

Evaluation Report for Category B, Subcategory B.2.1, B.2.3, B.2.4 Application

Application Number: 2007-5221

Application: B.2.1 (Product chemistry - Guarantee), B.2.3 (Product chemistry -

Identity of Formulants), B.2.4 (Product chemistry - Proportion of

Formulants)

Product: Harmony Grass 128EC Herbicide

Registration Number: 29202

Active ingredients (a.i.): Clodinafop-propargyl (CFP)

PMRA Document Number: 1693529

Purpose of Application

Syngenta Crop Protection Canada, Inc. a proposal for a new agricultural herbicide, Harmony Grass 128EC Herbicide (128 g clodinafop-propargyl/L, a Group 1 herbicide) for post-emergent control of wild and volunteer oats, green and yellow foxtail, Persian darnel and volunteer canaryseed in spring and Durum wheat at rates of 438-547 mL product/ha (56-70 g a.i/ha) to be applied once per year as a ground-based or aerial foliar spray. This proposal was for regional registration in the Prairie provinces and the Peace River, Okanagan and Creston Flats regions of British Columbia. The proposed use pattern and label is similar to that of Horizon 240EC Herbicide (Reg. No. 24067) which contains the same active ingredient.

Chemistry Assessment

Harmony Grass 128EC Herbicide is formulated as an emulsifiable concentrate containing clodinafop-propargyl at a nominal concentration of 128 g/L. This end-use product has a density of 1.01 g/mL and pH of 6-7. The chemistry requirements for Harmony Grass 128EC Herbicide are complete.

Health Assessments

Harmony Grass 128EC Herbicide was of low acute toxicity by the oral (male $LD_{50} = 2614$ mg/kg, female $LD_{50} = 3162$ mg/kg, combined $LD_{50} = 2933$ mg/kg), dermal ($LD_{50} = > 2020$ mg/kg) and inhalation ($LC_{50} = > 2.74$ mg/L) routes of exposure. Harmony Grass 128EC Herbicide was slightly irritating to the skin, moderately irritating to the eyes and was not a skin sensitizer.

The new end-use product, Harmony Grass 128EC Herbicide, fits within the existing use pattern for the active ingredient clodinafop-propargyl. No unacceptable risk is expected when workers follow the label directions and wear the personal protective equipment stated on the label.

The use of Harmony Grass 128EC Herbicide will not affect residues of the active ingredient clodinafop-propargyl on wheat, as the application rate of the active ingredient, PHI and use pattern on the proposed product label are similar to those of the registered product Horizon 240EC Herbicide. Residue data for clodinafop-propargyl in wheat was submitted to support the registration of the new end use product Harmony Grass 128EC Herbicide. Based on the data, no increase in dietary exposure is anticipated.

Maximum Residue Limit

Based on the maximum residues observed in wheat treated according to label directions, a maximum residue limit (MRL) to cover residues of up to 0.1 ppm in/on wheat grain will be established as shown in Table 1. Processed commodities not listed in Table 1 are covered under the established MRL for the raw agricultural commodity (RACs).

TABLE 1. Summary of Field trial Data Used to Establish Maximum Residue Limits (MRLs)							
Commodity	Application	PHI	Residue	s (ppm)	Currently	Recommended	
	Method/Max Application rate	(days)	Min	Max	Established MRL	MRL (ppm)	
Clodinafop-propargyl and CGA 193469							
Wheat grain	Ground application/ 70 g a.i./ha clodinafop-	51-56	<0.05 per analyte	<0.05 per analyte	None	0.1 ppm to cover residues of both clodinafop-	
	propargyl					propargyl and CGA 193469	

Following the review of all available data, an MRL of 0.1 ppm for wheat grain is recommended to cover residues of up to 0.05 ppm of clodinafop-propargyl, plus residues of up to 0.05 ppm for the acid metabolite CGA 193469. Combined residues of up to 0.1 ppm in this crop commodity at the established MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

As the intended use pattern and label is similar to that of Horizon 240EC Herbicide which contains the same active ingredient, the EAD does not require further information at this time. There is no potential increase in the environmental exposure and impact from that of the currently registered use of clodinafop-propargyl. Environmental concerns are mitigated with label statements.

Value Assessment

A total of 53 field trial studies conducted in Alberta, Saskatchewan and Manitoba over one year (1998) were submitted for review. Forty-two trials assessed efficacy and all 53 trials assessed crop tolerance of spring and durum wheat after post-emergence applications of Harmony Grass 128EC Herbicide.

Efficacy data collected for Harmony Grass 128EC Herbicide treatments applied alone and in tank mix were similar to Horizon 240EC Herbicide + Score adjuvant treatments. Harmony Grass 128EC Herbicide and Horizon 240EC Herbicide + Score adjuvant were shown to be agronomically equivalent. Antagonism was not observed with the proposed tank mixtures.

Crop injury was visually assessed throughout the growing season in spring and durum wheat. Data collected with Harmony Grass 128EC Herbicide alone and in tank mix were similar to Horizon 240EC Herbicide + Score adjuvant treatments and thus supported crop tolerance claims. Yield was assessed in five dedicated crop tolerance trials for spring wheat and six dedicated crop tolerance trials for durum wheat. Crop yield from Harmony Grass 128EC Herbicide treatments applied alone at the 1x and 2 x rates were similar to Horizon 240EC Herbicide + Score adjuvant treatments applied alone at the 1x and 2x rates.

Conclusion

The PMRA has completed an assessment of the application to register Harmony Grass 128EC Herbicide and have approved the registration.

References

PMRA# 1451284	2007, HORIZON 128EC Herbicide - Identification, DACO: 3.1.1,3.1.3,3.1.4
PMRA# 1451285 PMRA# 1451286	2007, HORIZON 128EC Herbicide - Identification, DACO: 3.1.2 CBI 2007, HORIZON 128EC Herbicide - Starting Materials, DACO: 3.2.1 CBI
PMRA# 1451287 PMRA# 1451288	2007, HORIZON 128EC Herbicide - Manufacturing Process, DACO: 3.2.2 CBI 2007, HORIZON 128EC Herbicide - Discussion of Formation of Impurities,
	DACO: 3.2.3 CBI
PMRA# 1451289	2007, HORIZON 128EC Herbicide - Certification of Limits, DACO: 3.3.1 CBI
PMRA# 1451290	1999, Analytical Method AF-1325/1 CGA-184927 / CGA-185072 in EC Formulation (A11914A), AF-1325/1, DACO: 3.4.1 CBI
PMRA# 1451291	2007, HORIZON 128EC Herbicide - Chemical and Physical Properties, DACO: 3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15, 3.5.2,3.5.3,3.5.4, 3.5.5, 3.5.6,3.5.7,3.5.8,3.5.9
PMRA# 1451292	2001, Chemical Stability of CGA-184927/CGA-185072 128EC (A-11914A) at Ambient Temperature, 552-98F, DACO: 3.5.1,3.5.10,3.5.11,3.5.12,
PMRA# 1555975	3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9 2008, DACO: 3.5.10: Chemical and Physical Properties: Storage Stability
	Data - Response to PMRA Clarifax, DACO: 3.5.10
PMRA# 1451293	1998, Summary of Acute Toxicology Studies, DACO: 4.1
PMRA# 1451294	1998, Acute Oral Toxicity Study in Rats, 285-98, DACO: 4.6.1
PMRA# 1451295	1998, Acute Dermal Toxicity Study in Rabbits, 286-98, DACO: 4.6.2
PMRA# 1451296	1998, Acute Inhalation Toxicity Study in Rats, 287-98, DACO: 4.6.3
PMRA# 1451297	1998, Primary Eye Irritation Study in Rabbits, DACO: 4.6.4
PMRA# 1451298	1998, Primary Dermal Irritation Study in Rabbits, 288-98, DACO: 4.6.5
PMRA# 1451299 PMRA # 1451308	1998, Dermal Sensitization Study in Guinea Pigs, 289-98, DACO: 4.6.6 2007, Three Crop residue trials to determine the residues of CGA 184927,
FWIKA # 1431300	CGA 185072 and their significant crop metabolites after application of
	HORIZON 128 EC as a post-emergent herbicide on wheat in comparison to
	a tank mixture of HORIZON 240 EC plus SCO
PMRA# 1451310	2007, HORIZON 128EC Herbicide - Efficacy Summary, DACO: 10.2.3.1
PMRA# 1451311 CBI	2007, HORIZON 128EC Herbicide - Efficacy Summary, DACO: 10.2.3.1
PMRA# 1451313	2007, Efficacy Abstract - CAAB0H0161998, DACO: 10.2.3.3
PMRA# 1451314	2007, Efficacy Abstract - CAAB0H0241998, DACO: 10.2.3.3
PMRA# 1451315	2007, Efficacy Abstract - CAAB0H0251998, DACO: 10.2.3.3
PMRA# 1451316	2007, Efficacy Abstract - CAAB0H0291998, DACO: 10.2.3.3
PMRA# 1451317	2007, Efficacy Abstract - CAMB0H6161998, DACO: 10.2.3.3
PMRA# 1451318	2007, Efficacy Abstract - CAMB0H6201998, DACO: 10.2.3.3
PMRA# 1451319	2007, Efficacy Abstract - CAMB0H6211998, DACO: 10.2.3.3
PMRA# 1451320	2007, Efficacy Abstract - CAMB0H6221998, DACO: 10.2.3.3
PMRA# 1451321	2007, Efficacy Abstract - CAMB0H6231998, DACO: 10.2.3.3
PMRA# 1451322	2007, Efficacy Abstract - CAMB0H6241998, DACO: 10.2.3.3
PMRA# 1451323	2007, Efficacy Abstract - CAMB0H6261998, DACO: 10.2.3.3

```
2007, Efficacy Abstract - CAMB0H6271998, DACO: 10.2.3.3
PMRA# 1451324
                 2007, Efficacy Abstract - CAMB0H6281998, DACO: 10.2.3.3
PMRA# 1451325
                 2007, Efficacy Abstract - CAMB0H6291998, DACO: 10.2.3.3
PMRA# 1451326
                 2007, Efficacy Abstract - CAMB0H6301998, DACO: 10.2.3.3
PMRA# 1451327
PMRA# 1451328
                 2007, Efficacy Abstract - CASK0H3161998, DACO: 10.2.3.3
                 2007, Efficacy Abstract - CASK0H3171998, DACO: 10.2.3.3
PMRA# 1451329
                 2007, Efficacy Abstract - CASK0H3181998, DACO: 10.2.3.3
PMRA# 1451330
                 2007, Efficacy Abstract - CASK0H3191998, DACO: 10.2.3.3
PMRA# 1451331
PMRA# 1451332
                 2007, Efficacy Abstract - CASK0H3201998, DACO: 10.2.3.3
                 2007. Efficacy Abstract - CASK0H3211998. DACO: 10.2.3.3
PMRA# 1451333
                 2007, Efficacy Abstract - CASK0H3221998, DACO: 10.2.3.3
PMRA# 1451334
PMRA# 1451335
                 2007, Efficacy Abstract - CASK0H3241998, DACO: 10.2.3.3
PMRA# 1451336
                 2007, Efficacy Abstract - CASK0H3251998, DACO: 10.2.3.3
                 2007, Efficacy Abstract - CASK0H3261998, DACO: 10.2.3.3
PMRA# 1451337
                 2007, Efficacy Abstract - CASK0H3321998, DACO: 10.2.3.3
PMRA# 1451338
PMRA# 1451339
                 2007, Efficacy Abstract - CASK0H3331998, DACO: 10.2.3.3
                 2007, Efficacy Abstract - CASK0H4161998, DACO: 10.2.3.3
PMRA# 1451340
                 2007, Efficacy Abstract - CASK0H4171998, DACO: 10.2.3.3
PMRA# 1451341
                 2007, Efficacy Abstract - CASK0H4181998, DACO: 10.2.3.3
PMRA# 1451342
PMRA# 1451343
                 2007, Efficacy Abstract - CASK0H4191998, DACO: 10.2.3.3
                 2007, Efficacy Abstract - CASK0H4201998, DACO: 10.2.3.3
PMRA# 1451344
PMRA# 1451345
                 2007, Efficacy Abstract - CASK0H4211998, DACO: 10.2.3.3
PMRA# 1451346
                 2007, Efficacy Abstract - CASK0H4221998, DACO: 10.2.3.3
                 2007, Efficacy Abstract - CASK0H4241998, DACO: 10.2.3.3
PMRA# 1451347
                 2007, Efficacy Abstract - CASK0H4261998, DACO: 10.2.3.3
PMRA# 1451348
                 2007, Efficacy Abstract - CASK0H4271998, DACO: 10.2.3.3
PMRA# 1451349
PMRA# 1451350
                 2007, Efficacy Abstract - CASK0H4291998, DACO: 10.2.3.3
                 2007, Efficacy Abstract - CASK0H4301998, DACO: 10.2.3.3
PMRA# 1451351
PMRA# 1451352
                 2007, Efficacy Abstract - CASK0H4311998, DACO: 10.2.3.3
PMRA# 1451353
                 2007, Efficacy Abstract - CASK0H4321998, DACO: 10.2.3.3
PMRA# 1451354
                 2007, Efficacy Abstract - CASK0H4331998, DACO: 10.2.3.3
PMRA# 1451355
                 2007, HORIZON 128EC Herbicide - Crop Tolerance Summary, DACO:
             10.3.1
PMRA# 1451356
                 2007, Crop Tolerance Abstract - CAAB0H0131998, DACO: 10.3.2
                 2007, Crop Tolerance Abstract - CAAB0H0151998, DACO: 10.3.2
PMRA# 1451357
                 2007, Crop Tolerance Abstract - CAMB0H6111998, DACO: 10.3.2
PMRA# 1451358
PMRA# 1451359
                 2007, Crop Tolerance Abstract - CAMB0H6121998, DACO: 10.3.2
PMRA# 1451360
                 2007, Crop Tolerance Abstract - CAMB0H6131998, DACO: 10.3.2
PMRA# 1451361
                 2007, Crop Tolerance Abstract - CAMB0H6141998, DACO: 10.3.2
                 2007, Crop Tolerance Abstract - CAMB0H6151998, DACO: 10.3.2
PMRA# 1451362
                 2007, Crop Tolerance Abstract - CASK0H3151998, DACO: 10.3.2
PMRA# 1451363
PMRA# 1451364
                 2007, Crop Tolerance Abstract - CASK0H4111998, DACO: 10.3.2
                 2007, Crop Tolerance Abstract - CASK0H4121998, DACO: 10.3.2
PMRA# 1451365
                 2007, Crop Tolerance Abstract - CASK0H4141998, DACO: 10.3.2
PMRA# 1451366
```

ISSN: 1911-8082
[®] Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2010
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.