Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2013-6132
Application: Change to Product Labels - New site or host
Product: Vivando SC Fungicide
Registration Number: 29765
Active ingredients (a.i.): Metrafenone
PMRA Document Number : 2439874

Purpose of Application

The purpose of this application was to expand the registration of Vivando SC Fungicide (Registration Number 29765; guarantee 300 g/L metrafenone) to include the control of powdery mildew on fruiting vegetables (Crop Group 8-09) and pome fruits (Crop Group 11-09) at the rates of 0.75 – 1.12 L/ha.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

A toxicology assessment was not required for this application.

The use of Vivando SC Fungicide on fruiting vegetables and pome fruit is not expected to result in risks of concern to chemical handlers, post-application re-entry workers, or bystanders provided the product is applied according to the label directions.

No new residue data for metrafenone in peppers, tomatoes, apples and pears were submitted to support the use expansion of this active on the Vivando SC Fungicide label. Metrafenone was applied to peppers, tomatoes, apples and pears, and harvested according to label directions. In addition, metabolism studies in wheat and cucumber, a confined crop rotation trial study, a goat metabolism study, a freezer storage stability study, and processing studies in treated apples and tomatoes were reviewed. A previously reviewed grape metabolism study was also reassessed in the framework of this petition.

The recommendation for maximum residue limits (MRLs) for metrafenone was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. MRLs to cover residues of metrafenone in/on crops and processed commodities are proposed as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the proposed MRLs for the raw agricultural commodities (RACs).

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TABLE 1. Summary of Field Trial and Processing Data Used to Support Maximum Residue Limits (MRLs)							
Commodity	**Application Method/ Total Application Rate (g a.i./ha)**	**PHI (days)**	**Residues (ppm)**		**Experimental Processing Factor**	**Currently Established MRL (ppm)**	**Recommended MRL (ppm)**
			Min	**Max**			
Bell peppers	1005-1017/ Foliar	7	0.083	0.271	--	None	0.7 ppm in/on Fruiting Vegetables (Crop Group 8-09)
Non-bell peppers	991-1014/ Foliar	7	0.062	0.296	--	None	
Tomatoes	999-1383/ Foliar	6-8	<0.01	0.188	0.39X (paste) 0.84X (puree)	None	
Apples	995-1027/ Foliar	6-7	0.0662	0.847	0.21X (raw juice) 4.46X (apple sauce)	None	4.0 ppm in/on apple sauce; 1.5 ppm in/on Pome Fruit (Crop Group 11-09)
Pears	1002-1024/ Foliar	6-7	0.123	0.519	--	None	

Residues in these commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The expected cumulative application rate resulting from the new use pattern taking into account the shorter application interval along with the estimated environmental dissipation is lower for soil; conversely, it is higher for water. Thus, a revised environmental risk assessment for non-target terrestrial organisms was not required, whereas one for non-target aquatic organisms was required.

Using current aquatic risk assessment methodology along with previously evaluated environmental fate and ecotoxicology information (ERC2011-10, *Metrafenone*), it has been determined that other than an incremental increase in acceptable risk and the addition of green algae to the short list of sensitive aquatic organisms, the previous conclusions regarding aquatic risk have not been altered from the original review.

In terms of mitigating the newly identified risks, it has been determined that the precautionary label statements that appear on the currently registered label are appropriate to inform the user of the risks resulting from the new application pattern, and were not modified. However, spray buffer zones were adjusted to reflect the new use pattern. For field sprayer application, one metre

buffer zones are required and for airblast application, three metre buffer zones are required.

Value Assessment

Data from seven efficacy trials on apples were reviewed to support the claim for control of powdery mildew on pome fruits. Overall, the efficacy data demonstrated that Vivando SC Fungicide provided an acceptable level of powdery mildew control on apple varieties tested under moderate disease pressure in the trials. Based on the data summary from the registrant, Vivando SC Fungicide at 224 and 337 g a.i./ha reduced powdery mildew disease severity on average by 87% (ranged from 67% to 99%) in seven trials, and reduced disease incidence on average by 86% (78 – 93%) in two trials, compared to the non-treated controls. There was no statistical difference between Vivando SC Fungicide and commercial standards in all trials. The causal pathogen tested in all seven trials was *Podosphaera leucotricha* which is the sole pathogen widely recognized causing economic damage on apple, pear and other members of pome fruits. Therefore, a claim to control powdery mildew (*Podosphaera leucotricha*) on pome fruits is supported according to the proposed use pattern.

Data from twelve efficacy trials on tomato and four trials on pepper were reviewed to support the proposed claim for control of powdery mildew on fruiting vegetables. Overall, Vivando SC Fungicide at the proposed rates achieved a high level of powdery mildew control (99 – 100%) under conditions of moderate to high disease pressure, as demonstrated in the efficacy trials on tomato against *Erysiphe polyphaga* and *Oidium neolycopersici.* Data from the efficacy trials on tomato and pepper also demonstrated that Vivando SC Fungicide significantly reduced *Leveillula taurica* infection by 73% to 98% in various trials under moderate or high disease pressure. The level of control achieved by Vivando SC Fungicide in both greenhouse and field trials was comparable with the commercial standards applied in the same trials. A claim to control powdery mildew (*Erysiphe polyphaga, Oidium neolycopersici* and *Leveillula taurica*) on fruiting vegetables is supported according to the proposed use pattern.

The value of registering Vivando SC Fungicide for powdery mildew on both pome fruits and fruiting vegetables is to provide Canadian growers with a new mode of action against the disease in the marketplace.

Conclusion

The PMRA has completed a review of available information in support of Vivando SC Fungicide and has found the information sufficient to support the control of powdery mildew on fruiting vegetables and pome fruits. MRLs, as proposed in Table 1, are recommended to cover residues of metrafenone in/on fruiting vegetables and pome fruits.

References

PMRA Document Number	Reference

2361494	2013, Use Site Description: Metrafenone (BAS 560 F) containing products on Crop Group 8 Fruiting Vegetables and Crop Group 11 Pome Fruit in Canada, BASF Canada Inc., DACO: 5.2
2385567	2002, BAS 560 F (AC 375839) - Metabolism of 14C BAS 560 F in the lactating goat, DACO: 6.2
2361521	2010, Metabolism of 14C-BAS 560 F in Cucumber, DACO: 6.3
2361501	2002, BAS 560 F (AC 375839): Metabolism of carbon-14 labeled AC 375839 in wheat under field conditions, DACO: 6.3
1620204	2001, AC 375839: Metabolism of carbon-14 labeled AC 375839 in grapevines, DACO: 6.3
2368905	2012, Investigation of the storage stability of BAS 560 F in plant matrices, DACO: 7.3
2361541	2013, Magnitude of the residue of BAS 560 F in peppers after applications with BAS 560 03 F, DACO: 7.4.1,7.4.2
2361545	2013, Metrafenone: Magnitude of the residue on tomato, DACO: 7.4.1,7.4.2
2361537	2013, Magnitude and decline of the residue of Metrafenone in or on pome fruit raw agricultural commodities following three foliar applications of BAS 560 03 F fungicide, DACO: 7.4.1,7.4.2
2361550	2002, BAS 560 F (AC 375839): Confined rotational crop study with carbon-14 labeled AC 375839, DACO: 7.8
2361547	2011, Determination of residues of BAS 560 F (Metrafenone) in tomatoes and their processed products after two applications of BAS 560 02 F in Germany, DACO: 7.4.1,7.4.5
2361549	2013, Magnitude of the residue of Metrafenone in or on apple processed commodities following three foliar applications of BAS 560 03 F fungicide, DACO: 7.4.1,7.4.5
2385573	2013, Metrafenone (BAS 560 F) dietary burden determination: BASF response to EPA questions on apple pomace, DACO: 7.5.1
2361490	2013, DACO 10 Value Vivando Fungicide Fruiting Vegetables Pome fruit, DACO: 10.1, 10.2, 10.2.1, 10.2.2, 10.2.3, 10.2.3.1, 10.2.3.2(D), 10.2.3.3, 10.2.3.3(D), 10.3, 10.3.1, 10.3.2(B), 10.4, 10.5, 10.5.3, 0.5.4.

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