UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 17, 2009

MEMORANDUM

SUBJECT: **Addendum to the 2005 Dodine Reregistration Eligibility Decision (RED): Antimicrobial Uses of Dodecylguanidine Hydrochloride (DGH)**
Case No. 0161
PC Code: 044303

FROM: Lance Wormell, Acting Team Leader
Regulatory Management Branch II
Antimicrobials Division (7510P)

TO: Mark Hartman, Chief
Regulatory Management Branch II
Antimicrobials Division (7510P)

Attached please find an addendum to the Reregistration Eligibility Decision for Dodine dated September 30, 2005. The antimicrobial uses of DGH were inadvertently omitted during the dodine reregistration process; therefore, this document presents EPA's reregistration eligibility decision for the antimicrobial uses of DGH and supplements the required label changes and confirmatory data requirements presented in the 2005 RED for Dodine.

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Dear Registrant:

The US Environmental Protection Agency ("EPA" or "the Agency") completed the Reregistration Eligibility Decision (RED) document for Dodine, including dodecylguanidine hydrochloride (DGH), on September 30, 2005. This document is an addendum to the 2005 Dodine RED and incorporates the ecological risk assessment and residential risk assessment for the antimicrobial uses of DGH. The antimicrobial uses of DGH were inadvertently omitted during the dodine reregistration process. DGH is formulated in antimicrobial products for use in once-through industrial cooling water systems; auxiliary water and waste water systems; enhanced oil recovery systems; recirculating cooling water systems; oil field water systems; oil recovery drilling fluids; pulp and paper mill systems; preservation of pulp and papermill processing chemicals, adhesives and coatings; process waters and non-potable water treatment; disposable diapers; food packaging; non-paper related aqueous systems; liquid concentrates; and air washers.

Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic data to support reregistration of antimicrobial products containing DGH. The Agency has determined that the data are sufficient to support reregistration of antimicrobial uses of DGH.

The Agency has completed its assessment of the ecological risk and residential risk associated with the use of DGH. This assessment supplements the dietary risk conclusions previously completed as part of the 2005 dodine RED. The Agency has determined that DGH-containing antimicrobial products are eligible for reregistration provided that label amendments are made as outlined in this RED addendum. Appendix A summarizes the uses of dodine that are eligible for reregistration.

Based on its evaluation of DGH, the Agency has determined that DGH products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA and FQPA. Accordingly, should a registrant fail to implement any of the reregistration requirements identified in this document, the Agency may take regulatory action to address the risk concerns from the use of DGH. If all changes outlined in this document are incorporated into the product labels, then all current risks for DGH will be adequately mitigated for the purposes of this determination. Once an

Endangered Species assessment is completed, further changes to these registrations may be necessary as explained under "Listed Species Considerations" below.

Human Health Risk Assessment

To support the 2005 dodine RED, EPA completed a dietary and non-dietary risk assessment (see the document titled, "Dodecylguanidine hydrochloride (DGH) – Dietary and Non-dietary Exposures and Risks from Antimicrobial Uses," dated June 21, 2005). This document was also used to support this RED addendum.

Dietary and Indirect Food Exposure and Risk

Potential risks resulting from dietary exposure to antimicrobial uses of DGH were considered as part of the 2005 Dodine RED. For additional information, refer to the document titled, "Reregistration Eligibility Decision (RED) document for Dodine," dated September 30, 2005.

Residential Exposure and Risk

DGH can be used as a materials preservative to inhibit the growth of microorangisms in aqueous systems such as paints and coatings; therefore, EPA assessed potential dermal and inhalation risks to residential painters. Since residential painters typically paint on an intermittent basis, it was appropriate to assess only the short-term exposure duration (1 -30 days) rather than intermediate- and/or long-term exposure duration. Post-application dermal contact with wet paint was not assessed because the paint is expected to dry within a day, so any potential exposure is expected to be negligible.

EPA's estimated risk for residential painters does not exceed the Agency's level of concern for any scenario (margin of exposure [MOE] $\geq$ 2,800; target MOE = 100). Because DGH has a low vapor pressure of DGH (<1x10-7 mmHg @25°C), the compound is not likely to generate sufficient vapor to cause an inhalation concern to residential populations performing post-application tasks or occupying recently treated areas; therefore, inhalation post-application exposures were not quantitatively evaluated and are not expected to exceed the Agency's level of concern.

DGH can also be used as a bacteriostatic in the manufacturing of the absorbent material used in disposable diapers; therefore, EPA assessed the residential dermal exposures and risks to infants (< 1 year old) who wear DGH impregnated diapers. Since infants typically wear diapers on a continuous basis, short-, intermediate- and long-term exposure durations were assessed.

EPA estimated risks using a default transfer factor of 100% and also estimated exposures and risks utilizing a more realistic transfer factor of 5%, which is based on the default percent transfer factor for pesticide residues migrating from carpets to skin surfaces. The MOEs for all durations do not exceed the Agency's level of concern when using the 5% transfer factor (MOE = 714; target MOE = 100); however, confirmatory are required to support the lower transfer factor assumption (see "Required Confirmatory Data" below).

Environmental Exposure and Ecological Risk Assessment

To support this RED amendment, EPA completed a screening level ecological hazard and environmental risk assessment (see the document titled, "Ecological Hazard and Environmental Risk Assessment – Antimicrobial Addendum to Dodine RED," dated May 14, 2009).

Methodology

The EPA Office of Water PDM4 Model was used to estimate exposure from once-through cooling tower uses. The Agency modeled once-through cooling tower uses because these uses represent reasonable worst-case scenarios for estimating potential environmental exposure and ecological risk. DGH releases were modeled for 30 steam electric power plants that were identified by EPA during development of the exposure assessment methodology for Alkyl Dimethyl Benzyl Ammonium Chloride or ADBAC (see the document titled, "Ecological Hazard and Environmental Risk Assessment Chapter, Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC)" dated August 2, 2006).

Control may be achieved by either an intermittent or a continuous application, and for each method there are recommended application rates for initial control and maintenance. To estimate potential ecological risk, three application scenarios were developed:

- Scenario 1 is based on the highest application rate (i.e., for initial control with either the intermittent or continuous method).
- Scenario 2 is an intermediate application rate consistent with the minimal recommended initial application rate and the maximum maintenance application rate.
- Scenario 3 is based on the lowest application rate indicated by the product label information.

For each scenario, the Agency estimated the numbers of days exceeding the concentration of concern (COC) for the taxa in Table 1.

Table 1. Concentrations of Concern (COC) by Taxa

COC	Taxa
0.05 µg/L	Acute, Endangered Plant
0.64 µg/L	Acute, Nontarget Plant
1.45 µg/L	Acute, Endangered Freshwater Invertebrate
3 µg/L	Acute, Endangered Marine/Estuarine Invertebrate
3.5 µg/L	Acute, Endangered Marine/Estuarine Mollusk
7.3 µg/L	Chronic, Freshwater Invertebrate
14.5 µg/L	Acute, Nontarget Freshwater Invertebrate
29.7 µg/L	Acute, Nontarget Marine/Estuarine Invertebrate
34.6 µg/L	Acute, Nontarget Marine/Estuarine Mollusk
44.5 µg/L	Acute, Endangered Freshwater Fish
99 µg/L	Chronic, Freshwater Fish
445 µg/L	Acute, Nontarget Freshwater Fish

Three different flow regimes were considered: high flow (e.g., power plants with average stream flow rates of approximately 1000 gallons per day), medium flow (e.g., power plants with average stream flow rates of approximately 500 gallons per day), and low flow (power plants with average stream flow rates of approximately 100 gallons per day). The Agency modeled exposure for the maximum, intermediate, and low application rates. For each modeled scenario, EPA estimated risk by calculating the average number of days per year that levels of concern (LOC) could be exceeded for each aquatic organism.

Limitations of PDM4 Tier 1 Modeling

While useful for screening level purposes, Tier I PDM4 modeling relies on "worst case" assumptions including maximum rainfall, minimum stream flow values, lowest available endpoints, and other factors intentionally used to produce a theoretical maximum exposure scenario. In addition, the methodology involves the following potential limitations:

- Because exceedences predicted by the PDM do not necessarily occur on consecutive days the assessment may overestimate the actual potential for ecological toxicity impacts. The numbers of days with exceedences of COCs have not been compared to the numbers of days of exposure used in the studies from which the COCs were obtained.
- Downstream concentrations of DGH are considered to exceed a COC on any given day if the COC is exceeded for any portion of the day. PDM does not identify the duration of the exceedences, and the daily scale results may overestimate the actual potential for DGH releases to result in ecological risks.
- The estimated numbers of days with downstream concentrations of DGH above COCs are averages calculated from the results for individual facilities. Facility level results varied considerably, as shown by the standard deviations presented with the averages. Thus, this assessment may under or overestimate the potential for the exceedences at specific facilities.
- The assessment used an assumed release period of 250 days. This assumption is likely to overestimate the number of release days for DGH treatment, especially for initial control. Thus, the results of the assessment may overestimate the number of days with downstream DGH concentrations above COCs.
- For this assessment, effluent discharge rates were assumed to equal the lower of either facility-specific effluent flow rates or the 7Q10 flows of the receiving streams. This approach may over or underestimate average actual effluent discharges.
- The assessment used flow and discharge data for a sample of 30 steam electric generating facilities. This sample is not necessarily statistically representative of the national population of facilities with once-through cooling water systems where DGH may be used.

Therefore, the risks presented in the ecological risk assessment, as summarized in this RED amendment, are considered conservative and are not necessarily representative of actual risk to nontarget species. Once additional data are received (see "Required Confirmatory Data" below), the Agency intends to refine its risk assessments, likely through the registration review process.

Aquatic Organism Exposure and Risk

Based on the results of the modeling described above, risks to non-target aquatic organisms from the once-through cooling uses of DGH are above EPA's levels of concern for most application rates and scenarios (see Table 2). As discussed above, the Agency considers these tier one modeling estimates to be conservative; however, EPA will require additional labeling as a result of this RED amendment. In addition, the Agency will require confirmatory data to support future refinements in the ecological risk assessment.

Table 2. Summary of Average Days Downstream Concentration of Concern is Exceeded

Taxa	Average Days Concentration of Concern Exceeded		
	Scenario 1	Scenario 2	Scenario 3
Acute, Endangered Plant	250	246	225
Acute, Nontarget Plant	240	220	178
Acute, Endangered Freshwater Invertebrate	231	205	159
Acute, Endangered Marine/Estuarine Invertebrate	222	191	138
Acute, Endangered Marine/Estuarine Mollusk	219	188	133
Chronic, Freshwater Invertebrate	206	175	107
Acute, Nontarget Freshwater Invertebrate	191	159	80
Acute, Nontarget Marine/Estuarine Invertebrate	179	138	51
Acute, Nontarget Marine/Estuarine Mollusk	177	133	44
Acute, Endangered Freshwater Fish	171	124	35
Chronic, Freshwater Fish	150	95	14
Acute, Nontarget Freshwater Fish	99	35	2

Terrestrial Organism Exposure and Risk

No model is available to estimate exposure and risk to birds and mammals from discharge of cooling system effluent into surface waters. However, acute risks to these species are likely lower than risks to aquatic species because birds and mammals are less sensitive than aquatic organisms to DGH.

Listed Species Considerations

Section 7 of the Endangered Species Act, 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and anadromous listed species, or the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if they are proposing an "action" that may affect listed species or their designated habitat. Each federal agency is required under the Act to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. To jeopardize the continued existence of a listed species means "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species." 50 C.F.R. ' 402.02.

To facilitate compliance with the requirements of the Endangered Species Act subsection (a)(2) the Environmental Protection Agency, Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA 2004). After the Agency's screening-level risk assessment is performed, if any of the Agency's Listed Species LOC Criteria are exceeded for either direct or indirect effects, a determination is made to identify if any listed or candidate species may co-occur in the area of the proposed pesticide use. If determined that listed or candidate species may be present in the proposed use areas, further biological assessment is undertaken. The extent to which listed species may be at risk then determines the need for the development of a more comprehensive consultation package as required by the Endangered Species Act.

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories such as material preservatives do not typically undergo a full screening-level risk assessment. However, certain antimicrobial use patterns have potential for environmental exposure. Considering current registered uses of DGH, this review has modeled once-thru industrial cooling water as a maximum exposure scenario.

If it is determined that there is potential for DGH uses to overlap with listed species and that a more refined assessment is warranted, to include direct, indirect and habitat effects, the refined assessment should involve clear delineation of the action area associated with DGH uses and best available information on the temporal and spatial co-location of listed species with respect to the action area. This analysis has not been conducted for this assessment. An endangered species effect determination will not be made at this time.

Labeling for DGH Products

To be eligible for reregistration, labeling changes are necessary. Specific language to incorporate these changes is presented in Table 3.

Table 3. Required Label Changes for Products Containing DGH

Description	Amended Labeling Language	Placement on Label
Environmental Hazard Statement	"This pesticide is toxic to fish, aquatic invertebrates, shrimp and oysters. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Environmental Hazard Statement

For end-use products containing the active ingredient DGH, the registrants need to submit five copies of the draft label incorporating all label amendments outlined in the Labeling Changes Summary Table below. This submission must occur within eight months from receipt of the product-specific data call-in (PDCI). Please see Section V. of the 2005 Dodine RED for more information regarding additional data requirements.

Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. However, specific existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors.

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision document. Persons other than the registrant may generally distribute or sell such products for 52 months from the approval of labels reflecting the mitigation described in this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy," *Federal Register*, Volume 56, No. 123, June 26, 1991.

Required Confirmatory Data

In order to be eligible for reregistration, registrants must submit the confirmatory data presented in Table 4.

Table 4. Confirmatory Data for DGH

GLN	Study Title
850.1075	Acute Bluegill sunfish
850.1735	Whole Sediment Acute Freshwater Invertebrates
850.1740	Whole Sediment, Acute Marine Invertebrates
850.4225	Seedling Emergence using rice (*Oryza sativa*)
850.4400	Floating Macrophyte Duckweed (*Lemna gibba*)
850.5400	Blue-green Cyanobacteria (*Anabaena flos-aquae*)
850.5400	Freshwater Diatom (*Navicula pelliculosa*)

GLN	Study Title
850.5400	Marine Diatom (*Skeletonema costatum*)
Special Study[1]	Water monitoring to assess levels and durations of DGH release into aquatic environments
Special Study[1]	Impregnated diaper migration study

[1] Registrants will be required to submit a protocol for EPA review prior to initiating the study.

Further Information

If you have questions on the reregistration eligibility decision for the antimicrobial uses of DGH or any of the revisions listed above, please contact the Chemical Review Manager, Monisha Harris, at (703) 308-0410. For questions about product reregistration please contact the Product Manager, Marshall Swindell, at (703) 308-6341.

Sincerely,

Joan Harrigan Farrelly

Joan Harrigan-Farrelly
Director, Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency

Appendix A. Antimicrobial Uses of Dodecylguanidine Hydrochloride (DGH) Eligible for Reregistration

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Materials preservatives				
Adhesive systems (non paper) Caulks and sealants Pastes Paints, coatings, and stains Pigments, dyes, and filer suspension Polymer dispersion and emulsions	Soluble concentrate Reg: 67869-44 Reg: 67869-43 Reg: 67869-30 Manufacturing use only: Reg: 68387-5 Reg: 68387-3 Reg: 67869-28	Incorporation	The product is effective in the range of 2.50 to 10.0 lbs (250 to 5000ppm) The exact amount for the preservative of any given formulation will depend on the components, storage time, temperature, etc… and can be determined by the actual testing based on formula weight. Dosage rate per 10,000 lbs of material to be preserved: 2.50 to 50.0 lbs (250 to 5000 ppm)	None
Pulp and paper mill processing chemicals, adhesives, and coatings	Soluble concentrate Reg: 67869-44 Reg: 55260-7 Reg: 67869-30 Reg: 67869-43 Reg: 74655-7 Reg: 74655-12 Manufacturing use only: Reg: 68387-5 Reg: 68387-3 Reg: 67869-28	Incorporation	Add directly to the material to be preserved prior to manufacturing into the finished product. The dosage rate will depend upon the material to be preserved and the storage time, The usual addition should be 0.10 to 0.30 lbs /10,000 lbs (10-30 ppm). Under extreme conditions of spoilage the dosage should be increased to 0.11 to 0.66 lbs/10,000 lbs (12.5 to 80 ppm). The dosage rates are based on a maximum storage time of 2 weeks. For storage times greater than 2 weeks the maximum concentration should be increased to 0.40 to 0.83 lbs/10,000 lbs (50 to 100 ppm) Do not use for adhesives or coatings that involve direct or	None

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			indirect food or human drinking water contact application	
Food packaging	Soluble concentrate Reg: 67869-44 Reg: 67869-30 Reg: 67869-43 Reg: 68387-1 Reg: 68387-4 Manufacturing use only: Reg: 68387-5 Reg: 68387-3 Reg: 67869-28	Incorporation	For paper and paperboard intended for use in contact with food, the rate of application must be adjusted so that the amount of active ingredient retained does not exceed 0.4 percent by weight of the paper or paperboard. Technical service is available from the manufacturer to assist customers in making the proper and most efficient use of this product	None
Metal working fluids, lubricants and mineral oil based products	Soluble concentrate Reg: 67869-44	Incorporation	Dosage rate per 10,00 lbs of material to be preserved 0.50 to 49.0% by weight	None
Disposable diapers	Soluble concentrate Reg: 67869-30	Incorporation	Add at the beginning of the manufacturing process at a range of 0.075% to 0.2% by weight of the treated material	None
Textiles	Soluble concentrate Reg: 67869-44	Dipping Spraying	Dissolve in suitable solvents such as ethanol, mineral sprits or paraffin's, or convert to a water diluted alkaline concentration and apply directly to the textile normally by dipping or spraying Recommended dosage: 0.90 to 8.70 % by weight	None
Temporary sap stain control for fresh cut lumber and other lumber	Soluble concentrate Reg: 67869-44	Dipping Spraying	Convert to alkaline liquid and water diluted formulation by adding sodium hydroxide or other bases, apply to freshly sawn lumber by either dipping or spraying. Recommended dosage	None

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			1.70 to 7.0 %	
Leather	Soluble concentrate Reg: 67869-44	Dipping Spraying	Add directly to the pickle solution Dosage range: 0.40 to 3.50 %	None
Industrial process and water systems				
Air washing system	Soluble concentrate Reg: 67869-43 Reg: 1706-216 Reg: 67869-44 Reg: 1706-216 Reg: 3876-121 Manufacturing use only: Reg: 68387-5 Reg: 68387-3 Reg: 67869-28	Incorporation	**Slug or intermittent method:** Initial dose: When system is noticeably fouled apply 6.6 to 13.2 oz/1000 gal (50 to 100 ppm) Repeat until control is achieved. **Subsequent dose:** When control is evident, apply 3.3 to 6.6 oz/1000 gal (25 to 50 ppm) every three days as needed. **Continuous method:** Initial dose: When system is noticeably fouled, apply 6.6 oz/1000 gal (25 to 50 ppm) per day. **Subsequent dose:** Maintain initial rate by continuously feeding 3.3 to 6.6 oz/1000 gal (25 to 60 ppm) per day	None
Industrial re circulating water cooling towers Once through industrial cooling water system Brewery pasteurizer water	Soluble concentrate Reg: 3876-145 Reg: 3876-121 Reg: 67869-30 Reg: 67869-44 Reg: 68387-2 Reg: 68387-6	Incorporation	**Slug or intermittent method:** Initial dose: When system is noticeably fouled apply 6.6 to 13.2 oz/1000 gal (50 to 100 ppm) Repeat until control is achieved. **Subsequent dose:** When control is evident, apply 3.3 to 6.6 oz/1000 gal (25	None

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Non potable water treatment	Reg: 1706-216 Reg: 3876-121 Reg: 3875-145 Reg: 55260-7 Manufacturing use only: Reg: 68387-5 Reg: 68387-3 Reg: 67869-28		to 50 ppm) every three days as needed. Initial dose: When system is noticeably fouled, apply 6.6 oz/1000 gal (25 to 50 ppm) per day. **Subsequent dose:** Maintain **Continuous method:** initial rate by continuously feeding 3.3 to 6.6 oz/1000 gal (25 to 60 ppm) per day	
Oil field water systems	Soluble concentrate Reg: 67869-44 Reg: 3876-145 Reg: 67869-30	Incorporation	**Slug or intermittent method:** Initial dose: When system is noticeably fouled apply 6.6 to 13.2 oz/1000 gal (50 to 100 ppm) Repeat until control is achieved. **Subsequent dose:** When control is evident, apply 3.3 to 6.6 oz/1000 gal (25 to 50 ppm) every three days as needed.	None

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			Continuous method: Initial dose: When system is noticeably fouled, apply 6.6 oz/1000 gal (25 to 50 ppm) per day. **Subsequent dose:** Maintain initial rate by continuously feeding 3.3 to 6.6 oz/1000 gal (25 to 60 ppm) per day	
Oil and gas fluids	Soluble concentrate Reg: 67869-44	Incorporation	Apply at 500 to 1000 ppm (4 to 8 pt/1000) gal or(0.18 to 0.36 pt per barrel) For well squeezed fluids add at 250 to 2000 ppm 92 to 16 pt/1000 gal	None
Oil process waters	Soluble concentrate Reg: 67869-44 Reg: 67869-30	Injection	Inject as a slug does at any convenient point at 250 to 1000 ppm (2 pt to 8 pt /1000 gal) .A slug dose should be applied from once per week to once per month depending on the severity of the contamination	None
Sewage disposal lagoons	Soluble concentrate Reg: 67869-44 Reg: 68387-2 Reg: 68387-6 Reg: 67869-30 Reg: 68387-2 Reg: 68387-6 Manufacturing	Spray	Dilute with water to accommodate the delivery characteristics of the pump and spray rig, and apply evenly to the surface of the lagoon. Dosage should be 1.0 to 1.5 ounces (by weight) per 100 sq feet of surface depending on the population density of the algae blooms. The interval between treatments will be determined by	None

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	use only: Reg: 68387-5 Reg: 68387-3 Reg: 67869-28		the reappearance of floating algae blooms and subsequent treatment should be made as spot treatments at the same dosage as the initial treatment. A small outboard motorboat equipped with a tank-pump spray assembly can be used to traverse the lagoon between opposite shores in order to lay down an even spray.	

Appendix B. Revised Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision for Dodine/DGH (PC Codes 044301, 044303)

GUIDE TO APPENDIX B

Appendix B contains a listing of data requirements which support the reregistration for active ingredients within the dodine/DGH case covered by the 2005 dodine RED and this RED addendum. It contains generic data requirements that apply dodine/DGH in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

1. Data requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which is available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.

   A. Terrestrial food
   B. Terrestrial feed
   C. Terrestrial non-food
   D. Aquatic food
   E. Aquatic non-food outdoor
   F. Aquatic non-food industrial
   G. Aquatic non-food residential
   H. Greenhouse food
   I. Greenhouse non-food
   J. Forestry
   K. Residential
   L. Indoor food
   M. Indoor non-food
   N. Indoor medical
   O. Indoor residential

3. Bibliographic Citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number is no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

Data Requirement			Use Patterns	Citations
New Guideline Number	Old Guideline Number	Description		
PRODUCT CHEMISTRY				
830.1550	61-1	Product Identity and Composition	All	40315501, 45322701, 46165601
830.1600	61-2A	Description of materials used to produce the product	All	40315501, 45322701, 46165601
830.1620	61-2B	Description of production process	Al	40315501, 45322701, 46165601
830.1670	61-2B	Formation of Impurities	All	40315501, 45322701, 46165601
830.1700	62-1	Preliminary Analysis	All	40315502, 45322702, 46146501 , 46165602
830.1750	62-0	Certification of Limits	All	40315502, 45322703, 46165601
830.1800	62-3	Analytical Method	All	40315502, 45322702, 46165601
830.6302	63-2	Color	All	40315503, 45322704
830.6303	63-3	Physical State	All	40315503, 45322704
830.6304	63-4	Odor	All	40315503, 45322704
830.6313	63-13	Stability to normal and elevated temperatures, metals, and metal ions	All	40315503, 40975701, 45322708,
830.6314	63-14	Oxidation/reduction: chemical incompatibility	All	45322704
830.6316	63-16	Explodability	All	45322704
830.6317	63-17	Storage stability	All	45322708
830.6320	63-20	Corrosion characteristics	All	45322708
830.7000	63-12	pH	All	45322705, 40315503
830.7050	None	UV/Visible Absorption	All	40975701, 46621301
830.7200	63-5	Melting Point	All	40315503
830.7300	63-7	Density	All	40315503, 45322704
830.7370	63-10	Dissociation Constants in Water	All	40315503, 45322705
830.7550	63-11	Partition coefficient, shake flask method	All	40315503, 45322707
830.7840	63-8	Solubility	All	40315503, 45322706,
830.7950	63-9	Vapor Pressure	All	45322709
ECOLOGICAL EFFECTS				
850.2100	71-1A	Avian Acute Oral Toxicity	A, B, D	Acc. 130888, Acc.

Data Requirement			Use Patterns	Citations
New Guideline Number	Old Guideline Number	Description		
				131455, 41671001 (under review), 41671003 (under review)
850.2200	71-2A	Avian Dietary Toxicity – Quail	A, B, D	Acc. 226855, 41671002 (under review)
850.2200	71-2B	Avian Dietary Toxicity – Duck	A, B, D	Acc. 226855, 41671004 (under review)
850.2300	71-4A	Avian Reproduction - Quail	A, B, D	43274601, 44985805
850.2300	71-4B	Avian Reproduction – Duck	A, B, D	44985705
850.1075	72-1A	Fish Toxicity Bluegill	A, B, D	Acc. 132149, 41900301 (under review)
850.1075	72-1C	Freshwater Fish Toxicity Rainbow Trout	A, B, D	Acc. 132149, 43485505, 41900302 (under review)
850.1010	72-2A	Freshwater Invertebrate Toxicity	A, B, D	42339601,42653501, Acc. 226855, 40756805, 46621305 (under review), 46621307 (under review)
850.1075	72-3A	Estuarine/Marine Toxicity – Fish	A, B, D	42653502, 43485506, 42501501 (under review)
850.1025	72-3B	Estuarine/Marine Toxicity – Mollusk	A, B, D	42653503, 43485508, 42501502 (under review)
850.1035	72-3C	Estuarine/Marine Toxicity – Shrimp	A, B, D	42653504, 43485507, 42501503 (under review)
850.1045	72-3	Panaeid Acute Toxicity Test	A, B, D	40940802
850.1300	72-4A	Daphnid Chronic Toxicity Test	A, B, D	43876501
850.1350	72-4B	Estuarine/Marine Invertebrate Life Cycle	A, B, D	Data Gap
850.1400	72-4C	Early-life Stage Freshwater Fish	A, B, D	43876502
850.4225	123-1A	Seedling Germination and Seedling Emergence, Tier 2	A, B, D	42695102
850.4250	123-1C	Vegetative Vigor, Tier 2	A, B, D	42695103

Data Requirement			Use Patterns	Citations
New Guideline Number	Old Guideline Number	Description		
850.4400	123-2	Aquatic Plant Toxicity	A, B, D	42695101, Data Gap
850.5400	122-2B	Aquatic Plant Growth, Tier 2	A, B, D	46621308 (under review), 46621309 (under review)
TOXICOLOGY				
870.1100	81-1	Acute Oral Toxicity - Rat	All	44922401, 00124280
870.1200	81-2	Acute Dermal Toxicity – Rabbit/Rat	All	00124280
870.1300	81-3	Acute Inhalation Toxicity – Rat	All	00157300
870.2400	81-4	Primary Eye Irritation - Rabbit	All	00124280
870.2500	81-5	Primary Skin Irritation	All	00124280
870.2600	81-6	Dermal Sensitization	All	00157386
870.3100	82-1A	Subchronic Oral Toxicity: 90-Day Study Rodent	A, B, D	44704401, 46585001
870.3150	82-1B	Subchronic Oral Toxicity: 90-Day Study Non-rodent	A, B, D	41316903 (DGH)
870.3200	82-2	21-Day Dermal – Rabbit/Rat	A, B, D	46420701, 41316901 (DGH)
870.3700A	83-3A	Developmental Toxicity – Rat	A, B, D	41900304, 41316902 (DGH)
870.3700B	83-3B	Developmental Toxicity – Rabbit	A, B, D	41900303
870.3800	83-4	2-Generation Reproduction – Rat	A, B, D	44246001
870.4100B	83-1B	Chronic Feeding Toxicity Study - Non-rodent	A, B, D	44246101
870.4200	83-2B	Carcinogenicity Mice	A, B, D	44703201
870.4300	83-5	Combined Chronic Toxicity/Carcinogenicity: Rats	A, B, D	44704401
870.5100	84-2	Bacterial Reverse Gene Mutation	A, B, D	40315504
870.5300		Gene Mutation (CHO)	A, B, D	41711002
870.5375		Cytogenics- Human Lymphocytes Chromosome Aberration Test	A, B, D	41711001
870.5385		Mammalian Bone Marrow Chromosomal Aberration Test	A, B, D	42311601
870. 5395	84-2	In Vitro Mammalian Cytogenetics Tests	A, B, D	41418901 (DGH), 41418902 (DGH)
870.5550	84-2	Unscheduled DNA Synthesis in Mammalian Cells in Culture	A, B, D	41418903 (DGH)

Data Requirement			Use Patterns	Citations
New Guideline Number	Old Guideline Number	Description		
870.7485	85-1	General Metabolism	A, B, D	42479001
870.7600		Dermal Penetration (Rat)	A, B, D	46621303, 46621304 (under review)
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis	A, B, D	42242601, 00101402, 00134831, 00144366, 42242601
835.2240	161-2	Photodegradation - Water	A, B, D	42419001, 46438203
835.2410	161-3	Photodegradation - Soil	A, B, D	46438204, 43506401
835.4100	162-1	Aerobic Soil Metabolism	A, B, D	43945201, 00058169, 40894801
835.4400	162-3	Anaerobic Aquatic Metabolism	A, B, D	42763001, 00058169, 42763002
835.4300	162-4	Aerobic Aquatic Metabolism	A, B, D	42327401, 46438202, 4394520, 42327401, 42414601
835.1240	163-1	Leaching/Adsorption/Desorption	A, B, D	42148901, 5001190
835.6100	164-1	Terrestrial Field Dissipation	A, B, D	44985701, 44985702, 00094615, 00101375
RESIDUE CHEMISTRY				
860.1300	171-4A	Nature of Residue – Strawberry	A, B, D	42703001
860.1300	171-4A	Nature of Residue – Apple	A, B, D	58170, 42553201
860.1300	171-4A	Nature of Residue – Pecan	A, B, D	44717601
860.1300	171-4B	Nature of Residue – Livestock (Goat)	A, B, D	44146401
860.1340	171-4C	Residue Analytical Method – Plants	A, B, D	34562, 89415, 90258, 94615, 101357, 101358, 101371, 101385, 101393, 43945202, 44146402, 44176402, 44176401
860.1380	171-4E	Plant commodities	A, B, D	44985704, Data Gap
860.1500	171-4K	Crop Field Trials		
		Apple	A, B, D	34962, 35127, 35128, 89415, 96154, 97630 101360, 101380,

Data Requirement			Use Patterns	Citations
New Guideline Number	Old Guideline Number	Description		
				101391, 101393, 44182801, Data Gap
		Pear	A, B, D	34562, 44182802, Data Gap
		Peach	A, B, D	35128, 29036, 93588, 101357,90258 44171801, Data Gap
		Plum	A, B, D	46438205, Data Gap
		Cherry	A, B, D	89417, 101357, 29036, 90111, 44171802, Data Gap
		Strawberry	A, B, D	89881, Data Gap
		Pecan	A, B, D	101358, Data Gap
		Spinach	A, B, D	101371, 101373, Data Gap
		Walnut	A, B, D	Data Gap
860.1850	165-1	Confined Accumulation in Rotational Crops	A, B, D	699066, Data Gap
860.1520	171-4L	Magnitude of Residue in Processed Food/Feed – Apple (juice and wet pomace)	A, B, D	44176401
OTHER				
885.4380	154A-24	Honey Bee Testing, Tier 1	A, B, D	401315505
875.2100	132-1	Foliar Dislodgeable Reside Dissipation	A, B, D	45192201
Non-guideline Study	Non-guideline Study	Acute Toxicity Study in Daphnia Magna	A, B, D	46621306 (under review)

Appendix C. Technical Support Documents

1. "Ecological Hazard and Environmental Risk Assessment of Dodecylguanidine hydrochloride (DGH), Antimicrobial Uses Addendum to the Reregistration Eligibility Decision (RED) Document." May 14, 2009

2. "Dodecylguanidine hydrochloride (DGH) – Dietary and Non-dietary Exposures and Risks from Antimicrobial Uses" June 21, 2005

Appendix D. Citations Considered to be Part of the Data Base Supporting the Reregistration Eligibility Decision

MRID	Citation
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43485505	Davis, J. and D.L. Youngerman. 1994. CT-334-87 - Dodecylguanidine Hydrochloride (DGH): Acute Toxicity to Rainbow Trout, *Oncorhynchus mykiss*, Under Flow-Through Conditions. Unpublished Data. Conducted by Toxikon Environmental Sciences for Cytec Industries.
40756805	Forbis, A. 1988. Acute Toxicity of CT-334-87 to *Daphnia magna*. Unpublished data. Conducted by Analytical Bio-Chemistry Laboratories, Inc., for the American Cyanamid Company.
43485510	Helsten, B.R., and A. M. Solatycki. 1994. 8-Day Acute Dietary LC50 Study with CT-334-87 (DGH) in Mallard Ducklings. Unpublished Data. Conducted by Bio-Life Associates, Ltd., for Cytec Industries.
42695101	Hoberg, J. 1993. Dodine - Toxicity to the Freshwater Green Alga, *Selenastrum capricornutum* During a 15 day Partial Renewal Test *Selenastrum capricornutum*. Unpublished study performed by Springborn Labs, Wareham, MA. Report No. 92-10-6147 and submitted by Ceres International LLCl, West Chester, PA. Experimental start date Sept. 08, 1995 and experimental termination date Oct. 02, 1995. Final report issued Oct. 27, 1995.
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41316905	Johnston, C.D. 1971. Safety Evaluation of Cytox 2013 by Oral Administration to Mallard Ducks. Unpublished Data. Conducted by Woodard Research Corporation for the American Cyanamid Company.
43485507	Jones, F., and J. W. Davis. 1994. CT-334-87 - Dodecylguanidine Hydrochloride (DGH): Acute Toxicity to the Mysid, *Mysidopsis bahia*, Under Continuous Flow-through Conditions. Unpublished Data. Conducted by Toxikon Environmental Sciences for Cytec Industries.
43274602	Pederson, C.A. 1994. Dodecylguanidine Acetate (Dodine) Technical Grade: Toxicity and Reproduction Study in Mallard Ducks. Unpublished Study Conducted by Bio-life Associates, Ltd. for Rhone-Poulenc Ag Company
44985705	Pederson, C.A. 1999. Avian Reproductive Toxicity Study with Dodecylguanidine Acetate (Dodine) Technical in Bobwhite Quail. Unpublished Study Conducted by Bio-life Associates,
43876501	Putt, A. 1995. Dodine Technical – The Chronic Toxicity to *Daphnia magna* Under Flow Through Conditions: Final Report: Lab Project no.: 95-10-6162:10566.1294.6356.130. Unpublished study prepared by Springborn Labs, Inc. 114 p.
40940803	Roberts, S., and R. L. Wineholz. 1976. 8-Day Dietary LC50 Study of Calgon Dodecylguanidine Hydrochloride (40.6%) in Bobwhite Quail and Mallard Ducks. Unpublished Data. Conducted by Cannon Laboratories for Calgon

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43485508 Youngerman, D., and J.W. Davis. 1994. CT-334-87 - Dodecylguanidine Hydrochloride (DGH): Acute Effect on New Shell Growth of the Eastern Oyster, *Crassostrea virginica.* Unpublished Data. Conducted by Toxikon Environmental Sciences for Cytec Industries.
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