

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.5, 3.10, 3.13 Application

Application Number: 2015-5959
Application: New EP / Product Chemistry – Guarantee, Identity and Proportion of Formulants, Formulation Type;
New Product Labels – Tank Mixes, Precautions
Product: Starane Dry Herbicide
Registration Number: 32565
Active ingredients (a.i.): Fluroxypyr, present as 1-methylheptyl ester
PMRA Document Number: 2604429

Purpose of Application

The purpose of this application was to register the end-use product Starane Dry Herbicide for postemergent control or suppression of broadleaf weeds in small grain cereals, rangeland, permanent pasture, rights-of-way, industrial and other non-crop areas. Starane Dry Herbicide is a water-dispersible granular formulation, based on a precedent emulsifiable concentrate end-use product containing fluroxypyr, present as 1-methylheptyl ester.

Chemistry Assessment

Starane Dry Herbicide is formulated as a water dispersible granule containing fluroxypyr (present as 1-methylheptyl ester) at a nominal concentration of 35%. This end-use product has a density of 0.6409 g/mL and pH of 5.52. The required chemistry data for Starane Dry Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Starane Dry Herbicide is of low acute toxicity by the oral, dermal and inhalation routes of exposure in rats. The formulation is minimally irritating to the rabbit eye and skin. It is not a skin sensitizer in mice.

An assessment was performed for mixers/loaders/applicators and postapplication workers using Starane Dry Herbicide. No risks of concern are expected from using Starane Dry Herbicide when workers follow the label directions and wear the personal protective equipment identified on the label.

No residue data were submitted in support of the registration of Starane Dry Herbicide, which contains fluroxypyr, present as 1-methylheptyl ester, for use on wheat (spring, winter and durum), spring barley, oats, rangeland, permanent pasture and other non-crop areas. The use pattern of Starane Dry Herbicide was determined to be within that of a registered precedent product. Therefore, previously reviewed data were reassessed in the framework of the current application, and confirmed that the use of Starane Dry Herbicide is not expected to result in an increase in the magnitude of fluroxypyr residues in/on the treated crops. Residues will be covered by the established maximum residue limits (MRLs) in/on crops and animal commodities. The use of Starane Dry Herbicide will not pose an unacceptable health risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use pattern for the wettable granule formulation Starane Dry Herbicide is the same as that of a currently registered emulsifiable concentrate end-use product. No increase in environmental exposure/impact will result from the use of Starane Dry Herbicide relative to the precedent product. Therefore, negligible risk of concern is expected. Environmental concerns have been mitigated through adequate statements on the product label.

Value Assessment

The registration of a wettable granular formulation of fluroxypyr provides users the opportunity to choose their preferred formulation, i.e., liquid formulation versus dry granular formulation. The inclusion of more tank-mix partners on the label gives users more flexibility to choose herbicide combinations based on weed spectrum in the fields.

Value information submitted demonstrated that the product performance of Starane Dry Herbicide, in terms of efficacy and crop tolerance, was agronomically equivalent to that of a precedent emulsifiable concentrate end-use product. Therefore, all uses and claims labelled for the precedent product are supported for inclusion on the Starane Dry Herbicide label. The information included data from 15 small plot replicated field trials conducted in the Canadian Prairies and the northern great plains of the USA in 2014 and 2015.

Additional information indicated that the inclusion of additional herbicide tank-mix partners on the Starane Dry Herbicide label had acceptable value. This information included data from three small plot replicated field trials conducted in Alberta and Saskatchewan in 2015 and scientific rationales.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of Starane Dry Herbicide.

References

PMRA Document Number	Reference
2580310	2015, Group A-Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Formulation Process, Discussion of Formation of Impurities, Certified Limits, and Enforcement Analytical Method for GF-3372, an End Use Product Containing Fluroxypyr-meptyl, DACO: 3.2,3.2.1,3.2.2,3.2.3,3.3.1,3.4,3.4.1,3.4.2 CBI
2580311	2015, Determination of Color, Odor, Physical State, Oxidizing and Reducing Action, Bulk Density, Tap Density and pH of GF-3372, an End-Use Product Fluroxypyr MHE, DACO: 3.5,3.5.1,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8 CBI
2580312	2015, Determination of Explosive Properties for GF-3372, DACO: 3.5.12 CBI
2588285	2015, Starane Dry Part 3 Chemistry - EP, DACO: 3.1.1,3.1.2,3.1.3,3.1.4 CBI
2588286	2015, Starane Dry Part 3 Chemistry - EP, DACO: 3.5.10,3.5.11,3.5.13,3.5.14, 3.5.15, 3.5.4,3.5.5,3.5.9 CBI
2651436	2016, GF-3372 Accelerated Storage Stability and Corrosion Characteristics in HDPE, non GLP stability report, DACO: 3.5.10,3.5.14 CBI
2580314	2015. Acute oral toxicity study of GF-3372 in rats. DAS Study No: 150212; DACO 4.6.1
2580315	2015. Acute dermal toxicity study of GF-3372 in rats. DAS Study No: 150213; DACO 4.6.2
2580316	2015. Acute inhalation toxicity study of GF-3372 in rats. DAS Study No: 150217; DACO 4.6.3
2580317	2015. Acute eye irritation study of GF-3372 in rabbits. DAS Study No: 150215; DACO 4.6.4
2580318	2015. Acute dermal irritation study of GF-3372 in rabbits. DAS Study No: 150214; DACO 4.6.5
2580319	2015. Skin sensitisation study of GF-3372 by local lymph node assay in mice. DAS Study No: 150216; DACO 4.6.6
2580323	2015, 15 field trial reports, DACO: 10.2.3.3
2582171	2015, Supplemental information to support Starane Dry Herbicide tank mixed with DuPont herbicide blends, DACO: 10.1, 10.2, 10.2.3, 10.2.3.1, 10.2.3.3(B), 10.3, and 10.3.2

ISSN: 1911-8082

8 Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2016

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.