Evaluation Report for Category B, Subcategory 2.6 & 3.12 Application

Application Number:	2012-2408
Application:	New EP Product Chemistry-New combination of TGIAs, New to Product Labels-New Site or Host
Product:	V-10233 Herbicide (Fierce Herbicide)
Registration Number:	31117
Active ingredients (a.i.):	Flumioxazin, Pyroxasulfone [FOX, PXF]
PMRA Document Number:	**2337202**

Purpose of Application

The purpose of this application was to register a new end-use product, V-10233 Herbicide (Fierce Herbicide), for the control of various grasses and broadleaf weeds in soybean, fallow land, non-crop areas around farms, orchards and vineyards and to maintain bare ground on non-crop areas.

Chemistry Assessment

Fierce Herbicide is formulated as wettable granules containing pyroxasulfone at a nominal concentration of 42.5% and flumioxazin at a nominal concentration of 33.5%. The end-use product has a bulk density of 0.617 g/mL and the pH of 8.7. The chemistry requirements for Fierce Herbicide are complete.

Health Assessments

Fierce Herbicide is of low acute toxicity via the oral, dermal and inhalation routes of exposure. It is moderately irritating to the eyes and mildly irritating to the skin. It is not a skin sensitizer.

No new flumioxazin residue data were submitted in support of the proposed use of Fierce Herbicide on soybeans. Data on file for flumioxazin support the proposed use on soybeans. The proposed use of Fierce Herbicide is not expected to increase the magnitude of flumioxazin residues in/on soybeans. Therefore, the dietary exposure to flumioxazin is not expected to increase and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Residue data for pyroxasulfone in soybeans conducted in the US were submitted to support the use of this active on the labels of Pyroxasulfone 85 WG Herbicide and Fierce Herbicide. In addition, a processing study in treated soybeans was included in the field trial studies to determine the potential for concentration of residues of pyroxasulfone into soybean processed commodities.

Maximum Residue Limit(s)

Based on the residue data in soybeans, a maximum residue limit (MRL) to cover residues of pyroxasulfone and the metabolite M-28 in dry soybeans will be established as shown in Table 1. Residues of pyroxasulfone and the metabolite M-28 in processed commodities not listed in Table 1 are covered under MRL for the raw agricultural commodities (RACs).

Table 1 Summary of Field Trial and Processing Data Used to Establish Maximum Residue Limit(s) (MRLs)

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues[1] (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			Min	Max			
Dry soybeans	Postemergent spraying/208	85-137	<0.018	0.036	Meal: 1.5× Hulls: 0.9× Refined oil: 0.8×	None	0.06

[1] Combined residues of pyroxasulfone and the metabolite M-28.

Following the review of the available data, an MRL for dry soybeans is recommended to cover residues of pyroxasulfone and the metabolite M-28 in the crop. Residues of pyroxasulfone and the metabolite M-28 in the soybean crop commodities at the established MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

The exposure from the use of Fierce Herbicide for weed control/suppression in soybean, fallow land and non-crop areas around farms, as well as to maintain bare ground on non-crop areas, should not exceed that from the registered use pattern of flumioxazin. For pyroxasulfone, the proposed use requires application equipment that is different than the registered use. Hence, a health risk assessment was conducted for chemical handlers, re-entry workers and bystanders in contact with pyroxasulfone. As a result, no risks of concern were identified or are expected when workers follow the use directions/restrictions and wear the personal protective equipment stated on the label.

Environmental Assessment

The risk to non-target organisms (vertebrates and invertebrates) was assessed previously and published in the proposed regulatory decision document for pyroxasulfone (PRD2012-20) and the evaluation report for flumioxazin (ERC2010-05). The initial risk assessments for each active ingredient adequately characterize the risks to non-target organisms in the environment with regards to the Fierce Herbicide uses. Risks to terrestrial and aquatic plants were identified. Environmental concerns can be mitigated with buffer zones of 10-20 m and 2-5 m for terrestrial and aquatic habitats, respectively.

Value Assessment

Information submitted included data from 41 adequate field trials conducted in Canada and in the US over a three year period for review. Efficacy of Fierce Herbicide applied pre-plant surface or pre-emergence at rates of 210 g/ha (i.e. 90 g a.i./ha pyroxasulfone plus 70 g a.i./ha flumioxazin) and up or at these rates in a tank mixture with glyphosate or glufosinate ammonium was assessed in these trials. Visual percent control of all the listed weeds was evaluated on two to five occasions up to 139 days after treatments (DAT) during the growing season.

The data indicated that the control of each of the listed weeds following an application of Fierce Herbicide at the labeled rate range of 210 to 315 g/ha was acceptable across soil types. Antagonism between pyroxasulfone and flumioxazin co-formulated in Fierce Herbicide was not observed. Information made available supports control claims for lamb's-quarters, common ragweed, waterhemp, dandelion, Eastern black nightshade, green foxtail, green pigweed, hairy nightshade, large crabgrass, redroot pigweed, palmer amaranth, Pennsylvania smartweed, velvetleaf, wild buckwheat, and wild mustard with Fierce Herbicide applied pre-plant surface and pre-emergence at the labeled rate ranges of 210-315 g/ha in soybeans and 420-580 g/ha on bare ground in non-crop areas. The higher application rates are for season long residual weed control on medium and fine soils.

Tolerance of 19 soybean varieties to Fierce Herbicide applied alone at the labeled rate and 2 x rate or at these rates in a tank mixture with glyphosate was reported on two to three occasions during the growing season in 29 trials. Crop injury following the application of these treatments was observed in the early season, but it declined in the late season. The final grain yield with these treatments was comparable to the untreated weed-free control. Based on the information made available, a host claim for soybean is supported for labeling including an injury warning statement (which appears on the Flumioxazin 51 WDG label) on the Fierce Herbicide label.

The rotational cropping portion of the Fierce Herbicide label was extrapolated from the individual component label and reflects the restrictions on those labels.

In addition, the registration of Fierce Herbicide provides soybean growers with an effective residual weed control option. Residual activity of Fierce Herbicide reduces the needs for subsequent herbicide applications for control of the same weed spectrum. Fierce Herbicide consists of flumioxazin (Group 14) and pyroxasulfone (a novel chemical family in Group 15); therefore the registration would help with weed resistance management in soybeans, fallow land, and bare ground in non-crop areas.

Conclusion

The PMRA has conducted a review of the available information to register a new end-use product, V-10233 Herbicide (Fierce Herbicide), for the control of various grasses and broadleaf weeds in soybean, fallow land, non-crop areas around farms, orchards and vineyards and to maintain bare ground on non-crop areas and has determined that full registration can be supported.

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ISSN: 1911-8082