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Evaluation Report for Category B, Subcategory 3.4 Application

Application Number: 2011-1425
Application: B.3.4 (Product labels - application method)
Product: Concept Liquid Insecticide
Registration Number: 29611
Active ingredients (a.i.): Deltamethrin (DBR), Imidacloprid (IMI)
PMRA Document Number: 2052552

Purpose of Application

The purpose of this application was to add aerial application to the Concept Liquid Insecticide label for use on soybeans. The proposed rate is the same as the registered rate on potatoes, 3 applications of 650 mL/ha (with 5 days intervals) which would create a yearly maximum application of 20g a.i./ha and 150g a.i./ha of deltamethrin and imidacloprid, respectively. This rate is identical to the ground application rate registered for use on potatoes, soybeans, tomatoes and head and stem brassica crops.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

A toxicology assessment was not required as there was no change to the product formulation.

A human health risk assessment was completed for Concept Liquid Insecticide, containing deltamethrin and imidacloprid guaranteed at 10 g/L and 75 g/L, respectively, to support aerial application on soybeans. Exposure to this product is acceptable for agricultural workers when mixers, loaders, and applicators wear a long-sleeved shirt, long pants, chemical-resistant gloves, and socks and boots during mixing, loading, application, cleanup, and repair. In addition, wear goggles or face shield during mixing, loading, clean-up, and repair. Bystander exposure, including pick-your-own scenarios, is also acceptable.

No new residue data were required to support the addition of an aerial application use of the Concept Liquid Insecticide to soybeans.

Canada

Since imidacloprid and deltamethrin are currently registered in Canada on soybeans at rates and restrictions similar to those proposed, from a food residue exposure point of view, no changes in the magnitude of the residues in soybeans are expected. Therefore, no increase in dietary exposure is anticipated. Residues of imidacloprid and deltamethrin will be covered by the proposed maximum residue limits (MRLs) of 3.5 ppm and 0.1 ppm, respectively.

Environmental Assessment

General Risk Characterization

The purpose of this risk assessment was to identify the environmental concerns, determine if aerial application poses a greater potential for exposure of non-target organisms relative to a ground application, and conduct a risk assessment considering the toxicity of the co-formulation. Proposed risk mitigation addressed areas of concern for both terrestrial and aquatic habitats. For this application, the potential risk to bees and other pollinators was characterized for the proposed use expansion of imidacloprid to aerial application on soybeans (for the control of Soybean aphid, Japanese beetle and Bean leaf beetle) in a co-formulation with deltamethrin, a pyrethroid insecticide. Honey bees are known to be a major contributor to soybean pollination (Chiari *et al*., 2005); thus, exposure to this non-target group from aerial application to soybeans is likely. Risk to aquatic non-target organisms was also addressed.

There is uncertainty regarding the most relevant route(s) (nectar, pollen, foliar residues, guttation drops) of exposure and the amount of neonicotinoid pesticide residues that honey bees and other pollinators are currently being exposed to. For this assessment, however, it has been assumed that both oral and contact exposure to imidacloprid are likely and, as such, both were considered in this risk assessment for on-field and off-field scenarios. With regard to these two areas of concern, the following three sections are a discussion of whether or not aerial application could present greater exposure and risk than ground application.

The exposure of non-target aquatic organisms to Concept Liquid Insecticide was also addressed as deltamethrin is highly toxic to aquatic organisms, much more so than imidacloprid.

Overspray and On-field Foliar Residues - Contact and Oral Exposure

If bees and other pollinators are present in the field when the application takes place, they can be exposed to the product through direct exposure to spray droplets (overspray) from the spray cloud. However, as Concept Liquid Insecticide is not to be applied while the treated crops are flowering, the exposure to the spray cloud is more likely going to be due to off-field exposure to the product’s downwind spray drift. Nevertheless, bees and other pollinators could be exposed to wet or dried residues following the overspray deposition.

There is considerable uncertainty as to how much imidacloprid may reach pollen and nectar of flowering soybeans by direct contamination through foliar spray. We can assume that bees may be exposed to imidacloprid while foraging on soybean flowers either through nectar/pollen contamination (oral route) or by being in contact with residues (wet or dry) on the flower parts itself where the bees are landing. Moreover, the on-field exposure to wet or dry residues (or re-solubilized residue in dew water) may not be significantly greater than with currently registered ground foliar application of imidacloprid on soybeans. In conclusion, we can assume that the on field exposure of honey bees and other pollinators to Concept Liquid Insecticide is not likely to be greater following an aerial application than following a ground application, for which this product is already registered for use.

Carryover – Oral Exposure

It is known that imidacloprid, as with other neonicotinoid insecticides, is a persistent chemical and can carryover from one growing season to another; i.e., a product applied one season can be found in the soil the next growing season. It is also systemic thus application from one season can be taken up by plants growing in the second season and be translocated either to pollen and/or nectar, or exuded in guttation drops. Guttation is a natural phenomenon by which plants excrete xylem fluid at the leaf margins. Girolami *et al*. (2009), have found that guttation drops collected from plants for which the seed had been treated with neonicotinoid insecticides were toxic enough to kill bees. However, it is unlikely that the concentration of imidacloprid in pollen, nectar or guttation water will be higher following aerial application than following currently registered ground application.

Off-field Spray drift - Contact and Oral Exposure

As mentioned above, Concept Liquid Insecticide is not to be applied while the treated crops are flowering, thus making exposure more likely to be due to off-field exposure to the product's downwind spray drift. The spray drift resulting from an aerial application is potentially greater than from a ground application as it is sprayed from higher off the ground than a spray boom, and, therefore an aerial spray cloud is more likely to remain in the air for a longer period of time. According to Wolf and Caldwell (2001), the spray drift 1m downwind of the aerial spray site is equivalent to 26% of the on-field application rate whereas it is equivalent to 11% of the on-field application rate for ground application using fine spray droplets (ASAE). In these circumstances, not only can bees and other pollinators be exposed directly to the spray cloud but also acutely through direct contact to wet or dry residues of Concept Liquid Insecticide on foliage and/or flower parts (petals, while landing, nectar and pollen) in habitats outside of the treated field where flowering plants/weeds can be found. As such, this route of exposure was considered in order to characterise the risk to bees and other pollinators exposed to aerial spray drift of Concept Liquid Insecticide

Although imidacloprid is registered as a foliar spray on soybeans using ground equipment, the aerial application of imidacloprid to soybeans could also increase overall exposure to pollinators in an agricultural landscape as an aircraft can treat a larger number of fields in a shorter period of time than a tractor driven ground boom, thus reducing the number of insect refuges not contaminated with spray drift.

The off-field spray drift of Concept Liquid Insecticide following an aerial application to soybeans may also cause an increased exposure to non-target aquatic organisms compared to ground application. This will be addressed in the risk assessment due to the known toxicity of deltamethrin to aquatic organisms.

Risk Assessment

For characterizing acute risk, acute toxicity values (e.g., LC_{50}, LD_{50}, and EC_{50}) are divided by an uncertainty factor. The uncertainty factor is used to account for differences in inter- and intra-species sensitivity as well as varying protection goals (e.g., community, population, individual). Thus, the magnitude of the uncertainty factor depends on the group of organisms that are being evaluated (e.g., 10 for fish, 2 for aquatic invertebrates). The difference in value of the uncertainty factors reflects, in part, the ability of certain organisms at a certain trophic level (i.e., feeding position in a food chain) to withstand, or recover from, a stressor at the level of the population. When assessing chronic risk, the NOEC or NOEL is used and an uncertainty factor is not applied.

Bees and other pollinators

For this part of the risk assessment, acute oral and contact honey bee imidacloprid endpoints (0.0037 µg/bee and 0.0081 µg/bee, respectively) were used as a surrogate to bees and other pollinators. The toxicity of imidacloprid was used initially by itself as it is much more toxic (20x) to bees than deltamethrin. The toxicity of the co-formulation (combining the toxicity of imidacloprid and deltamethrin), was addressed as a second step.

The terrestrial risk assessment was conducted following 3 aerial applications of Concept Liquid Insecticide at a rate of 650 mL end-use product/ha (48.75 g imidacloprid per hectare; 6.5 g deltamethrin per hectare) per application with a 5 day interval, a default foliar half-life of 10 days and assuming fine spray droplets.

Although the screening level (on-field) risk quotients (RQ) for acute oral exposure were 11.8, 20.1 and 26.0 after the 1^{st}, 2^{nd} and 3^{rd} (cumulative) applications, respectively, and 5.4, 9.2 and 11.9 after the 1^{st}, 2^{nd} and 3^{rd} (cumulative) application, respectively for acute contact exposure, both these sets of RQs were not considered a concern as bees and other pollinators are not expected to be exposed to the product on-field, as mentioned above. However, the further characterized (off-field) RQs for acute oral were 3.1, 5.2 and 6.8 after the 1^{st}, 2^{nd} and 3^{rd} (cumulative) applications, respectively and 1.4, 2.4 and 3.1 after the 1^{st}, 2^{nd} and 3^{rd} (cumulative) applications, respectively for acute contact. As such, a risk to bees and other pollinators was identified off-field using either oral or contact exposure routes with the imidacloprid toxicity values alone. The risk assessment to the co-formulation is addressed below.

Toxic Equivalent Factor/Toxic Equivalent approach

Imidacloprid and deltamethrin have different mode of actions (MOA). Neonicotinoids, such as imidacloprid, are acetylcholine receptor stimulants, whereas pyrethroids, such as deltamethrin, are sodium channel modulators. At best, it can be assumed that the toxicity of both chemicals combined is additive. To consider the additivity of the toxicity of two chemicals in a mixture, a toxic equivalency quotient (TEQ) can be used.

Toxic equivalency factors (TEF) and toxic equivalency quotient (TEQ) were used to calculate the combined toxicity of both chemicals on the honey bee, a well-known surrogate species for pollinators. The TEF/TEQ approach is routinely used to estimate the relative toxicity of chemicals with the same MOA, such as dioxins and dioxin-like compounds, PCBs and Furans (Van den Berg *et al*., 2005). Although this is a limitation that should be considered when using this method for imidacloprid and deltamethrin, the lack of information regarding the potential synergy or additivity of these chemicals supports using this approach.

In Table 1, data show that imidacloprid is more toxic to bees for both the oral and the contact endpoints. Specifically, imidacloprid is 20 times more toxic than deltamethrin to the honey bee, when exposed orally, and 5 times more toxic through contact exposure. As such, imidacloprid is the numerator and deltamethrin, the denominator for the TEF calculation of each endpoint. Therefore, toxicity equivalence will be based on the imidacloprid fraction of the actual end-use product application rate (see

Table 2)

Table 1 Toxic Equivalency Factors (TEF) calculations for imidacloprid (IMI) and deltamethrin (DBR) on oral and contact endpoints using the honey bee (*Apis mellifera*)

	Imidacloprid	Deltamethrin	TEFs (IMI/DBR)
Oral honey bee endpoints	0.0037 µg/bee	0.0790 µg/bee	0.046835443
Contact honey bee endpoints	0.0081 µg/bee	0.0470 µg/bee	0.172340426

Table 2 Imidacloprid (IMI) Toxic Equivalence (TEQ) calculations for deltamethrin (DBR) on oral and contact endpoints using the honey bee (*Apis mellifera*)

	Conc.	EP App. rate	A.I. Application rate (g/a.i./ha)	Oral TEF	oral TEQ (g IMI/ha)	Contact TEF	Contact TEQ (g IMI/ha)
Imidacloprid	75 g/L	650 mL/ha	48.75	1.000	48.75	1.000	48.75
Deltamethrin	10 g/L		6.50	0.047	0.30	0.172	1.12
				Total	49.05 g IMI/ha	Total	49.87 g IMI/ha

Using the TEF/TEQ approach, the application rates based on toxicity equivalency between these two chemicals are 49.05 g IMI/ha and 49.87 g IMI/ha for oral and contact endpoints, respectively (cumulative rates 108.4 g IMI/ha and 110.1 g IMI/ha, respectively). The screening level on-field RQs for acute oral exposure are 12.0, 20.5 and 26.6 after the 1st, 2nd and 3rd (cumulative) applications, respectively. The off-field RQs are 3.1, 5.3 and 6.9 after the 1st, 2nd and 3rd (cumulative) applications, respectively. Using acute contact exposure and the same application parameters, the screening level on field RQs are 5.4, 9.2 and 11.9 after the 1st, 2nd and 3rd (cumulative) application, respectively. The off-field RQs are 1.4, 2.4 and 3.1 after the 1st, 2nd and 3rd (cumulative) applications, respectively.

As indicated above, including the deltamethrin toxicity does not contribute significantly to the “total” toxicity because imidacloprid is much more toxic to bees than deltamethrin. Also, as previously mentioned, caution is needed in using the TEF/TEQ approach in situation where the chemicals have a different MOA. As such, to assess the risk to bees and other pollinators, the TEF/TEQ approach was not considered necessary in the risk assessment to bees exposed to aerial applications of Concept Liquid Insecticide, therefore, only the imidacloprid endpoints (acute oral and contact exposure) were considered.

Aquatic organisms

As deltamethrin is currently registered for aerial application on potatoes, oilseeds (Canola, mustard) and wheat at rates similar or higher than proposed on this label, the aquatic mitigative measures found on currently registered deltamethrin products will be use to address the risk to aquatic non-target organisms following the use of Concept Liquid Insecticide.

Proposed Risk Mitigation

To mitigate the risk to bees on the field, the label should clearly state that this product is not to be applied when soybeans are flowering.

In order to mitigate the risk to bees and other pollinators off the field, one option could be to establish terrestrial buffer zones using the honey bee endpoint instead of terrestrial plants. This would potentially mitigate the risk to off-field bees and other pollinators from spray drift. As calculating terrestrial buffer zones using endpoints other than terrestrial plants are not included in our current risk mitigation practices, terrestrial buffer zones using honey bees will not be considered at this time but could be used in the future.

The aquatic buffer zones for currently registered uses of deltamethrin (Registration number 17734) (100 m, aerial) are based on historical default values. Calculated buffer zone values, based on modern methods, are much higher than this, but will not be changed until a re-evaluation of deltamethrin has been completed. Re-evaluations of imidacloprid and deltamethrin have been initiated in both the PMRA and U.S. EPA. The outcome for this application may be affected by the outcome of the re-evaluation decision for both of these active ingredients.

Conclusion

Although there is uncertainty concerning the actual exposure route and amount of Concept Liquid Insecticide that bees and other pollinators may be exposed to, an increased risk to bees and other pollinators was identified when exposed to aerial spray drift of this product on soybeans compared to the ground application. Terrestrial buffer zones, which could potentially mitigate the risk to off-field bees and other pollinators from spray drift are not conducted using a terrestrial endpoint other than plants at this time. As the re-evaluation of both imidacloprid and deltamethrin has been initiated, the risk characterization and mitigative measures (label statements) will be revisited and may affect the decision for this application.

Value Assessment

Three field trials conducted during 2009 in Ontario assessed the efficacy of Concept Liquid Insecticide at the rate of 325 mL/ha against soybean aphids by spraying plots with a reduced spray volume (45 L/ha) to simulate aerial application and a standard ground application volume (200 L/ha). The results demonstrated that the aerial simulation treatments (45 L/ha application volume) of Concept Liquid Insecticide applied at the lower rate of 28 g a.i./ha gave a level of soybean aphid control that was comparable to that obtained with a standard ground application (200 L/ha application volume). The higher application rate is currently registered for this use pattern and thus, the proposed rate range of 325-650 mL/ha is supported.

The control of Japanese beetle and suppression of bean leaf beetle were supported based on the following reasons: 1) the product is registered against these pests at the same rate by ground application on soybean, 2) efficacy data against aphids submitted under the current application demonstrated no difference in the simulated aerial application and ground application and 3) no differences in efficacy were observed when Concept Liquid Insecticide was applied by ground or in simulated aerial trials against two coleopteran pest species (Colorado potato beetle and potato flea beetle) in potato in a previous application.

Based on the efficacy data and rationales provided, the aerial use-pattern of Concept Liquid Insecticide (28 - 55 g a.i./ha) on soybean for control of soybean aphid and Japanese beetle and suppression of bean leaf beetle is acceptable.

Conclusion

The PMRA has completed an assessment of the available information and is able to support the addition of aerial application to soybeans on the label of Concept Liquid Insecticide.

References

Supplied by the Applicant:

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Additional Information Considered:

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