

Evaluation Report for Category B, Subcategory 2.3, 2.4 Application

Application Number: 2017-1355
Application: New EP/Product Chemistry-Identity and Proportion of Formulants
Product: Next 70 WDG Herbicide
Registration Number: 33620
Active ingredient (a.i.): Imazamox
PMRA Document Number : 2759624

Purpose of Application

The purpose of this application was to register Next 70 WDG Herbicide, based on a precedent product, for use on Clearfield canola, Clearfield sunflowers, Clearfield lentils and Clearfield canola quality *Brassica juncea*.

Chemistry Assessment

Next 70 WDG Herbicide is formulated as wettable granules containing imazamox at a concentration of 70%. This end-use product has a density of 0.56 g/mL and pH of 2.9. The required chemistry data for Next 70 WDG Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Next 70 WDG Herbicide is considered toxicologically equivalent to the precedent product. Subsequently no toxicological data were submitted or are required.

The use of Next 70 WDG Herbicide containing imazamox on Clearfield canola, Clearfield sunflowers, Clearfield lentils and Clearfield canola quality *Brassica juncea* is not expected to result in potential occupational or bystander exposure over the registered use of imazamox. No health risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

No new residue data for imazamox were submitted to support the registration of Next 70 WDG Herbicide. The use pattern, including the target crops, application rates, timing and number of applications, spray volumes, adjuvant use, pre-harvest intervals, feeding restrictions and follow cropping, were compared to the registered use pattern on the label of the precedent end-use product.

The changes in the formulation components of Next 70 WDG Herbicide are not expected to significantly impact the magnitude of imazamox residues in/on treated Clearfield canola, Clearfield sunflowers, Clearfield canola quality *Brassica juncea* and Clearfield lentils.

Based on this assessment, residues of imazamox in/on treated commodities

are not expected to increase and will be covered under the maximum residue limits (MRLs) currently established for imazamox at 0.3 ppm in/on sunflower seeds, 0.25 ppm in/on dry lentils and 0.05 ppm in/on rapeseeds (canola) (<http://pr-rp.hc-sc.gc.ca/mrl-lrm/results-eng.php>). Consequently, the dietary exposure to residues of imazamox is not expected to increase with the registration of Next 70 WDG Herbicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use of Next 70 WDG Herbicide is within the registered use pattern of the active ingredient imazamox, and therefore, no additional risk is expected from the use of Next 70 WDG Herbicide. The label includes the required environmental precautions and hazards statements, including the buffer zones information, which adequately mitigates risks to the environment.

Value Assessment

The availability of Next 70 WDG Herbicide would provide farmers another option to manage both grasses and broadleaf weeds in Clearfield crops. Registration of generic products may increase product competition in the marketplace thereby potentially reducing purchasing costs of similar products.

The formulation of Next 70 WDG Herbicide was compared to the formulation of the cited precedent product. It was concluded that minor differences in the formulations were unlikely to result in any significant impact on product performance, in terms of both efficacy and crop tolerance. Value information from field research trials conducted in the Canadian Prairies in 2016 was also submitted for review. The trial information was considered in conjunction with the conclusion from formulation comparison.

Based on the weight of evidence, the agronomical equivalence between Next 70 WDG Herbicide and the cited precedent product can be established. Therefore, all labelled uses and claims found on the precedent product label are supported for inclusion on the Next 70 WDG Herbicide label.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to register Next 70 WDG Herbicide.

References

PMRA

Document

Number

Reference

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- 2741940 2017, Description of Formulation Process of Imazamox 70% WDG, DACO: 3.2.1,3.2.2,3.3.1 CBI
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- 2741942 2016, Imazamox 70% WDG: Determination of the Physio-Chemical Properties, DACO: 3.5.1,3.5.11,3.5.2,3.5.3,3.5.6,3.5.7
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