



Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2022-5976
Application: New End-Use Product Chemistry-New Combination of Technical Grade Active Ingredients
Product: Extinguish XL Herbicide
Registration Number: 35112
Active ingredients (a.i.): 2,4-D (present as 2-ethylhexyl ester), florasulam, halauxifen (present as methyl ester)
PMRA Document Number: 3551104

Purpose of Application

The purpose of this application was to register a new commercial-class end-use product, Extinguish XL Herbicide, with a new combination of active ingredients, for post-emergent control or suppression of broadleaf weeds and barnyard grass in spring wheat, durum wheat, winter wheat, and spring barley.

Chemistry Assessment

Extinguish XL Herbicide is formulated as an emulsifiable concentrate containing halauxifen, (present as methyl ester) at a concentration of 6 g/L; florasulam at a concentration of 6 g/L; and 2,4-D (present as 2-ethylhexyl ester) at a concentration 300 g ae/L. This end-use product has a specific gravity of 1.06 and a pH of 3.3. The required chemistry data for Extinguish XL Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Extinguish XL Herbicide is of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It is corrosive to the eyes, non-irritating to the skin, and is a potential skin sensitizer.

Chemical handler and post-application worker exposure risk assessments were conducted and adequate margins of exposure (MOEs) were calculated for all scenarios. No health risks of concern were identified for workers or bystanders provided that appropriate personal protective equipment are worn and all label directions are followed.

No new residue data for halauxifen-methyl, florasulam, or 2,4-D in spring wheat (including durum), winter wheat and spring barley were submitted or were required to support the use expansion of these active ingredients on the Extinguish XL Herbicide label. Previously reviewed residue data from field trials conducted in/on wheat and barley were reassessed in the framework of this application. In addition, processing studies in treated wheat were reassessed to determine the potential for concentration of residues of halauxifen-methyl, florasulam, and 2,4-D into processed commodities.

Established maximum residue limits (MRLs) for residues of halauxifen-methyl, florasulam, and 2,4-D in/on wheat and barley raw agricultural commodities and their processed commodities, and livestock commodities, are considered adequate to cover residues in/on these commodities as a result of these uses. Residues at the established MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use of Extinguish XL Herbicide on wheat is within the currently registered use patterns for halauxifen (present as methyl ester), florasulam, and 2,4-D (present as 2-ethylhexyl ester); however, Extinguish XL Herbicide is a new combination of active ingredients. Studies on aquatic organisms conducted using Extinguish XL Herbicide were submitted to assess whether this combination of active ingredients would be more toxic than each component alone.

An environmental risk assessment was conducted as described in the PMRA guidance document, *Health Canada's Approach to Environmental Risk Assessment for Pest Control Products*, to estimate the potential for adverse effects on non-target species. Environmental exposure and ecotoxicology information were integrated by comparing estimated environmental concentrations (EECs) to the levels at which adverse effects occur. EECs were estimated using standard models that consider application rate(s) and chemical and environmental fate properties.

In the risk assessment, toxicity endpoints were adjusted via an uncertainty factor to calculate the effects metrics. The effects metrics account for potential differences in species sensitivity as well as varying protection goals (i.e., protection at the community, population, or individual level). The screening-level risk assessment used simple methods, conservative exposure scenarios and sensitive effects metrics. A risk quotient (RQ) was calculated by dividing the EEC by the effects metric and was then compared to the level of concern (LOC). When the screening level RQ was below the LOC, the risk was considered to be acceptable, and no further risk characterization was necessary. When the screening level RQ was equal to or greater than the LOC, a refined risk assessment was performed to further characterize the risk.

The screening level risk assessment, assuming direct overspray to waterbodies, showed that risks to aquatic invertebrates, fish and amphibians were acceptable (RQs ≤ 0.30). The RQ for freshwater algae was 3.64, exceeding the LOC of 1; thus, the risks to freshwater algae were further characterized by considering exposure via spray drift and runoff.

The aquatic EEC was adjusted to account for the deposition of spray drift 1 m downwind from the point of application using a spray drift factor of 3% for application via field sprayer (ASAE coarse). After this refinement, the RQ was 0.11, well below the LOC of 1; thus, risks to freshwater algae from spray drift are acceptable.

For the runoff assessment, the Extinguish XL Herbicide endpoint was divided by the proportion of the active ingredients present in the formulation to determine approximate endpoints for those components. The EECs in surface water from runoff were modelled in the previous PMRA assessments of each active ingredient (PACR2005-01, PRVD2021-03, PRD2014-12) at levels equal to or higher than those expected with the use of Extinguish XL Herbicide. Using the previously modelled EECs, the refined RQs ranged from 0.88 to 2.83. Considering that the EECs were calculated using application rates higher than those for Extinguish XL Herbicide and the RQs were close to 1, the risk to freshwater algae from runoff of Extinguish XL Herbicide can be mitigated by label statements.

The assessment showed that risk to aquatic organisms is acceptable when Extinguish XL Herbicide is used according to the label, which contains precautionary statements and spray buffer zones (1–2 m) to mitigate risks to the environment.

Value Assessment

The registration of Extinguish XL Herbicide provides users with an alternative solution to control annual broadleaf weeds and barnyard grass in wheat (spring, durum, and, winter) and barley with a one pass application. In addition, growers would require fewer jugs to deliver, mix, and apply Extinguish XL Herbicide as a pre-formulated mixture of three active ingredients.

As Extinguish XL Herbicide is co-formulated with active ingredients from two herbicide mode of action groups, it would provide users with another valuable tool that may help to manage the development of herbicide-resistant weed biotypes.

Value information submitted for review consisted of scientific rationales, precedent registrations, and data from replicated field trials. This information collectively demonstrated that the performance, in terms of efficacy and crop tolerance, of Extinguish XL Herbicide was similar to that of the tank mixture that delivers the same active ingredients at the same rates. As such, efficacy and host crop claims labelled for the tank mix components are supported for inclusion on the Extinguish XL Herbicide label. In addition, a claim of control of smartweed was supported for labelling with trial data. The rotational crop claims are supported based on the more restrictive rotational crop claims labelled for the tank mix components.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the registration of Extinguish XL Herbicide.

References

PMRA

Document

Number	Reference
3405678	2022, Product Identification, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.13, 3.5.14,3.5.15,3.5.16,3.5.4,3.5.5 CBI
3405679	2022, Group A Report, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.4,3.4.1 CBI
3405680	2021, PhysChem Properties, DACO: 3.5.1,3.5.11,3.5.12,3.5.2,3.5.3, 3.5.6,3.5.7,3.5.8,3.5.9 CBI
3405681	2022, Storage Stability Report, DACO: 3.5.10 CBI
3544120	2024, 3.4.1 Response to PMRA regarding Internal Standard_Jan 2024.pdf, DACO: 3.4.1 CBI
3405692	2022, Efficacy and crop safety, DACO: 10.1
3405693	2022, Field trials reports, DACO: 10.2.3.2
3405682	2021, Acute Oral Toxicity Study in Rats, DACO: 4.6.1
3405683	2021, Acute Dermal Toxicity Study in Rats, DACO: 4.6.2
3405684	2022, Acute Inhalation Toxicity Study in Rats, DACO: 4.6.3
3405685	2021, Acute Dermal Irritation Study in Rabbits, DACO: 4.6.5
3405686	2022, Skin Sensation Study Study in Mice, DACO: 4.6.6
3405687	2022, EpiOcular Eye Irritation Test, DACO: 4.6.4
3447434	2023, GF-5160 A 48-Hour Static-Renewal Acute Toxicity Test with the Cladoceran (<i>Daphnia magna</i>), DACO: 9.3.2
3447435	2023, GF-5160 A 96-Hour Static-Renewal Acute Toxicity Test with the Rainbow Trout (<i>Oncorhynchus mykiss</i>), DACO: 9.5.2.1
3447436	2023, GF-5160 A 72-Hour Toxicity Test with the Freshwater Alga (<i>Raphidocelis subcapitata</i>), DACO: 9.8.2

© His Majesty the King in Right of Canada, as represented by the Minister of Health Canada, 2024

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 Health Canada, Ottawa, Ontario K1A 0K9.