OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

October 21, 2024

PC Code: 002203
TG Barcode: 485372

SUBJECT: **Veratrine:** Environmental Fate and Ecological Risk Assessment and Biological Evaluation (BE) for Proposed Section 3 New Chemical Registration

FROM: Ibrahim Abdel-Saheb, Ph.D., Environmental Scientist
Tamara Johnson, Risk Assessment Process Leader (Acting)
Environmental Fate and Effects Division (7507P)

Ibrahim Abdel-saheb Digitally signed by Ibrahim Abdel-saheb Date: 2024.10.21 13:09:31 -04'00'

Tamara Johnson Digitally signed by Tamara Johnson Date: 2024.10.21 13:02:43 -04'00'

THRU: Mark Corbin, Branch Chief
Jerrett Fowler, Senior Scientist
William Eckel, Ph.D., Senior Science Advisor
Environmental Fate and Effects Division (7507P)

Digitally signed by Mark Corbin Date: 2024.10.21 20:24:21 -04'00'

WILLIAM ECKEL Digitally signed by WILLIAM ECKEL Date: 2024.10.21 13:20:03 -04'00'

JERRETT FOWLER Digitally signed by JERRETT FOWLER Date: 2024.10.21 13:16:08 -04'00'

TO: Deanna Colby, Branch Chief
Marianne Lewis, Risk Manager
Venus Eagle, Product Manager, PM Team 1
Invertebrate and Vertebrate Branch 3
Registration Division

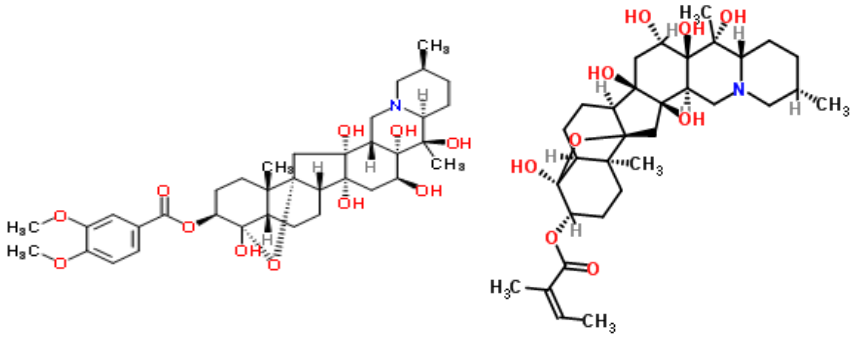
The Environmental Fate and Effects Division (EFED) has completed an ecological risk assessment (ERA) and Biological Evaluation (BE) for a proposed Section 3 new chemical registration for veratrine (formerly known as SABA-10). Veratrine is considered distinct from the previously registered active ingredient sabadilla alkaloids due to a change in the prevalence of alkaloids (% ai) in the mixture resulting from a new manufacturing process. Veratrine is a mixture of sabadilla alkaloids (an extract of the ground seeds from the sabadilla plant) consisting of primary active alkaloids, veratridine and cevadine (total of approximately 10%) plus impurities. Other alkaloids with pesticidal activity make up <1% of the mixture. Veratrine is an insecticide which binds to the voltage-dependent sodium channels in the insect nervous system in ways similar to the pyrethroid insecticides, but potentially without the cross-resistance seen among the various pyrethroid active ingredients.
McLaughlin Gormley King Company (MGK) has proposed outdoor spot (2 feet x 2 feet), crack and crevice (1 ft x 100 linear ft) on the exterior vertical surfaces of man-made structures only). EFED concludes that, due to limited exposure to aquatic and terrestrial animals and plants from the proposed use pattern, veratrine does not result in risk concerns under the Federal Insecticide, Fungicide Rodenticide Act (FIFRA). This product is only intended to be applied as a spot treatment to crack and crevices on the exterior vertical surfaces of man-made structures. The proposed label indicates that the applicator may not apply this product directly to or allow it to drift to blooming crops or weeds while bees or other pollinating insects are actively visiting the treatment area. EFED expects that impacts on terrestrial invertebrates, especially target insects, would be limited to the

directly treated area, and non-target taxa are not reasonably expected to be exposed to veratrine beyond this limited footprint. Therefore, there is a low potential for risks of concern expected.

EFED has also determined that exposure is not reasonably expected to occur to any listed species based on the proposed use pattern, which results in greatly limited expected environmental exposures and the fate properties of the chemical. Because exposure and thus effects to listed species are not reasonably certain to occur, EFED makes 'No Effect' determinations for federally listed endangered, threatened and proposed species and their designated critical habitats under the Endangered Species Act (ESA).

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ecological Risk Assessment and Biological Evaluation for the Proposed Section 3 New Chemical Registration of Veratrine



CAS Numbers
8051-02-3
PC Code: 002203

October 21, 2024

Prepared by:
Ibrahim Abdel-Saheb, Ph.D., Environmental Scientist
Jerrett Fowler, Acting Senior Scientist
Environmental Fate and Effects Division (7507P)

Reviewed by:
William P. Eckel, Ph.D., Senior Advisor
Tamara Johnson, Acting RAPL
Mark Corbin, Branch Chief, ERB6

U.S. Environmental Protection Agency
Office of Pesticide Programs
Environmental Fate and Effects Division
Environmental Risk Branch I
1200 Pennsylvania Ave., NW
Mail Code 7507P
Washington, DC 20460

Table of Contents

1.0 Executive Summary

Veratrine is a mixture of a class of insecticidal compounds (sabadilla alkaloids) which contains the specific isomers:

> [(3beta,4alpha,16beta)-4,12,14,16,17,20-Hexahydroxy-4,9-epoxycevan-3-yl 3,4-dimethoxybenzoate], and (3beta,4alpha,9beta,16beta)-4,12,14,16,17,20-Hexahydroxy-4,9-epoxycevan-3-yl (2Z)-2-methyl-2-butenoate)].

McLaughlin Gormley King Company (MGK) is proposing to register products containing veratrine as a new active ingredient (a.i.). Veratrine is a mixture of sabadilla alkaloids (an extract of the ground seeds from the sabadilla plant) consisting of primary active alkaloids, veratridine and cevadine (total of approximately 10%) plus impurities (The proposed uses are small spot (2 x 2 sq ft), and vertical crack and crevice uses (1 x 100 linear ft length) to control ants (including carpenter, harvester, pharaoh and red imported fire ants), German cockroaches, house flies, and mosquitoes on man-made structures.

Environmental fate data indicate veratrine is non-volatile (1.51×10^{-24} torr at 25°C), hardly mobile in soil (estimated mean K_{oc} of 40,541 L/kg-OC) and undergoes microbial degradation in a matter of days in soil and weeks in aquatic systems, with low potential to bioaccumulate. The compound is hydrolytically unstable at pH 9 (DT_{50} =10 days), but the DT_{50} is 227 days at pH 7, 25 °C, suggesting that the compound is immobile and likely to remain in or near the treated area.

Major degradates in aquatic system are CO_2 (40.0%, 100 days), and unextracted residues (31.2%, 28 days) of the applied a.i. Similarly, in soil, the major degradates were unextracted residues (23.4%, 120 days), and CO_2 (72.0%, 45 days). For the proposed use, EPA granted a waiver for anaerobic soil study (MRID 51457858, DP465779; see **Appendix C**) because information derived from the anaerobic aquatic metabolism study (MRID 50505702) can provide a reasonable simulation of anaerobic soil conditions and the kinetic data from an anaerobic soil study is not used in risk assessment.

The ecotoxicity data package for this chemical is sufficient to support the proposed use pattern. MGK requested some data waivers, which EPA granted based on the limited exposure potential, rapid dissipation and degradation of the ai in the environment, and hazard profile as evidenced by the submitted veratrine studies (see **Appendix C**). Given the limited exposure potential and availability of studies for taxa in the veratrine dataset, further data are not necessary at this time. However, if MGK (or a subsequent applicant) requests to add outdoor broadcast uses that increase the footprint of veratrine use in the future, EFED expects additional data would be needed, consistent with Title 40 Part 158 of the Code of Federal Regulations (40 CFR 158) (Sections §630, §660 and §1300) for the registration of conventional pesticides.

Veratrine's immobility and susceptibility to photolysis means it will stay where it is applied and break down over the course of two weeks via sun exposure, making transport to areas where it is not applied unlikely. This product is only intended to be applied as a spot treatment to crack and crevices on man-made structures. The proposed label indicates not to apply this product directly to or allow it to drift to blooming crops or weeds while bees or other pollinating insects are actively visiting the treatment area.

EFED expects that impacts on terrestrial invertebrates, especially target insects, would be limited to the directly treated area, and non-target taxa are not reasonably expected to be exposed to veratrine beyond this limited footprint. Exposure and overlap modeling (*i.e.,* Federally listed endangered, threatened or proposed species' ranges and their designated critical habitat with proposed use sites) were not completed for the chemical. Neither terrestrial nor aquatic exposure modeling was completed because the spot treatment use pattern on developed structures does not meet the assumptions of EFED's quantitative modeling (*e.g.,* treated field with organisms foraging 100% of the time on the field). Although standard models like T-REX (v1.5.2) have been adapted in some unique situations, the limited use pattern for veratrine would makes any assumption of 100% foraged on treated material untenable. Overlap modeling was not used since the use pattern tailored to developed structures would apply to the geospatial footprint of developed areas, which would greatly overestimate the potential overlap from veratrine's use pattern.

EFED concludes that, due to limited exposure to non-target aquatic and terrestrial animals and plants from the proposed use pattern, veratrine does not result in risk concerns under the Federal Insecticide, Fungicide Rodenticide Act (FIFRA). EFED has determined that exposure to veratrine is not reasonably expected to occur to any listed species[1] based on the fate properties of the chemical and the proposed use pattern, which greatly limit expected environmental exposures. Because exposure and thus effects to listed species are not reasonably certain to occur, EFED makes 'No Effect' determinations for federally listed endangered, threatened and proposed species and their designated critical habitats under the Endangered Species Act (ESA) for veratrine.

EPA has made a NE call for the co-formulant, pyrethrins, in the proposed veratrine end use products for all listed species, as the use pattern drives the rationale behind the effects determination. The co-formulant, pyrethrins, will be applied with veratrine; and therefore, are also anticipated to have low likelihood of exposure to listed species.

[1] "Listed species" refers to federally listed endangered, threatened and proposed species under the Endangered Species Act.

2.0 Problem Formulation

Veratrine, a mixture of sabadilla alkaloids veratridine and cevadine, is an insecticide that has not been previously registered in its present form for use in the United States. MGK is proposing to register veratrine for application to exterior vertical surfaces of man-made structures as crack and crevice (1 x 100 linear ft) and small (2 x 2 ft) spot treatments. Because of the very limited environmental exposure expected from the proposed use pattern, limited data were required by EPA for the proposed spot, crack and crevice uses. Additional data will be needed to fully assess risks to non-target species if additional proposed outdoor uses that expand the exposure footprint (*e.g.,* broadcast applications) are submitted for registration consideration.

3.0 Use Characterization and Methods of Application

Veratrine, as described on the proposed label, is to be dispersed from hand-held sprayers and backpack sprayers. It is to be applied on exterior vertical surfaces of man-made structures. The proposed label recommends the product should be applied at the rate of 19 fl. oz. per 100 sq. ft. by 4 sq. ft spots for crack and crevice applications[2]. Spot treatments must not exceed two square feet in size (EPA Reg. No. 1021-UNASSIGNED EPA Est. No. 1021-MN-2). The proposed label indicates that veratrine is:

For use outdoors (on the exterior vertical surfaces of the following man-made structures): commercial warehouses (non-food), commercial buildings, office buildings, theaters, hotels, motels, homes, garage buildings, resort buildings, industrial buildings, apartment buildings, dumpsters/trash cans, commercial kennel buildings, commercial horse stable buildings, zoo buildings, transportation equipment (non-food), commercial truck trailers (non-food), railroad cars (non-food).

4.0 Environmental Fate and Transport

Veratrine is not volatile (1.51×10^{-24} torr at 25°C), hardly mobile in soil (mean K_{oc} of 40,541 L /kg-OC) and undergoes microbial degradation in a matter of days in soil and weeks in aquatic systems, with no potential to bioaccumulate. The compound is hydrolytically unstable at pH 9 (DT_{50} = 10 days, 25 °C), but the DT_{50} is 227 days at pH 7, 25 °C.

Environmental fate studies were conducted using veratridine as the test substance. Both compounds (veratridine and cevadine) are similar enough in structure that they are expected to have similar environmental fate pathways. Physical/chemical and environmental fate and transport properties of veratrine are listed in **Table 1**.

[2] The crack and crevice dimensions are (100 sq. ft./100 linear ft. in a 1 ft. wide band)/ one pint (16 fl. oz.) covers (85 sq. ft./85 linear ft. in a 1 ft. wide band)] [One (unit of volume) covers (x) sq. ft. (at the proposed label rate of 1 fl. oz. per 5.3 sq. ft.)]. Where X is ratio of sq. ft. per fl. Oz. of product.

Table 1. Physical/chemical and environmental fate/transport properties of Veratrine.

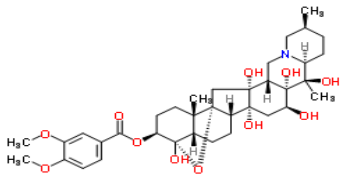
PARAMETER	VALUE(S)	SOURCE
Chemical Name	(3beta,4alpha,16beta)-4,12,14,16,17,20-Hexahydroxy-4,9-epoxycevan-3-yl 3,4-dimethoxybenzoate	
Molecular Formula	$C_{36}H_{51}NO_{11}$	EPI Suite v 4.1
Molecular Weight	673.8 g/mol	
CAS No	8051-02-3	
Structure		

Table 2. Chemical properties of Veratrine.

PARAMETER	VALUE(S)	SOURCE
SMILES	C[C@H]1CC[C@H]2[C@@]([C@]3([C@H](C[C@]4([C@@H]5CC[C@H]6[C@]7([C@]5(C[C@]4([C@@H]3CN2C1)O)O[C@@]6([C@H](CC7)OC(=O)C8=CC(=C(C=C8)OC)OC)O)C)O)O)O)(C)O	Chem Spider[3]
Solubility Limit in Water (20°C)	141 µg/L	EPI Suite v 4.1
Octanol/Water Partition Coefficient	Log K_{ow} = 0.678 at 20°C	
Vapor Pressure	1.51 ×10^{-24} Torr	
Hydrolysis Half-life (25°C)	227 days (pH 7) 10.0 days (pH 9)	MRID 50508303
Aqueous Photolysis	16.3 days pH 5, 25°C (Buffer) latitude not specified	MRID 50518501

[3] CSID:391289, http://www.chemspider.com/Chemical-Structure.391289.html (accessed 15:06, Jun 4, 2015)

PARAMETER	VALUE(S)	SOURCE
Aerobic Soil Metabolism Half- life (20^oC)	Loam soil (pH not determined t1/2 = 11.5 days (SFO) Sand soil (pH 7.3) t1/2 = 50.1 days (SFO) Sandy loam soil (pH 7.8) t1/2 = 118 day (IORE) Sandy clay loam soil (pH 8.0) t1/2 = 78.8 days (SFO)	MRID 50506101
Aerobic Aquatic Metabolism Half-life (20^oC)	209 days (Water pH 6.4, sediment pH 4.9) 64.9 days (Water pH 6.1, sediment pH 4.8)	MRID 50505701
Anaerobic soil Metabolism	Waived	DP Barcode: 465779
Organic Carbon Partition Coefficient (Koc)	64,466 L/kgoc (pH 5.4) 17,765 L/kgoc (pH 7.3) 15,620 L/kgoc (pH 7.6) 44,020 L/kgoc (pH 7.8) 60,836 L/kgoc (pH 8.0)	MRID 50508301 Mean: 40,541
BCF in Fish Depuration half-life	Not determined Not determined	MRID 50508302 Lack of [^{14}C]residues in whole body fish tissue from the low-and high-dose test groups at all sampling intervals precluded the determination of % TRR by LSC and HPLC/RAM. A depuration phase was not conducted since residues did not accumulate in the fish during the uptake phase.

4.1 Mobility

Veratrine is hardly mobile (FAO classification in EFED Guidance, USEPA 2010) based on an estimated mean K_{oc} of 40,541 (MRID 50508301). Because it is immobile, veratrine is not expected to be an exposure concern to non-target species. Even if rainfall dislodges veratrine from the treated crack or crevice, the material will be most likely bind to the adjacent soil or degrade in a matter of days. Based on the proposed use pattern of veratrine, EFED believes that the likelihood of exposure to non-target species is low enough that it is not reasonably expected to occur.

4.2 Degradation

Veratrine is hydrolytically stable at pH 7 (DT_{50} = 222 days), but the DT_{50} is 10 days at pH 9, 25 °C (MRID 49617824). The DT_{50} for aerobic aquatic metabolism ranges from 64.9-209 days at 20 °C. Major degradates in aquatic systems are CO_2 (40.0%, 100 days), and unextracted residues (31.2%, 28 days) of the applied a.i. (MRID 50505701). The aerobic soil metabolism DT_{50} is 11.5-118 days. The major degradates were unextracted residues (23.4%, 120 days), and CO_2 (72.0%, 45 days) (MRID 50506101). No minor degradates were reported in submitted fate studies. An aqueous photolysis study shows that Veratrine degrades in water with an adjusted half-life of 16.6 days based on its UV absorption spectrum (MRID 50518501).

4.3 Field Dissipation and Bioaccumulation

No field dissipation studies are needed for the proposed use because Veratrine is limited to only include spot treatment and crack and crevice applications outdoors. However, if broadcast use patterns are added in the future, terrestrial field dissipation studies would need to be submitted.

Veratrine has low potential to bioaccumulate based on its log K_{ow} (0.678 at 20^{o}C), and there was no accumulation in the fish during the uptake phase (MRID 50508302).

4.4 Data Gaps

No fate data gaps exist currently. A waiver request for the anaerobic soil metabolism study was submitted and EFED concurred (DP Barcode: 465779; see **Appendix C**).

4.5 Monitoring Data

Veratrine is a new chemical that has not been registered in the United States. Although other sabadilla alkaloids were previously registered, there are no monitoring data available for veratrine.

5.0 Analysis Plan

5.1 Conceptual Model

For the proposed use pattern, Veratrine is applied to the pests found on the exterior vertical surfaces in the spot, cracks and crevices. The active ingredient (veratrine) is then present in the spot, cracks and crevices, and to some degree, proximal surfaces, probably from a small percentage of (highly localized) drift. Exposure to non-target aquatic and terrestrial entities is not reasonably expected to occur because of the fate properties (immobility) and limitations on use areas.

5.2 Characteristics of Ecosystems Potentially at Risk

The ecosystems potentially at risk are often extensive in scope; therefore, it is not always possible to identify specific ecosystems during the development of a nation-wide ecological risk assessment. However, in general terms, terrestrial ecosystems potentially at risk from conventional pesticide uses could include the areas immediately adjacent to the application site. Aquatic ecosystems potentially at risk include water bodies adjacent to or downstream from, the application site. However, for the proposed use, exposure to non-target species is not reasonably expected to occur due to the proposed label limitations which specify application sites on exterior vertical surfaces of man-made structures.

5.3 Risk Hypothesis

The following ecological risk hypothesis is being employed for this national-level ecological risk assessment:

> Veratrine, with its immobile fate properties and when used in accordance with the proposed label that limits the application to exterior vertical surface areas, is reasonably certain not to result in off-site movement of the compound leading to exposure of non-target plants and animals. On-site exposure to veratrine is expected to be below levels where adverse effects to survival, growth, and reproduction of non-target terrestrial and aquatic organisms would occur.

To address the risk hypothesis, a qualitative assessment was used to assess the potential for adverse effects from veratrine to non-target organisms. Due to the lack of exposure modeling, a quantitative risk quotient approach was not possible for veratrine, because the exposure hypotheses are inconsistent with standard risk assessment modeling approach, as previously discussed.

5.4 Measures of Aquatic and Terrestrial Exposure

Because the proposed use pattern is directed application to exterior vertical surfaces of man-made structures in spot, cracks and crevices, current quantitative modeling approaches were not used to characterize the risk conclusions for aquatic or terrestrial taxa as discussed below. Exposure to non-target taxa is not reasonably expected to occur beFcause the product is immobile and it can only be used on exterior vertical surfaces of man-made structure in a limited area .

5.5 Measures of Effect

Given that exposure in not reasonably certain to occur, the nature of the effects is not as relevant for the proposed use pattern as they might be for conventional uses. Sublethal effects observed in both registrant-submitted and open literature studies are evaluated qualitatively because of various issues, such as a lack of verification of dosages. Quantitative assessments of risks, though, are limited to those endpoints that can be directly linked to the Agency's assessment endpoints of impaired survival, growth, and reproduction. The assessment of risk for direct effects to non-target organisms employs the standard EFED assumption that toxicity of a chemical to birds is similar to that of terrestrial-phase amphibians and reptiles. The same standard assumption is made for fish and aquatic-phase amphibians. The acute measures of effect used for animals in this screening-level assessment are the acute LD_{50}, LC_{50}, and EC_{50}. Endpoints for chronic measures of exposure for listed and non-listed animals are the NOAEL and/or NOAEC.

5.6 Integration of Exposure and Effects

Risk characterization is the integration of exposure and ecological effects characterization to determine the potential ecological risk from the proposed use of veratrine. Because non-target organisms are not reasonably certain to occur, a qualitative assessment is conducted.

6.0 Ecological Effects Characterization

The toxicity data are sufficient for the proposed new use. The registrant did not initially submit valid data for green algae (OCSPP Guideline 850.4500). However, the registrant submitted an update to the study which resulted in a Supplemental classification, deeming the study sufficient for use in risk assessment. There is considered to be limited exposure potential (limited use pattern, fate properties, and generally limited toxicity as evidenced by the submitted veratrine and sabadilla alkaloid toxicity studies summarized in this section). Given the limited exposure potential and hazard profile, gaps in the dataset are not needed to evaluate the proposed use pattern. No acceptable toxicity data are available for terrestrial plants (the application rate tested in the available study was too low for EFED to conduct a risk analysis). Plant studies, up to the field application rate, would be necessary if additional proposed broadcast uses were submitted in the future.

Veratrine has a variety of hazard values, ranging from practically non-toxic to highly toxic. The active ingredient (a.i.) is highly toxic to honey bees on an acute exposure basis. A summary of the submitted toxicity data and the resulting measures of ecological effect selected for quantifying the risks for each taxonomic group are included in **Table 3** and **Table 4**. **Appendix B** also includes toxicity study information that was previously reported in the 2022 90-day screen (USEPA, 2022).

6.1 Aquatic Taxa

The available toxicity studies for aquatic taxa are provided in **Table 3**. **Appendix B** also includes toxicity study information that was previously reported in the 2022 90-day screen (USEPA, 2022). Most aquatic toxicity studies relied on the use of surfactants to increase solubility of veratrine; EFED generally discourages the use of surfactants in animal toxicity studies (i.e., studies are generally tested using the TGAI) because of the possibility of chemical interactions that could limit the ability to understand the toxic effects from the TGAI alone. However, the submitted studies do not need to be repeated at this time due to the limited exposure potential from the proposed uses.

Table 3. Summary of the Endpoints from Submitted Aquatic Toxicity Studies for Veratrine. Note: surfactant used for solubility in most studies.

Taxa Represented	Species (common name)	Toxicity Value (µg a.i./L)	Citation (MRID)	Study Classification	Comments
Freshwater fish and aquatic-phase amphibians	*Pimephales promelas* (fathead minnow)	96-hr LC_{50} = 1600	505370015 1457873	Acceptable	Practically nontoxic Probit slope = not applicable (Spearman-Karber used)
	Pimephales promelas (fathead minnow)	LOAEC=120 NOAEC = 65	506095015 1457881	Acceptable	LOAEC based on post hatch survival and time to hatch
Estuarine/ Marine Fish	See **Appendix B** for information on toxicity studies reported in the 2022 90-day screen.				
Freshwater invertebrates	*Daphnia magna* (Daphnid)	48-hr EC_{50} = 210	505615015 1457876	Acceptable	Highly toxic Slope = 7.3 Sublethal effects include lethargy
		LOAEC=180 NOAEC = 85	50642902 51457879	Acceptable	LOAEC based on effect to parental survival, offspring per adult
Estuarine/ Marine Invertebrates	See **Appendix B** for information on toxicity studies reported in the 2022 90-day screen.				
Freshwater Sediment-dwelling Invertebrates	See **Appendix B** for information on toxicity studies reported in the 2022 90-day screen.				

Taxa Represented	Species (comm on name)	Toxicity Value (µg a.i./L)	Citation (MRID)	Study Classification	Comments
Estuarine marine Sediment-dwelling invertebrates	See **Appendix B** for information on toxicity studies reported in the 2022 90-day screen.				
Non-vascular Aquatic Plants	*Pseudokirchneriella subcapitata* (green algae)	IC_{50}>800 NOAEC =300	50561401 51546302	Acceptable	Yield is most sensitive endpoint
Vascular Aquatic Plants	*Lemna gibba* (duckweed)	IC_{50}=1200 NOAEC = 110	50562501 51457899	Supplemental but considered adequate for the current risk assessment	Yield is most sensitive endpoint

6.2 Terrestrial Taxa

The available avian and mammalian toxicity data indicate that veratrine is at least moderately toxic to most species tested. The most sensitive data are presented in **Table 4**.

Table 4. Summary of the Most Sensitive Endpoints from Submitted Terrestrial Toxicity Studies for Veratrine

Taxa Represented	Species	Endpoint	Citation (MRID)	Study Classification	Comment
Birds, terrestrial- phase amphibians and reptiles	*Colinus virginianus* (Northern Bobwhite Quail)	LD_{50} =36.1 mg a.i./kg-bw	51457867	Acceptable	Highly toxic Observational NOAEC <5.6 mg a.i./kg bw based on mortality
	Taeniopygia guttata (zebra finch)	LD_{50} =79.1 mg a.i./kg-bw	51457868	Acceptable	Moderately toxic Observational NOAEC 45 mg a.i./kg bw based on mortality and regurgitation
	Colinus virginianus (Northern Bobwhite Quail)	LC_{50} = 224 mg a.i./kg-diet	51457869	Acceptable	Highly Toxic Observational NOAEC <57.3 mg a.i./kg bw based mortality; Probit slope 9.6
	Anas platyrhynchos (mallard duck)	LC_{50} =338 mg a.i./kg-diet	51457870	Acceptable	Highly Toxic Observational NOAEC <57.3 mg a.i./kg bw based on body weight and food consumption; Probit slope 7.8
	Colinus virginianus (Northern Bobwhite Quail)	LOAEC=27.9 mg a.i./kg diet NOAEC=9.6 mg a.i./kg diet	51457871	Acceptable	14-day number hatched (10% reduction)
	Anas platyrhynchos (mallard duck)	Reproduction data not available; required study for conventional use patterns. This lack of data is not considered a data gap; data are expected for any possible broadcast use.			
Terrestrial mammals	*Rattus norvegicus* (laboratory rat)	Estimated LD_{50} = 550 mg/kg bw (95% PL CI: 380.9- 1710 mg/kg bw)	51457814	--	
		NOAEL Males: **36.2** mg/kg bw/day Females: **43.7** mg/kg bw/day	51457838	Acceptable	Based on decreased pup weight. Effects on grooming, posture, and back bone prominence at lower levels.

Table 4. Summary of the Most Sensitive Endpoints from Submitted Terrestrial Toxicity Studies for Veratrine					
Taxa Represented	**Species**	**Endpoint**	**Citation (MRID)**	**Study Classification**	**Comment**
Terrestrial invertebrates	*Apis mellifera* (Honey bee)	LD_{50} (contact exposure to adults) = 0.56 µg a.i./bee	50506004 51457889	Supplemental-qualitative	Highly Toxic Mortalities ranged to 90% at the highest concentration tested;
		LD_{50} (oral exposure to adults) =0.54 µg a.i./bee	50506003 51457890	Supplemental-quantitative	Highly Toxic Mortalities ranged to 87% at the highest concentration tested;
		LD_{50} (oral exposure to larvae) =0.39 µg a.i./bee	50506001 51457891	Acceptable	Highly Toxic Mortalities ranged to 92% at the two highest concentrations tested;
		(Larval chronic oral) LOAEC =0.12 µg a.i./bee NOAEC =0.63 µg a.i./bee	50505703 51457893	Acceptable	
		(Adult chronic oral) LOAEC =0.27 µg a.i./bee NOAEC =0.12 µg a.i./bee	50506002 51457892	Acceptable	
Non-target terrestrial plants	Available data insufficient for risk assessment (rate tested too low). However, for the proposed use, exposure to plants is expected to be limited. See **Appendix B** for more information on terrestrial plant data and waiver requests.				

6.3 Incident Data

Because veratrine is not currently registered within the U.S., there are no reported ecological incidents associated with the product.

7.0 Risk Estimation and Characterization

7.1 Terrestrial Birds and Mammals

Exposure to birds, reptiles, terrestrial-phase amphibians, and mammals is not likely to occur; therefore, risk under FIFRA is expected to be low to all taxa. The intended application methods (spot/crack/crevice)

would make exposure to dietary items very limited and would result in negligible drift from the application site. Veratrine fate properties indicate off-site movement via runoff, bioaccumulation and volatility are not a concern. While insects exposed to veratrine may be consumed by some non-target species, contaminated individuals are not expected to be a large amount of any diet given the highly localized application sites and potential inaccessibility of insects within the cracks and crevices or spots. Additionally, many insectivores are hunters and would not prey upon a dead insect. For a species to be exposed, terrestrial invertebrates making up a large amount of a mammal or bird diet would have to be foraging on the treated area at approximately the same time as the application. The small and specific treatment area reduces the probability of this exposure to the point that it is not reasonably certain to occur, and the fate properties do not suggest a likely route of exposure beyond the treated area.

7.2 Terrestrial Invertebrates

Veratrine is a neural insecticide, but it is highly unlikely that non-target terrestrial invertebrates are present or will enter the limited treated areas (crack or crevice) on man-made structures. Therefore, such exposure is not reasonably certain to occur. For a non-target organism to be exposed, an individual would have to be present in an application site at the time of application. Otherwise, an efficacious amount of veratrine will have to migrate from the treated area, which has previously been described in detail as not reasonably certain to occur (*e.g.,* through runoff or drift). The small and specific treatment area reduces the probability of this exposure, and the fate properties do not suggest a reasonable route of exposure.

7.3 Terrestrial and Aquatic Plants

Exposure to plant species is not reasonably certain to occur and no effects to these taxa are expected as the proposed use pattern is not expected to lead to direct exposure to plant species. Consistent with conclusions in Sections 7.1 (Terrestrial Birds and Mammals) and 7.2 (Terrestrial Invertebrates) the small and specific treatment area reduces the probability of this exposure to terrestrial and aquatic plants, and the fate properties do not promote a reasonable route of exposure.

7.4 Aquatic Animals

Because runoff and drift are not expected to be reasonable dissipation routes from the proposed use pattern, exposures to aquatic organisms ares not reasonably certain to occur and no adverse effects to aquatic taxa are expected.

8.0. No Effect Determination Justification (Biological Evaluation)

For veratrine, EPA has made No Effect (NE) determinations for all listed species and proposed and designated critical habitats. EPA concludes that exposure and thus effects to listed species is not reasonably certain to occur based on the limited treatment areas (*i.e.,* veratrine treatment is proposed for use on exterior vertical surfaces of man-made structures), low likelihood that non-target organisms would intersect with a route of exposure, and immobility of veratrine fate keeping the chemical limited to its treatment area.

Non-target organisms are not reasonably expected to be directly exposed to veratrine. Based on the use pattern of veratrine, non-target organisms have a low likelihood of exposure to the the treated crack or crevice—low enough that exposure is not reasonably certain to occur. The fate properties of veratrine reduce the likelihood of offsite exposure. Veratrine has a low potential for volatilization and bioaccumulation because of its low vapor pressure and low octanol-water partitioning coefficient. The ai is immobile with a high K_{oc} (**Section 4**). The immobility means even if rainfall dislodges veratrine from the treated crack or crevice, the material will most likely bind to the adjacent soil or degrade in a matter of days. Finally, the proposed label instructions direct users to only treat a 2 sq. ft. treated spot or a 100 ft linear treated area on exterior vertical surfaces of man-made structures. The fate properties and the scale and scope of the application method led the EPA to conclude that spray drift and runoff from veratrine uses are unlikely, and offsite exposure is not reasonably expected to occur.

Because of the lack of overlap of potential use sites and relevant non target areas and the low likelihood of veratrine exposure, EPA does not reasonably expect effects to the prey, pollinators, habitat, and dispersal mechanisms of listed species. Based on the weight of evidence, EPA made No Effect (NE) determinations for all currently listed and proposed species, and for all designated and proposed critical habitats.

EPA has made a NE call for the co-formulant, pyrethrins, in the proposed veratrine end use products for all listed species, as the use pattern drives the rationale behind the effects determination. The co-formulant, pyrethrins, will be applied with veratrine; and therefore, are also anticipated to have low likelihood of exposure to listed species. Any changes in the proposed use patterns for veratrine or the co-formulated product would require a new effects determination process that could result in differing effects determinations than for the current action (USEPA, 2024).

9.0 Conclusions

This assessment concludes that there are no FIFRA risk concerns for non-target terrestrial or aquatic plants or animals for the proposed use pattern. This is mainly a function of the limited exposure to non-target organisms. Exposure and effects are not reasonably certain to occur because the application area is expected to be on small areas (*e.g.,* 1 ft x 100 ft area) that are in places not reasonably expected to be occupied by listed species, and due to immobility of veratrine. EFED makes 'No Effect' determinations for federally listed endangered, threatened and proposed species and their designated critical habitats because exposure and thus effects to listed species are not reasonably certain to occur.

10.0 References

USEPA 2010. EFED Guidance for Reporting on the Environmental Fate and Transport of the Stressors of Concern in Problem Formulations. Table 5 FAO Mobility Classification Based on Koc. https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-reporting-environmental-fate-and-transport

USEPA 2021a. SABA-10: Environmental Fate and Ecological Effects New Chemical Screen. DP Barcode 463144. August 19, 2021

USEPA 2021b. SABA-10: New Chemical Screen Addendum. DP Barcode 463456. October 13, 2021.

USEPA 2022. SABA-10: Environmental Fate and Ecological Effects New Chemical 90-day Screen for Proposed Insecticide SABA-10. DP Barcode 465234. May 4, 2022.

USEPA 2024. Effects Determinations for the Proposed Co-formulants of Veratrine, New AI, based on Proposed Uses in New Registration. TG Barcode 631639. September 25, 2024.

Appendix A. Environmental Fate Data Requirements and Studies Submitted for Veratrine, As Previously Reported the 2022 90-day Screen (USEPA, 2022).

MRID	OCSPP Guideline	Study Title	Test Substance	Potential Issues Reported
51457854 (50508303)	835.2120	Hydrolysis	Veratridine (TGAI), dimethoxybenzoic acid label	None
51457855 (50518501)	835.2240	Photodegradation in Water	Veratridine (TGAI), dimethoxybenzoic acid label	None
51457856 (50518401)	835.2410	Photodegradation on Soil	Veratridine (TGAI), dimethoxybenzoic acid label	None
51457857 (50506101)	835.4100	Aerobic Soil Metabolism	Veratridine (TGAI), dimethoxybenzoic acid label	None
51457858 (waiver requested)	835.4200	Anaerobic Soil Metabolism	NA	EFED recommends waiver be granted. See Table 5.
51457859 (50505701)	835.4300	Aerobic Aquatic Metabolism	Veratridine (TGAI), dimethoxybenzoic acid label	None
51457860 (50505702)	835.4400	Anaerobic Aquatic Metabolism	Veratridine (TGAI), dimethoxybenzoic acid label	None
51457861 (50508301)	835.1230	Mobility - Adsorption/ Desorption	Veratridine (TGAI), dimethoxybenzoic acid label	None
51457862 & 51674206 (waiver requested)	835.6100	Terrestrial Field Dissipation	NA	EFED recommends waiver be granted. See Table 5.
51457863	850.6100	ECM in Soil	Veratridine (TGAI), dimethoxybenzoic acid label	None
51457864	850.6100	ECM in Water	Veratridine (TGAI), dimethoxybenzoic acid label	None
51457865	850.6100	ILV in Soil and Water	Veratridine (TGAI), dimethoxybenzoic acid label	None
51457866 (waiver requested)	835.2120 835.2240 835.2410 835.4100 835.4300 835.4400 835.1230	Sabadilla Alkaloids: Waiver Request for Cevadine Environmental Fate Studies	NA	EFED recommends waiver be granted. See Table 5.
51457884 (50508302)	850.1730	Fish Bioconcentration	Veratridine (TGAI), dimethoxybenzoic acid label	None

NA = not applicable

Appendix B. Terrestrial and Aquatic Nontarget Organism Toxicity Data Requirements and Studies Submitted for Veratrine As Previously Reported the 2022 90-day Screen (USEPA, 2022).

MRID & Classification (when available)	OCSPP Guideline	Study Title	Species	Test Substance	Potential Issues Reported
Aquatic Animals – Invertebrates					
51457876/Acceptable (50561501)	850.1010	Aquatic Invertebrate Acute Toxicity Test, Freshwater Daphnids	*Daphnia magna*	TGAI, veratrine (5.27% as cevadine and 4.56% as veratridine)	None
51546305	850.1010	Aquatic Invertebrate Acute Toxicity Test, Freshwater Daphnids	*Daphnia magna*	TGAI, Sabadinine (sterol moiety in propylene glycol; 9.44%)	None
51457877	850.1025	Oyster Acute Toxicity Test (Shell Deposition)	*Crassostrea virginica*	TGAI, veratrine (12.00% a.i.)	None
51457878	850.1035	Mysid Acute Toxicity Test	*Americamysis bahia*	TGAI, veratrine (12.00% a.i.)	None
51457879/Acceptable (50642902)	850.1300	Daphnid Chronic Toxicity Test	*Daphnia magna*	TGAI, veratrine(5.27% as cevadine and 4.56% as veratridine)	None
51457880/51674209 Waiver request	850.1350	Mysid Chronic Toxicity Test	*Americamysis bahia*	NA	No study submitted. However, EFED recommends granting the waiver request. See Table 5.
51457885 Waiver request	850.1735	Spiked Whole Sediment 10-Day Toxicity Test, Freshwater Invertebrates	*Hyalella azteca* and *Chironomus dilutus*	NA	No study submitted. However, EFED recommends granting the waiver request. See Table 5.
	850.1740	Spiked Whole Sediment 10-Day Toxicity Test, Saltwater Invertebrates	*Leptocheirus plumulosus*		
51457886	Non-Guideline	Life-Cycle Toxicity Test	*Chironomus dilutus*	TGAI, veratrine (6.86% as cevadine and 5.14% as veratridine)	None
51457887	Non-Guideline	42-Day Sediment Toxicity Test Exposing Freshwater Amphipods	*Hyalella azteca*	TGAI, veratrine (6.86% as cevadine and 5.14% as veratridine)	None

MRID & Classification (when available)	OCSPP Guideline	Study Title	Species	Test Substance	Potential Issues Reported
51457888	Non-Guideline	28-Day Sediment Toxicity Test	*Leptocheirus plumulosus*	TGAI, veratrine (6.86% as cevadine and 5.14% as veratridine)	No dose-response. Preliminary review of the study found non-dose response growth effects that EFED will investigate fully when reviewing the study. Based on the results of the review then EFED will fully decide if another study is needed. Not a showstopper.
Aquatic Animals- Fish					
51457873/Acceptable (50537001)	850.1075	Freshwater and Saltwater Fish Acute Toxicity Test	*Pimephales promelas*	TGAI, SABA10 (5.27% as cevadine and 4.56% as veratridine)	None
51457874	850.1075	Freshwater and Saltwater Fish Acute Toxicity Test	*Oncorhynchus mykiss*	TGAI, SABA10 (5.27% as cevadine and 4.56% as veratridine)	None
51457875	850.1075	Freshwater and Saltwater Fish Acute Toxicity Test	*Cyprinodon variegatus*	TGAI, veratrine (12.00% a.i.)	None
51546304	850.1075	Freshwater and Saltwater Fish Acute Toxicity Test	*Pimephales promelas*	TGAI, Sabadinine (sterol moiety in propylene glycol; 9.44%)	None
51457881/Acceptable (50609501)	850.1400	Fish Early Life Stage Toxicity Test (Freshwater)	*Pimephales promelas*	TGAI, veratrine (5.27% as cevadine and 4.56% as veratridine)	None
51457882 Waiver request	850.1400	Fish Early Life Stage Toxicity Test (Saltwater)	*Cyprinodon variegatus*	NA	No study submitted. However, EFED recommends granting the waiver request. See Table 5.
51457883 Waiver request	850.1500	Fish Life Cycle Toxicity (Freshwater and Saltwater)	Freshwater fish *Pimphales promelas* Estuarine-marine *Cyprinodon variegatus*	NA	No studies submitted. However, EFED recommends granting the waiver request. See table 5.

MRID & Classification (when available)	OCSPP Guideline	Study Title	Species	Test Substance	Potential Issues Reported
Aquatic Plants					
51546303	850.4500	Response to EPA's Preliminary Review of Algal Testing on *Pseudokirchneriella subcapitata.*	*Pseudokirchneriella subcapitata*	NA	EFED agrees with the registrant's response and has updated the classification of the algal toxicity study (MRID 51546302 / 50561401) to acceptable.
51546302/Acceptable (50561401)	850.4500	Algal Toxicity	*Pseudokirchneriella subcapitata*	TGAI, veratrine (5.27% as cevadine and 4.56% as veratridine)	None.
51546301 Waiver request	850.4500	Algal Toxicity	*Navicula pelliculosa* and *Skeletonema costatum*	NA	No studies submitted. However, these studies are not necessary for the current proposed spot treatment and crack and crevice uses. See Table 5.
	850.4550	Cyanobacteria Toxicity	*Anabaena flos-aquae*		
51546306	850.4500	Algal Toxicity	*Raphidocelis subcapitata*	TGAI, Sabadinine (sterol moiety in propylene glycol; 9.44%)	None
51457899/Supplemental (50562501)	850.4400	Aquatic Plant Toxicity Test Using Lemna spp.	*Lemna gibba*	TGAI, veratrine (5.27% as cevadine and 4.56% as veratridine)	The registrant adequately addressed previous EPA comment.
Terrestrial Animals- Birds					
51457867	850.2100	Avian Acute Oral Toxicity Test	*Colinus virginianus*	TGAI, veratrine (5.27% cevadine plus 4.56% veratridine)	None
51457868	850.2100	Avian Acute Oral Toxicity Test	*Taeniopygia guttata*	TGAI, veratrine (3.84% as veratridine and 4.76% as cevadine)	None
51457869	850.2200	Avian Dietary Toxicity Test	*Colinus virginianus*	TGAI, veratrine (3.84% as veratridine and 4.76% as cevadine)	None
51457870	850.2200	Avian Dietary Toxicity Test	*Anas platyrhynchos*	TGAI, veratrine (3.84% as veratridine and 4.76% as cevadine)	None

MRID & Classification (when available)	OCSPP Guideline	Study Title	Species	Test Substance	Potential Issues Reported
51457871	850.2300	Avian Reproduction Test	*Colinus virginianus*	TGAI, veratrine (4.56% as veratridine and 5.27% as cevadine)	None
51457872 Waiver request	850.2300	Avian Reproduction Test	*Anas platyrhynchos*	NA	No study submitted. However, EFED recommends granting the waiver request. See Table 5.
Terrestrial Animals – Bees					
51457892/Acceptable (50506002)	Non-Guideline	Honey Bee Adult Chronic Oral (ACO)	*Apis mellifera*	TGAI, veratrine (5.19% as cevadine and 4.70% as veratridine)	None
51457890/Supplemental (50506003)	Non-Guideline	Honey Bee Adult Acute Oral (AAO)	*Apis mellifera*	TGAI, veratrine (5.19% as cevadine and 4.70% as veratridine)	The study author did not analytically verify the test concentrations at any level. Analytical verification was not performed for the control to check for cross contamination. This study may be used for risk characterization purposes. This is a not a potential show-stopper for the current proposed use. If broadcast use patterns are added in the future, a new study will need to be submitted.
51457889/Supplemental (50506004)	850.3020	Honey Bee Acute Contact Toxicity Test	*Apis mellifera*	TGAI, veratrine (5.19% as cevadine and 4.70% as veratridine)	The study author did not analytically verify the test concentrations at any level. Analytical verification was not performed for the control to check for cross contamination. This study may be used for risk characterization purposes. This is a not a potential show-stopper for the current proposed use. If broadcast use patterns are added in the future, a new study will need to be submitted.
51457891/Acceptable (50506001)	Non-Guideline	Honey Bee Larval Acute Oral (LAO)	*Apis mellifera*	TGAI, veratrine (5.19% as cevadine and 4.70% as veratridine)	None
51457893/Acceptable (50505703)	Non-Guideline	Honey Bee Larval Chronic Oral (LCO)	*Apis mellifera*	TGAI, veratrine (5.19% as cevadine and 4.70% as veratridine),	None

MRID & Classification (when available)	OCSPP Guideline	Study Title	Species	Test Substance	Potential Issues Reported
51457894	850.3030	Honey Bee Toxicity of Residues on Foliage	*Apis mellifera*	TEP, Veratran D (0.1044% as cevadine, 0.08908% as veratridine)	None
51457896 Waiver Request	850.3040	Field Testing for Pollinators	*Apis mellifera*	NA	The studies are not needed for the proposed use pattern. See Table 5.
	Non-Guideline	Residues on Nectar and Pollen			
	Non-Guideline	Semi-Field/Tunnel Testing or Colony Feeding			
Terrestrial Plants					
51457897	850.4100	Seedling Emergence and Seedling Growth	Monocots: *Zea mays, Allium cepa, Avena sativa, Lolium perenne* Dicotyledons: *Phaseolus vulgaris, Cucumis sativa, Brassica napus, Glycine max, Lycopersicon esculentum, Raphanus sativus*	TEP, Veratran D (F2994 Revision 8; 0.1961% a.i.)	None
51457895 Waiver request	850.4100	Seedling Emergence and Seedling Growth	NA	NA	EFED recommends granting the request to rely on Veratran D data for the seedling emergence study.

MRID & Classification (when available)	OCSPP Guideline	Study Title	Species	Test Substance	Potential Issues Reported
51457898	850.4150	Vegetative Vigor	Monocots: *Allium cepa, Avena sativa, Lolium perenne, Zea mays* Dicotyledons: *Brassica oleracea, Cucumis sativus, Glycine max, Helianthus annuus, Lycopersicon esculentum, Raphanus sativus*	TEP, MGK Formula 3159 (4.3092% a.i.)	None
51674202	850.3020; OECD213	Response to 10-day Deficiency Letter Regarding Pollinator Testing with Veratrine	*Apis mellifera*		Satisfactorily resolved. See MRIDs 51457889 and -90.
51674203	850.4400; NG *Leptocheirus*	Comments on EPA's 90-day Review of Selected Ecotoxicology Studies:SABA-10 Lemna Study and Saba-10 Leptocheirus			Satisfactorily resolved.
51674209	850.1350	Comments on EPA's Request for Chronic Mysid Testing for Non-Food Uses of Saba-10	Mysid		Not necessary for the proposed use.

NA = not applicable

Appendix C. Waiver Requests Submitted for Veratrine, As Previously Reported the 2022 90-day Screen (USEPA, 2022).

MRID	Guideline[1]	EFED Recommendation to Waive (Y/N)	Registrant Rationale for Waiver Request	Rationale for EFED Recommendation
Environmental Fate				
51457858	835.4200	Y	*Sabadilla Alkaloids: Waiver Request for Anaerobic Soil Metabolism* **Rationale**: The information derived from an anaerobic aquatic metabolism study is a reasonable simulation of anaerobic soil conditions. Furthermore, the kinetic data from an anaerobic soil study is not used in risk assessment.	Little useful scientific information would be obtained from an anaerobic soil metabolism study given that an anaerobic aquatic metabolism study has been conducted. A waiver is recommended.
51457866	835.2120 835.2240 835.2410 835.4100 835.4300 835.4400 835.1230	Y	*Sabadilla Alkaloids: Waiver Request for Cevadine Environmental Fate Studies* **Rationale**: The route of degradation is the same for cevadine and veratridine, new scientific information on metabolite formation would be unlikely from environmental fate studies conducted with both active ingredients.	The waiver for cevadine e-fate studies is recommended because the two insecticidally active ingredients (veratridine and cevadine) have the same route of degradation (hydrolysis of the ester linkage) to form the sterol cevine and veratric acid. Based on this, the e-fate studies for veratridine are representative of cevadine in the environment.
51457862 & 51674206	835.6100	Y	*SABA-10 Alkaloids: Requests for a Waiver from Terrestrial Field Dissipation Testing for Non-Food Uses* **Rationale**: A waiver from terrestrial field dissipation testing with veratrine based on the low application rate of the active ingredient, the small amount of applied, the small areas or spot applications that are treated for these uses, and the applications do not involve direct application to soil or crops.	The waiver is recommended, as the labels have been updated to only include spot treatment and crack and crevice applications outdoors. However, if broadcast use patterns are added in the future, TFD studies will need to be submitted.

MRID	Guideline[1]	EFED Recommendation to Waive (Y/N)	Registrant Rationale for Waiver Request	Rationale for EFED Recommendation
Ecological Effects				
51457880 51674209	850.1350	Y	*Waiver Request for the Aquatic Invertebrate Life Cycle (Saltwater) Test.* **Rationale**: based on the proposed non-food use pattern, low active ingredient content of the end use product, low chronic risk to freshwater invertebrates from uses, and low estimated chronic risk to estuarine invertebrates from the proposed uses.	Preliminary review of the 96-h acute toxicity test with the saltwater mysid (*Americamysis bahia)* and the 48-h toxicity test with the freshwater daphnid indicates that veratrine is highly toxic to the mysid shrimp (LC50: 161 µg a.i./L**; MRID 51457878**) and highly toxic to the freshwater daphnid (LC50: 210 µg a.i./L; MRID 51457876). As outlined in the CFR, the chronic toxicity test for the mysid shrimp is required if the acute LC50 is <1 mg/L. Based on the proposed limited outdoor uses and exposure potential, EFED recommends granting the waiver request. EFED will re-evaluate this requirement in the future if broadcast uses are proposed.
51457885	850.1735 850.1740	Y	*Waiver Request for Acute Whole Sediment Toxicity Test with Freshwater and Estuarine-Marine Sediment Dwelling Invertebrates*. **Rationale**: Based on the proposed use pattern for non-food uses, low sediment and pore water EECs associated with these uses, and the physical-chemical and environmental fate properties of veratrine.	The half-life of veratrine (represented by veratridine) in sediment in aerobic soil metabolism testing in four soils ranged from 11.5 days to 79 days, above the 10-day half-life criterion (as outlined in the CFR). Similarly, the half-life of veratrine in sediment in two aquatic metabolism studies was 65.5 and 179 days based on SFO modeling. A waiver is recommended.
51457882	850.1400	Y	*Waiver request for Fish Early Life Stage Toxicity Test* (E*stuarine-Marine fish*). **Rationale:** Based on the low active ingredient content of the end-use products, the small treated areas for the proposed non-food use patterns, the low aquatic estimated environmental concentrations (EECs) for these use patterns, the low acute toxicity of veratrine to freshwater fish and sheepshead minnows, the similar sensitivity of freshwater and estuarine fish to veratrine, the low acute risk to freshwater and estuarine-marine fish from the proposed veratrine uses, and the low chronic risk to freshwater fish from these proposed uses.	As outlined in the CFR, data for 850.1400 are required if the acute LC50 for estuarine-marine fish is < 1 mg/L. Acute toxicity testing with estuarine-marine fish, the sheepshead minnows, resulted in an LC50 of 1.7 mg a.i./L (MRID 51457875). A waiver is recommended.

MRID	Guideline[1]	EFED Recommendation to Waive (Y/N)	Registrant Rationale for Waiver Request	Rationale for EFED Recommendation
51457883	850.1500	Y	*Waiver request for Fish Life Cycle Toxicity Test (Freshwater and Estuarine-marine fish)* **Rationale:** Based on the low active ingredient content of the end-use products, the types of proposed non-food use patterns, the low aquatic estimated environmental concentrations (EECs) for these use patterns, the low toxicity of veratrine to freshwater and estuarine fish, the low acute and chronic risk displayed by veratrine to freshwater fish and the low acute risk of veratrine to estuarine fish.	None of the proposed non-food uses involve direct application to water, veratrine is moderately toxic to the representative freshwater (LC50: 1,600 µg a.i./L) and estuarine fish species (LC50: 1,700 µg a.i./L), there are no indications that veratrine could adversely affect the reproductive physiology of the fish, and the low potential for veratridine bioaccumulation in the fish study with the bluegill sunfish (MRID 51457884). A waiver is recommended. Therefore, we would use the ELS freshwater endpoint for risk characterization.
51457872	850.2300	Y	*Waiver request for Avian Reproduction Test* **Rationale**: Based on the limited proposed non-food use patterns result in limited potential exposure of birds through these uses; a number of the proposed non-food uses are not attractive feeding sites for birds. Avian short-term dietary testing data and preliminary mallard reproduction pilot study data indicate that bobwhite quail are more sensitive to veratrine than mallards.	Avian dietary testing with the mallard duck and the bobwhite quail indicates that the bobwhite quail (LC50: 2602mg whole product/kg feed; MRID 51457869) is more sensitive than the mallard duck (LC50: 3924 mg whole product/kg feed; MRID 51457870). Therefore, the submitted reproduction study with the bobwhite quail is sufficient to evaluate potential risks to birds associated with non-food uses. A waiver is recommended.
51546301	850.4500 850.4550	Y	*Waiver request for Algal Toxicity Test and Aquatic Plants Field Study* **Rationale:** Based on the proposed use pattern for non-food uses, low aquatic EECs associated with these uses, and the very low risk displayed by veratrine to tested algal and aquatic plant species (Pseudokirchneriella subcapitata and Lemna gibba) from these non-food uses.	The waiver request for algal toxicity studies (diatoms *Navicula pelliculosa* and *Skeletonema costatum,* and cyanobacteria *Anabaena flos-aquae*) are acceptable based on the low toxicity to the green algae *Pseudokirchneriella subcapitata* (yield, growth rate, and area under the curve EC50: >8.0 mg a.i./L; MRID 51546302) and moderate toxicity to the *Lemna gibba* (Frond density EC50: 1.3 mg a.i./L). A waiver is recommended.

MRID	Guideline[1]	EFED Recommendation to Waive (Y/N)	Registrant Rationale for Waiver Request	Rationale for EFED Recommendation
51457895	850.4100	Y	*Request to rely on Veratran D data to satisfy Seedling Emergence study and Toxicity of Residues on Foliage study.* **Rationale**: Both of these studies have already been conducted with Veratran D (TEP). MGK believes that due to the similarities in composition of Veratran D and VERATRINE with respect to constituent Sabadilla alkaloids, which are the active ingredient in both Veratran D and veratrine, data generated using Veratran D adequately satisfies the corresponding data requirements for veratrine end-use products; there should be no need to generate duplicate data and conduct duplicate studies on veratrine end-use products when adequate Veratran D data are available.	EPA guidelines indicate that both the seedling emergence and toxicity of residues on foliage studies should be conducted with typical end-use products (TEPs). Moreover, the relative ratios of the active ingredients in Veratran D (veratridine and cevadine) are representative of the ratios for these alkaloids in TGAI VERATRINE. Given the similarity in alkaloid content between Veratran D and veratrine products, studies conducted with Veratran D are sufficient to proceed with a risk assessment. EFED recommends granting the waiver request.
	850.3030	Y		
51457896	Non Guideline/ 850.3040	Y	*Request to waive higher-tiered pollinator studies:* • Semi-field/tunnel testing • Residues on nectar and pollen • Field testing for pollinators **Rationale**: Based on the proposed use patterns for non-food uses, low exposure potential for bees from these use patterns, and the rapid dissipation displayed by veratrine with field use.	There is potential for exposure to honeybees via the proposed uses (*i.e.*, outdoor uses). Potential risk to honeybees cannot be estimated due to the lack of analytical verification of the test concentrations with the submitted acute adult oral (AAO), and acute adult contact (OCSPP 850.3020) toxicity test. Based on the proposed limited spot treatment and crack and crevice use pattern, a waiver is recommended. If broadcast use patterns are added in the future, the need for higher tier pollinator studies will evaluated based on the full suite of Tier 1 honey bee data.