Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.3 Application

Application Number: 2022-1782
Application: Changes to Product Chemistry; Identity of Formulants
Product: Addit Adjuvant
Registration Number: 29263
Active ingredient (a.i.): Surfactant blend
PMRA Document Number: 3506346

Purpose of Application

The purpose of this application was to amend the formulation of Addit Adjuvant and to add alternate formulating sites. Addit Adjuvant is registered to be mixed with herbicide Bison 400L (registration number 29256), containing the active ingredient tralkoxydim.

Chemistry Assessment

Addit Adjuvant is formulated as an emulsifable concentrate containing a surfactant blend at a concentration of 36.9%. This end-use product has a density of 0.867 g/mL and pH of 5 – 7. The chemistry requirements for this product have been fulfilled.

Health Assessments

Addit Adjuvant is considered to be of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It is considered to be a moderate eye and skin irritant and is not considered to be a dermal sensitizer.

The amendment to Addit Adjuvant can be supported from an occupational exposure perspective as no changes were made to the use pattern of the product, and as it fits within the use pattern of registered tank-mix partner product. As such, occupational and bystander exposures are not expected to exceed the current exposure to the registered uses. No health risks of concern are expected, provided that workers wear the appropriate personal protective equipment and follow all label directions for use.

No new residue data were submitted or were required to support the amendment to the registration of Addit Adjuvant. Previously reviewed residue data on file for the active ingredient tralkoxydim contained in the tank-mix partner product Bison 400L are adequate to support the use of Addit Adjuvant mixed with Bison 400L.

Exposure to residues of the active ingredient in the tank-mix partner product of Addit Adjuvant in/on treated food commodities is not expected to be greater than that from the current uses and will be covered under the established maximum residue limits (MRLs) given that the herbicide end-use product to be applied with Addit Adjuvant is already registered for

use with this specific adjuvant at similar rates. Consequently, dietary exposure to residues of tralkoxydim is not expected to increase with the addition of alternate formulants as well as additional formulation and manufacturing sites of Addit Adjuvant and will not pose health risks of concern to any segment of the population, including infants, children, adults, and seniors.

Environmental Assessment

The changes to the formulation of Addit Adjuvant are not expected to lead to any additional risks to the environment.

Value Assessment

The provision of alternative formulant options allows the manufacturer greater flexibility to formulate Addit Adjuvant according to formulant availability.

A rationale was provided demonstrating that the alternative formulants would not be expected to impact product performance (efficacy or crop tolerance).

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to amend the registration of Addit Adjuvant.

References

PMRA Document Number	Reference
3385474	2022, Scientific Rationale Part 3 and Part 10, DACO: 10.6.

© His Majesty the King in Right of Canada, as represented by the Minister of Health Canada, 2023

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.