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DATA EVALUATION RECORD

STUDY 3

CHEM 128867 Lambda-cyhalothrin §162-4
CAS No. 68085-85-8
FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 44861506
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CONCLUSIONS

Metabolism - Aerobic Aquatic

1. This study is not scientifically valid and does not provide useful information on the aerobic aquatic metabolism of lambda-cyhalothrin. The data used to calculate the half-life may not accurately depict the metabolism of the parent under aerobic aquatic conditions because the sediment was flooded prior to treatment. Additionally, the test compound adsorbed to the test vessels, possibly causing the observed variability and losses in the material balances for both sediment/water systems. Any test material adsorbed to the walls of the test vial was not available for microbial or other degradation in the sediment/water systems.

2. This study does not meet Subdivision N Guidelines for the fulfillment of EPA data requirements on aerobic aquatic metabolism for the following reasons:

   (i) the pesticide was not applied at the same time the sediment was flooded; and

   (ii) material balances were not within the reasonable range of 90-110%.

3. Cyclopropyl ring-labeled [1-^{14}C]lambda-cyhalothrin, at a nominal application rate equivalent to 8 g a.i./ha, degraded with registrant-calculated half-lives (reported as DT_{50}'s; first-order multi-compartment model) of 15 days in flooded sandy loam sediment and 7 days in flooded sand sediment (r^2 values not reported) incubated aerobically in darkness at 20 ± 2°C for up to 98 days. However, the reported data may not accurately depict the metabolism of the parent under aerobic aquatic conditions because a 40- to 41-day pre-incubation period was used, during which the sediment was flooded (prior to treatment with the pesticide). Additionally, not all of the test compound may have been available for degradation in the test systems. All data, designated as percentages of the applied radioactivity, represent percentages of the nominal application.

   In the total sandy loam sediment (Old Basing)/water system, the parent was initially 85.9% of the applied radioactivity, decreased to 50.0% by 14 days and 26.5% by 30 days, and was 12.7% at 98 days posttreatment. In the water phase, the parent was initially 71.5% of the applied radioactivity, decreased to 10.2% by 1 day, was 2.4-7.4% from 4 to 14 days, and was last detected at 0.3% at 30 days posttreatment. The major degradate Compound 1a (R119890) was initially (time 0) 2.1% of the applied radioactivity, was a maximum of 11.4% at 30 days, and was 0.6% at 98 days posttreatment. The minor degradate Compound XV (R211133) was detected at 0.1-0.7% of the applied radioactivity from 0 to 14 days posttreatment. In the sediment phase, the parent was initially 14.4% of the applied radioactivity, increased to 46.9% by 0.25 days and 70.2% by day 1, was 47.6-63.5% at 2-14 days, and was 12.7% at 98 days posttreatment. The major degradate Compound 1a (R119890) was initially (day 1) 0.9% of the applied

radioactivity, increased to 6.7% by 14 days and 10.6% by 30 days, and was 2.5% at 98 days posttreatment. The minor degradate Compound XV (R211133) was initially (day 1) 1.6% of the applied radioactivity, was 4.0-4.4% at 4-30 days, and was 1.6% at 98 days posttreatment. Nonextractable [^{14}C]residues were 0.1-5.1% of the applied radioactivity from 1 to 14 days, increased to 12.7% by 30 days, and were 20.0-24.4% at 58-98 days posttreatment. Evolved $^{14}CO_2$ accounted for 0.2-2.9% of the applied radioactivity from 4 to 30 days, increased to 9.1% by 58 days, and was 15.2% of the applied at 98 days posttreatment; [^{14}C]organic volatiles were negligible. Residues increased in the sediment phase over time; the sediment:water distribution ratio (reviewer-calculated) was approximately 1:4 at time 0, changed to @ 5:1 by 1 day posttreatment, was @ 3:1 at 2-98 days posttreatment.

In the total sand sediment (Virginia Water)/water system, the parent was initially 78.9% of the applied radioactivity, was a maximum of 84.5% at 0.25 days, decreased to 45.9% by 7 days and 37.7% by 14 days, and was 5.8% at 98 days posttreatment. In the water phase, the parent was initially 49.3% of the applied radioactivity, decreased to 28.1-29.7% by 0.125-0.25 days and 10.1% by 2 days, was 1.7-5.4% at 4-14 days, and was last detected at 0.2% at 30 days posttreatment. The major degradate Compound 1a (R119890) was initially (time 0) 2.1% of the applied radioactivity, was a maximum of 14.4% by 14 days, and was last detected at 8.8% at 30 days posttreatment. The minor degradate Compound XV (R211133) was detected at 0.4-1.3% of the applied radioactivity from 0.125 to 7 days posttreatment. In the sediment phase, the parent was initially 29.6% of the applied radioactivity, increased to 56.4% by 0.25 days, was a maximum of 60.9% at 4 days, was 36-43.3% at 7-14 days, and was 5.8% at 98 days posttreatment. The minor degradate Compound 1a (R119890) was detected at 0.7-3.3% of the applied radioactivity from 4 to 30 days, was not detected at 58 days, and was 0.4% at 98 days posttreatment. The minor degradate Compound XV (R211133) was a maximum of 8.7% of the applied radioactivity at 7 days and was 0.9% at 98 days posttreatment. Nonextractable [^{14}C]residues were 0.2-0.8% of the applied radioactivity from 0 to 1 day posttreatment, increased to 7.7% by 7 days, was a maximum of 33.2% by 30 days, and was 17.4% at 98 days posttreatment. Evolved $^{14}CO_2$ accounted for 0.1-0.9% of the applied radioactivity from 1 to 4 days, increased to 9.7% by 14 days and 20.2% by 30 days, and was 47.8% at 98 days posttreatment; [^{14}C]organic volatiles were negligible. Residues increased in the sediment phase over time; the sediment:water distribution ratio (reviewer-calculated) was approximately 1:3 at time 0, changed to @ 4:1 by 14 days posttreatment, was >2:1 at 30 days, and was approximately 15:1 at 98 days posttreatment.

METHODOLOGY

Samples of sieved (2 mm; p. 13) sandy loam sediment (27 g; Old Basing; collected from Basingstoke, Hampshire, UK; 57% sand, 25% silt, 18% clay, 12.8% organic matter, pH 7.8, CEC 16.3 meq/100 g; Tables 1, 4, pp. 35, 36; see Comment #5) OR sand sediment

(45 g; Virginia Water; collected from Windsor, Berkshire, UK; 96% sand, 1% silt, 3% clay, 0.85% organic matter, pH 7.1, CEC 1.3 meq/100 g) were measured into glass cylinders and flooded with 200 mL of respective filtered (250 μm) natural water from the Old Basing site (pH 7.8, conductivity 528 μS/cm, hardness 324 mg/L as $CaCO_3$; Table 5, p. 37) or from the Virginia Water site (pH 7.2, conductivity 364 μS/cm, hardness 447 mg/L as $CaCO_3$; Table 6, p. 38). The final sediment:water ratio was 7:1 and 4:1 (w:w) for the sandy loam and sand sediment/water systems, respectively (p. 14). The sediment/water systems were pre-incubated at 20°C for 40-41 days. Following the pre-incubation period, the sediment/water systems were treated with cyclopropyl ring-labeled [1-^{14}C]lambda-cyhalothrin {PP321; (*S*)-cyano-3-phenoxybenzyl (*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoropropenyl)-2,2-dimethylcyclopropane carboxylate and (*R*)-α-cyano-3-phenoxybenzyl (*Z*)-(1*S*,3*S*)-3-(2-chloro-3,3,3-trifluoropropenyl)-2,2-dimethylcyclopropanecarboxylate; radiochemical purity ≥97.5%, specific activity 2.2 GBq/mmol; pp. 12, 20), dissolved in acetone, at a nominal application rate equivalent to 8 g a.i./ha (p. 9; see Comment #10). Additional samples were treated with cyclopropyl ring-labeled [1-^{14}C]lambda-cyhalothrin OR uniformly phenoxy ring-labeled [^{14}C]lambda-cyhalothrin (radiochemical purity ≥93.2%, specific activity 2.7 GBq/mmol; pp. 12, 20), at an exaggerated rate (80 g a.i./ha; see Comments #9, 10) for metabolite identification (p. 22). To measure biomass, pre-equilibrated (36 days) samples were treated with nonradiolabeled parent at a nominal rate equivalent to 8 g a.i./ha (p. 15). The sediment/water systems were incubated in darkness at 20 ± 2°C for up to 98 days (pp. 14, 16; Figure 2, p. 28). A vacuum source was utilized to draw moist air through the systems and into a carbon molecular sieve (Carbosieve S-III), a graphitized carbon trap (Carbotrap 20/40) and two carbon dioxide traps (ethanolamine; Figure 3, p. 29). Duplicate sediment/water samples were removed for analysis at 0, 3, 6, 24, and 48 hours posttreatment; and at 4, 7, 14, 28, 58, and 98 days posttreatment (p. 16). The volatile traps were collected for analysis at each sampling interval from 48 hours to 98 days posttreatment; the traps were replaced with fresh solutions or sieves following each collection. The majority of the sediment and water samples were analyzed within 30 days of the sampling event (p. 19).

At 0, 3, 6, and 24 hours posttreatment, aliquots of the water phase were transferred to volumetric flasks (200 mL), brought to volume with water, and analyzed for total radioactivity by LSC (p. 16; see Comment #3); aliquots of the water phase from the remaining samples (48 hours to 98 days) were directly analyzed by LSC. The water phase was acidified (pH 2, HCl) and partitioned four time with ethyl acetate OR the water phase was diluted with acetonitrile:water (5:100, v:v), passed through a pre-conditioned solid phase column (C18 Mega Bond-Elute) eluted with methanol, vacuum-dried, and eluted with ethyl acetate (p. 17). The extracts were concentrated by rotary evaporation and analyzed by LSC and by normal-phase TLC on silica gel plates developed in cyclohexane:diethyl ether:formic acid (60:40:2, v:v:v, p. 18). Samples were co-chromatographed with nonradiolabeled reference standards of the parent and the potential degradates R119890, R041207, R079406, and R211133 (Figure 1, pp. 26-27) which were

visualized with UV (unspecified wavelength) light; reference compound R119890 was visualized using iodine crystals. Areas of radioactivity on the TLC plates were quantitated by radioimage scanning (p. 19). To confirm compound identities, selected samples were further analyzed by reverse-phase TLC on Merck RP 18F plates developed in methanol:glacial acetic acid:water (7:1:2) and by normal-phase TLC on silica gel plates developed in toluene:acetone:methanol:water:formic acid (60:40:10:1:1).

Sediment samples were extracted twice by shaking and sonication with acetonitrile, and the supernatant was decanted and vacuum filtered (p. 16). The metabolism vessel was washed with acetonitrile, and the rinsate was added to the sediment extracts. The combined extracts were analyzed for total radioactivity by LSC. The extracts were concentrated by rotary evaporation and analyzed by LSC (p. 17). Aliquots of the concentrated extracts were analyzed by normal- and reverse-phase TLC as previously described for the water phase. Post-extracted sediment samples were air dried, ground using a mortar and pestle, and triplicate subsamples were analyzed by LSC following combustion.

Aliquots of the ethanolamine volatile trapping solutions were analyzed for total radioactivity by LSC at each sampling interval following 48 hours posttreatment (p. 17). To elute volatiles, the carbon sieves were rinsed with methanol and the eluent was analyzed by LSC.

To confirm the presence of aerobic conditions in the aerobic phase of the study (see Comment #1), the redox potential (E_h), pH, and dissolved oxygen content were measured at weekly intervals during the pre-incubation period and at each sampling interval throughout the study period (p. 14). In the water phase of the sandy loam sediment/water system, conditions were strongly oxidizing, with redox potentials of 442-517 mV, dissolved oxygen contents of 32-72%, and pH values of 7.0-7.8 (Table 7, p. 39). Conditions were moderately reducing in the sandy loam sediment, with redox potentials of 91-170 mV. In the water phase of the sand sediment/water system, conditions were strongly oxidizing, with redox potentials of 472-569 mV, dissolved oxygen contents of 34-78%, and pH values of 6.7-7.2 (Table 8, p. 40). Conditions were moderately reducing in the sand sediment, with redox potentials of 117-198 mV (with the exception of 211 mV at day 51).

To confirm the viability of the sediment/water systems, the microbial biomass was measured by substrate-induced respiration (Appendix 1, p. 49); soil samples were reportedly viable.

DATA SUMMARY

Cyclopropyl ring-labeled [1-^{14}C]lambda-cyhalothrin (radiochemical purity ≥97.5%), at a nominal application rate equivalent to 8 g a.i./ha (see Comment #10), degraded with registrant-calculated half-lives (reported as DT_{50}'s; first-order multi-compartment model; p. 19) of 15 days in flooded sandy loam sediment and 7 days in flooded sand sediment (r^2 values not reported) incubated aerobically in darkness at 20 ± 2°C for up to 98 days (p. 21; Appendix 6, pp. 57, 60). However, the reported data may not accurately depict the metabolism of the parent under aerobic aquatic conditions because a 40- to 41-day pre-incubation period was used, during which the sediment was flooded (prior to treatment with the pesticide). Additionally, not all of the test compound may have been available for degradation in the test systems. All data, designated as percentages of the applied radioactivity, represent percentages of the nominal application.

Sandy loam sediment (Old Basing)

In the total sediment/water system, the parent compound was initially present at 85.9% of the applied radioactivity, decreased to 50.0% by 14 days and 26.5% by 30 days, and was 12.7% of the applied at 98 days posttreatment (Table 11, p. 43). In the water phase, the parent compound was initially present at 71.5% of the applied radioactivity, decreased to 10.2% of the applied by 1 day posttreatment, was 2.4-7.4% of the applied from 4 to 14 days posttreatment, and was last detected at 0.3% of the applied radioactivity at 30 days posttreatment. The major degradate

(1*RS*)-cis-3(*ZE*)-2-chloro-3,3,3-trifluro-1-propenyl)-2,2-dimethylcylopropanecarboxylate (R119890; Compound 1a)

was initially (time 0) detected at 2.1% of the applied radioactivity, was 6.8-9.6% of the applied from 2 to 14 days posttreatment, was a maximum of 11.4% of the applied at 30 days posttreatment, and was 0.6% of the applied at 98 days posttreatment. The minor degradate (1*R*) *cis* α-(*S*) *cis* α-(*R*) α-cyano-3-(4-hydroxyphenoxy)benzyl 3-(Z-2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate (1:1; Compound XV; R211133) was detected at 0.1-0.7% of the applied radioactivity from 0 to 14 days posttreatment. Uncharacterized baseline material was detected at 0.2-0.9% of the applied radioactivity throughout the incubation period. Unidentified radioactivity (designated as others; described as a group of minor metabolites, each <10% of the applied; pp. 22-23) was initially (time 0) detected at 2.3% of the applied radioactivity, was 2.1-5.5% of the applied at 1-14 days posttreatment, increased to 10.3% by 30 days and a maximum of 14% by 58 days, and was 13% of the applied at 98 days posttreatment.

In the sediment phase, the parent compound was initially present at 14.4% of the applied radioactivity, increased to 46.9% by 0.25 days and 70.2% by day 1, was 47.6-63.5% of

the applied at 2-14 days posttreatment, and was 12.7% of the applied at 98 days posttreatment. The major degradate

Compound 1a (R119890)

was initially (day 1) detected at 0.9% of the applied radioactivity, increased to 6.7% by 14 days and 10.6% by 30 days, and was 2.5% of the applied at 98 days posttreatment. The minor degradate Compound XV (R211133) was initially (day 1) detected at 1.6% of the applied radioactivity, was 4.0-4.4% of the applied at 4-30 days posttreatment, and was 1.6% of the applied at 98 days posttreatment. Uncharacterized baseline material was detected at 0.1-1.9% of the applied radioactivity throughout the incubation period. Unidentified radioactivity (designated as others; described as a group of minor metabolites, each <10% of the applied; pp. 22-23) was initially (time 0) present at 6.3% of the applied radioactivity, increased to 13.3% by 14 days and a maximum of 25.4% by 58 days, and was 21.9% of the applied at 98 days posttreatment. Nonextractable [^{14}C]residues were 0.1-5.1% of the applied radioactivity from 1 to 14 days posttreatment, increased to 12.7% of the applied by 30 days posttreatment, and were 20.0-24.4% of the applied at 58-98 days posttreatment (Table 9, p. 41). Evolved $^{14}CO_2$ accounted for 0.2-2.9% of the applied radioactivity from 4 to 30 days posttreatment, increased to 9.1% of the applied by 58 days posttreatment, and was 15.2% of the applied at 98 days posttreatment; [^{14}C]organic volatiles were negligible (p. 21). Residues increased in the sediment phase over time; the sediment:water distribution ratio (reviewer-calculated using data in Table 9, p. 41) was approximately 1:4 at time 0, changed to @ 5:1 by 1 day posttreatment, was @ 3:1 at 2-98 days posttreatment.

Material balances (based on LSC analysis) were 81.4-105.8% of the applied radioactivity throughout the incubation period, with no observed clear pattern of decline (Table 9, p. 41; see Comment #2).

Sand sediment (Virginia Water)

In the total sediment/water system, the parent compound was initially present at 78.9% of the applied radioactivity, was a maximum of 84.5% of the applied at 0.25 days posttreatment, was 66.3% at 4 days, decreased to 45.9% by 7 days and 37.7% by 14 days, and was 5.8% of the applied at 98 days posttreatment (Table 12, p. 44). In the water phase, the parent compound was initially present at 49.3% of the applied radioactivity, decreased to 28.1-29.7% of the applied by 0.125-0.25 days posttreatment, decreased to 10.1% of the applied by 2 days posttreatment, was 1.7-5.4% of the applied at 4-14 days posttreatment, and was last detected at 0.2% of the applied at 30 days posttreatment. The major degradate

Compound 1a (R119890)

was initially (time 0) detected at 2.1% of the applied radioactivity, was 1.3-6.9% of the applied from 0.125 to 4 days posttreatment, increased to 11.8% by 7 days and a maximum of 14.4% by 14 days, and was last detected at 8.8% of the applied at 30 days posttreatment. The minor degradate Compound XV (R211133) was detected at 0.4-1.3% of the applied radioactivity from 0.125 to 7 days posttreatment. Uncharacterized baseline material was initially (time 0) 3.2% of the applied radioactivity and was 0.1-1.8% of the applied from 0.125 to 30 days posttreatment. Unidentified radioactivity (designated as others; described as a group of metabolites, each <10% of the applied; pp. 22-23) was initially (time 0) 8.6% of the applied radioactivity, increased with variability to 13.1% of the applied by 4 days posttreatment, was a maximum of 13.7% of the applied at 14 days posttreatment, and was last detected at 10.9% of the applied at 30 days posttreatment.

In the sediment phase, the parent compound was initially present at 29.6% of the applied radioactivity, increased to 56.4% of the applied by 0.25 days, was 30.1% at day 1 then increased to a maximum of 60.9% of the applied by 4 days posttreatment, was 36-43.3% of the applied at 7-14 days posttreatment, and was 5.8% of the applied at 98 days posttreatment (Table 12, p. 44). The minor degradate Compound 1a (R119890) was detected at 0.7-3.3% of the applied radioactivity from 4 to 30 days posttreatment, was not detected at 58 days posttreatment, and was 0.4% of the applied at 98 days posttreatment. The minor degradate Compound XV (R211133) was initially (0.25 to 1 day) 0.6-0.7% of the applied radioactivity, increased to a maximum of 8.7% of the applied by 7 days posttreatment, and was 0.9% of the applied at 98 days posttreatment. Uncharacterized baseline material was detected at 0.5-1.4% of the applied radioactivity from 0.25 to 98 days posttreatment (with the exception of no detection at day 14). Unidentified radioactivity (designated as others; described as a group of metabolites, each <10% of the applied; pp. 22-23) was 3-8.3% of the applied radioactivity throughout the incubation period (with the exception of 34.3% at day 1). Nonextractable [^{14}C]residues were 0.2-0.8% of the applied radioactivity from 0 to 1 day posttreatment, increased to 7.7% of the applied by 7 days posttreatment, were a maximum of 33.2% of the applied by 30 days posttreatment, and were 17.4% of the applied at 98 days posttreatment (Table 9, p. 41). Evolved $^{14}CO_2$ accounted for 0.1-0.9% of the applied radioactivity from 1 to 4 days posttreatment, increased to 9.7% by 14 days and 20.2% by 30 days, and was 47.8% of the applied radioactivity at 98 days posttreatment; [^{14}C]organic volatiles were negligible (p. 21). Residues increased in the sediment phase over time; the sediment:water distribution ratio (reviewer-calculated using data in Table 9, p. 41) was approximately 1:3 at time 0, changed to @ 4:1 by 14 days posttreatment, was >2:1 at 30 days, and was approximately 15:1 at 98 days posttreatment.

Material balances (based on LSC analysis) were 94.3-104.4% of the applied radioactivity at 0-30 days posttreatment, with no clear pattern of decrease through 30 days, and then decreased to 72.5-77.8% of the applied by 58-98 days posttreatment (Table 9, p. 41; see Comment #2).

COMMENTS

1. The data may not accurately represent the aerobic aquatic metabolism of the parent because the sediment was not treated with the test compound and flooded simultaneously. The sediment/water systems were flooded 40-41 days prior to the application of the parent compound (p. 14). Subdivision N Guidelines require that the pesticide be applied to the sediment at the same time the sediment is flooded so that both aerobic and anaerobic conditions exist in the sediment and the predominant microorganism population is aerobic.

2. The material balances were incomplete. In the sandy loam sediment/water system, material balances were 81.4-105.8% of the applied radioactivity throughout the incubation period, with no observed pattern of decline (Table 9, p. 41). In the sand sediment/water system, material balances were 94.3-104.4% of the applied radioactivity from 0 to 30 days posttreatment and were 72.5-77.8% of the applied at 58-98 days posttreatment. The study authors did not provide an explanation for this material loss; however, the reviewer noted that the parent compound was reported to adsorb to glassware (also see Comment #3). Subdivision N Guidelines require that material balances be 90-110% of the applied radioactivity.

3. The study authors stated that the parent compound is known to adsorb to glassware (p. 17). Therefore, the water phase (0, 3, 6, and 24 hours; p. 16) was removed from the volumetric flask and the flask was sonicated with ethyl acetate; the flask rinsate was analyzed by LSC. The radioactivity recovered from the rinsate was added to the radioactivity recovered from the water phase for these sampling intervals. In addition, ethyl acetate and/or methanol was used to wash the water phase sample storage containers, and the organic solvent was used for partitioning or eluting the solid phase extraction column (p. 17). After sediment removal from the metabolism vessels, selected sample vessels were rinsed with n-hexane and the rinsate was analyzed by LSC (p. 16); the study authors stated that no radioactivity was detected. The reviewer notes that any test material adsorbed to the walls of the test vial, whether later recovered or not, was not available for microbial or other degradation in the sediment/water systems.

4. Residue data were only reported in the form of percentages of the applied radioactivity. Additionally, the application rate for the samples was only reported in terms of its equivalence to the field application rate. In future studies submitted to the EPA, it is necessary that the residue data and the application rate also be reported in units of concentration, such as ppm.

5. The reviewer calculated the soil organic matter content by multiplying the reported percentages of organic carbon (Table 4, p. 36) by 1.7.

6. The water and sediment phases were separated by pipetting (p. 16); however, it is preferred that water and sediment phases be separated by centrifugation, as this removes more water from the sediment phase with greater consistency.

7. Method detection limits were not reported for LSC or TLC analyses. Both limits of detection and quantitation should be reported for each analytical method utilized to allow the reviewer to evaluate the adequacy of the methods for the determination of the parent and its degradates.

8. The proposed metabolic pathway of the parent under aerobic aquatic conditions was provided in Figure 6 (p. 31).

9. Parent and degradate data from the exaggerated rate samples (80 g a.i./ha; cyclopropyl and phenoxy labels) were reported in Tables 9 and 13-16 (pp. 41; 45-48).

10. The aqueous solubility of the parent compound was reported as 5.0 ng/mL at 20°C and pH 6.5 (p. 12). The study authors stated that the maximum label rate use (80 g a.i./ha) exceeds the solubility (p. 11); therefore, this study was conducted at a rate (1/10 of the maximum rate) that was calculated "assuming a 10% spray drift from the maximum application rate." The study authors stated that the reported application rate represented "a rate equivalent of 8 g a.i./ha, evenly distributed throughout a 30 cm deep body of water" (p. 11). The application rate was not reported on a water volume basis.

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