

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.11, 3.12 Application

Application Number: 2017-8114
Application: Application to register a new end use product; changes to formulation, new pests and new sites.
Product: Heat Harvest
Registration Number: 33378
Active ingredients (a.i.): Saflufenacil
PMRA Document Number: 2954508

Purpose of Application

The purpose of this application was to register Heat Harvest, containing saflufenacil, for pre-harvest weed management and as a crop desiccant.

Chemistry Assessment

Heat Harvest is formulated as a liquid containing saflufenacil at a concentration of 21.4 g/L. This end-use product has a density of 1.055 g/cm³ and pH of 5.58. The required chemistry data for Heat Harvest have been provided, reviewed and found to be acceptable.

Health Assessments

Heat Harvest was found to be of low acute toxicity to rats via the oral, dermal, and inhalation routes. It was mildly irritating to the eye and slightly irritating to the skin in rabbits. It was not a dermal sensitizer in guinea pigs.

The occupational exposure and risk from the registration of Heat Harvest was assessed. No risks of concern are expected from the use of the new end-use product, provided that workers follow the label directions and wear the personal protective equipment identified on the label.

No new residue data for saflufenacil were submitted to register Heat Harvest containing saflufenacil. Previously reviewed residue data from field trials conducted in/on canola, dry beans, dry peas and sunflower were reassessed in the framework of this petition. In addition, processing studies in treated canola and sunflower were also reassessed to determine the potential for concentration of residues of saflufenacil into processed commodities. The resulting residues on these crops from the use of Heat Harvest are expected to be covered under the MRLs currently established for these commodities. Residues in these crops 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 uses of Heat Harvest are within the previously registered use pattern of the active ingredient saflufenacil, and therefore, no additional environmental risk is expected from the use of Heat Harvest. The label includes the required environmental precautions and hazards statements, including the appropriate buffer zones information, which adequately mitigates risks to the environment.

Value Assessment

The transfer of the pre-harvest application uses from the precedent product label to the Heat Harvest label streamlines the “Directions for Use” for both products. In addition, Heat Harvest, which is formulated with saflufenacil and built-in surfactants, is more easily and conveniently handled by users.

Value information submitted for review consisted of scientific rationales and data from replicated field research trials. Based on the information available, it was concluded that the performance of Heat Harvest was agronomically equivalent to that of the precedent product in combination with the recommended adjuvant. Therefore, all pre-harvest uses registered for the precedent product are supported for inclusion on the Heat Harvest label from a value perspective.

Furthermore, data from field trials supported the inclusion of (1) claims of pre-harvest improved dry down of Canada thistle, lamb’s-quarters, and cleavers and (2) the desiccation use on the list of crops for which Heat Harvest may be applied for pre-harvest weed management, i.e., canola, chickpeas, dry common beans, faba beans, flax, lentils (red varieties), mustard, dried field peas, soybeans, and sunflower.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to register Heat Harvest.

References

PMRA

Document

Number	Reference
2835650	2017, Registration of Heat Harvest, a Water-Based Suspension Concentrate Formulation of Kixor(R) (Saflufenacil), for Harvest Aid and Pre-Harvest Weed Management, DACO: 10.1,10.2,10.2.1,10.2.2,10.2.3,10.2.3.1,10.2.3.3(B),10.3,10.4,10.5.1
2835657	2017, Field Trial Reports - Heat Harvest, DACO: 10.2.3.3(B)
2835659	2017, Description Of Starting Materials, DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1 CBI
2835660	2017, GLP validation of analytical method AFR0129/01 and certification of BAS 800 07 H, Lot FD-170307-0014, DACO: 3.4.1
2835661	2017, Method AFR0129/01: Determination of Saflufenacil (BAS 800 H) content in BAS 800 07 H formulation by reverse-phase HPLC using UV detection, DACO: 3.4.1
2835662	2017, Determination of physical and chemical properties of BAS 800 07 H: Accelerated storage stability and corrosion characteristics after 2 weeks at 54 °C in commercial containers, DACO: 3.5.1, 3.5.10, 3.5.14, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.9
2835664	2017, BAS 800 07 H - Determination of physico-chemical properties according to UN transport (Regulation and Directive 94/37/EC No. 440/2008), DACO: 3.5.11, 3.5.12
2835665	2017, Miscibility of Heat Harvest, DACO: 3.5.13
2835666	2017, Dielectric Breakdown Voltage - Heat Harvest, DACO: 3.5.15
2835667	2017, Formulation Type of Heat Harvest, DACO: 3.5.4
2835668	2017, Container Material and Description, DACO: 3.5.5
2835669	2017, Determination of oxidation/reduction, chemical incompatibility of BAS 800 07 H, DACO: 3.5.8
2835671	Acute Oral Toxicity Study in Rats
2835672	Acute Dermal Toxicity Study in Rats
2835673	Acute Inhalation Toxicity Study in Wistar Rats – 4-hour Liquid Aerosol Exposure (Nose-only)
2835674	Acute Eye Irritation in Rabbits
2835675	Acute Dermal Irritation/Corrosion in Rabbits
2835676	Assessment of Sensitising Properties on Albino Guinea Pigs by Repeated Applications – Buehler Test With 3 Applications
2835650	2017, Registration of Heat Harvest, a water-based suspension concentrate formulation of KIXOR (saflufenacil), for harvest aid and pre-harvest weed management, DACO: 10.1, 10.2, 10.2.1, 10.2.2, 10.2.3, 10.2.3.1, 10.2.3.3(B), 10.3, 10.4, and 10.5.1
2835657	2017, Field trial reports - Heat Harvest, DACO: 10.2.3.3(B).

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services
Canada 2019

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.