chemical Properties for GF-1280, A Liquid End-use Product Containing Glyphosate, NAFST-05-100, MRID: N/A, DACO: 3.5.1,3.5.10,3.5.11,3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.8,3.5.9
1261920	2006, Two Week Accelerated Storage Stability of GF-1280 in Glass, FOR-05-059, MRID: N/A, DACO: 3.5.10
1261921	2006, GF-1240 - Corrosion Characteristics, N/A, MRID: N/A, DACO: 3.5.14
1261922	2006, GF-1280 Container Material and Description, N/A, MRID: N/A, DACO: 3.5.5

Health Assessments

1261924	2005, GF-1280: Acute Oral Toxicity Up and Down Procedure in Rats, 050311, MRID: N/A, DACO: 4.6.1
1261925	2005, GF-1280: Acute Dermal Toxicity Study in Rats - Limit Test, 050312, MRID: N/A, DACO: 4.6.2
1261926	2005, GF-1280: Acute Liquid Aerosol Inhalation Toxicity Study in F433/DUCRL Rats, 051151, MRID: N/A, DACO: 4.6.3
1261927	2003, GF-1280: Primary Eye Irritation Study in Rabbits, 030135, MRID: N/A, DACO: 4.6.4

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| 1261928 | 2005, GF-1280: Primary Skin Irritation Study in Rabbits, 050313, MRID: N/A, DACO: 4.6.5 |
| 1261929 | 2006, GF-1280: Local Lymph Node Assay in Balb/cAnNCrl Mice, 051095, MRID: N/A, DACO: 4.6.6 |

Value Assessment

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| 1261914 | 2005, 2003 Post-Harvest Hi-Load and Green Glyphosate formulations for Perennial Thistle Control in 2004 Crop Year., NMS0334, MRID: N/A, DACO: 10.2.3.3,10.3.1,10.3.2 |
| 1261915 | 2005, 2003 Post-Harvest Hi-Load and Green Glyphosate formulations for Perennial Thistle Control in 2004 Crop Year., NMS0341, DACO: 10.2.3.3,10.3.1,10.3.2 |
| 1334709 | 2006, GF-1280 RR Efficacy Trials (12), DACO: 10.2.3.3 |

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