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OFFICE OF
PREVENTION, PESTICIDES AND
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MEMORANDUM

SUBJECT: Clothianidin Registration of New Products Sepresto 75WS and PROCEED™ OPTIMUM, for Seed Treatment; New Uses for the Chemical on Tuberous and Corm Vegetables (CSG 1C), Bulb Vegetables (Seed Treatment only) (CG 3), Leafy Greens (CG 4), Brassica (Cole) Vegetables (CG 5), Fruiting Vegetables (CG 8), Cucurbit Vegetables (CG 9), Cranberry and Low Growing Berries (Except Strawberry) (CSG 13-07H), Tree Nuts (CG 14), Cereal Grains (Except Rice, Seed Treatment Only) (CG 15), Figs, Pomegranates, Cotton, Soybeans, Peach and Potato Seed Pieces Treatment

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EFED has conducted a revision of the proposed new uses for clothianidin. At this time, a new ecological risk assessment is not required because the previously issued assessments cover the new uses. The risks found in previous assessments should be similar for the new uses. The previous assessments are the following: D278110, D287186+, D335254.

Background:
The registrants of clothianidin, Bayer CropScience and Valent U.S.A., are applying for registration of new multiactive ingredient products for seed treatment and for several new uses of the chemical. This review covers only the active ingredient clothianidin.

The first registrant Bayer CropScience is petitioning registration of two multiactive ingredient products for seed treatment. One product is Sepresto 75WS (EPA Reg. No. 264-XXX), containing clothianidin (56.25%) and imidacloprid (18.75%). This product is for the treatment of seeds of root vegetables (CG 1), bulb vegetables (CG 3), leafy green vegetables (CSG 4A), brassica (cole) vegetables (CG 5), fruiting vegetables (CG 8), cucurbit vegetables (CG 9), cereal grains (except rice) (CG 15) and potato seed pieces. The other product is PROCEED™ OPTIMUM (EPA Reg. No. 264-XXX), containing clothianidin (1.46%), and the fungicides prothioconazole (1.46%), tebuconazole (0.29%) and methalaxil (0.59%), for the treatment of seeds of barley, wheat & triticale.

The second registrant Valent U.S.A. is petitioning new uses of clothianidin for its products Arena 50WDG (EPA Reg. No. 59639-152), V-10170 2.13 SC (EPA Reg. No. 59639-150), V-10170 5FS (EPA Reg. No. 59639-151), CLUTCH 50 WDG (EPA Reg. No. 59369-152) and Belay 16WSG (EPA Reg. No. 59639-153). Of these products, V-10170 5FS is for seed treatment only. The new uses involved are tuberous and corm vegetables (CSG 1C), leafy greens (CG 4), brassica (cole) vegetables (CG 5), fruiting vegetables (CG 8), cucurbit vegetables (CG 9), cranberry and low growing berries (except strawberry) (CSG 13-07H), tree nuts (CG 14), figs, pomegranates, cotton, soybeans and peach.

It is noted that there is overlap between the petitions by Bayer CropScience and Valent U.S.A. A table of the uses is included in the Appendix A. The new uses are shaded yellow and bolded, while the current uses are not shaded.

Previous Assessments Cover Current Uses
EFED has previously conducted various assessments of uses of clothianidin. For example, on 2/20/03, EFED conducted an assessment of the use of the chemical for canola and corn seed treatment (D278110). Later, on 11/4/05 and 9/28/05, assessments of the use of clothianidin on tobacco, turf, apples, pears, ornamentals, potatoes and grapes, and seed treatment of sorghum and cotton were conducted (D287186+ and D313414). The assessment of the treatment of sugarbeet seeds (D335254, 6/12/07), was based on a previously issued Section 18 for the same use (D326569+, 2/23/06).

Of the previously assessed uses, the one that involves the greatest exposure to aquatic organisms, is turf, with a single application at 0.4 lb a.i./A. For ornamentals in commercial and residential outdoor landscapes, a single soil application at 0.4 lb a.i./A is also allowed. Of the new uses for seed treatment, it appears that the highest application rate is for root and tuberous vegetables (represented by carrots) and potato seed pieces (application rate of approximately 0.25 lb a.i./A). The maximum seasonal application rate for the new uses, according to the labels, is specified in Sepresto 75WS. It is 0.375

lb a.i./A for root and tuberous vegetables, bulb vegetables, leafy green vegetables, brassica (cole) leafy vegetables, fruiting vegetables and cucurbit vegetables. This rate is still lower than the one for turf.

The aquatic exposure for the new uses is expected to be similar to those previously found for turf and other crops, and the risks found for aquatic organisms should be similar for the new crops. The exposure to terrestrial organisms related to the new uses should be similar to the ones for previously assessed uses, such as turf and ornamentals (maximum application rate 0.4 lb a.i./A), and for apples, pears and potatoes (for which a seasonal rate of 0.2 lb a.i./A was assessed). A listing of endangered species was not attached due to the volume of such a listing because of the multitude of crop uses.

Reported Incident

Bayer has submitted an interim report (MRID 477987-01) on a study they are conducting in Austria. According to the report, the objective of the study was to investigate the frequency at which maize seedlings exude guttation fluid and to assess the relevance of guttation fluid to honeybees. Although not specifically mentioned in the text of the report, the study material appears to be clothianidin (based on one of the report figures). Over the two study areas, roughly 83% of the maize seedlings exuded guttation liquid. According to the report 16% of the assessment days at which guttation fluid was observed, honeybees were present when no alternative water supply was available; however, when alternative water was available, the honeybee visitation rate was 4%. Clothianidin residue levels in bees were greater than the level of quantification up to 14 days after seedling emergence; in bees without alternative water supply, honeybee mortality appeared to be correlated with clothianidin residues; however, the number of bees for which this relationship existed is uncertain. The study authors state that despite an increased bee mortality in some hives for 1 - 3 days during the survey, the overall development of the hives was not adversely affected by guttation fluid even under realistic, worst case exposure conditions.

This is an interim report and it does not contain sufficient detail or raw data with which to understand the study. The methods section does not describe the placement of colonies with and without water, nor is it possible to determine what bees were actually foraging on during the study period. It appears from the study that at least some of the bees did take advantage of the guttation liquid and that they were exposed to clothianidin. In some cases, bees exhibited behavioral effects and increased incidence of mortality that appeared to be associated with elevated clothianidin residues.

Clothianidin is a neonicotinoid insecticide that is relatively persistent in the environment; the compound is intended to be systemic in plants and the extent to which residues may be present in various plant tissues from seed treatments is uncertain. Clothianidin is highly toxic to bees on both an acute contact and oral exposure basis. A concern from the current seed treatment uses may be to beneficial insects (pollinators) that forage on crops grown from treated seed where exposure may occur through ingestion of residues in pollen and nectar as well as through guttation water produced by developing seedlings. Seed treatments are normally considered a lower exposure element to bees due to full

ground incorporation of the seeds as well as a low drift component of the application to adjacent areas where bees may forage. However, recent incidents in Europe resulting from seed treatments where appropriate stickers were not utilized, indicate that dust-off drift can also have a significant impact on pollinators foraging in the vicinity of recently seeded fields under some environmental conditions. As such, there is uncertainty regarding the extent to which seed treatments may represent a route of exposure due to the compound's systemic and persistent nature.

Appendix A: Summary of Use Information for Clothianidin

Table 1. Summary use information for clothianidin, including current uses (not shaded) and proposed uses (shaded gray and bolded) [from proposed labels for Arena 50WDG (EPA Reg. No. 59639-152), V-10170 2.13 SC (EPA Reg. No. 59639-150), V-1017 5FS (EPA Reg. No. 59639-151), CLUTCH 50 WDG (EPA Reg. No. 59369-152), Belay 16WSG (EPA Reg. No. 59639-153), Sepresto 75WS[3] (EPA Reg. No. 264-XXX) and PROCEED™ Optimum[4] (EPA Reg. No. 264-XXX)].

PURPOSE/ SOURCE	USE	oz a.i./ 100 lb seed	oz a.i./ 1000 seed	MAX. IND. APP. RATE (lb. a.i./A)[12]	SEASONAL APP. RATE (lb. a.i./A)	Comments
Sepresto 75WS[4]	**Root & Tuber veg.(CG1)**	**NA**	**0.01575**	**0.24[5]**	**0.375**	**Seed Treatment**
Arena 50WDG, V-10170 2.13SC	**Tuberous and corm veg (CSG 1C)**	**NA**	**NA**	**0.05 In furrow 0.2**	**0.2**	
Sepresto 75WS	**Potato Seed pieces**	**0.20**	**NA**	**0.25***	**NS**	**Seed Treatment**
Arena 50WDG, V-10170 2.13SC, Belay 16WSG	Potato	NA	NA	0.05 In furrow 0.2	0.2	
V-10170 2.13SC	Potato Seed pieces	0.14	NA	0.175*	NS	
V-1017 5FS	Potato Seed pieces	0.12	NA	0.15*	NS	Seed Treatment – *based on seeding rate of 2000 lb/A (from this label)
Sepresto 75WS	**Bulb veg. (CG 3)**	**NA**	**0.0071**	**0.19[6]**	**0.375**	**Seed Treatment**
Sepresto 75WS	**Leafy Greens veg. (CG 4 or 4A)**	**NA**	**0.028**	**0.075[7]**	**0.375**	**Seed Treatment**
Arena 50WDG, V-10170 2.13SC		**NA**	**NA**	**0.067 Soil-0.2**	**0.2**	
Sepresto 75WS	**Brassica (Cole) Leafy veg (CG 5)**	**NA**	**0.0416**	**0.11[8]**	**0.375**	**Seed Treatment**
Arena 50WDG, V-10170 2.13 SC		**NA**	**NA**	**Foliar-0.067 Soil-0.2**	**0.2**	
Sepresto 75WS	**Fruiting veg. (CG 8)**	**NA**	**0.0174**	**0.001[9]**	**0.375**	**Seed Treatment**
Arena 50WDG, V-10170 2.13SC		**NA**	**NA**	**0.067 Soil-0.2**	**0.2**	
Sepresto 75WS,	**Cucurbit veg. (CG 9)**	**NA**	**0.034**	**0.046[10]**	**0.375**	**Seed Treatment**
Arena 50WDG, V-10170 2.13SC		**NA**	**NA**	**0.067 Soil-0.2**	**0.2**	
Arena 50WDG, V-10170 2.13SC	**Tree Nut (CG 14)**	**NA**	**NA**	**0.1**	**0.2**	

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PURPOSE/ SOURCE	USE	oz a.i./ 100 lb seed	oz a.i./ 1000 seed	MAX. IND. APP. RATE (lb. a.i./A)[12]	SEASONAL APP. RATE (lb. a.i./A)	Comments
Sepresto 75WS	**Cereal Grain (CG 15 w/o rice) (*e.g.* corn, barley, sorghum, wheat)**	**1.13**	**NA**	**0.094[1]**	**NA**	**Seed Treatment**
PROCEED™ OPTIMUM[5]	**Barley, wheat & triticale**	**0.11**	**NA**	**0.0090[1]**	**NA**	**Seed Treatment**
V-10170 5FS	Sorghum	3.1	NA	0.02[13]		Seed Treatment
V-10170 5FS	Canola, Rapeseed	4.89	NA	0.05[13]		Seed Treatment
V-10170 5FS	Corn (field, pop, seed & sweet corn)	NA	NA	0.1[13]		Seed Treatment: 5.64 oz product/ 80,000 seed; 1.25 mg a.i./ kernel
Arena 50WDG, V-10170 2.13SC	**Figs**	**NA**	**NA**	**0.0938**	**0.2**	
Arena 50WDG, V-10170 2.13SC	**Pomegranates**	**NA**	**NA**	**0.0938**	**0.2**	
Arena 50WDG, V-10170 2.13SC	**Cotton**	**NA**	**NA**	**0.067**	**0.2**	**Foliar applic.**
V-10170 5FS	**Soybeans**	**0.612**	**NA**	**0.02[11]**	**NS**	**Seed treatment**
Arena 50WDG, V-10170 2.13SC		**NA**	**NA**	**0.067**	**0.2**	
Arena 50WDG	**Peach**	**NA**	**NA**	**0.1**	**0.2**	
Arena 50WDG, V-10170 2.13SC	**Cranberry and low growing berry, except strawberry (CSG 13-07H)**	**NA**	**NA**	**0.066 Soil: 0.2**	**0.2**	
Arena 50WDG, V-10170 2.13SC, Clutch 50WDG	Grapes	NA	NA	0.1 soil 0.2	0.2	
Arena 50WDG, V-10170 2.13SC, Clutch 50WDG	Pome Fruits (various)	NA	NA	0.2	0.2	
Arena 50WDG, V-10170 2.13SC, Belay 16WSG	Tobacco	NA	NA	0.0625 soil 0.2	0.2	
Arena 50WDG, V-10170 2.13SC	Turfgrass	NA	NA	0.4	0.4	Highest individual & seasonal appln. rate.

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PURPOSE/ SOURCE	USE	oz a.i./ 100 lb seed	oz a.i./ 1000 seed	MAX. IND. APP. RATE (lb. a.i./A)[12]	SEASONAL APP. RATE (lb. a.i./A)	Comments
Arena 50WDG	Residential apple & pear trees	NA	NA	0.188	0.2	Apply by ground in 200 gal solution/ A
Arena 50WDG,+ V-10170 2.13SC	Non-bearing fruits & nut trees (in landscapes not for commercial prod.)	NA	NA	0.2	0.2	+Apply in 200 gal soln/ A
Arena 50WDG	Containerized Ornamental Plants in Production Greenhouse and Field Nurseries	NA	NA	NS	0.4	2 oz prod/100 gal water, drench application
Arena 50WDG	Ornamentals in Production Greenhouse and Field Nurseries	NA	NA	NS	0.4	1.26 oz prod/100 gal water, foliar application
V-10170 2.13SC	Ornamentals	NA	NA	NS	0.4	2.4 oz prod/100 gal water, foliar application
V-10170 2.13SC	Ornamentals grown in flat benches or beds	NA	NA	0.21	0.4	*2.4 oz product/7500 sq ft
Arena 50WDG	In-Ground Plants in Production Greenhouse and Field Nurseries	NA	NA	NS	0.4	Shrubs-2.4 g per ft of hght; Multi-Trunk Trees 4.8 g/cumulat. inch of trunk diameter at breast hght (soil drench or soil injection)
Arena 50WDG	Ornamentals in Commercial and Residential Outdoor Landscapes and Interior Plantscapes	NA	NA	NS	0.4	Foliar (1.26 oz prod/ 100 gal water)
						Soil drench or soil injection - Shrubs-2.4 g per ft of hght; Multi-Trunk Trees 4.8 g/cumulat. inch of trunk diameter at breast hght
				0.4	0.4	Soil applic. for plants grown in beds

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PURPOSE/ SOURCE	USE	oz a.i./ 100 lb seed	oz a.i./ 1000 seed	MAX. IND. APP. RATE (lb. a.i./A)[12]	SEASONAL APP. RATE (lb. a.i./A)	Comments

CG = Crop Group; CSG = Crop Sub-Group; NA = Not Available; N/A = Not Applicable; NS = Not Specified; No aerial applications are allowed.

1. Seeding rate 131 lb seeds/A for wheat (representative crop); Source: http://www.uky.edu/Ag/Wheat/seedrate.html
2. Seeding rate 1600-2200 lb seeds/A, source: http://aggie-horticulture.tamu.edu/extension/vegetable/cropguides/potato.html
3. Sepresto 75WS is a combination product, containing clothianidin (56.25%) and imidacloprid (18.75%).
4. PROCEED™ OPTIMUM is a combination product, containing clothianidin (1.46% a.i.), and prothioconazole, tebuconazole and methalaxil.

5. Carrots, representative crop, source for approximate seeding rate: http://pmep.cce.cornell.edu/piap/carrot96/agpractices.html - and http://aggie-horticulture.tamu.edu/extension/vegetable/cropguides/carrot.html (23000 seeds/oz and 2-2.5 lb seeds/A => 920,000 seeds/A; app rate for carrots 0.0042 oz/1000 seeds => 0.24 lb a.i./A)

6. Onions, representative crop, source for approximate seeding rate: http://www.ag.ndsu.edu/pubs/alt-ag/onions.htm (8000 seeds/oz and 2-4 lb/A => 512000 seeds/A; app. rate for onions 0.006 oz a.i/1000 seeds. => 0.19 lb a.i./A)

7. Lettuce, representative crop, source of approximate seeding rate: http://www.ipmcenters.org/cropprofiles/CP_form.cfm (ultimately, 43000 plants/A => 0.075 lb a.i./A)

8. Same source as above (7). In CA about 44,000 plants cabbage /A => 0.11 lb a.i./A

9. Same source as above (7): In FL, maximum plant density of tomatoes is around 4,840/A; for tomatoes, the max. application rate is 0.00348 oz a.i./1000 seed => 0.001 lb a.i./A (note, transplants are not considered)

10. Same source as above (7), in FL, cucumbers maximum plant population is 21,780/A => 0.046 lb a.i./A

11. http://www.ces.purdue.edu/extmedia/AY/AY-217-W.pdf Max seeding rate 210,025 seeds/A; http://www.ipm.iastate.edu/ipm/icm/1998/10-12-1998/lowersoycost.html 2000-4000 seeds/lb

12. For seed treatment, the maximum individual application rate is the estimate of the equivalent application rate of the active ingredient in the field, assuming that the a.i. is uniformly distributed in the field.

13. Data obtained from previously issued assessments.