



Evaluation Report for Category B, Subcategory 3.4, 3.12 Application

Application Number: 2024-1803
Application: Changes to Product Labels – New Site or Host; Application Method
Applicant: ISK Biosciences Corp.
Product: Carbine Insecticide
Registration Number: 34659
Active ingredient (a.i.): Flonicamid
PMRA Document Number : 3743771

Purpose of Application

The purpose of this application was to add new crops (**specifically Crop Subgroup 20A, Rapeseeds (revised), and Crop Subgroup 20B, Sunflowers (revised)**), and to add aerial application to the label of Carbine Insecticide.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

The occupational exposure and risk from the addition of the use on Crop Subgroups 20A and 20B, and the addition of aerial application to the Carbine Insecticide label were assessed. No risks of concern are expected from the uses provided that workers follow the label directions and wear the personal protective equipment identified on the label.

Residue data from field trials on canola and flax conducted in Canada were submitted, reviewed, and assessed collectively with previously reviewed residue data for oilseed crops, to support the use of Carbine Insecticide on Crop Subgroup 20A: Rapeseeds (revised) and Crop Subgroup 20B: Sunflowers (revised). Flonicamid was applied to canola, flax, and sunflower at the label rates, and harvested according to label directions. Previously reviewed residue data from field trials conducted in/on beans, peas, alfalfa, and clover were reassessed in the framework of this application to support the aerial application of Carbine Insecticide. In addition, previously reviewed processing studies in treated canola and sunflower were reassessed to determine the potential for concentration of residues of flonicamid in processed commodities.

The recommendation for proposed maximum residue limits (MRLs) for flonicamid was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover total residues of flonicamid, TFNA, TFNA-AM, and TFNG (expressed as parent equivalents) 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).

TABLE 1. Summary of Field Trial and Processing Data Used to Support Maximum Residue Limits (MRLs)							
Commodity	Appl. Method/ Total Appl. Rate (g a.i./ha)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Proposed MRL (ppm)
			LAFT¹	HAFT¹			
Canola	Foliar/ 293-305	6-8	0.059	1.044	<i>Canola oil:</i> Flonicamid: 0.09x; TFNA, TFNA-AM, TFNG: <1x	None.	1.5 (CSG20A-R) ²
Flax	Foliar/ 300-302	6-7	0.082	0.981		1.5 (Flaxseeds)	
Sunflower	Foliar/ 295-316	0, 14	<0.04	0.392	<i>Sunflower oil:</i> Flonicamid: 0.02x; TFNA, TFNA-AM, TFNG: <1x	None.	0.7 (CSG20B-R)

ppm = parts per million; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial

¹ Sum of residues of flonicamid, TFNA, TFNA-AM, and TFNG, expressed as parent equivalents.

² This MRL will replace the current MRL of 1.5 ppm in/on flaxseeds.

Following the review of all available data, the MRLs proposed in Table 1 are recommended to cover total residues of flonicamid, TFNA, TFNA-AM, and TFNG (expressed as parent equivalents). Dietary risks from exposure to total residues of flonicamid in these crop commodities at the proposed MRLs were shown to be acceptable for the general population and all subpopulations, including infants, children, adults and seniors. Thus, the foods that contain residues as listed in Table 1 are considered safe to eat.

A toxicology assessment was not required for this application.

Environmental Assessment

The additions to the Carbine Insecticide label are acceptable from an environmental perspective. The risks are acceptable when Carbine Insecticide is used in accordance with the label, which includes statements to mitigate risks to the environment. The updated pollinator risk assessment results in precautionary label statements and the requirement of mitigation measures to protect pollinators.

Value Assessment

A submitted rationale and reports from five field trials conducted on canola, flax, sunflower and field pea supported the use of Carbine Insecticide on Crop Subgroup 20A, Crop Subgroup 20B and aerial application on all crops. These amendments provide Canadian growers with an

additional product to manage aphids and tarnished plant bugs on the crops under Crop Subgroups 20A and 20B and the option to use aerial application methods.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support adding new crops (**specifically Crop Subgroup 20A and 20B**), and adding aerial application to the label of Carbine Insecticide.

References

PMRA

Document Number

Reference

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| 3584585 | 2023, Analytical Phase Report Magnitude of the Residue of Flonicamid and its Metabolites in or on Flax and Canola Raw Agricultural Commodities Following Three Foliar Broadcast Applications of Beleaf(r) 50SG (2022), DACO: 7.4.1 |
| 3584586 | 2023, Final Study Report Magnitude of the Residue of Flonicamid and its Metabolites in or on Flax and Canola Raw Agricultural Commodities Following Three Foliar Broadcast Applications of Beleaf(r) 50SG (2022), DACO: 7.4.1 |
| 3584571 | 2024, Value Summary for Carbine (tm) Insecticide Label Expansion to Oilseeds group (CG 20A and 20B) and Addition of Aerial Application, DACO: 10.1,10.2,10.2.2,10.2.3,10.2.3.1,10.2.3.2,10.2.3.3,10.2.3.4,10.2.4,10.3,10.3.1,10.3.2,10.3.3,10.4,10.5,10.5.1,10.5.2,10.5.3,10.5.4,10.5.5,10.6 |
| 3584572 | 2024, Value Summary for Carbine (tm) Insecticide Label Expansion to Oilseeds group (CG 20A and 20B) and Addition of Aerial Application, DACO: 10.2.3.1 |
| 3584573 | 2024, Canola Trial 4202, DACO: 10.2.3.3 |
| 3584574 | 2024, Canola Trial 4210, DACO: 10.2.3.3 |
| 3584575 | 2024, Flax Trial 4203, DACO: 10.2.3.3 |
| 3584576 | 2024, Pea Trial 4227, DACO: 10.2.3.3 |
| 3584577 | 2024, Sunflower Trial 4204, DACO: 10.2.3.3 |
| 3667478 | 2021, ASSESSMENT OF SIDE EFFECTS OF IKI-220 500WG (TEPPEKI) ON THE HONEYBEE (APIS MELLIFERA L.), IN A SEMI-FIELD STUDY IN SOUTHERN FRANCE AFTER ONE APPLICATION ON PHACELIA TANACETIFOLIA IN 2020 FOLLOWING THE EPPO 170 GUIDELINE, DACO: 9.2.4.6 |
| 3667479 | 2021, IKI-220 50% WG : A SEMI-FIELD BROOD STUDY TO EVALUATE POTENTIAL EFFECTS ON BROOD DEVELOPMENT AND MORTALITY OF ADULT WORKER HONEYBEES, APIS MELLIFERA L. (HYMENOPTERA: APIDAE), FOLLOWING THE APPLICATION ON PHACELIA TANACETIFOLIA, DACO: 9.2.4.6 |
| 3667480 | 2008, TOXICITY TESTING OF TEPPEKI (IKI-220 50% WG) ON HONEY BEES (APIS MELLIFERA L.) IN THE FIELD, DACO: 9.2.4.7 |
| 3667481 | 2008, TEPPEKI (IKI-220 50% WG) A Field Study to Evaluate Side Effects on Honeybees (Apis mellifera L.) Following the Application on Phacelia tanacetifolia After Daily Bee-Flight in Germany, DACO: 9.2.4.7 |

- 3667482 2020, Determination of Residues in Leaves, Flowers, Pollen, and Nectar of Apple Following Foliar Applications of Beleaf(r) 50SG (2019), DACO: 9.2.4.8
- 3667483 2020, Determination of Residues in Leaves, Flowers, Pollen, and Nectar of Canola Following Foliar Applications of Beleaf(r) 50SG (2019), DACO: 9.2.4.8
- 3667484 2020, Determination of Residues in Leaves, Flowers, Pollen, and Nectar of Strawberry Following Foliar Applications of Beleaf(r) 50SG (2019), DACO: 9.2.4.8
- 3667485 2020, Determination of Residues in Leaves, Flowers, Pollen, and Nectar of Orange Following Foliar Applications of Beleaf(r) 50SG (2019), DACO: 9.2.4.8
- 3667486 2004, Determination of Residues of IKI-220 in Pollen After One Treatment of IKI-220 50% WG (IBE 3894) (North France - Season 2002), DACO: 9.2.4.8
- 3667487 2004, Determination of Residues of IKI-220 In Honey and Pollen After One Treatment of IKI-220 50% WG (IBE 3894) (North France - Season 2002), DACO: 9.2.4.8
- 3667488 2004, Determination of Residues of TFNG, TFNA AND TFNA-AM 220 In Honey and Pollen After One Treatment of IKI-220 50% WG (IBE 3894) (North France - Season 2002), DACO: 9.2.4.8
- 3667489 2004, Determination of Residues of TFNG, TFNA AND TFNA-AM 220 In Honey and Pollen After One Treatment of IKI-220 50% WG (IBE 3894) (North France - Season 2002), DACO: 9.2.4.8
- 3667490 2021, Determination of Residues in Leaves, Flowers, Pollen, and Nectar of Apple Following Foliar Applications of Beleaf 50SG (2020), DACO: 9.2.4.8
- 3667496 2003, Tunnel Test - Acute And Short Term Effects of IBE 3894 (IKI-220 50% WG), Applied On Oil Seed Rape, On Honey Bees (*Apis Mellifera* L), DACO: 9.2.4.6
- 3667497 2003, Tunnel Test - Acute And Short Term Effects of IBE 3894 (IKI-220 50% WG), Applied On White Mustard, On Honey Bees (*Apis Mellifera*), DACO: 9.2.4.6
- 3667498 2020, IKI-220 50% WG - A semi-field brood study to evaluate potential effects on brood development and mortality of adult worker honeybees, *Apis mellifera* L. (Hymenoptera: Apidae), following the application on *Phacelia tanacetifolia*, DACO: 9.2.4.6
- 3667499 2020, ASSESSMENT OF SIDE EFFECTS OF IKI-220 S00WG (TEPPEKI) ON THE HONEYBEE (*APIS MELL/FERAL.*) IN A SEMI-FIELD STUDY IN THE NETHERLANDS AFTER ONE APPLICATION ON *PHACELIA TANACETIFOLIA* IN 2019, DACO: 9.2.4.6
- 3667500 2020, ASSESSMENT OF SIDE EFFECTS OF IKI-220 S00WG (TEPPEKI) FOLLOWING THE OEPP/EPP0 GUIDELINE NO. 170 ON THE HONEYBEE (*APIS MELL/FERAL.*) IN A SEMI-FIELD STUDY IN THE NETHERLANDS AFTER ONE APPLICATION ON *PHACELIA TANACETIFOLIA* IN 2019, DACO: 9.2.4.6
- 3667501 2021, ASSESSMENT OF SIDE EFFECTS OF IKI-220 500WG (TEPPEKI) ON THE HONEYBEE (*APIS MELLIFERA* L.) IN A SEMI-FIELD STUDY IN SOUTHERN FRANCE AFTER ONE APPLICATION ON *PHACELIA TANACETIFOLIA* IN 2020 FOLLOWING THE OECD 75 GUIDELINE, DACO: 9.2.4.6

- 3667502 2021, ASSESSMENT OF SIDE EFFECTS OF IKI-220 500WG (TEPPEKI) FOLLOWING THE OECD GUIDANCE DOCUMENT 75 ON THE HONEYBEE (APIS MELLIFERA L.) IN A SEMI-FIELD BROOD STUDY IN GERMANY AFTER ONE APPLICATION ON PHACELIA TANACETIFOLIA IN 2020, DACO: 9.2.4.6
- 3667503 2021, ASSESSMENT OF SIDE EFFECTS OF IKI-220 500WG (TEPPEKI) ON THE HONEYBEE (APIS MELLIFERA L.) IN A SEMI-FIELD STUDY IN SOUTHERN FRANCE AFTER ONE APPLICATION ON PHACELIA TANACETIFOLIA IN 2020 FOLLOWING THE OECD 75 GUIDELINE, DACO: 9.2.4.6
- 3667504 2021, ASSESSMENT OF SIDE EFFECTS OF IKI-220 500WG (TEPPEKI) ON THE HONEYBEE (APIS MELLIFERA L.), IN A SEMI-FIELD STUDY IN SOUTHERN FRANCE AFTER ONE APPLICATION ON PHACELIA TANACETIFOLIA IN 2020 FOLLOWING THE OEPP/EPPO GUIDELINE NO. 170, DACO: 9.2.4.6
- 3667506 2015, IKI-220 TGAI: Acute Contact Toxicity Test with the Honey Bee (Apis mellifera), DACO: 9.2.4.1
- 3667507 2014, IKI-220 50 SG: Acute Contact Toxicity Test with the Honey Bee (Apis mellifera), DACO: 9.2.4.1
- 3667508 2015, IKI-220 50WG Formulation: Acute Contact Toxicity Test with the Honey Bee (Apis mellifera), DACO: 9.2.4.1
- 3667509 2001, Laboratory Testing For Toxicity (Acute Contact And Oral) of IKI-220 TGAI On Honey Bees (Apis Mellifera L.), DACO: 9.2.4.1,9.2.4.2
- 3667510 2002, Laboratory Testing for Toxicity (Acute Contact and Oral) of IKI-220 50 % WG on Honey Bees (Apis mellifera L.), DACO: 9.2.4.1,9.2.4.2
- 3667511 2020, TFNA: ACUTE ORAL AND CONTACT TOXICITY TO THE HONEY BEE, APIS MELLIFERA L., UNDER LABORATORY CONDITIONS, DACO: 9.2.4.1,9.2.4.2
- 3667512 2020, TFNG: ACUTE ORAL AND CONTACT TOXICITY TO THE HONEY BEE, APIS MELLIFERA L., UNDER LABORATORY CONDITIONS, DACO: 9.2.4.1,9.2.4.2
- 3667513 2020, TFNG-AM: ACUTE ORAL AND CONTACT TOXICITY TO THE HONEY BEE, APIS MELLIFERA L., UNDER LABORATORY CONDITIONS, DACO: 9.2.4.1,9.2.4.2
- 3667514 2020, TFNA-AM: ACUTE ORAL AND CONTACT TOXICITY TO THE HONEY BEE, APIS MELLIFERA L., UNDER LABORATORY CONDITIONS, DACO: 9.2.4.1,9.2.4.2
- 3667515 2018, IKI-220 100 OD: ACUTE ORAL AND CONTACT TOXICITY TO THE HONEY BEE, APIS MELLIFERA L., UNDER LABORATORY CONDITIONS, DACO: 9.2.4.1,9.2.4.2
- 3667516 2019, IKI-220 100 OD: ACUTE ORAL AND CONTACT TOXICITY TO THE BUMBLE BEE, BOMBUS TERRESTRIS L., UNDER LABORATORY CONDITIONS, DACO: 9.2.4.1,9.2.4.2
- 3667517 2014, IKI-220 50 SG: Acute Oral Toxicity Test with the Honey Bee (Apis mellifera), DACO: 9.2.4.2
- 3667518 2014, IKI-220 TGAI: Acute Oral Toxicity Test with the Honey Bee (Apis mellifera), DACO: 9.2.4.2

- 3667519 2015, IKI-220 50WG Formulation: Acute Oral Toxicity Test with the Honey Bee (*Apis mellifera*), DACO: 9.2.4.2
- 3667520 2016, IKI-220: ACUTE SURVIVAL OF HONEY BEE LARVAE, *APIS MELLIFERA* L., DURING AN IN VITRO EXPOSURE, DACO: 9.2.4.3
- 3667521 2016, 22-DAY SURVIVAL OF HONEY BEE LARVAE, *APIS MELLIFERA* L., DURING AN IN VITRO EXPOSURE, DACO: 9.2.4.3
- 3667522 2021, Colony feeding study evaluating the chronic effects of flonicamidfortified sugar diet on honey bee (*Apis mellifera*) colony performance under free foraging conditions, DACO: 9.2.4.3
- 3667523 2020, TFNA: HONEY BEE (*APIS MELLIFERA* L.) LARVAL TOXICITY TEST FOLLOWING REPEATED EXPOSURE UNDER LABORATORY CONDITIONS, DACO: 9.2.4.3
- 3667524 2020, TFNG: HONEY BEE (*APIS MELLIFERA* L.) LARVAL TOXICITY TEST FOLLOWING REPEATED EXPOSURE UNDER LABORATORY CONDITIONS, DACO: 9.2.4.3
- 3667525 2020, TFNG-AM: HONEY BEE (*APIS MELLIFERA* L.) LARVAL TOXICITY TEST FOLLOWING REPEATED EXPOSURE UNDER LABORATORY CONDITIONS, DACO: 9.2.4.3
- 3667526 2020, TFNA-AM: HONEY BEE (*APIS MELLIFERA* L.) LARVAL TOXICITY TEST FOLLOWING REPEATED EXPOSURE UNDER LABORATORY CONDITIONS, DACO: 9.2.4.3
- 3667527 2022, COLONY FEEDING STUDY EVALUATING THE CHRONIC EFFECTS OF FLONICAMID-FORTIFIED SUGAR DIET ON HONEY BEE (*Apis mellifera*) COLONY PERFORMANCE UNDER FREE FORAGING CONDITIONS, DACO: 9.2.4.3
- 3667528 2017, IKI-220: 10-DAY ORAL TOXICITY TEST WITH THE ADULT HONEY BEE (*Apis mellifera*), DACO: 9.2.4.4
- 3667529 2019, IKI-220: 13-Day Oral Toxicity Test with the Adult Honey Bee (*Apis mellifera*), DACO: 9.2.4.4
- 3667530 2016, IKI-220: A CHRONIC DIETARY TOXICITY TEST WITH THE ADULT HONEY BEE (*Apis mellifera*), DACO: 9.2.4.4
- 3667531 2020, TFNA: CHRONIC ORAL TOXICITY TEST (10-DAY FEEDING) TO THE HONEY BEE, *APIS MELLIFERA* L., UNDER LABORATORY CONDITIONS, DACO: 9.2.4.4
- 3667532 2020, TFNG: Chronic Oral Toxicity Test (10-Day Feeding) to the Honey Bee, *Apis mellifera* L. under Laboratory Conditions, DACO: 9.2.4.4
- 3667533 2020, TFNG-AM: CHRONIC ORAL TOXICITY TEST (10-DAY FEEDING) TO THE HONEY BEE, *APIS MELLIFERA* L., UNDER LABORATORY CONDITIONS, DACO: 9.2.4.4
- 3667534 2020, TFNA-AM: CHRONIC ORAL TOXICITY TEST (10-DAY FEEDING) TO THE HONEY BEE, *APIS MELLIFERA* L., UNDER LABORATORY CONDITIONS, DACO: 9.2.4.4
- 3667535 2009, POLLINATOR PESTICIDE SAFETY TRIALS 2007, DACO: 9.2.4.5
- 3667536 2019, Determination of Residues in Leaves, Flowers, Pollen, and Nectar of Orange Following One Foliar Application of Beleaf 50SG (2018), DACO: 9.2.4.8

- 3667537 2019, Determination of Residues in Leaves, Flowers, Pollen, and Nectar of Canola Following Foliar Application(s) of Beleaf 50SG (2018), DACO: 9.2.4.8
- 3667538 2000, TUNNEL TRIAL ASSESSMENT OF THE PRODUCT IBE 3894 - SHORT-TERM TOXICITY ON HONEY BEES, DACO: 9.2.4.6
- 3667539 2001, TUNNEL TEST - ACUTE AND SHORT TERM EFFECTS OF IBE 3894, APPLIED ON WHITE MUSTARD, ON HONEY BEES (APIS MELLIFERA), DACO: 9.2.4.6
- 3667540 2002, TUNNEL TEST - ACUTE AND SHORT TERM EFFECTS OF IBE 3894 (IKI-220 50% WG), APPLIED ON OIL SEED RAPE, ON HONEY BEES (APIS MELLIFERA L), DACO: 9.2.4.6
- 3667541 2001, EVALUATION OF IMPACT ON HONEY BEES WITH AN APPLICATION OF IBE 3894, INSECTPROOF TUNNEL TRIAL ON WINTER WHEAT, DACO: 9.2.4.6
- 3682223 2017, TEPPEKI - Acute Oral and Contact Toxicity to the Bumblebee (*Bombus terrestris* L.) under Laboratory Conditions, DACO: 9.2.4.1,9.2.4.2
- 3682224 2019, IKI-220 100 OD - Honey Bee Larval (*Apis mellifera* L.) Toxicity Test following Repeated Exposure under laboratory conditions, DACO: 9.2.4.3
- 3682225 2021, Assessment of Brood Development and Mortality during the Life Cycle of the Honeybee (*Apis mellifera* L.) in a Pulsed Oscillating Dose Colony Feeding Test with IKI-220 500WG (Teppeki) in France 2021, DACO: 9.2.4.3
- 3682226 2020, IKI-220 100 OD - Chronic Toxicity to the Honey Bee, *Apis mellifera* L. under Laboratory Conditions, DACO: 9.2.4.4
- 3682222 2025, Formulation Description, DACO: 3.7.
- 3667475 2021, Pollinator Risk Assessment for Flonicamid, DACO: 9.2.4.9.

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