

Evaluation Report for Category B, Subcategory B.2.3,B.2.4,B.3.1,B.3.10 Application

Application Number: 2008-0218
Application: New / Changes EP or MA Product Chemistry-Identity of Formulants and Proportion of Formulants; New or Changes to Product Labels-Application Rate Increase and Tank Mixes
Product: Bison 400 L
Registration Number: 29256
Active ingredients (a.i.): Tralkoxydim (TRA)/herbicide
PMRA Document Number: 1721945

Purpose of Application

Makteshim Agan of North America Inc. (MKC) has submitted a proposal for a new herbicidal product, MANA Tralkoxydim 400 SC (guarantee 400 g/L tralkoxydim), based on the precedent product, Achieve Liquid Herbicide (Reg. No. 27011), which has the same active guarantee and use pattern, but a different formulation and adjuvant. This application travels with an application for a duplicate product proposed by Interprovincial Cooperative, Ltd. (INT), and marketed as IPCO Tralkoxydim 400 SC (Sub. No. 2008-0217, dependent on this submission), and an application for a new adjuvant to be used with these new products, MANA Tralkoxydim Adjuvant (Sub. No. 2008-0224).

Chemistry Assessment

MANA Tralkoxydim 400 SC is a suspension containing the active ingredient tralkoxydim at a nominal concentration of 400g/L. This product has a density of 1.105-1.135g/mL and pH of 4-6. With the exception of the storage stability and corrosion characteristics studies that are currently being conducted, the chemistry requirements for MANA Tralkoxydim 400 SC have been completed.

Health Assessments

MANA Tralkoxydim 400 SC is of low toxicity to rats via the oral (LD_{50} : 2000 mg/kg bw), dermal (LD_{50} >5000 mg/kg), and inhalation routes (LC_{50} >2.55 mg/L). It is minimally irritating to the eye and slightly irritating to the skin of rabbits. It is not a dermal sensitizer in guinea pigs.

The proposed use pattern of MANA Tralkoxydim 400 SC fits within the existing use pattern for tralkoxydim. As such exposure to workers mixing, loading, applying, or entering treated fields is not expected to increase over the currently registered use pattern for tralkoxydim.

No new residue data were submitted for this application. The proposed use pattern for MANA Tralkoxydim 400 SC is the same as the currently registered Achieve Liquid Herbicide. No impact on the magnitude of residues is expected. Consequently, no increase in dietary exposure is anticipated.

Environmental Assessment

MANA Tralkoxydim 400 SC has the same formulation type and use pattern to the registered product Achieve Liquid Herbicide. MANA Tralkoxydim 400 SC is proposed to be applied once per year post-emergent at a rate of 0.5 L product/ha (200 g a.i./ha) to control annual grasses in small-grain cereals and selected forage grasses grown for seed. There will be no additional environmental impacts from the use of MANA Tralkoxydim 400 SC. No additional environmental data were required. Environmental mitigation measures, including buffer zones for the protection of terrestrial habitat, appear on the label. Tralkoxydim is undergoing re-evaluation, therefore, the label statements concerning environmental mitigation must be amended for this product once a re-evaluation decision for tralkoxydim has been reached.

Value Assessment

Data from 25 field research trials conducted in Alberta (8 trials), Saskatchewan (10 trials), and Manitoba (7 trials), during a 3 year period (2005-2007), were submitted to support the registration of MANA Tralkoxydim 400SC. Efficacy and crop safety of MANA Tralkoxydim 400SC herbicide alone and in combination with 2,4-D, Buctril M, Pardner, or Thumper were directly compared to that of the cited precedent product, Achieve Liquid Herbicide (Reg. No. 27011), alone and in combination with the same tank mix partners in these trials.

Control of wild oats, green foxtail, redroot pigweed, volunteer canola, lamb's-quarters, wild buckwheat, wild mustard, stinkweed, Canada thistle, cleavers, kochia, and lady's-thumb was visually assessed from 2 to 3 times during the growing season. Mean control of these weeds following the application of MANA Tralkoxydim 400SC herbicide alone (for wild oats and green foxtail only) and in combination with 2,4-D, Buctril M, Pardner, or Thumper was comparable to that for Achieve Liquid Herbicide alone and in combination with the same tank mix partners.

The tolerance of spring wheat, durum wheat, and spring barley to MANA Tralkoxydim 400SC herbicide alone and in combination with 2,4-D, Buctril M, Pardner, or Thumper was visually assessed from 3 to 4 times during the growing season. Mean crop injury following the application of MANA Tralkoxydim 400SC herbicide alone and in combination with 2,4-D, Buctril M, Pardner, or Thumper was comparable to that for Achieve Liquid Herbicide alone and in combination with the same tank mix partners. Data for final grain yield further supported the crop tolerance claim.

The performance of MANA Tralkoxydim 400SC was, therefore, concluded to be similar to that of Achieve Liquid Herbicide.

The inclusion of the new tankmix partners, Badge, Mextrol 450, Logic M, Bromotril 240EC, Brotex, Koril, Thrasher, Leader, and Approve, is also supported from a value standpoint based on the following facts:

- Pardner is presently labeled as a tank mix partner for Achieve Liquid Herbicide, and is included on the label of the latter. Agronomic equivalency among the presently registered liquid formulations of bromoxynil in Canada, including Pardner, Koril 235, Bromotril 240EC, and IPCO Brotex 240, has been previously established (refer to the PMRA # 1406225).
- The labels for Badge, Mextrol 450, Logic M, Thrasher, and Approve include a tank mix with the precedent product, Achieve Liquid Herbicide.
- The label for Leader includes a tank mix with Liquid Achieve Herbicide which was registered as a master copy product of Achieve Liquid Herbicide.

Conclusion

The PMRA has evaluated all of the data submitted in support of this application and has determined that sufficient information is available to support full registration of MANA Tralkoxydim 400 SC. However, submission and review of the storage stability and corrosion characteristics studies will be required as conditions of full registration.

References

PMRA 1538419 2007, DACO 3.1.1-3.1.4, DACO: 3.1.1,3.1.2,3.1.3,3.1.4 CBI

PMRA 1538420 2007, Tralkoxydim 400 SC - Product Properties, DACO: 3.2.1,3.2.2,3.2.3, 3.3.1, 3.4.1,3.4.2, 3.5.6,3.5.7,3.5.9 CBI

PMRA 1534821 2007, Tralkoxydim 400 SC - Storage Stability and Corrosion Characteristics of Tralkoxydim 400 SC Storage at 54 C for 14 Days, F06-10/7, DACO: 3.4.1,3.5.1,3.5.13,3.5.14, 3.5.2,3.5.3 CBI

PMRA 1538422 2007, Tralkoxydim 400 SC - Determination of Storage Stability and Shelf Life Specification of Tralkoxydim 400 SC Stored at 54 C for 14 Days, F06-10/9, DACO: 3.4.1,3.5.1,3.5.10,3.5.13,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9 CBI

PMRA 1538423 2007, Tralkoxydim 400 SC - Flash Point and Flammability, DACO: 3.5.11, 3.5.12 CBI

PMRA 1538424 2006, Tralkoxydim 400 SC Explosive Properties, AGM/0268; AGM0268/063975, DACO: 3.5.12 CBI

PMRA 1538425 2007, 3.5.15, DACO: 3.5.15 CBI

PMRA 1538426 2007, 3.5.4, 3.5.4, DACO: 3.5.4,3.5.5 CBI

- PMRA 1538427 2006, Tralkoxydim 400SC - Physical and Chemical Characteristics: Oxidation/Reduction, 20343, DACO: 3.5.8 CBI
- PMRA 1538428 2007, Tralkoxydim Vapour Pressure, AGM/0267; AGM0267/072049, DACO: 3.7 CBI
- PMRA 1600285 General chemical characteristics of Silicaid AF-100, DACO: 3.0 CBI
- PMRA 1538429. Acute Oral Toxicity Up and Down Procedure in Rats. Eurofins Product Safety Laboratories. Laboratory report number 20344. Study report date: 08-November-2006. DACO 4.6.1.
- PMRA 1538430. Acute Dermal Toxicity Study in Rats – Limit Test. Eurofins Product Safety Laboratories. Laboratory report number 20345. Study report date: 02-November-2006. DACO 4.6.2.
- PMRA 1538431. Acute Inhalation Toxicity Study in Rats. Eurofins Product Safety Laboratories. Laboratory report number 20346. Study report date: 23-February-2007. DACO 4.6.3.
- PMRA 1538432. Primary Eye Irritation Study in Rabbits. Eurofins Product Safety Laboratories. Laboratory report number 20347. Study report date: 07-November-2006. DACO 4.6.4.
- PMRA 1538433. Primary Skin Irritation Study in Rabbits. Eurofins Product Safety Laboratories. Laboratory report number 20348. Study report date: 07-November-2006. DACO 4.6.5.
- PMRA 1538434. Dermal Sensitization Study in Guinea Pigs (Buehler Method). Eurofins Product Safety Laboratories. Laboratory report number 20349. Study report date: 07-November-2006. DACO 4.6.6.
- PMRA 1538394 to 1538418 Trial reports. Makhteshim Agan of North America. DACO. 10.2.3.3. and 10.3.2. A total of 556 pages.
- PMRA 1406225 Efficacy Review. Submission number 2007-0269. DACO 10.2.3.3. April 25, 2007. pp. 11.

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.