United States Environmental Protection Agency
Prevention, Pesticides And Toxic Substances (7508W)
EPA738-R-96-025
September 1996

Reregistration Eligibility Decision (RED)

Chlorhexidine diacetate

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case Chlorhexidine diacetate which includes the active ingredient Chlorhexidine diacetate. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses are due 90 days from the receipt of this letter. The second set of required responses are due 8 months from the receipt of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

Please note that this RED was finalized and signed prior to August 3, 1996. On that date, the Food Quality Protection Act of 1996 ("FQPA") became effective, amending portions of both the pesticide law (FIFRA) and the food and drug law (FFDCA). This RED does not address any issues raised by FQPA, and any tolerance-related statements in the RED did not take into account any changes in tolerance assessment procedures required under FQPA. To the extent that this RED indicates that a change in any tolerance is necessary, that determination will be reassessed by the Agency under the standards set forth in FQPA before a proposed tolerance is issued. To the extent that the RED does not indicate that a change in the tolerance is necessary, that tolerance, too, will be reassessed in the future pursuant to the requirements of FQPA.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative CP Moran (703) 308-8590. Address any questions on required generic data to the Special Review and Reregistration Division representative Bonnie Adler (703) 308-8523.

Sincerely yours,

Lois Rossi, Division Director
Special Review
and Reregistration Division

Enclosures

SUMMARY OF INSTRUCTIONS FOR RESPONDING TO THE REREGISTRATION ELIGIBILITY DECISION (RED)

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, another DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific letter will be enclosed describing such data. Complete the two response forms provided with each DCI letter (or four forms for the combined) by following the instructions provided. **You must submit the response forms for each product and for each DCI within 90 days of the receipt of this letter (RED issuance date); otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for data waivers must be submitted as part of the 90-day response. Requests for time extensions should be submitted in the 90-day response, but certainly no later than the 8-month response date. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"--You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-487-4650).

c. **Generic or Product Specific Data**. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must **make sure that they meet the Agency's acceptance criteria** (attached to the DCI).

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must

comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Data Compensation Requirements**. Complete and sign EPA form 8570-31 for each product.

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

REREGISTRATION ELIGIBILITY DECISION

Chlorhexidine diacetate

LIST C

CASE 3038

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION

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CHLORHEXIDINE DIACETATE REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Division

Frank Hernandez	Economic Analysis Branch
Phyllis Johnson	Biological Analysis Branch
Rafael Prieto	Biological Analysis Branch

Environmental Fate and Effects Division

Karen Angulo	Science Analysis and Coordination Staff
Laura Dye	Ecological Effects Branch
Laura Parsons	Environmental Fate and Groundwater Branch
Mary Powell	Science Analysis and Coordination Staff

Health Effects Division

Thomas Campbell	Occupational and Residential Exposure Branch
Kathleen Martin	Risk Characterization and Analysis Branch
Irving Mauer	Toxicology Branch I

Registration Division

Valdis Goncarovs	Antimicrobial Program Branch
Tina Levine	Registration Support Branch
Sami Malak	Registration Support Branch

Special Review and Reregistration Division

Bonnie Adler	Accelerated Reregistration Branch
Kathy Davis	Accelerated Reregistration Branch

Office of Research and Science Integration:

Vivian Turner	Planning and Science Review Staff

Office of Enforcement and Compliance:

Rick Colbert	Agricultural and Ecosystems Division

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No effect concentration

GLOSSARY OF TERMS AND ABBREVIATIONS

NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
FAO/WHO	Food and Agriculture Organization/World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

As required under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended in 1988, the U.S. Environmental Protection Agency has completed its reregistration eligibility decision for the pesticide active ingredient chlorhexidine diacetate. This decision includes a comprehensive reassessment of the required target data base and use patterns of currently registered products. The Agency compared its risk assessment to current science and regulatory policies. Where appropriate, it has imposed changes to the terms for continued registration in order to reduce risks to human health and the environment.

The Agency has determined that the uses as described below will not cause unreasonable risk to humans or the environment and all uses are eligible for reregistration provided specified mitigation measures are adopted. These measures include the requirement for product handlers to wear personal protective equipment (chemical resistant gloves, long-sleeved shirts, long pants, shoes with socks and respirators). In addition, re-entry of workers without personal protective equipment into areas treated by wet-mist fogging applications is restricted until application is absorbed, set or dried and ventilation is complete.

Use Patterns

Chlorhexidine diacetate is used to control bacteria on agricultural premises and on equipment, egg handling and packing equipment, meat processing plants, and for veterinary hospital/clinic premises to control certain viruses.

Human Health Assessment

From its review of the toxicology data, the Agency concluded that chlorhexidine diacetate is mildly to moderately toxic when administered by inhalation, oral and dermal routes. However, in repeat primary eye irritation studies, the chemical is severely toxic. In a subchronic dermal rabbit toxicity study there was minimal dermal irritation observed at the lowest dose tested, along with systemic effects: decreased enzyme activity with microscopically observed degenerative changes in livers of low-dose females. This is indicative of a chemical-induced hepatic effect. The 250 mg/kg/day dose was considered to be a NOEL because of the minimal response observed at that dose. A battery of mutagenicity studies were negative for mutagenic effects.

A developmental toxicology study with rats resulted in dose-related reduced body weight gain, rales, and increased salivation. No observable malformations or significant developmental toxicity were found at any dose level tested. The Agency concluded the developmental toxicity NOEL is equal to or greater than the highest dose tested, 62.5 mg/kg/day, and the maternal toxicity NOEL is 15.63 mg/kg/day.

There are no acute toxicological endpoints of concern for occupational uses of chlorhexidine diacetate. For short- and intermediate-term exposures, the Agency's calculated margins of exposure (MOE = NOEL/exposure) for chlorhexidine diacetate product handlers (mixer/loaders/applicators) represent acceptable margins of exposure (MOEs $\geq$ 100) for all uses except the use in wet-mist foggers. Data were not available for the wet-mist fogger use, therefore, MOEs were not calculated. To further reduce potential exposure the Agency is imposing the use of personal protective equipment during any mixing/loading/application of chlorhexidine diacetate products.

Environmental Assessment

Chlorhexidine diacetate is slightly toxic to practically nontoxic to avian species on an acute and subacute oral dietary basis, moderately to highly toxic to fish, and very highly toxic to aquatic invertebrates. Current uses of chlorhexidine diacetate, considered to be limited to indoor, are expected to result in minimal exposure or risk to the environment. Therefore, no environmental risk mitigation measures are being imposed at this time.

Product Reregistration

Before reregistering the products containing chlorhexidine diacetate, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registration and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products that contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of chlorhexidine diacetate. The document consists of six sections. Section I is the introduction. Section II describes chlorhexidine diacetate, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for chlorhexidine diacetate. Section V discusses the reregistration requirements for chlorhexidine diacetate. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredient is covered by this Reregistration Eligibility Decision:

- **Common Name:** Chlorhexidine diacetate
- **Chemical Name:** 1,1'- hexamethylene bis [5-(p-chlorophenyl) biguanide] diacetate
- **CAS Registry Number:** 56-95-1
- **OPP Chemical Code:** 045502
- **Empirical Formula:** $C_{26}H_{38}Cl_2N_{10}O_4$
- **Trade and Other Names:** Nolvasan, Bactigras
- **Basic Manufacturer:** Fort Dodge Laboratories

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of these uses of chlorhexidine diacetate is in Appendix A.

For **chlorhexidine diacetate**:

Type of Pesticide: Limited disinfectant, virucide

Use Sites: Indoor Non-food: (with prescribed directions listed under Use Practice Limitations)
Agricultural/Farm Premises
Egg Handling Equipment (commercial)
Egg Packing Plants (commercial)
Meat Processing Plant Equipment (food contact)
Meat Processing Premises (non-food contact)

Poultry Processing Plant Equipment (food contact)
Poultry Processing Plant Premises (non-food contact)
Agricultural/Farm Equipment/Shoe Baths

Indoor Medical: (for veterinary uses only)
Medical Institutions/Premises

Target Pests:

Bacteria; Viruses: Canine distemper, Equine Influenza, Transmissible Gastroenteritis, Hog Cholera, Parainfluenza 3, Bovine Rhinotracheitis, Bovine Diarrhea, Infectious Bronchitis, Newcastle, Venezuelan Equine Encephalitis, Equine Rhinopneumonitis, Feline Rhinotracheitis, Pseudorabies, Equine Arteritis, Canine Coronavirus, Rabies.

Formulation Types Registered:

Form: End use product - 2% active ingredient soluble concentrate/liquid

Method and Rates of Application:

Types of Treatment: Animal feeding/watering equipment treatment, Surface Treatment, Soak by saturation

Method and Rate (Concentrations)

Animal feeding/watering equipment treatment: 154 to 462 ppm a.i. by weight

Surface Treatment: 154 to 462 ppm a.i. by weight

Soak: 157 ppm a.i. by weight

Use Practice Limitations:

Remove all animals and feed from premises, vehicles and other equipment prior to treatment. Proper ventilation required. Do not house livestock or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed tracks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse. All food products and packaging material must be removed from the room or carefully covered and protected. Remove any loose dirt, litter, etc., that might be lying on the floor or attached to the equipment. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with the recommended

disinfecting solution for a period of 10 minutes. Expose or soak all equipment and/or utensils with the recommended disinfecting solution for a period of 10 minutes. After disinfection all equipment and/or utensils must be thoroughly rinsed with potable water before operations are resumed. Nolvasan Solution may be used in wet-mist fogging operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. Fog until the area is moist using automatic foggers according to manufacturer's use directions.

Currently the regulation of teat dips and udder washes by the FDA is guided by Compliance Policy Guide 7125.30 entitled, "Teat Dips and Udder Washes for Dairy Cows and Goats."

C. Data Requirements

Data required by the Agency in the March 4, 1987 Antimicrobial Data Call-In included mammalian toxicity and exposure data. The March 31, 1992 Phase IV Data Call-In required studies on product chemistry, ecological effects, and environmental fate. These data were required to support reregistration of the uses listed. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

D. Regulatory History

Products formulated with chlorhexidine diacetate as an active ingredient were registered in the United States as early as 1955 for use as a farm premise disinfectant/virucide. Later, products were registered for hospital settings but eventually these uses were voluntarily cancelled. Currently, two end-use products with 2% chlorhexidine diacetate are registered for use as hard surface-treatment disinfectant/virucides.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

The physical and chemical properties of the chlorhexidine diacetate technical grade are summarized below:

Color: White

Physical State: Powdered Solid

Odor: Odorless

Melting Point: 158.7°C

Bulk Density: 1.2 gm/cm^3

Solubilities:

Solvent	Solubility
Water	Solubilizes
Ethanol	6.7 gm/100 ml
Glycerol	slightly soluble
Propane	slightly soluble

pH: 6.8 (in 1% solution)

Stability: Stable under ambient warehouse conditions to moisture and simulated sunlight.

B. Human Health Assessment

1. Toxicology Assessment

The toxicology data base for chlorhexidine diacetate (1,1'-hexamethylene bis[5-(p-chlorophenyl)biguanide]diacetate) is adequate and will support reregistration eligibility.

a. Acute Toxicity

Chlorhexidine diacetate has been evaluated for acutely toxic effects. Table 1 summarizes the results of the submitted studies.

Table 1. Acute Toxicity

Test (Guideline) (MRID)	Reported Results	Toxicity 50 Category
Acute oral-rat (81-1) (42706701)[a]	LD_{50} (males) = 1710 mg/kg LD_{50} (females) = 1180 mg/kg	III
Acute dermal-rabbit (81-2) (42706702)[a]	LD_{50} > 2000 mg/kg	III
Acute inhalation-rat (81-3) (42684201)[a]	LC_{50} (males) = 0.30 mg/L LC_{50} (females) = 0.43 mg/L	II
Primary eye irritation-rabbit (81-4) (42706704)[a]	PII = 66.4	I
Primary dermal irritation-rabbit (81-5) (42706705)[a]	PIS = 0.0	IV
Dermal sensitization-guinea pig (81-6) (42706706)[a]	Not a sensitizer	N/A

[a]This study is a requirement for manufacturing-use and end-use products (40 CFR Section 158). For chlorhexidine diacetate data have been generated on the TGAI and are presented here for informational purposes.

The technical grade active ingredient (97.7 percent to 98.3 percent ai) is mildly (toxicity category III and IV) to moderately (toxicity category II) acutely toxic when administered by dermal, oral and inhalation routes. In a repeat primary eye irritation study, chlorhexidine diacetate was severely toxic (toxicity category I).

b. Subchronic Dermal Toxicity

Subchronic toxicity data were submitted from a 13-week dermal toxicity study on New Zealand White rabbits that were treated topically, at chlorhexidine diacetate doses of 0, 250, 500, or 1000 mg/kg/day (MRID 40952201). These data satisfy the requirement for this type of assay. Minimal dermal irritation (erythema, edema, desquamation and/or fissuring) was evident at the lowest dose tested (250 mg/kg/day). In addition, the finding of decreased enzyme activity, coupled with microscopically-observed degenerative changes in the liver are indicative of a hepatic effect in females at this dose level; (systemic) liver effects were noted at the 500 mg/kg/day level. However, for occupational exposure risk assessment purposes, the 250 mg dose is considered to be a NOEL because of the minimal response observed at that dose.

c. Chronic Toxicity/Carcinogenicity/Reproductive Toxicity

Oral chronic toxicity studies are not required for this use pattern.

d. Developmental Toxicity

Acceptable developmental toxicity data were provided in a study using Sprague-Dawley rats that were dosed by gavage at 0, 15.63, 31.25, or 62.5 mg/kg/day; gestation dosing was done at days six through 15 (MRID 42102101). From this study a maternal toxicity NOEL for orally-administered chlorhexidine diacetate was established at 15.63 mg/kg/day. Higher doses resulted in dose-related reduced body weight gain, rales, and increased salivation (LOEL of 31.25 mg/kg/day, and a HDT of 62.5 mg/kg/day). No observable malformations or developmental toxicity were found at any dose level tested. The developmental toxicity NOEL is equal to or greater than the highest dose, 62.5 mg/kg/day.

e. Mutagenicity

Acceptable data were submitted for a battery of mutagenicity studies that assayed for the potential of chlorhexidine diacetate to induce changes in several genetic endpoints (MRIDs 40231003, 40231004, and 40231005). The technical formulation tested negative for gene mutation up to cytotoxic levels (6 µg/ml in non-activated assays and 15-16 µg/ml in activated assays) with mammalian mouse lymphoma cells in culture. Negative results were also obtained in in vitro cytogenetic assays with Chinese hamster ovary cells (negative for chromosomal breakage, with and without activation at test levels up to 10 µg/ml, that reduced cell growth 30 percent of control). Similarly, there was no DNA damage/repair in a study using primary rat hepatocyte cultures (negative for increased net nuclear counts at 18 hours with exposure levels up to 2.42 µg/ml).

A singular test for gene mutation with bacteria (Salmonella/Ames Assay) reported negative results, but this study was considered unacceptable due to major procedural deficiencies. The studies discussed above are more appropriate for an evaluation of genotoxic potential of an antimicrobial agent. Therefore, a new Salmonella test is not required.

f. Toxicology Endpoints for Risk Assessment

Toxicology Endpoints

The endpoints for chlorhexidine diacetate were established by the HED Less-Than-Lifetime Exposure committee on May 16, 1995. Short-term occupational or residential exposure (one to seven days) had a NOEL of 250 mg/kg based on systemic (liver) effects at 500 mg/kg from a 13-week dermal toxicity study (MRID 40952201). Intermediate term occupational/residential exposure (one week to several months) and chronic exposure indicated the same endpoints as the short-term exposures accompanied by severe skin effects (MRID 40952201). An endpoint for acute dietary exposures is not required for this active ingredient.

g. Other Hazard Information

A review of Agency incident data shows that there are two recorded anecdotal reports of human reactions to chlorhexidine diacetate products (OPP-Incident Data System, 04/10/95). However,

these reactions do not alter the conclusions the Agency has drawn from the toxicology database because both incidents were associated with product misuse.

2. Exposure Assessment

a. Dietary Exposure

Chlorhexidine diacetate is registered for use in federally inspected meat, poultry, egg, and rabbit processing plants, as a disinfectant on processing surfaces. The labeling for these products requires that food products and packaging materials are removed or carefully covered prior to application and that a potable water rinse is employed after treatment. The U.S. Department of Agriculture and the EPA have determined that disinfectants, when applied to federally inspected meat, poultry, egg, and rabbit processing plants as described above, do not present dietary exposure risks (USDA, FSIS publication #1419, "List of Proprietary Substances and Nonfood Compounds").

b. Occupational Exposure

The Agency has determined that an exposure assessment is required for chlorhexidine diacetate based on the toxicity endpoint from the subchronic dermal study (MRID 40952201) described above. The registrant is a participant in the Chemical Manufacturer's Association (CMA) Antimicrobial Exposure Assessment study, therefore, data from that study were used in the exposure assessment (MRIDs 41412201, 41742601, and 42587501). No dermal absorption data on chlorhexidine diacetate exists, therefore, the Agency assumes 100% absorption.

Application methods include open-pouring, wet-mist fogging, surface wiping, mopping, low- and high-pressure spray applications. EPA assumes the frequency of repeated product application can be 50 to 250 times per year, depending upon the type of application.

Handler Exposure

The Agency has determined that mixers, loaders, applicators and other handlers may be potentially exposed to chlorhexidine diacetate during normal use and application of products. Specifically, EPA has focused on exposures to loaders and applicators using chlorhexidine diacetate to disinfect veterinary and/or farm premises or animal-product processing facilities.

Based on the use pattern, several exposure scenarios are plausible as defined by the use-site. The potential exposure scenarios include (1) open-pour loading of liquid formulations, (2) applying the disinfectant by hand by wiping surfaces, (3) applying the disinfectant by hand by dipping tools/implements into dilute disinfectant solution, (4) applying the disinfectant by mopping surfaces, (5) applying the disinfectant with hand-held high-pressure spray equipment, (6) applying the disinfectant with hand-held low-pressure spray equipment, and (7) applying the disinfectant with a wet-mist fogger (automatic fogger).

Table 2 provides the exposure estimates for the above scenarios, except for applications by hand by dipping tools/implements into the dilute disinfectant solution and applications with a wet-mist fogger. EPA believes that exposures to applicators applying the disinfectant by wiping is a reasonable surrogate for applying by dipping tools/implements into the disinfectant. The exposure estimates range from 14.7 μg/kg/day for application by mop (no gloves) to 572 μg/kg/day for application with a wipe (no gloves) based on amortized average daily doses. The exposure data were derived from the CMA study where workers wore (except where noted) long-sleeved shirts, long pants, and chemical resistant gloves. Please note that the CMA study does not provide data for the wet-mist fogger; therefore, no exposure assessment was conducted for this scenario.

The unit exposure (UE) is a combination of both dermal and inhalation exposure values. The dermal exposure component of the UE was derived from the sum of dermal deposition measurements that were taken at multiple body locations. Dermal deposition measurements that were less than the level of detection (i.e. non-detects) were included in the calculation at one-half of the limit of detection. Attempts to measure the inhalation exposure resulted in non-detectable values. Therefore, the inhalation exposure component was added at one-half of the limit of detection to the dermal exposure component; the inhalation exposure component is considered to be minimal in comparison to the dermal exposure component.

EPA estimated the volume of disinfectant solution used per day for the low-pressure and high-pressure hand-held spray equipment as 40 and 100 gallons per day, respectively. These estimates are higher than the volume per day estimated in the CMA studies because of the relatively larger size of the treated areas (meat- and poultry-processing premises and egg-laying facilities) for some of the use scenarios.

Post-Application Exposure

EPA believes there are potential exposures to persons reentering areas that have been treated with chlorhexidine diacetate, especially following wet-mist fogging applications and other applications in enclosed areas. Exposures from wet-mist fogging are not quantified because unlike the other application scenarios where some handler data are available (i.e., the CMA data), neither handler nor post-application data are available for this scenario.

Due to the toxicological characteristics of chlorhexidine diacetate, the Agency has determined that a post-application exposure assessment is appropriate. However, there are no data available to directly assess any post-application exposure scenario. Therefore, only a qualitative assessment can be done. EPA believes it is reasonable to assume that post-application exposures of workers to chlorhexidine diacetate are much lower than exposure to occupational handlers. This assumption is based on the belief that handlers (mixers/loaders/applicators) will have more dermal contact with the pesticide than a person who has incidental contact with a treated surface.

Table 2. Exposure Estimates for Chlorhexidine Diacetate Use Scenarios

SCENARIO	USE	AMOUNT OF PESTICIDE USED PER DAY			WORKER EXPOSURE				
		USE RATE (oz/gal)	VOLUME USED/DAY (gallons)	lb ai used/day	UE (µg/lb ai)	BW (kg)	EF	ADE (µg/kg/day)	ADD (µg/kg/day)
Pour Liquid	Disinfectant	32	100	4.15	35,490	70	50	2104	288
High Pressure Spray	Disinfectant	3	100	0.4	299,680	70	50	1710	235
Low Pressure Spray (ungloved)	Disinfectant	3	40	0.16	190,560	70	50	436	59.6
Wipe (ungloved)	Disinfectant	3	5	0.02	2,922,645	70	250	835	572
Mop (ungloved)	Disinfectant	3	5	0.02	75,280	70	250	21.5	14.7
Wet-Mist Fogger	Disinfectant	1	no data	no data	no data	70	no data	no data	no data

EXPLANATORY NOTES:

USE RATE = The amount of 2% ai Nolvasan solution diluted into a gallon of water. The indicated rate is the maximum label rate.
VOLUME USED/DAY = The amount of solution used per day. This was obtained from the CMA study.
UE = Unit Exposure, which was derived from the CMA Study.
BW = Body Weight, which is assumed to be 70 kg.
EF = Exposure Frequency, which is the number of times the product is applied per year. This information was obtained from the CMA study.
ADE = Actual Daily Exposure.
ADD = amortized Average Daily Dose.

FORMULAS:

lb ai used/day = Use Rate (oz/gal) × %ai × Vol. used/day (gal) × gal/128 oz × 8.3 lb/gal

ADE (µg/kg/day) = (Unit Exposure (µg/lb ai) × lb ai used/day) ÷ BW (kg)

ADD (µg/kg/day) = ADE (µg/kg/day) × EF (days)/365 days

3. Risk Assessment

a. Dietary

A risk assessment from dietary exposures to chlorhexidine diacetate is not required, based on the current use pattern. The U.S. Department of Agriculture and the EPA have determined that disinfectants, when applied to federally inspected meat, poultry, egg, and rabbit processing plants as described previously, do not present dietary exposure risks.

b. Occupational

Based on available toxicity data and use patterns for chlorhexidine diacetate, the Agency has determined that risk characterizations for mixer/loader/applicators (occupational) and post-application exposures are appropriate. Because of the selected toxicology endpoint for chlorhexidine diacetate, the Agency is characterizing the risks by margins of exposure (MOE), that is, the ratio of the toxicological endpoint NOEL to the estimate of exposure. The Agency is using the calculated units of exposure from Table 2: actual daily exposure (ADE) for short and intermediate term exposures and the amortized average daily exposure (ADD) for chronic exposures. Formulas for these risk calculations are as follows:

Formulas for MOE Calculations

Margin-of-Exposure (MOE) (*short and intermediate*)	=	NOEL (µg/kg/day)	÷	ADE (µg/kg/day)

Margin-of-Exposure (MOE) (*chronic*)	=	NOEL (µg/kg/day)	÷	ADD (µg/kg/day)

Mixer/Loader/Applicator (Handler) Risk

Adequate data are available to characterize the occupational risk for most handler exposure scenarios. A summary of MOE calculations for each of the five use scenarios is provided in Table 3. These MOEs range from 119 for the Pour Liquid Scenario to 17,007 for the Mop

Scenario (ungloved). These values are greater than 100 which is the Agency's regulatory level of concern threshold for noncarcinogenic endpoints. Therefore, exposures to handlers in these scenarios are not of concern to the Agency.

Table 3. Margins of Exposures for Handler Exposure

SCENARIO	MOE (short and intermediate exposure)	MOE (chronic exposure)
Pour Liquid	119	Not Applicable*
High Pressure Spray	146	Not Applicable*
Low Pressure Spray (ungloved)	573	Not Applicable*
Wipe (ungloved)	299	437
Mop (ungloved)	11,628	17,007

NOEL = 250 mg/kg/day

* Based on exposure frequency of 50 times a year, EPA does not consider this scenario to be chronic.

The CMA study does not provide data for the wet-mist fogger method of application. While EPA cannot estimate levels of exposure or MOEs for this scenario, EPA is concerned about potential inhalation and ocular exposures to applicators during fogging and other workers who may enter the treated area before the fog has dissipated.

Post-Application Risk

There are no data available to directly assess potential exposures to chlorhexidine diacetate by post-application workers. However, EPA assumes that exposures to occupational handlers are much higher than post-application exposures to occupational workers, provided entry into treated areas is restricted immediately following applications. Because all the MOEs for occupational handlers are greater than 100, EPA believes that occupational exposures to post-application workers would not be of concern, provided that the product is used in accordance with label instructions as specified in this document.

C. Environmental Assessment

For chlorhexidine diacetate, like other pesticides whose uses are limited to indoor sites, the Agency requires only a limited set of ecotoxicology and environmental fate studies. Minimal to no environmental exposure is expected from the indoor use patterns. For this reason, the Agency does not routinely conduct full

environmental assessments on pesticides limited to indoor uses. Therefore, this has not been done for chlorhexidine diacetate. However, the Agency recognizes that a limited set of studies are necessary to have in order to characterize such a pesticide's hazard potential in the case of unanticipated environmental exposures caused by transportation accidents, spills, or improper disposal or use. These studies for chlorhexidine diacetate have been submitted, are acceptable and fulfill the guideline requirements. The conclusions are reported below.

1. Ecological Toxicity Data

The ecotoxicological data base is adequate to characterize the toxicity of chlorhexidine diacetate to nontarget terrestrial and aquatic organisms when it is used as an indoor nonfood antimicrobial.

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

To establish the toxicity of chlorhexidine diacetate to birds, the following tests were conducted using the technical grade material: one avian single-dose oral (LD_{50}) study on the bobwhite quail; and two subacute dietary studies (LC_{50}) on the mallard duck and the bobwhite quail. Tables 4 and 5 summarize these three studies.

Table 4. Avian Acute Oral Toxicity Findings (LD_{50})

Species	% A.I.	LD_{50} mg/kg	MRID No. Author/Year	Toxicity Category
Northern Bobwhite	100.78	2,013	42197501 Campbell, Grimes et.al., 1991	slightly toxic

Table 5. Avian Subacute Dietary Toxicity Findings (LC_{50})

Species	% A.I.	LC_{50} ppm	MRID No. Author/Year	Toxicity Category
Northern Bobwhite	100.78	>5,620	42197502, Long, Hoxter & el., 1991	practically nontoxic
Mallard	100.78	>5,620	42197503, Long, Hoxter & el., 1991	practically nontoxic

These results indicate that chlorhexidine diacetate is slightly toxic to practically nontoxic to avian species based on acute and subacute dietary data (MRIDs 42197501, 42197502 and 42197503).

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

The 96-hour acute toxicity studies were conducted on two species of freshwater fish - a coldwater species (rainbow trout) and a warmwater species (bluegill sunfish). The results of these studies indicate that chlorhexidine diacetate is moderately to highly toxic to freshwater fish (MRIDs 42197504 and 42197505). Table 6 summarizes these studies.

Table 6. Freshwater Fish Acute Toxicity Findings

Species	% A.I.	LC_{50} ppm	MRID No., Author/Year	Toxicity Category
Rainbow trout	100.78	1.9	42197504 Murphy & Smith, 1991	moderately toxic
Bluegill sunfish	100.78	0.6	42197505 Murphy & Smith, 1991	highly toxic

(2) Freshwater Invertebrates

The freshwater aquatic invertebrate toxicity test using *Daphnia magna* characterizes chlorhexidine diacetate as very highly toxic to aquatic invertebrates (MRID 42197506). Table 7 shows these results.

Table 7. Freshwater Invertebrate Toxicity Findings

Species	% A.I.	EC_{50} (mg/l)	MRID No. Author/Year	Toxicity Category
Daphnia magna	100.78	0.06	42197506 Murphy & Smith, 1991	very highly toxic

2. Environmental Fate

a. Environmental Fate Assessment

For chlorhexidine diacetate the Agency did not conduct an environmental fate assessment because it is unlikely for the environment to be exposed to the pesticide when it is used as labeled.

A conjectural environmental fate assessment could be that chlorhexidine diacetate would probably decompose by microbial metabolism and that the parent compound is probably mobile in soil systems. The rationale for this assessment is that chlorhexidine is a very

large molecule ($C_{22}H_{30}Cl_2N_{10}$; molecular weight 505.5 g/mole) with several carbon-carbon and carbon-nitrogen bonds that are probably vulnerable to microbial decomposition. Chlorhexidine diacetate is very water soluble at 19 g/L water at 20 °C, which can indicate mobility in a soil system. Also, according to the Merck Index, aqueous solutions of chlorhexidine diacetate decompose at temperatures higher than 70 °C, so the inference can be made that chlorhexidine diacetate probably does not hydrolyze at lower temperatures.

3. Exposure and Risk Characterization

As explained above, the Agency does not conduct an assessment of the risk to nontarget organisms for pesticides having indoor uses without effluents, as is the case for chlorhexidine diacetate. From the available data, the Agency concludes that chlorhexidine diacetate is slightly toxic to practically nontoxic to avian species on an acute oral and subacute dietary basis, moderately to highly toxic to fish, and very highly toxic to aquatic invertebrates. However, the indoor uses of chlorhexidine diacetate are expected to result in minimal exposure to the environment.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing chlorhexidine diacetate active ingredients. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing chlorhexidine diacetate. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of chlorhexidine diacetate, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B are sufficient to allow the Agency to assess the registered uses of chlorhexidine diacetate and to determine that chlorhexidine diacetate can be used, as specified in this document, without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing chlorhexidine diacetate as the active ingredient and with the modifications as stipulated in this document are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc. and the data identified in Appendix B. Although the Agency has found that all uses of chlorhexidine diacetate are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing chlorhexidine diacetate, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient chlorhexidine diacetate, the Agency has sufficient information on the health effects of chlorhexidine diacetate and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that chlorhexidine diacetate products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency concludes that products containing chlorhexidine diacetate for all uses are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that all currently registered uses of chlorhexidine diacetate are eligible for reregistration.

B. Regulatory Position

The following is a summary of the regulatory positions and rationales for chlorhexidine diacetate. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Human Exposure Risk Rationale

The Agency has determined that mixer/loader/applicator exposures to chlorhexidine diacetate are not of concern based on margins of exposure that range from 119 to over 17,000. These margins of exposure are based on all use scenarios except the wet-mist fogger. EPA is concerned about potential exposures, particularly inhalation and ocular exposures, to applicators and other workers exposed to chlorhexidine diacetate fogs. To reduce exposures and risk, the Agency is imposing PPE requirements.

The Agency also believes that post-application occupational exposures are not of concern provided entry into treated areas is restricted immediately following applications and ventilation is complete. Post-application exposure is likely to be lower than exposure to pesticide handlers.

2. Personal Protective Equipment and Re-entry Requirements

For each end-use product, PPE requirements for pesticide handlers are set during reregistration in one of two ways:

1. If EPA determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE must be established using the process described in PR Notice 93-7 or more recent EPA guidelines.

2. If EPA determines that regulatory action on an active ingredient must be taken as the result of very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc.):

- In the RED for that active ingredient, EPA may establish minimum or "baseline" handler PPE requirements that pertain to all or most end-use products containing that active ingredient.
- These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of the end-use product.
- The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

Personal protective equipment requirements usually are set by specifying one or more pre-established PPE units -- sets of items that are almost always required together. For example, if chemical-resistant gloves are required to mitigate risk, then long-sleeve shirts, long pants, socks, and shoes are also included in the required minimum attire. If the requirement is for two layers of body protection (coveralls over a long- or short-sleeve shirt and long or short pants), the minimum must also include (for all handlers) chemical-resistant footwear and chemical-resistant headgear for overhead exposures and (for mixers, loaders, and persons cleaning equipment) chemical-resistant aprons.

Personal protective equipment requirements, described in Section V of this document, are indicative of the dermal protection used in the CMA study, in which most study subjects wore long-sleeve shirts and long pants, chemical resistant gloves, shoes and socks. Estimated units of exposure and risk (MOEs) for chlorhexidine diacetate were based on this fact. In addition, because of EPA's presumption that workers entering areas during or after fogging applications before adequate ventilation could receive exposures to chlorhexidine diacetate, inhalation and ocular protection is also required for persons exposed to the wet-mist fog. Label statements for PPE are provided for occupational uses.

V. ACTIONS REQUIRED OF REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of chlorhexidine diacetate for the above eligible uses has been reviewed and determined to be substantially complete.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

Personal Protective Equipment Requirements for Pesticide Handlers

For **sole-active-ingredient** end-use products that contain chlorhexidine diacetate, the product labeling must be revised to adopt the handler personal protective equipment (PPE) requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed.

For **multiple-active-ingredient** end-use products that contain chlorhexidine diacetate, the handler PPE requirements set forth in this section must be compared to the requirements on the current labeling and the more protective must be retained. For guidance on which requirements are considered more protective, see PR Notice 93-7.

Products Intended Primarily for Occupational Use -- Application

Minimum (Baseline) PPE Requirements

The minimum (baseline) PPE for persons applying chlorhexidine diacetate with mopping and hand wiping is:

"Applicators and other handlers must wear:

- Long sleeve shirt and long pants
- Socks plus shoes."

The minimum (baseline) PPE for occupational uses of chlorhexidine diacetate end-use products with the exception of the wet-mist fogging is:

"Applicators and other handlers must wear:

- Long-sleeve shirt and long pants
- Chemical-resistant gloves*
- Socks plus shoes."

* For the glove statement, use the statement established for chlorhexidine diacetate through the instructions in Supplement 3 of PR Notice 93-7.

For the wet-mist fogging, the following PPE is required:

"Applicators and other handlers exposed to the fog during wet-mist fogging applications and until the fog has dissipated and the enclosed area has been thoroughly ventilated, they must wear:

- Long-sleeve shirt and long pants
- Chemical-resistant gloves*
- Socks plus shoes
- A full face respirator with a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G)."

* For the glove statement, use the statement established for chlorhexidine diacetate through the instructions in Supplement 3 of PR Notice 93-7.

Determining PPE Requirements for End-Use Product Labels

The PPE that would be established on the basis of the acute toxicity category of the end-use product must be compared to the active-ingredient-based minimum (baseline) PPE specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, its placement, format, and wording refer to PR Notice 93-7.

Entry Restrictions

For **sole-active-ingredient** end-use products that contain chlorhexidine diacetate, the product labeling must be revised to adopt the entry restrictions set forth below. Any conflicting entry restrictions on the current labeling must be removed.

For **multiple-active-ingredient** end-use products that contain chlorhexidine diacetate the entry restrictions set forth in this section must be compared to the entry restrictions on the current labeling and the more protective must be retained. A specific time period in hours or days is considered more protective than"sprays have dried" or "dusts have settled."

Products Intended Primarily for Occupational Use -- Post-Application

Entry Restrictions

The Agency is establishing the following entry restrictions for all occupational uses of chlorhexidine diacetate end-use products:

"Thoroughly ventilate buildings, vehicles, and closed spaces following application. Do not enter, allow other persons to enter, house livestock, or use equipment in the treated area until ventilation is complete and the liquid chlorhexidine diacetate has been absorbed, set, or dried."

For wet-mist fogging applications add:

"For entry into fogged areas before ventilation is complete and the fog has completely dissipated, absorbed, set or dried, all persons must wear:

- Long sleeved shirt
- Long pants
- Chemical-resistant gloves*
- Socks plus shoes
- A full-face respirator with a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G)."

* For the glove statement, use the statement established for chlorhexidine diacetate through the instructions in Supplement 3 of PR Notice 93-7.

Other Labelling Requirements for Products Intended Primarily for Occupational Use

The Agency is requiring the following labeling statements to be located on all end-use products containing chlorhexidine diacetate that are intended primarily for occupational use:

Application Restrictions (This statement is required on all end-use product labeling where spray or fog applications are permitted.)

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

User Safety Requirements

The registrant must place the following statement on the end-use product label only if coveralls are required for pesticide handlers:

"Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."

The registrant must place the following statement on all end-use product labels:

"Follow manufacturer's instructions for cleaning/ maintaining personal protective equipment. If there are no such instructions for washables, use detergent and hot water. Keep and wash personal protective equipment separately from other laundry."

User Safety Recommendations

- "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

- "Users should remove clothing immediately if pesticide gets on or inside it. Then wash both skin and clothing thoroughly and put on clean clothes."

- "Users should remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash skin and clothing thoroughly and change into clean clothes."

Other Labeling Requirements

The label directions as specified in the Agency's labeling document entitled, "Label Requirements for Farm Premise

Disinfectants," number DIS/TSS-18, dated January 17, 1980, are required for farm premise disinfectants to permit their classification as non-food use products.

The following label directions are required for meat, poultry, rabbit and egg establishment disinfectants to permit their classification as non-food use products:

> "All food products and packaging material must be removed from the room or carefully covered and protected.
>
> Remove any loose dirt, litter, etc., that might be lying on floor or attached to the equipment.
>
> Thoroughly clean all surfaces with soap or detergent and rinse with water.
>
> Saturate all surfaces with the recommended disinfecting solution for a period of 10 minutes.
>
> Expose or soak all equipment and/or utensils with the recommended disinfecting solution for a period of 10 minutes.
>
> After disinfection all equipment and/or utensils must be thoroughly rinsed with potable water before operations are resumed."

The registrant must specify the application method equipment and timing on all labeling.

C. Existing Stocks

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 (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of 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.

The Agency has determined that registrants may distribute and sell chlorhexidine diacetate products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

APPENDIX A REPORT

Case 3038[Chlorhexidine derivs.] Chemical 045502[Chlorhexidine diacetate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED													
AGRICULTURAL/FARM EQUIPMENT/SHOE BATHS				Use Group: INDOOR NON-FOOD									
Immersion, Not on label, Not on label, Hard, Not applicable for this use	SC/L	W 154	W 154	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C04, C16, CSB, CSD
	SC/L	W 157	W 157	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C04, C16, CSB, CSD
	SC/L	W 456	W 456	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C04, C16, CSB, CSD
	SC/L	W 462	W 462	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C04, C16, CSB, CSD
Surface treatment, Not on label, Not on label, Hard, Not applicable for this use	SC/L	W 154	W 154	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C04, C16, CSB, CSD
	SC/L	W 157	W 157	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C04, C16, CSB, CSD
	SC/L	W 456	W 456	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C04, C16, CSB, CSD
	SC/L	W 462	W 462	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C04, C16, CSB, CSD
AGRICULTURAL/FARM PREMISES				Use Group: INDOOR NON-FOOD									
Animal feeding/watering equipment treatment, Not on label, Not on label, Hard, Not applicable for this use	SC/L	W 154	W 154	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C04, C16, CSB, CSD
	SC/L	W 157	W 157	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C04, C16, CSB, CSD
	SC/L	W 456	W 456	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C04, C16, CSB, CSD

APPENDIX A REPORT

Case 3038[Chlorhexidine derivs.] Chemical 045502[Chlorhexidine diacetate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
AGRICULTURAL/FARM PREMISES (con't)				Use Group: INDOOR NON-FOOD (con't)									
	SC/L	W 462	W 462	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C04, C16, CSB, CSD
Surface treatment, Not on label, Not on label, Hard, Not applicable for this use	SC/L	W 154	W 154	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C04, C16, CSB, CSD
	SC/L	W 157	W 157	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C04, C16, CSB, CSD
	SC/L	W 456	W 456	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C04, C16, CSB, CSD
	SC/L	W 462	W 462	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C04, C16, CSB, CSD
EGG HANDLING EQUIPMENT (COMMERCIAL)				Use Group: INDOOR NON-FOOD									
Fog, Not on label, Fogger, Hard, Not applicable for this use	SC/L	W 157	W 157	*	NS	NS	NS	NS	NS	NS			A06, A08, A10(10), A40, C17
Soak, Not on label, Not on label, Hard, Not applicable for this use	SC/L	W 157	W 157	*	NS	NS	NS	NS	NS	NS			A06, A08, A10(10), A40, C17
EGG HANDLING ROOMS (COMMERCIAL)				Use Group: INDOOR NON-FOOD									
Fog, Not on label, Fogger, Hard, Not applicable for this use	SC/L	W 157	W 157	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C17
Surface treatment, Not on label, Not on label, Hard, Not applicable for this use	SC/L	W 157	W 157	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C17
EGG PACKING PLANTS (COMMERCIAL)				Use Group: INDOOR NON-FOOD									
Fog, Not on label, Fogger, Hard, Not applicable for this use	SC/L	W 157	W 157	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C17

APPENDIX A REPORT

Case 3038[Chlorhexidine derivs.] Chemical 045502[Chlorhexidine diacetate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop cycle	/year	Max. Rate unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
EGG PACKING PLANTS (COMMERCIAL) (con't)				Use Group: INDOOR NON-FOOD (con't)									
Surface treatment, Not on label, Not on label, Hard, Not applicable for this use	SC/L	W 157	W 157	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C17
HOSPITALS/MEDICAL INSTITUTIONS PREMISES (HUMAN/VETERINARY)				Use Group: INDOOR MEDICAL									
Animal feeding/watering equipment treatment, Not on label, Not on label, Hard, Not applicable for this use	SC/L	W 154	W 154	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C04, C16, CSB, CSD
	SC/L	W 157	W 157	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C04, C16, CSB, CSD
	SC/L	W 456	W 456	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C04, C16, CSB, CSD
	SC/L	W 462	W 462	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C04, C16, CSB, CSD
Immersion, Not on label, Not on label, Hard, Not applicable for this use	SC/L	W 154	W 154	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C04, C16, CSB, CSD
	SC/L	W 157	W 157	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C04, C16, CSB, CSD
	SC/L	W 456	W 456	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C04, C16, CSB, CSD
	SC/L	W 462	W 462	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C04, C16, CSB, CSD
Surface treatment, Not on label, Not on label, Hard, Not applicable for this use	SC/L	W 154	W 154	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C04, C16, CSB, CSD
	SC/L	W 157	W 157	*	NS	NS	NS	NS	NS	NS			A08, A10(10), A40, C04, C16, CSB, CSD

APPENDIX A REPORT

Case 3038[Chlorhexidine derivs.] Chemical 045502[Chlorhexidine diacetate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
NON-FOOD/NON-FEED (con't)												
HOSPITALS/MEDICAL INSTITUTIONS PREMISES (HUMAN/VETERINARY) (con't)				**Use Group: INDOOR MEDICAL (con't)**								
	SC/L	W 456	W 456	*	NS	NS	NS	NS	NS	NS		A08, A10(10), A40, C04, C16, CSB, CSD
	SC/L	W 462	W 462	*	NS	NS	NS	NS	NS	NS		A08, A10(10), A40, C04, C16, CSB, CSD
MEAT PROCESSING PLANT EQUIPMENT (FOOD CONTACT)				**Use Group: INDOOR NON-FOOD**								
Fog, Not on label, Fogger, Hard, Not applicable for this use	SC/L	W 157	W 157	*	NS	NS	NS	NS	NS	NS		A06, A08, A10(10), A40, C17
Soak, Not on label, Not on label, Hard, Not applicable for this use	SC/L	W 157	W 157	*	NS	NS	NS	NS	NS	NS		A06, A08, A10(10), A40, C17
MEAT PROCESSING PLANT PREMISES (NONFOOD CONTACT)				**Use Group: INDOOR NON-FOOD**								
Fog, Not on label, Fogger, Hard, Not applicable for this use	SC/L	W 157	W 157	*	NS	NS	NS	NS	NS	NS		A08, A10(10), A40, C17
Surface treatment, Not on label, Not on label, Hard, Not applicable for this use	SC/L	W 157	W 157	*	NS	NS	NS	NS	NS	NS		A08, A10(10), A40, C17
POULTRY PROCESSING PLANT EQUIPMENT (FOOD CONTACT)				**Use Group: INDOOR NON-FOOD**								
Fog, Not on label, Fogger, Hard, Not applicable for this use	SC/L	W 157	W 157	*	NS	NS	NS	NS	NS	NS		A06, A08, A10(10), A40, C17
Soak, Not on label, Not on label, Hard, Not applicable for this use	SC/L	W 157	W 157	*	NS	NS	NS	NS	NS	NS		A06, A08, A10(10), A40, C17
POULTRY PROCESSING PLANT PREMISES (NONFOOD CONTACT)				**Use Group: INDOOR NON-FOOD**								
Fog, Not on label, Fogger, Hard, Not applicable for this use	SC/L	W 157	W 157	*	NS	NS	NS	NS	NS	NS		A08, A10(10), A40, C17
Surface treatment, Not on label, Not on label, Hard, Not applicable for this use	SC/L	W 157	W 157	*	NS	NS	NS	NS	NS	NS		A08, A10(10), A40, C17

APPENDIX A REPORT

Case 3038[Chlorhexidine derivs.] Chemical 045502[Chlorhexidine diacetate]

LEGEND

Sort: Uses Eligible or Ineligible for Re-registration, Food/Feed or Non-Food/Non-Feed Uses, Alpha Site Name, Use Group Name, Alpha Application Type/Timing/Equipment Description, Formulation, Maximum Application Rate Unit/Area Quantity, Minimum Application Rate, Maximum Number of Applications at Maximum Rate, Maximum Dose per Crop Cycle or per Year, Minimum Interval Between Applications (Days), Restricted Entry Interval (Days), Allowed/Disallowed Geographical Areas, Use Limitations Codes.

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise)	: Minimum dose for a single application to a single site. System calculated. Microbial claims only.
Max. Appl. Rate (AI unless noted otherwise)	: Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose	: Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate	: Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose [(AI unless noted otherwise)/A]	: Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (days)	: Minimum Interval between Applications (days)
Restr. Entry Interv (days)	: Restricted Entry Interval (days)
PRD Report Date	: LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE

*	: Non-specific
C	: Coarse
M	: Medium
F	: Fine
O	: Others

FORMULATION CODES

SC/L	: SOLUBLE CONCENTRATE/LIQUID

ABBREVIATIONS

AN	: As Needed
NA	: Not Applicable
NS	: Not Specified (on label)
UC	: Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, --

APPLICATION RATE

DCNC	: Dosage Can Not be Calculated
No Calc	: No Calculation can be made
W	: PPM calculated by weight
V	: PPM Calculated by volume
U	: Unknown whether PPM is given by weight or by volume
cwt	: Hundred Weight
nnE-xx	: nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

USE LIMITATIONS CODES

A06 : Potable water rinse (non-residual claim).

APPENDIX A REPORT

Case 3038[Chlorhexidine derivs.] Chemical 045502[Chlorhexidine diacetate]

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USE LIMITATIONS CODES (Cont.)

A08 : Preclean claim.
A10 : __ minute(s) contact time.
A40 : For animal use premises only.
C04 : Proper ventilation required.
C16 : Remove food and animals from premises prior to treatment.
C17 : Remove or carefully protect food products and food packaging.
CSB : Do not house poultry, or other animals or employ equipment until treatment has been absorbed, set or dried.
CSD : Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case Chloehexidine diacetate covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Chloehexidine diacetate in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are 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 if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Chlorhexidine Diacetate

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	ALL	42459901
61-2A	**Start. Mat. & Mnfg. Process**	ALL	42459901
61-2B	**Formation of Impurities**	ALL	42459901
62-1	**Preliminary Analysis**	ALL	42459902
62-2	**Certification of limits**	ALL	42459902
62-3	**Analytical Method**	ALL	42459902
63-2	**Color**	ALL	42468001
63-3	**Physical State**	ALL	42468001
63-4	**Odor**	ALL	42468001
63-5	**Melting Point**	ALL	42468001
63-6	**Boiling Point**	ALL	N/A
63-7	**Density**	ALL	42468001
63-8	**Solubility**	ALL	42468001
63-9	**Vapor Pressure**	ALL	N/A
63-10	**Dissociation Constant**	ALL	N/A
63-11	**Octanol/Water Partition**	ALL	N/A
63-12	**pH**	ALL	42468001
63-13	**Stability**	ALL	42468001
63-14	**Oxidizing/Reducting Action**	ALL	42468001

Data Supporting Guideline Requirements for the Reregistration of Chlorhexidine Diacetate

REQUIREMENT		USE PATTERN	CITATION(S)
63-15	**Flammability**	ALL	N/A
63-16	**Explodability**	ALL	42468001
63-17	**Storage Stability**	ALL	42468001
63-18	**Viscosity**	ALL	N/A
63-19	**Miscibility**	ALL	N/A
63-20	**Corrosion Characteristics**	ALL	42468001
63-21	**Dielectric Breakdown Volt**	ALL	N/A
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	ALL	42197501
71-2A	**Avian Dietary - Quail**	ALL	42197502
71-2B	**Avian Dietary - Duck**	ALL	42197503
72-1A	**Fish Toxicity Bluegill**	ALL	42197505
72-1C	**Fish Toxicity Rainbow Trout**	ALL	42197504
72-2A	**Invertebrate Toxicity**	ALL	42197506
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	ALL	**42706701**
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	ALL	**42706702**
81-3	**Acute Inhalation Toxicity - Rat**	ALL	**42684201**
81-4	**Primary Eye Irritation - Rabbit**	ALL	**42706704**
81-5	**Primary Dermal Irritation - Rabbit**	ALL	**42706705**

Data Supporting Guideline Requirements for the Reregistration of Chlorhexidine Diacetate

REQUIREMENT		USE PATTERN	CITATION(S)
81-6	**Dermal Sensitization - Guinea Pig**	ALL	**42706706**
81-7	**Acute Delayed Neurotoxicity - Hen**	ALL	**WAIVED**
82-1A	**90-Day Feeding - Rodent**	ALL	**WAIVED**
82-1B	**90-Day Feeding - Non-rodent**	ALL	**WAIVED**
82-2	**21-Day Dermal - Rabbit/Rat**	ALL	**WAIVED**
82-3	**90-Day Dermal - Rodent**	ALL	**40952201**
83-3A	**Developmental Toxicity - Rat**	ALL	**42102101**
84-2A	**Gene Mutation (Ames Test)**	ALL	**40231005**
84-2B	**Structural Chromosomal Aberration**	ALL	**40231004**
84-4	**Other Genotoxic Effects**	ALL	**40231003**
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
233	**Estimation of Dermal Exposure at Indoor Sites**	ALL	**41412201, 41742601, 42587501**
234	**Estimation of Inhalation Exposure at Indoor Sites**	ALL	**41412201, 41742601, 42587501**
ENVIRONMENTAL FATE			
160-5	**Chemical Identity**	ALL	42459901

GUIDE TO APPENDIX C

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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MRID	CITATION
00058615	Foulkes, D.M. (1973) Some toxicological observations on Chlorhexidine. Journal of Periodontal Research 8(Suppl. 12):55-57. (Also In unpublished submission received Feb 20, 1981 under 2097-12; submitted by Beecham Laboratories, Bristol, Tenn.; CDL:244436-D)
00063591	Fort Dodge Laboratories (1955) Experiments, Clinical Trials Indicating Safety. (Unpublished study received Jun 6, 1955 under unknown admin. no.; CDL:110210-A)
40230903	Myhr, B. (1983) Primary Rat Hepatocyte Unscheduled DNA Synthesis Assay: Chlorhexidine Hydrochloride: Final Report. Unpublished study prepared by Litton Bionetics, Inc. 15 p.
40230904	Farrow, M. (1983) In-vitro Chromosome Aberrations in Chinese Hamster Ovary Cells Assay with Chlorhexidine Hydrochloride: Final Report: Hazleton Project No. 2191-101. Unpublished study prepared by Hazleton Laboratories America. 24 p.
40230905	Cifone, M. (1984) Mouse Lymphoma Forward Mutation Assay: Chlorhexidine Hydrochloride: LBI Project No. 20989. Unpublished study prepared by Litton Bionetics, Inc. 24 p.
40231001	Kuzdas, C.; Frinch, R.(1980) Ames--Salmonella/Microsome Mutagenicity Test: Chlorhexidine Diacetate: Laboratory Project No.: 728366: 748579. Unpublished study prepared by Raltech Scientific Service. 18 p.
40231002	Farrow, M. (1982) Mouse Lymphoma Forward Mutation Assay: Chlorhexidine Hydrochloride: Hazleton Project No. 2191-100. Unpublished study prepared by Hazleton Laboratories America. 18 p.
40231003	Myhr, B. (1983) Primary Rat Hepatocyte Unscheduled DNA Synthesis Assay: Chlorhexidine Hydrochloride: LBI Project No. 20991. Unpublished study prepared by Litton Bionetics, Inc. 15 p.
40231004	Farrow, M. (1983) In-vitro Chromosome Aberrations in Chinese Hamster Ovary Cells Assay: Chlorhexidine Hydrochloride: Hazleton Project No. 2191-101. Unpublished study prepared by Hazleton Laboratories America. 24 p.
40231005	Cifone, M. (1984) Mouse Lymophoma Forward Mutation Assay: Chlorhexidine Hydrochloride: LBI Project No. 20989. Unpublished study prepared by Litton Bionetics, Inc. 24 p.

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40231103	Myhr, B. (1983) Primary Rat Hepatocyte Unscheduled DNA Synthesis Assay Using Chlorhexidine Hydrochloride: LBI Project No. 20991. Unpublished study prepared by Litton Bionetics, Inc. 15 p.
40853001	Henwood, S. (1988) Range-finding Teratology Study with Chlorhexidine Acetate in Rats: Final Report: Laboratory Project ID: HLA 6247-100. Unpublished study prepared by Hazleton Laboratories America, Inc. 55 p.
40853101	Henwood, S. (1988) Range-finding Teratology Study with Chlorhexidine Acetate in Rats: Final Report: Laboratory Project ID: HLA 6247-100. Unpublished study prepared by Hazleton Laboratories America, Inc. 55 p.
40853201	Henwood, S. (1988) Range-finding Teratology Study with Chlorhexidine Acetate in Rats: Laboratory Project ID HLA 6247-100. Unpublished study prepared by Hazleton Laboratories America, Inc. 55 p.
40952201	Henwood, S. (1988) 13-Week Dermal Toxicity Study with Chlorhexidine Acetate in Rabbits: Final Report: Laboratory Project ID HLA 6247-102. Unpublished study prepared by Hazleton Laboratories America, Inc. 283 p.
40964201	Henwood, S. (1988) Teratology Study with Chlorhexidine Acetate in Rats: Laboratory Project ID HLA 6247-101. Unpublished study prepared by Hazleton Laboratories America, Inc. 179 p.
42102101	Lamb, I. (1991) A Developmental Toxicity Study of Chlorhexidine Diacetate in Rats: Final Report: Lab Project Number: WIL-173001. Unpublished study prepared by WIL Research Labs. 361 p.
42197501	Campbell, S.; Grimes, J.; Smith, G.; et al. (1991) Chlorhexidine Diacetate: An Acute Oral Toxicity Study with the Northern Bobwhite: Lab Project Number: 277-103. Unpublished study prepared by Wildlife Interntional, Ltd. 20 p.
42197502	Long, R.; Hoxter, K.; Smith, G.; et al. (1991) Chlorhexidine Diacetate: A Dietary LC50 Study with the Northern Bobwhite: Lab Project Number: 277-101. Unpublished study prepared by Wildlife International, Ltd. 26 p.
42197503	Long, D.; Hoxter, K.; Smith, G.; et al. (1991) Chlorhexidine Diacetate: A Dietary LC50 Study With The Mallard: Lab Project Number: 277-102. Unpublished study prepared by Wildlife International, Ltd. 25 p.
42197504	Murphy, D.; Smith, G. (1991) Chlorhexidine Diacetate: A 96-Hour Static Acute Toxicity Test With The Rainbow Trout (Oncorhynchus Mykiss): Lab

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MRID	CITATION
	Project Number: 277A-101. Unpublished study prepared by Wildlife International, Ltd. 28 p.
42197505	Murphy, D.; Smith, G. (1991) Chlorhexidine Diacetate: A 96-Hour Static Acute Toxicity Test With The Bluegill (Lepomis Macrochirus): Lab Project Number: 277A-102. Unpublished study prepared by Wildlife International, Ltd. 28 p.
42197506	Murphy, D.; Smith, G. (1991) Chlorhexidine Diacetate: A 48-Hour Static Acute Toxicity Test With The Cladoceran (Daphnia Magna): Lab Project Number: 227A-103. Unpublished study prepared by Wildlife International, Ltd. 29 p.
42442601	Wood, C. (1991) Freeze/Thaw Study for Nolvasan-S: Lab Project Number: 3639. Unpublished study prepared by Fort Dodge Laboratories. 13 p.
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42468001	Walzer, E. (1992) Chlorhexidine Diacetate (CHAC): Physical and Chemical Characteristics. Unpublished study prepared by Degussa AG. 9 p.
42633201	Reagan, E. (1989) Acute Oral Toxicity Study of Chlorhexidine Acetate in Sprague-Dawley Rats: Lab Project Number: 89.1810.003. Unpublished study prepared by Food and Drug Research Labs. 77 p.
42684201	Shapiro, R. (1993) EPA Acute Inhalation Toxicity--Defined LC50: Chlorohexidine-Diacetate: Lab Project Number: T-1813. Unpublished study prepared by Product Safety Labs. 37 p.
42706701	Miller, E. (1993) Acute Oral Toxicity Evaluation of Chlorhexidine Diacetate Technical in Rats: Lab Project Number: 9096-92: P952-1: KVR-P952-1. Unpublished study prepared by Stillmeadow, Inc. 70 p.

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42706703	Miller, E. (1993) Acute Inhalation Toxicity Evaluation of Chlorhexidine Diacetate Technical in Rats: Lab Project Number: 9098-92: KVP-P952-3. Unpublished study prepared by Stillmeadow Inc. 113 p.
42706704	Miller, E. (1993) Primary Eye Irritation Evaluation of Chlorhexidine Diacetate Technical in Rabbits: Lab Project Number: 9099-92: KVP-P952-4. Unpublished study prepared by Stillmeadow Inc. 60 p.
42706705	Miller, E. (1993) Primary Dermal Irritation Evaluation of Chlorhexidine Diacetate Technical in Rabbits: Lab Project Number: 9100-92:KVR-P952-5. Unpublished study prepared by Stillmeadow Inc. 50 p.
42706706	Miller, E. (1993) Evaluation of Sensitization Potential of Chlorhexidine Diacetate Technical in Guinea Pigs: Lab Project Number: 9101-92: KVP-P952-6. Unpublished study prepared by Stillmeadow Inc. 58 p.
42707001	White, W. (1993) Chlorhexidine Acetate Ph Eur Chemistry and Pharmacy Data: Lab Project Number: 2/IC/US/1000502. Unpublished study prepared by Zeneca Pharmaceuticals. 32 p.
43438501	Rhodes, M. (1994) Chlorhexidine Acetate Product Identity. Unpublished study prepared by Zeneca Pharmaceuticals. 6 p.
43438502	Rhodes, M. (1994) Description of Starting Materials and Manufacturing Process and Discussion of the Formation of Impurities for Chlorhexidine Acetate. Unpublished study prepared by Zeneca Pharmaceuticals. 15 p.
43438503	Rhodes, M. (1994) Chlorhexidine Acetate: Preliminary Analysis, Certified Limits and Analytical Methods. Unpublished study prepared by Zeneca Pharmaceuticals. 15 p.
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93065001	Henwood, S. (1990) Fort Dodge Laboratories Phase 3 Summary of MRID 40952201. 13-Week Dermal Toxicity Study with Chlorhexidine Acetate in Rabbits: HLA 6247-102. Prepared by Hazleton Laboratories America, Inc. 21 p.

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93065002	Henwood, S. (1990) Fort Dodge Laboratories Phase 3 Summary of MRID 40853101. Range-Finding Teratology Study with Chlorhexidine Acetate in Rats: HLA 6247-100. Prepared by Hazleton Laboratories America, Inc. 19 p.
93065003	Henwood, S. (1990) Fort Dodge Laboratories Phase 3 Summary of MRID 40964201. Teratology Study with Chlorhexidine Acetate in Rats: HLA 6247-101. Prepared by Hazleton Laboratories America, Inc. 28 p.
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93065005	Farrow, M. (1990) Fort Dodge Laboratories Phase 3 Summary of MRID 40230904. In-vitro Chromosome Aberrations in Chinese Hamster Ovary Cells Assay: Project No. 2191-101. Prepared by Hazleton Laboratories America. 15 p.
93065006	Myhr, B. (1990) Fort Dodge Laboratories Phase 3 Summary of MRID 40230903. Primary Rat Hepatocyte Unscheduled DNA Synthesis Assay: Project No. 20991. Prepared by Litton Bionetics, Inc. 15 p.
93065007	Farrow, M. (1990) Fort Dodge Laboratories Phase 3 Summary of MRID 40230902. Mouse Lymphoma Forward Mutation Assay: Project No. 2191-100. Prepared by Hazleton Laboratories America. 15 p.
93065008	Cifone, M. (1990) Fort Dodge Laboratories Phase 3 Summary of MRID 40230905. Mouse Lymphoma Forward Mutation Assay: Project No. 20989. Prepared by Litton Bionetics, Inc. 15 p.

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 6; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of product specific data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 03-31-96).

This Notice is divided into six sections and six Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I - Why You Are Receiving This Notice
Section II - Data Required By This Notice
Section III - Compliance With Requirements Of This Notice
Section IV - Consequences Of Failure To Comply With This Notice
Section V - Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI - Inquiries And Responses To This Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
4 - List of Registrants Receiving This Notice
5 - Cost Share and Data Compensation Forms

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form, within the time frames provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this notice or (c) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, Attachment 2 and Attachment 3. The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form in Attachment 2). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form. If you choose this option, this is the only form that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select item number 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified time frame (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the

request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless

you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " 'raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70

which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5, Upgrading a Study -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies

generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, as appropriate.

III-D REQUESTS FOR DATA WAIVERS

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

   a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form;

   b. fulfill the commitment to develop and submit the data as required by this Notice; or

   c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited

to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form and a completed Requirements Status and Registrant's Response Form (Attachment 2 and Attachment 3 for product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form need be submitted.

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
4 - List of Registrants Receiving This Notice
5 - Cost Share and Data Compensation Forms and the Confidential Statement of Formula Form

CHLOEHEXIDINE DIACETATE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing Chloehexidine diacetate.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of Chloehexidine diacetate. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this Chloehexidine diacetate Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for Chloehexidine diacetate are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Chloehexidine diacetate are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible Chloehexidine diacetate products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact C.P. Moran at (703) 308-8590.

All responses to this Notice for the Product Specific data requirements should be submitted to:

C.P. Moran
Chemical Review Manager Team 81
Product Reregistration Branch
Special Review and Reregistration Branch 7508W
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **Chloehexidine diacetate**

INSTRUCTIONS FOR COMPLETING THE **DATA CALL-IN RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-4. Already completed by EPA.

Item 5. If you wish to **voluntarily cancel** your product, answer "**yes**." If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)**; you would **not** complete the "Requirements Status and Registrant's Response" form. Examples of such products include **repackaged** products and **Special Local Needs (Section 24c)** products which are identical to federally registered products.

Item 7a. For each **manufacturing use product** (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**."

Item 7b. For each **end use product** (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**." If you are requesting a **data waiver**, answer "**yes**" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with **Option 7** (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

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INSTRUCTIONS FOR COMPLETING THE **REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-3 Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.

Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. It is normally based on **8 months after issuance of the Reregistration Eligibility Document** unless EPA determines that a longer time period is necessary.

Item 9. **Enter only one of the following response codes for each data requirement to show how you intend to comply with the data requirements listed in this table.** Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is

committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed "**Certification of Offer to Cost Share in the Development Data" form**. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two

completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

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This page is removed and page 4 of the sample Product Specific DCI is inserted here.

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EPA'S BATCHING OF CHLORHEXIDINE PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing chlorhexidine as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwith-standing the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or

Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Two products were found which contain chlorhexidine as an active ingredient, 1117-30 and 1117-48. The products have not been placed into a batch. However, data generated on 1117-48 may be used to support both products.

Table 1

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
1	13808-7	1.0	Liquid
	35975-4	1.0	Liquid
	35978-8	1.0	Liquid
	39508-2	1.0	Liquid
	46779-1	1.0	Liquid
	56228-22	1.0	Liquid

The following table lists a product that was either considered not to be similar or the Agency lacked sufficient information for decision making and were not placed in any batch. The registrant of this product is responsible for meeting the acute toxicity data requirements separately.

Table 2 (No Batch)

EPA Reg. No.	% Active Ingredient	Formulation Type
56228-26	90.0	Solid

Attachment 5. List of All Registrants Sent This Data Call-In (insert) Notice

Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

a. All the blocks on the form must be filled in and answered completely.

b. If any block is not applicable, mark it N/A.

c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.

d. All applicable information which is on the product specific data submission must also be reported on the CSF.

e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.

f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.

g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.

h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.

i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.

j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).

k. All the items under column 13.b. must total 100 percent.

1. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for ail active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*

2. Name and Address of Producer *(Include ZIP Code)*

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	13. b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	14. b. Lower Limit	15. Purpose in Formulation
16. Typed Name of Approving Official				17. Total Weight	100%			

18. Signature of Approving Official	19. Title	20. Phone No. *(Include Area Code)*	21. Date

EPA Form 8570-4 (Rev. 12-90) **Previous editions are obsolete.** If you can photocopy this, please submit an additional copy. White - EPA File Copy (original) Yellow - Applicant copy

EPA	United States Environmental Protection Agency Washington, DC 20460 **CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA**	Form Approved OMB No. 2070-0106 2070-0057 Approval Expires 3-31-96

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)	Date of Offer

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	

EPA Form 8570-32 (5/91) Replaces EPA Form 8580, which is obsolete

United States Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0107, 2070-0057
Approval Expires 3-31-96

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Please fill in blanks below.

Company Name	Company Number

Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistratiion under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(F) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are. (check one)

[ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"

3. That I have previously complied with section 3(c)(1)(F) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date

Name and Title (Please Type or Print)

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA section 3(c)(1)(F) and 3(c)(2)(D).

Signature	Date

Name and Title (Please Type or Print)

EPA Form 8570-31 (4-96)

The following is a list of available documents for Chloehexidine diacetate that my further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

Electronic
File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, GOPHER.EPA.GOV, or using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV., or contact C.P. Moran at (703)-308-8590.

1. PR Notice 86-5.

2. PR Notice 91-2 (pertains to the Label Ingredient Statement).

3. A full copy of this RED document.

4. A copy of the fact sheet for Chloehexidine diacetate.

The following documents are part of the Administrative Record for Chloehexidine diacetate and may included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet.

1. Health and Environmental Effects Science Chapters.

2. Detailed Label Usage Information System (LUIS) Report.

The following Agency reference documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet of this RED document.

1. The Label Review Manual.

2. EPA Acceptance Criteria