



Evaluation Report for Category B, Subcategory 3.14 Application

Application Number: 2022-6119
Application: New Product Labels - Classifications
Product: TOPBUXUS Anti Caterpillar
Registration Number: 34953
Active ingredient (a.i.): *Bacillus thuringiensis* subsp. *kurstaki* strain ABTS-351
PMRA Document Number : 3497939

Purpose of Application

The purpose of this application was to register TOPBUXUS Anti Caterpillar, as a domestic class insecticide.

Product Characterization and Analysis

Product guarantee, potency, and physical properties data for five batches of TOPBUXUS Anti Caterpillar were provided and found to be acceptable. Microbial contaminant analysis data on the end-use product was considered supplementary as testing is only required for the technical grade active ingredient (TGAI).

Microbial contaminant testing must continue to be conducted on all batches of the TGAI. Testing and release standards must be in compliance with the requirements outlined in the OECD Issue paper on Microbial Contaminant Limits for Microbial Pest Control Products [ENV/JM/MONO(2011)43].

The available information is sufficient to support the domestic use of TOPBUXUS Anti Caterpillar as a biological insecticide on boxwood (*Buxus* spp.).

Health Assessments

No new toxicological information was required for TOPBUXUS Anti Caterpillar as it is comparable to the precedent product. The registered uses of TOPBUXUS Anti Caterpillar are consistent with the registered uses of the precedent product.

Although the frequency of application is slightly shorter in comparison to registered uses of the precedent product, no additional occupational, bystander or dietary exposure concerns were identified as the active ingredient in TOPBUXUS Anti Caterpillar is not toxic or pathogenic via the oral, pulmonary, intraperitoneal, and dermal routes of exposure (see PACR2006-09 *Re-evaluation of Bacillus thuringiensis*).

The label for TOPBUXUS Anti Caterpillar instructs users to avoid contact with skin, eyes or clothing and to avoid breathing dust or spray mist. Furthermore, the label instructs users to wear a long-sleeved shirt, long pants, waterproof gloves, shoes and socks and eye goggles when handling, mixing/loading or applying the product and during all clean-up and

repair activities.

The available information is sufficient to support the domestic use of TOPBUXUS Anti Caterpillar as a biological insecticide on boxwood.

Environmental Assessment

No new environmental fate or environmental toxicology information was required for TOPBUXUS Anti Caterpillar as it is comparable to the precedent product. The registered uses of TOPBUXUS Anti Caterpillar are consistent with the registered uses of the precedent product.

Although the frequency of application is slightly shorter in comparison to registered uses of the precedent product, no additional environmental toxicology concerns were identified as the active ingredient in TOPBUXUS Anti Caterpillar is not toxic or pathogenic to non-target avian, freshwater fish, freshwater aquatic invertebrates, estuarine and marine animals, arthropod predators/parasites, honeybees, annelids and mammalian wildlife (see PACR2006-09 *Re-evaluation of Bacillus thuringiensis*).

The label includes standard environmental precautions to minimize non-target exposure.

The available information is sufficient to support the domestic use of TOPBUXUS Anti Caterpillar as a biological insecticide on boxwood.

Value Assessment

Support for TOPBUXUS Anti Caterpillar was based on extrapolation from registered claims on the precedent product. As the TOPBUXUS Anti Caterpillar application rate for control of box tree moth is within the registered application rate range of 560 to 1120 g product per hectare for this pest on the precedent product label, TOPBUXUS Anti Caterpillar is expected to provide a similar level of control. Box tree moth (*Cydalima perspectalis*) is an invasive pest species recently introduced into Canada that can cause significant damage to boxwoods, leading to the destruction of infested plants. TOPBUXUS Anti Caterpillar has value as it provides a domestic-class product for homeowners to use to control this pest.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found the information acceptable to register TOPBUXUS Anti Caterpillar.

References

PMRA Document Number	Reference
1353469	Valent Biosciences Corp., Response to question concerning use of HPLC methods to determine Product Guarantee, DACO: M2.9.2
1353470	2000, Bio-Assay for Bacillus Thuringiensis, DACO: M2.9.2

1353472 1999, Safety Test, Bacillus thuringiensis, DACO: M2.10.2
1353473 Microbial Contaminants-Results of Mouse Safety Tests (5 lots), DACO: M2.10.2
1353475 2000, Two-Year Potency Stability Study for DiPel DF (ABG-6404) Final Report, DACO: M2.11
1366482 1998, Manufacturing Process for DiPel 2XDF (ABG-6404) At Abbott Laboratories, DACO: M2.8
1366483 Potency Estimation and product guarantee-DiPel 2XDF, DACO: M2.9.2
1366485 Unintentional Ingredients-DiPel 2XDF, DACO: M2.10.2,M2.10.3,M2.9.3
1366486 1997, Standard Procedure - Coliform Enumeration & Identification from Product (STM.0309600), DACO: M2.10.2,M2.9.3
1366487 1997, Standard Procedure - Enterococci Screening (STM.0154700), DACO: M2.10.2,M2.9.3
1366490 Analysis for microbial contaminants, DACO: M2.10.2
1366491 DiPel 2XDF Storage Stability Testing, DACO: M2.11
1366492 Summary of Physical and Chemical Properties, DACO: M2.12
1366493 Physical and Chemical Property Characterization of ABG-6404, DACO: M2.12
1366494 Comparison between DiPel 2XDF, DiPel 2X and DiPel WDG, DACO: M2.8,M2.9,M2.9.1,M2.9.2
1367326 DiPel 2XDF-Attachment 2-Mouse Safety Raw Data Files; Attachment 3-Storage Stability Testing Statistical Analysis Project No. 43B-2000-53 Supplement to: 48D-98-004, DACO: M2.10.2,M2.11
3038171 2004, DiPel WG Storage Stability, DACO: M2.11
3421386 2021, M2.9.2 Background on Slurry Lots Under New Manufacturing Plant, DACO: M2.9.2
3421387 2016, M2.8 M2.10.2 Bio burden analysis of dipel DF, DACO: M2.10.2,M2.8
3424789 2023, DACO M2.4 Trade names for TGAI for TOPBUXS, DACO: M2.4

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