

Evaluation Report for Category B, Subcategory 2.3, 2.4 Application

Application Number:	2007-0226
Application:	Category B, subcategory 2.3 (Identity of formulants), 2.4
	(Proportion of formulants)
Product:	Accurate Herbicide
Registration Number:	29242
Active ingredients (a.i.):	Metsulfuron methyl at 60% w/w
PMRA Document Number:	: 1713119

Background

The active ingredient metsulfuron-methyl used to formulate Accurate Herbicide is currently in the PSR II process (Sub. No. 2005-0461; Level C3). Chemical equivalency for the active ingredient has been granted, but the registration number has not yet been assigned. This application for registration of the new end-use product Accurate Herbicide was permitted to proceed. Metsulfuron-methyl is also currently under re-evaluation within the Agency and the PACR is expected in 2008. Future amendments to the active ingredient and end-use products, including label comments, are pending the outcome of this re-evaluation.

Purpose of Application

The purpose of this application was to register Accurate Herbicide (guarantee 60% metsulfuronmethyl), an end-use product which is substantially similar to the currently registered product, Ally Herbicide (Reg. No. 24388; guarantee 60% metsulfuron-methyl). Accurate Herbicide is used for the control or suppression of selected broadleaf weeds in wheat (spring and durum), barley and established creeping red fescue, orchard grass, crested and intermediate wheat grass (seed or forage) in the Prairie Provinces and the Peace River Region of British Columbia (soil pH of 7.9 or lower). The product is to be applied with ground equipment only as a postemergent spray alone or in a tank mixture with other registered herbicides with a recommended surfactant at a rate of 5 or 7.5 g a.i./ha metsulfuron methyl. The requested use pattern of this product is similar to that of Ally Herbicide (Reg. No. 24388) that is also used in combination with a recommended surfactant. For specific details of uses, application rates and methods, precautions, restrictions, and personal protective equipment requirements, refer to the product label.

Chemistry Assessment

Accurate Herbicide, is formulated as a solid containing metsulfuron methyl at a nominal concentration of 60.0%. This end-use product has a density of 1.31 g/mL and pH of 3.9. The chemistry requirements for Accurate Herbicide are complete.



Health Assessments

Accurate Herbicide is of low toxicity to rats via the oral ($LD_{50} > 2000 \text{ mg/kg bw}$), dermal ($LD_{50} > 2000 \text{ mg/kg bw}$), and inhalation routes ($LC_{50} > 3.75 \text{ mg/L}$). It is minimally irritating to the eyes and skin of rabbits. It is not a dermal sensitizer in mice.

To support the registration of Accurate Herbicide containing a new source of metsulfuron methyl, and similar to the registered end-use product Ally Herbicide, no new residue data were submitted. The food residue risk profile of the new herbicide is expected to be similar to that of other registered metsulfuron methyl products. Therefore, no increase in dietary exposure is anticipated. The new metsulfuron methyl product from a new source will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

The requested use of ACCURATE Herbicide fits within the existing use patterns for Metsulfuron methyl. As part of the re-evaluation of the active ingredient, a risk assessment was conducted using the Pesticide Handler's Exposure Database (PHED) to quantify exposure while mixing, loading, and applying by farmer and custom applicators. Acceptable margins of exposure were also calculated for post-application tasks.

Environmental Assessment

No environmental studies were required to support registration of Accurate Herbicide since the use pattern and formulation are sufficiently similar to the registered product Ally Herbicide. Therefore, no additional impact to the environment is expected from the use of Accurate Herbicide. The applicant should be aware that changes to the environmental label statements for Accurate Herbicide may be required pending the outcome of the PMRA's re-evaluation of the active ingredient, metsulfuron-methyl.

Value Assessment

Value data were submitted to establish whether Accurate Herbicide was agronomically equivalent to Ally Herbicide or Ally Herbicide Toss-N-Go.

Efficacy data were submitted from four field trials conducted in 2006. The level of weed control in treatments of Accurate Herbicide applied alone or in tank mixtures was similar to that in treatments of the same rate of Ally Herbicide applied alone or in combination with the same tank mix partner products. While not all proposed tank mixes were evaluated, each tank mix with Accurate Herbicide would be expected to be of similar performance to the relevant tank mix registered for Ally Herbicide.

Crop phytotoxicity data were available from six field trials conducted in 2006 in Alberta (5 trials) and Manitoba (1 trial) on barley (3 trials) and spring wheat (3 trials). In all trials, the tolerance of wheat or barley to an application of Accurate Herbicide was compared to that of wheat or barley treated with the same rate of the registered precedent product, Ally Herbicide.

Injury to barley and wheat treated with Accurate Herbicide alone or in tank mix combination with other labelled herbicides was low and similar to the level of injury observed in treatments of Ally Herbicide applied alone or in tank mix combination with the same partner herbicide products. Crop tolerance was confirmed with grain yield data collected in four of the six trials.

Conclusion

The registration of Accurate Herbicide (60% metsulfuron methyl) can be supported, **provided the TGAI from Cheminova is first granted registration under Sub. No. 2005-0461** (**following completion of the PSR II process**). The formulation and use rates for Accurate Herbicide are therefore not expected to present any increased risk to people or the environment over that of the currently registered Ally Herbicide product (Reg. No. 24388). Changes are required to the proposed label, however the registrant should be made aware that future label changes for Accurate Herbicide may also be required as a result of the re-evaluation of metsulfuron-methyl currently under way within the Agency.

References

1362907 1411600	2006, DACO: 4.1,4.6,4.6.1,4.6.2,4.6.3,4.6.4,4.6.5,4.6.6 DACO: Clarification_Email
1414028	a-Hexylcinnamaldehyde: Local Lymph Node Assay in the Mouse, 039/687, DACO: 4.2.6
1414029	a-Hexylcinnamaldehyde: Local Lymph Node Assay in the Mouse, 039/688, DACO: 4.2.6
1414030	DACO: 0.8
1362905	Chemistry Requirements for the Registration of Manufacturing Concentrates and End-Use Products Formulated form Registered Techncial Grade of Active Ingredients or Integrated System Products, DACO 3.2.1,3.2.2,3.2.3
1362906	2006, DACO: 3.5,3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6, 3.5.7,3.5.8,3.5.9,3.6
1262310	Chemistry Requirements for the Registration of a Technical Grade Active Ingredient: Identity and Composition. CONFIDENTIAL ATTACHMENT. PP. 95-138. DACO 2.13.1
1362910	2006, DACO: 10.1, 10.2
1369781	Re-evaluation of Metsulfuron methyl, Occupational Exposure Assessment, Input to Monograph (2004-0191)
1369976	Re-evaluation of Metsulfuron-Methyl Dermal Absorption Rationale
1455619	Acute toxicity studies

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2009

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.