

Evaluation Report for Category B Subcategory 2.2, 2.3, 2.6, 3.1, 3.11, 3.12, 3.13, 3.2 Application

Application Number: 2011-5368
Application: B.2.2 New / Changes EP or MA Product Chemistry-Form of TGIA or ISP
B.2.3 New / Changes EP or MA Product Chemistry-Identity of Formulants
B.2.6 New / Changes EP or MA Product Chemistry-New combination of TGIAs
B.3.1 New or Changes to Product Labels-Application Rate Increase or Decrease
B.3.11 New or Changes to Product Labels-New Pests
B.3.12 New or Changes to Product Labels-New Site or Host
B.3.13 New or Changes to Product Labels-Precautions
B.3.2 New or Changes to Product Labels-Application Timing
Product: GF-2726 TSOY Herbicide
Registration Number: 30960
Active ingredients (a.i.): 2,4-D, present as choline salt
Glyphosate, present as dimethylamine salt
PMRA Document Number : 2403864

Purpose of Application

The purpose of this submission is to register a new end use product which is a combination of glyphosate present as dimethylamine salt and 2-4-D present as choline salt for control of annual and perennial weeds on a new genetically modified soybean (Enlist™ soybean), in summerfallow or prior to seeding or after seeding (but before crop emergence), in spring and winter varieties of wheat (including durum), barley and rye.

Chemistry Assessment

GF-2726 TSOY Herbicide is formulated as a solution containing 2,4-D, present as choline salt, at a nominal concentration of 194 g/L and glyphosate, present as dimethylamine salt, at a nominal concentration of 204 g/L. This end-use product has a density of 1.1676 g/mL and a pH of 6.17. The chemistry requirements for GF-2726 TSOY Herbicide are complete.

Health Assessments

The use of glyphosate on ENLIST soybeans, summerfallow and cereals and the use of 2,4-D on summerfallow and cereals falls within the registered use pattern for this active ingredient. 2,4-D is not currently registered for use on soybeans at the proposed application rate and in addition, the application rate is higher than the currently registered rate on other crops. An updated risk assessment for the use of 2,4-D choline salt on soybeans was conducted for chemical handlers and postapplication workers, and no risks of concern are expected provided that all label statements and precautions are followed.

Metabolism and residue data for 2,4-D in genetically modified soybeans (AAD-12 soybeans) were submitted to support the registration of the new end-use product GF-2726 TSOY Herbicide, containing the choline salt of 2,4-D and the dimethylamine salt of glyphosate, for use on ENLIST soybeans. No new residue data were submitted for application prior to or after seeding (but prior to crop emergence) of wheat, rye and barley, or for use in summerfallow. Given that the application rates approved for use on wheat, barley and rye are lower than those registered for early post-emergent application to wheat, barley and rye, exposure to residues of 2,4-D in wheat, barley and rye commodities treated according to the approved rates should not increase. Based on the results of the previously reviewed confined accumulation study, there should be minimal uptake of residues in crops planted subsequent to the treatment in summerfallow according to the approved use directions.

No new residue data were submitted for glyphosate. Given that the application rates for glyphosate approved for use on ENLIST soybeans, wheat, barley, rye and summerfallow are within the registered rates for glyphosate on glyphosate tolerant soybeans, and for cropland use including wheat, barley, rye and summerfallow, exposure to residues of glyphosate in treated crop commodities will not increase for any segment of the population, and will remain acceptable and below the level of concern.

Maximum Residue Limits

Residue data from field trials conducted in Canada and the United States were submitted to support the domestic use of GF-2762 TSOY Herbicide on AAD-12 soybeans. 2,4-D dimethylamine was applied to AAD-12 soybeans at exaggerated rates, and harvested according to label directions. In addition, a processing study in treated AAD-12 soybeans was reviewed to determine the potential for concentration of residues of 2,4-D into processed commodities. Residues of 2,4-D in processed commodities not listed in Table 1 are covered under established MRL for the raw agricultural commodity (RAC).

TABLE 1. Summary of Field Trial and Processing Data on AAD-12 Soybeans.

Commodity	Application Method/ Total Application Rate (kg a.i./ha)	PHI (days)	2,4-D Residues (ppm)		Experimental Processing Factor	Currently Established MRL	Recommended MRL
			Min	Max			
Transgenic soybean seed	Pre- and Post-emergence broad applications/ 3.3-3.5	51-103	<0.01	<0.01	Could not be determined as residues of 2,4-D were <0.01 ppm in soybean seed and refined oil when treated at exaggerated rates	0.02 ppm Dry soybeans (under promulgation)	None

Based on the anticipated dietary burden to livestock and the residue data provided, maximum residue levels (MRLs) of 3.0 ppm in the kidney of cattle, goats, horses and sheep; 0.3 ppm in the meat, meat byproducts (except kidney) of cattle, goats, horses and sheep; 0.05 ppm in the meat, meat byproducts and fat of hogs and poultry; 0.03 ppm in milk; 0.05 ppm in the meat, meat byproducts and fat of hogs and poultry; and 0.01 ppm in eggs are recommended.

Following the review of all available data, residues of 2,4-D in transgenic soybean seed and refined oil will be covered under the MRL of 0.02 ppm being promulgated for dry soybeans. MRLs of 3.0 ppm in the kidney of cattle, goats, horses and sheep; 0.3 ppm in the meat, meat byproducts (except kidney) of cattle, goats, horses and sheep; 0.05 ppm in the meat, meat byproducts and fat of hogs and poultry; 0.03 ppm in milk; 0.05 ppm in the meat, meat byproducts and fat of hogs and poultry; and 0.01 ppm in eggs are recommended based on the anticipated dietary burden to livestock. Residues of 2,4-D in these crop and livestock commodities at the established and proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

GF-2726 T-Soy Herbicide was of slight acute oral ($LD_{50} = 1200$ mg/kg bw) and of low acute dermal ($LD_{50} > 5000$ mg/kg bw) and inhalation ($LC_{50} > 5.21$ mg/L) toxicity in rats. It is severely irritating to the eye and slightly irritating to the skin of rabbits. It is not a dermal sensitizer in the mouse. Table 2 shows the summary of acute toxicity studies.

Table 2. Summary of Acute Toxicity Studies with GF-2726 TSOY Herbicide and Label Recommendations

Parameter	Species	Result	Primary Display Panel Labelling
Acute Oral LD ₅₀ Up and Down (425)	rat 2 at 600 mg/kg 2 at 1200 mg/kg 1 at 2390 mg/kg	LD ₅₀ ♀ = 1200 mg/kg	CAUTION - POISON
Acute Dermal LD ₅₀	5 rats/sex/dose Dosed at 5000 mg/kg	LD ₅₀ ♂♀ > 5000 mg/kg	No hazard signal words required.
Acute Inhalation LC ₅₀	5 rats/sex/dose Dosed at 5.21 mg/L	LC ₅₀ ♂♀ > 5.21 mg/L	No hazard signal words are required.
Primary Eye Irritation	3 male rabbits Dosed with 0.1 mL	MAS ^a = 35.3/110 MIS ^b = 35.3/110	DANGER - EYE IRRITANT
Primary Skin Irritation	3 female rabbits Dosed with 0.5 g	MAS = 0.7/8	No hazard signal words are required.
Skin Sensitization LLNA	6 female mice/dose Dosed with 5, 25 or 50%	Stimulation Index 5% - 1.4 25% - 1.4 50% - 1.2	No hazard signal words required.

^a MAS = Maximum Average Score for 24, 48 and 72 hrs

^b MIS = Maximum Irritation Score

Environmental Assessment

2,4-D choline salt is considered equivalent to the acid/amine forms of 2,4-D. As the proposed application rates of GF-2726 TSOY Herbicide are within the registered rates for products containing 2,4-D, it is not expected that an additional environmental risk will be associated with the use of 2,4-D choline.

Adequacy of proposed mitigation measures such as spray buffer zones will be assessed upon completion of the re-evaluation of glyphosate.

Value Assessment

The efficacy claims supported for GF-2726 Herbicide under App. No. 2011-5211 are also supported for GF-2726 TSOY Herbicide under App. No. 2011-5368. In addition to the “in-crop” data submitted under App. No. 2011-5211, data were submitted to support efficacy claims for the preseed and summerfallow uses for GF-2726 TSOY Herbicide.

Over four trials that were conducted in fallow, the efficacy of treatments of GF-2726 TSOY Herbicide was similar to that of tank mixtures of 2,4-D (ester formulation) plus glyphosate applied at the same rates of active ingredient, on an acid equivalent basis, for control of wild oats, volunteer canola, shepherd’s-purse, round-leaved mallow, wild buckwheat and chickweed.

In one trial in which herbicides were applied to emerged weeds one day prior to planting spring wheat (to simulate pre-plant burnoff), the efficacy of treatments of GF-2726 TSOY Herbicide was similar to that of tank mixtures of 2,4-D (ester formulation) plus glyphosate applied at the same rates of active ingredient, on an acid equivalent basis, for control of volunteer canola, cleavers, annual sow-thistle and dandelion.

GF-2726 TSOY Herbicide is supported for application in summerfallow and either prior to seeding or prior to emergence of spring wheat, winter wheat, barley and rye since the efficacy of GF-2726 TSOY Herbicide was demonstrated to be similar to that of tank mixtures of glyphosate with amine and ester formulations of 2,4-D applied at equivalent rates in both in-crop and non-crop situations, and since use in summerfallow and prior to seeding or prior to emergence of these cereal crops is currently registered for tank mixtures of 2,4-D plus glyphosate. It should be noted that ‘spring wheat’ includes durum wheat.

Fourteen dedicated crop tolerance trials were conducted to assess the tolerance of soybean with the AAD-12 gene and a glyphosate tolerance gene to tank mixes of glyphosate plus 2,4-D, formulated as the dimethylamine salt (DMA), and to GF-2726 TSOY Herbicide. The crop tolerance parameters evaluated included percent injury, chlorosis, epinasty, growth inhibition and necrosis. Soybean varieties with the AAD-12 gene plus a glyphosate tolerance gene exhibited adequate tolerance to 2,4-D alone, whether formulated as the choline or DMA salt, to tank mixtures of 2,4-D plus glyphosate, and to GF-2726 TSOY Herbicide regardless of crop growth stage at the time of application. The growth stage of soybean ranged from the third trifoliolate stage (V3) to full bloom (R2).

The availability of GF-2726 TSOY Herbicide for post-emergence application to 2,4-D- and glyphosate-tolerant soybean, i.e. varieties designated as Enlist, at up to the full flowering stage of the crop, will provide farmers an effective broad spectrum weed control option while mitigating the potential for the development of resistance of weeds to other commonly used herbicides. Also, GF-2726 TSOY Herbicide, will provide farmers with a co-formulated option for broad spectrum weed control in summerfallow, prior to seeding, or prior to crop emergence, in wheat, winter wheat, barley and rye.

Conclusion

The Pest Management Regulatory Agency (PMRA) has carried out an evaluation of available information and has concluded that the registration for a new end-use product with a new salt form of 2,4-D (present as choline salt) in combination with glyphosate (as dimethylamine salt) for ground application on a new genetically modified soybean (Enlist™ soybean), in summerfallow or prior to seeding or after seeding (but before crop emergence), in spring and winter varieties of wheat (including durum), barley and rye can be supported.

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Chemistry

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