Health Canada Santé Canada

Betamix ß Herbicide (EP)
Evaluation Report for Category B
Subcategory B.2.1, B.2.3, B.2.4, B.3.1-S-N-EP

Application Number: 2005-3560
Application: B.2.1, B.2.3, B.2.4, B.3.1-S-N-EP
Product: Betamix ß Herbicide (EP)
Registration Number: 28650
Active ingredients (a.i.): Desmedipham and Phenmedipham
PMRA Document Number: 1642489

Background

Betamix ß is a selective post-emergence herbicide intended for the control of weeds in sugar beets. It is a new formulation with an increase in the actives, i.e., desmedipham (153 g/L) and phenmedipham (153 g/L), as against the currently registered product for sugar beets, Betamix Emulsifiable Concentrate (Reg No. 19652) which has 75 g/L each. Betamix ß Herbicide is applied either by single application (4.75 L EP in 200 L water/ha), repeat application (3.5 L EP/ha with 7 days interval) or split application (1.75 L EP/ha with 5-7 days interval). The maximum application rate per crop season is 8.25 L/ha and is applied by ground application only (broadcast spray or band application). For specific details of uses, application rates and methods, precautions and restrictions, refer to the product label.

Purpose of Application

The purpose of this submission is to register a new formulation product, Betamix ß Emulsifiable Concentrate Herbicide (EP), with changes in the concentration of actives, identity and proportion of formulants, application rates and precautionary label statements.

Chemistry Assessment

Betamix ß Emulsifiable Concentrate Post-emergence Herbicide is a solution with a density of 1.020 g/mL at 20˚C and a pH of 2.8. The chemistry requirements for this product are complete.

Health Assessments

A toxicology assessment was performed for Betamix ß Emulsifiable Concentrate Post-emergence Herbicide. Betamix ß is of low toxicity to rats via the oral (LD_{50} > 2000 mg/kg), dermal (LD_{50} > 2000 mg/kg), and inhalation routes (LC_{50} >2.06 mg/L). It is moderately irritating to the eye and mildly irrigating to the skin of rabbits. It is not a dermal sensitizer in guinea pigs.

Canada

The requested use of Betamix ß Herbicide is identical to the registered formulation and fits within the existing use patterns for phenmedipham and desmedipham. A significant increase in exposure for mixer/loader, applicators, or for workers re-entering for post-application activities is not expected.

Residue data for desmedipham in sugar beets was submitted to support the change in guarantee, the identity and proportion of formulants, and the increase in the application rate for desmedipham on the Betamix ß Emulsifiable Concentrate Post-emergency Herbicide label.

Maximum Residue Limit

Based on the maximum residues observed in sugar beets treated according to label directions, a maximum residue limit (MRL) to cover residues of up to 0.05 ppm in/on sugar beets will be established as shown in Table 1. Processed commodities not listed in Table 1 are covered under the established MRL for the raw agricultural commodity (RACs).

TABLE 1. Summary of Field Trial Data Used to Establish Maximum Residue Limits (MRLs)

Commodity	Application Method/ Max Application Rate	PHI (days)	Residues (ppm)		Currently Established MRL	Recommended MRL (ppm)
			Min	Max		
Desmedipham						
Sugar beet roots	Foliar broadcast/ 1263 g a.i./ha	60	<0.05	<0.05	None	0.05

Following the review of all available data, an MRL of 0.05 ppm for sugar beet roots is recommended to cover residues of up to 0.05 ppm for desmedipham. Residues of up to 0.05 ppm in this crop commodity at the established MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The active ingredients, desmedipham and phenmedipham, are currently under re-evaluation. This assessment/ recommendation is, therefore, contingent upon the outcome of this re-evaluation and subject to future changes.

The amended label statements provide adequate protection to the non-target plants and aquatic organisms. The formulants in Betamix B Herbicide will not pose a TSMP concern.

Value Assessment

Data from 11 trials conducted in 2005 were submitted for review, 7 of which were conducted in Canada and 4 others were conducted in the US. Efficacy and crop safety of Betamix ß Herbicide applied alone or in tankmix with Upbeet Herbicide were directly compared to the registered Betamix EC Herbicide applied alone or in tankmix with the same herbicide partner in these trials.

Efficacy data were presented for a number of weed species listed on the label, including lamb's-quarters, wild buckwheat, yellow foxtail, redroot pigweed, black nightshade, kochia, stinkweed, and velvetleaf. Based on the evidence provided, the efficacy of Betamix ß Herbicide was equivalent to Betamix EC Herbicide, when applied alone or tank-mixed with Upbeet Herbicide.

Tolerance of sugarbeet to Betamix ß Herbicide was visually assessed 3 times during the growing season. Mean crop injury following the application of Betamix ß Herbicide was comparable to that of Betamix EC Herbicide, when applied alone or in tankmix with Upbeet Herbicide. The performance of Betamix ß Herbicide was, therefore, concluded to be similar to that of Betamix EC Herbicide.

Conclusion

The PMRA has completed an assessment of available information for Betamix ß Emulsifiable Concentrate Post-emergence Herbicide and has found the information sufficient to allow for registration for use for the control of weeds in sugar beets.

References

List of Studies/Information Submitted by Registrant

PMRA 1094645:	PMRA, Product Chemistry data review for the registration of a manufacturing concentrate (MA) or an end-use (EP)., N/S, DACO: 3.1.1
PMRA 1094646:	Confidential Appendix A: Manufacturing, Composition and Formulant Information., Betamix B EC Postemergence Herbicide Part 3 Data Review., DACO: 3.2.1
PMRA 1094647:	2005, Product Chemistry of Betanal Forte Herbicide., BR 2410, DACO: 3.1
PMRA 1094648:	2005, Product Chemistry of Betanal Forte Herbicide., BR 2410, DACO: 3.1
PMRA 1248801:	2006, U.S. EPA, Response to Clarifax: Attachment Attachment 3 - CSF for Betamix Beta (aka Betanal Forte), DACO: 3.7
PMRA 1347327:	2006, Product Chemistry of Betamix Ultra Herbicide, 201524 (BR2514), MRID: 46893201, DACO: 3.5.10,3.5.14.
PMRA 1094649:	AE B038584 01 EC30 B0 - An Acute Oral Toxicity Up and Down Procedure in Rats Product Safety Laboratories, 2394 Highway 130, Dayton, NJ 08810. Laboratory report number: 17335. 14-June-2005. MRID 46595202. DACO 4.6.1.
PMRA 1094650:	AE B038584 01 EC30 B0 - Acute Dermal Toxicity Study in Rats - Limit Test Product Safety Laboratories, 2394 Highway 130, Dayton, NJ 08810. Laboratory report number: 17336. 14-June-2005. MRID 46595203. DACO 4.6.2.
PMRA 1094651:	AE B038584 01 EC30 B0 - An Acute Inhalation Toxicity Study in Rats - Limit Test Product Safety Laboratories, 2394 Highway 130, Dayton, NJ 08810. Laboratory report number: 17337. 14-June-2005. MRID 46595204. DACO 4.6.3.

PMRA 1094652: AE B038584 01 EC30 B0 - Primary Eye Irritation Study in Rabbits Product Safety Laboratories, 2394 Highway 130, Dayton, NJ 08810. Laboratory report number: 17002. 16-March-2005. MRID 46595205. DACO 4.6.4.

PMRA 1094653: AE B038584 01 EC30 B0 - Primary Skin Irritation Study in Rabbits Product Safety Laboratories, 2394 Highway 130, Dayton, NJ 08810. Laboratory report number: 17003. March 16, 2005. MRID 46595206. DACO 4.6.5.

PMRA 1094654: AE B038584 01 EC30 B0 - Dermal Sensitization Study in Guinea Pigs (Buehler Method) Product Safety Laboratories, 2394 Highway 130, Dayton, NJ 08810. Laboratory report number: 17338. June 14, 2005. MRID 46595207. DACO 4.6.6.

PMRA 1094656: 2002, Bayer CropScience, Regina, Magnitude of Residues on Sugar Beets Treated with Different Formulations of the Herbicide Betamix, Study # 02AC04, Doc # B004166, DACO: 7.4.1

PMRA 1094666: Part 10 trial report: Value data in support of Betamix ß Herbicide, isophorone-free formulation. Trial ID: HDOSNARDNlGDNl. pp. 8.

PMRA 1094667: Part 10 trial report: Value data in support of Betamix ß Herbicide, isophorone-free formulation. Trial ID: HDOSNARDNlGDN2. pp. 7.

PMRA 1094668: Part 10 trial report: Value data in support of Betamix ß Herbicide, isophorone-free formulation. Trial ID: HDOSNARDNlGDN3. pp. 8.

PMRA 1094669: Part 10 trial report: Value data in support of Betamix ß Herbicide, isophorone-free formulation. Trial ID: HDOSNARDNlGDN4. pp. 7.

PMRA 1094670: Part 10 trial report: Value data in support of Betamix ß Herbicide, isophorone-free formulation. Trial ID: HDOSNARDNlGDNS. pp. 7.

PMRA 1094671: Part 10 trial report: Value data in support of Betamix ß Herbicide, isophorone-free formulation. Trial ID: HDOSNARDNlGDN6. pp. 7.

PMRA 1094672: Part 10 trial report: Value data in support of Betamix ß Herbicide, isophorone-free formulation. Trial ID: HDOSNARCYBDANl. pp. 6.

PMRA 1094673: Part 10 trial report: Value data in support of Betamix ß Herbicide, isophorone-free formulation. Trial ID: HDOSNARCYBTKTl. pp. 8.

PMRA 1094674: Part 10 trial report: Value data in support of Betamix ß Herbicide, isophorone-free formulation. Trial ID: HDOSNARCYBTGKl. pp. 9.

PMRA 1094675: Part 10 trial report: Value data in support of Betamix ß Herbicide, isophorone-free formulation. Trial ID: HDOSNARCYBDDMl. pp. 10.

PMRA 1094676: Part 10 trial report: Value data in support of Betamix ß Herbicide, isophorone-free formulation. Trial ID: HD05NARDN1GDN7. pp. 7.

ISSN: 1911-8082