Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.5, 3.12 Application

Application Number: 2012-1672
Application: New end-use product; changes in active guarantee, formulants, formulation type and new application sites
Product: Facet L
Registration Number: 31539
Active ingredients (a.i.): Quinclorac, present as dimethlylamine salt
PMRA Document Number : 2461124

Purpose of Application

The purpose of this application was to register a new end-use product, Facet L, for use on wheat (spring and durum), spring barley, canary seed, Clearfield canola, canola, and brown and oriental tame mustard. Facet L can also be tank mixed with Liberty 150 SN Herbicide (registration number 288337) or Liberty 150 SN Herbicide and Crop Desiccant MP (registration number 24081) with or without Centurion (registration number 27598) for use on Liberty Link canola.

Facet L is similar to Accord Dry Flowable Herbicide (registration number 25118) however it is a soluble formulation with the active ingredient, quinclorac, present as a dimethylamine salt.

Chemistry Assessment

Facet L is formulated as a solution containing quinclorac, present as dimethylamine salt, at a nominal concentration of 180 g/L. This end-use product has a density of 1.13 g/mL and a pH of 9-10. The chemistry requirements for Facet L are complete.

Health Assessments

Facet L is of low oral, dermal and inhalation toxicity in rats. It is minimally irritating to the eyes and non-irritating to the skin of rabbits. It was not a dermal sensitzer.

Quinclorac, present as dimethylamine salt, was considered toxicologically equivalent to quinclorac acid and no further toxicological data was requested or required.

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The occupational exposure and risk from Facet L used on wheat (spring and durum), spring barley, canary seed, canola, Clearfield canola, brown and oriental tame mustard was assessed. No risks of concern are expected from this new product, provided that workers follow the label directions and wear the personal protective equipment identified on the label.

Residue data for quinclorac, present as dimethylamine salt, on cereals and canola were submitted to support the registration of Facet L. Quinclorac in the acid form is already registered for use as a dry flowable formulation (Accord Dry Flowable Herbicide) with a similar use pattern. The new form of the active ingredient and the new formulation are not anticipated to have an impact on the magnitude of the residues in the registered crops. No increase in dietary exposure to quinclorac is expected. The resulting residues will be covered under the maximum residue limits (MRLs) specified at 0.5 ppm on wheat, 2.0 ppm on barley and 3.5 ppm on barley bran for quinclorac, and the MRL specified at 1.5 ppm on commodities of Crop Subgroup 20A - Rapeseed (Revised) for quinclorac and the methyl ester metabolite BH 514ME. Residues of quinclorac and the methyl ester metabolite will not pose an unacceptable health risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

No additional environmental data were required to support the registration of Facet L. The uses, methods of application and rates of quinclorac in Facet L are similar to the precedent product Accord Dry Flowable Herbicide. No increase in environmental exposure to quinclorac is expected from the use of Facet L.

Value Assessment

The formulation of Facet L was compared to the formulation of the precedent product Accord Dry Flowable Herbicide. It was considered that the differences in the formulations between Facet L and Accord Dry Flowable Herbicide were significant (>10%); therefore, data from 15 efficacy trials and 14 dedicated crop tolerance trials (five trials on *Brassica napus* and nine trials on *Brassica juncea*) were further evaluated.

Control of cleavers, barnyard grass, green foxtail, and volunteer flax following the application of Facet L was comparable to that of Accord Dry Flowable Herbicide in the efficacy trials. Therefore, it was concluded that the treatment of Facet L is agronomically similar to the treatment of Accord Dry Flowable Herbicide when applied at the same rate on an a.i. per hectare basis. Efficacy claims registered on the Accord Dry Flowable Herbicide label are supported to be included on the Facet L.

Injury to five spring wheat varieties, two durum wheat varieties, four spring barley varieties, and two canary seed varieties following the application of Facet L at the labeled rate of 100 g a.i./ha or up to 2.5 x rate (250 g a.i./ha) was reported in five trials. Crop injury with Facet L at the labeled rate was either slight or not detectable in these trials. Yield data further confirmed that small grain cereals are expected to exhibit an adequate margin of crop safety to Facet L when applied in accordance with the label instructions.

Injury to six canola varieties and 11 *Brassica juncea* varieties (including three brown mustard varieties, three oriental mustard varieties, and five Clearfield canola quality *Brassica juncea* varieties) following the application of Facet L at the labeled rate of 100 g a.i./ha or the 2 x rate (200 g a.i./ha) was reported in nine trials. Crop injury was either minor or not observed for the treatment of Facet L at the labelled rate. Yield data further confirmed that these crops are expected to exhibit an adequate margin of crop safety to Facet L when applied in accordance with the label instructions.

Value information in support of the requested 2-way tank mix with either Liberty 150 SN Herbicide or Liberty 150 SN Herbicide and Crop Desiccant MP for enhanced and more consistent control of cleavers, and the 3-way tank mix with the addition of Centurion for enhanced and more consistent control of cleavers and annual grasses was also evaluated. Value information supported the inclusion of these tank mixes as per label instructions.

Rotational crop claims for Accord Dry Flowable Herbicide can be extrapolated to Facet L because the maximum application rate is the same for both products.

Conclusion

Following review of the application, the PMRA has approved the registration of Facet L for use on wheat (spring and durum), spring barley, canary seed, Clearfield canola, canola, and brown and oriental tame mustard. In addition tank mixes were approved with Liberty 150 SN Herbicide or Liberty 150 SN Herbicide and Crop Desiccant MP with or without Centurion when used on Liberty Link canola

References

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ISSN: 1911-8082

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