Rm-816, CM-2
H7509C

EXPEDITE

72-HOUR REVIEW

To: JANE SMITH, CCB

CHEMICAL(s): **169160 and 107401**

CASE NO.: **3148**

This DCI is being sent to you for a 72-hour review. Please contact Alan Dixon at one of the numbers listed below by writing, by phone or by FAX. We must hear from you within 72 hours if you have any comments/corrections **OR IF EVERYTHING IS ACCEPTABLE.**

WE MUST HEAR FROM YOU.

THANK YOU VERY MUCH FOR YOUR ASSISSTANCE.

CONTACT: **Alan Dixon** PHONE: **308-8043** FAX: **308-8773**

MAIL CODE: **H7508W**

DELIVERY DATE: 8/3/93

DUE DATE: 8/5/93

This is Jane + THOA's together.
HED concurs w/ comments... see inside
8/4/93

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-9(

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary

1. Company name and Address

2. Case # and Name
3148 Trimethoxysilyl quats
Chemical # and Name 107401
Trimethoxysilyl)propyl dimethyl octadecyl ammonium chloride

3. Date and Type of DCI
GENERIC

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-4	Odor					all		12 mos.	
63-5	Melting Point					all		12 mos.	
63-8	Solubility					all		12 mos.	
72-1(a)	Fish toxicity bluegill					CK		12 mos.	
72-1(c)	Fish toxicity rainbow trout					CKMNO		12 mos.	
72-2(a)	Invertebrate toxicity					CKMNO		12 mos.	
83-3(a)	Teratogenicity - rat		Y			CKMNO		24 mos.	
161-1	Hydrolysis					CK		12 mos.	

10. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

DRAFT - Phase 3 Submission 08/03/93

Company: 034292 *DOW CORNING CORP.*
MIDLAND, MI

Chemical: 107401 Trimethoxysilyl)propyl dimethyl octadecyl ammonium chloride

Case: 3148 EPA Manager: Margarita Collantes

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION
61-1	Chemical Identity	130316-St	Accept
61-1	Chemical Identity	164909-St	Accept
61-1	Chemical Identity	42456501-St	Denied/Def.
	Comments: This is a Confidential Statement of Formula and does not appear to fulful this guidleine requirement.		
61-1	Chemical Identity	42456508-St	Accept
	Comments: This MRID was incorrectly labeled to satisfy the 63 series guidlelines.		
61-2(a)	Begin. mat. & mnfg. proc	130316-St	Accept
61-2(a)	Begin. mat. & mnfg. proc	164909-St	Accept
61-2(a)	Begin. mat. & mnfg. proc	42456502-St	Accept
61-2(b)	Discussion of Impurities	130316-St	Accept
61-2(b)	Discussion of Impurities	164909-St	Accept
61-2(b)	Discussion of Impurities	42456502-St	Accept
62-1	Preliminary Analysis	42456507-St	Accept
62-2	Certification of limits	42456505-St	Accept

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Chemical: 107401
Company: 034292

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION
62-3	Analytical Method	42456504-St	Accept
62-3	Analytical Method	42456506-St	Accept
63-2	Color	70190-St	Accept
63-2	Color	129655-St	Accept
63-2	Color	130316-St	Accept
63-3	Physical State	70190-St	Accept
63-3	Physical State	129565-St	Accept
63-3	Physical State	130316-St	Accept
63-4	Odor		Data Gap
63-4	Odor	70190-St	Denied/Def.
63-4	Odor	42456508-St	Denied/Def.
63-5	Melting Point	N/A	Accept
	Comments: The TAGI is a liquid at room temperature.		
63-6	Boiling Point	70190-St	Accept
63-6	Boiling Point	129565-St	Accept
63-6	Boiling Point	130316-St	Accept
63-7	Density	70190-St	Accept

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Chemical: 107401
Company: 034292

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION
63-7	Density	123565-St	Accept
63-7	Density	130316-St	Accept
63-8	Solubility		Data Gap
	Comments:	The registrant must upgrade product chemistry for this guideline by reporting the amount of AI soluble in grams per 100 ml of solvent.	
63-8	Solubility	70190-St	Upgradable
63-8	Solubility	129565-St	Upgradable
63-8	Solubility	130316-St	Upgradable
63-9	Vapor Pressure	N/A	Accept
	Comments:	Not applicable. The TGAI is a reactive silane which polymerizes in the presence of moisture.	
63-10	Dissociation Constant	N/A	Accept
	Comments:	Not applicable. The TGAI is a cationic with hydrolyzable alkoxy silane functionality. As a cationic quaternary ammonium salt, the TGAI will completely ionize in an aqueous solution.	
63-11	Oct/Water partition Coef.	N/A	Accept
	Comments:	Not Applicable. The TGAI is highly polar.	

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Chemical: 107401
Company: 034292

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION
63-12	pH	70190-St	Accept
63-12	pH	130316-St	Accept
63-13	Stability		

Comments: Only thermostability was conducted showing stability of the TGAI to elevated temperatures with slow decomposition reported at 125½C. Further, exposure to ambient light showed no changes in the test substance. No stability tests were conducted, however, for metals or metal ions since, according to the registrant, packaging and use of the product does not encounter metals or metal ions.

63-13	Stability	70190-St	Accept
63-13	Stability	130316-St	Accept
63-13	Stability	42456509-St	Accept
63-13	Stability	42456510-St	Accept
63-17	Storage stability	42456510-St	Accept

Comments: The submitted storage stability for Dow Corning 5700 Antimicrobial Agent is adequate. No additional data is needed.

In the study five samples from two lots of Dow Corning 5700 Antimicrobial Agent were stored under room temperature for a period of 14 months. Analysis for total amines and the quat salt showed no changes in the contents at the conclusion of the study.

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Chemical: 107401
Company: 034292

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION
	MRID Comments Continued:		
71-1(a)	Acute avian oral quail/duck	93218033-Re	Denied/Def.
71-1(a)	Acute avian oral quail/duck	40385218-St	Denied/Def.
	Comments:	The avian acute oral LD50 study with the mallard duck was categorized as "supplemental". Although a NOEL could not be determined and birds regurgitated feed at the highest test concentration, no mortality was observed at the three lowest test concentrations and only one bird died at the second highest test level (1,500 mg/Kg). EPA will not require a new study unless registration for outdoor uses are requested.	
71-2(b)	Acute avian diet. duck	93218034-Re	Denied/Def.
71-2(b)	Acute avian diet. duck	40385217-St	Denied/Def.
	Comments:	The acute dietary LC50 study was scientifically sound but did not meet guideline requirements. This study was categorized as "supplemental" due to the failure to use properly aged birds. While this study fails to support an avian acute dietary data requirement, the Agency will not require a new study unless registration for outdoor uses are requested.	
72-1(a)	Fish toxicity bluegill		Data Gap
72-1(a)	Fish toxicity bluegill	40385202-St	Denied/Def.
	Comments:	The acute fish toxicity studies submitted were conducted at the Industrial Bio Test Laboratories,	

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Chemical: 107401
Company: 034292

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION

MRID Comments Continued:
Inc. The EPA does not accept data generated by this facility. The fish acute toxicity data were categorized as invalid, therefore this data requirement has not been fulfilled. Either the Bluegill or Rainbow Trout study will need to be repeated by a recognized facility to meet this data requirement.

72-1(c)	Fish toxicity rainbow trout		Data Gap
72-1(c)	Fish toxicity rainbow trout	40385202-St	Denied/Def.

Comments: The acute fish toxicity studies submitted were conducted at the Industrial Bio Test Laboratories, Inc. The EPA does not accept data generated by this facility. The fish acute toxicity data were categorized as invalid, therefore this data requirement has not been fulfilled. Either the Bluegill or Rainbow Trout study will need to be repeated by a recognized facility to meet this data requirement.

72-2(a)	Invertebrate toxicity		Data Gap
72-2(a)	Invertebrate toxicity	93218037-Re	Denied/Def.
72-2(a)	Invertebrate toxicity	40385215-St	Denied/Def.

Comments: The acute invertebrate toxicity study was categorized as "supplemental". The study does not fulfill guideline requirements for an invertebrate acute toxicity study, and a new study will be

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Chemical: 107401
Company: 034292

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION

MRID Comments Continued:
required for the current use.

81-1 Acute oral tox. rat 40385201-St Accept

Comments: A summary of MRID 40385201 was submitted to the Agency. This study was previously reviewed and graded core Minimum. The following deviations were noted: 1) individual observations done on day 1, 7 and 14; and 2) gross necropsy not done. However, due to the high LD50 (12.27 g/kg) it is not necessary to repeat the study and it remains graded core Minimum.

81-1 Acute oral tox. rat 42456511-St Pending

Comments: This study is tentatively accepted for review.

81-2 Acute dermal tox. rabbit/rat

Comments: A study (summary) with the 72% formulation (tested to limit dose) was submitted by ~~YRK~~ FMC. This study is acceptable for review.

Note: Once the Registrant officially submits this study a MRID No. will be assigned.

81-2 Acute dermal tox. rabbit/rat 41339402-St

Comments: This is a 14-day rangefinding study for dermal toxicity in rats.
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Chemical: 107401
Company: 034292

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION

MRID Comments Continued:
The following deviations exist:
1) 2 animals/sex/group (5 animals/sex/group);
2) animals dosed for five consecutive days a week for fourteen days (Dosing, single dermal); and
3) material left in contact for a period of 6 hours/day, 5 days per week. The highest dose group tested was 1,000 mg/kg/day. The material was suspended in propylene glycol.

81-2 Acute dermal tox. rabbit/rat 42456512-St

Comments: This submission was reviewed with MRID 41339402. Please see the comments for MRID 41339402.

81-3 Acute inhal. tox rat 40385219-St Denied/Def.

Comments: This study is unacceptable for review

81-3 Acute inhal. tox rat 93218038-Re Accept

81-3 Acute inhal. tox rat 41157803-St Accept

Comments: Summary of MRID 41157803 previously submitted and reviewed by the Agency. The study was graded core Suplimentary, and was upgradable if the purity was supplied. This summary states the purity to be 72.1%. The Registrant supplied additional information by ~~vax~~ FAX that allows this study to be upgraded to core Minimum.

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Chemical: 107401
Company: 034292

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION
	MRID Comments Continued:		
81-4	Primary eye irration-rabbit	40385201-St	Accept
	Comments: Summary of MRID 40385201 previously submitted and reviewed by the Agency, and graded core Minimum. The following minor deviation was noted: left eye washed within 30 seconds of dosing and right eye washed 1 hour post dosing (24 hours required in guideline).		
81-4	Primary eye irration-rabbit	41157801-St	Denied/Def.
	Comments: Summary of MRID 41157801 previously submitted to the Agency. The following deviations were noted: 1) only 1 rabbit used (guideline requires 6); and 2) left eye washed within 30 seconds of dosing and right eye washed 1 1/2 hours post dosing (24 hours required in guideline). The study is Core Supplemental and not upgradable.		
81-4	Primary eye irration-rabbit	41157802-St	Denied/Def.
	Comments: Summary of MRID 41157802 previously submitted to the Agency. The following deviations were noted: 1) only 1 rabbit used (guideline requires 6); and 2) left eye washed within 30 seconds of dosing and right eye washed 1 1/2 hours post dosing (24 hours required in guideline). The study is Core Supplemental and not upgradable.		
81-5	Primary dermal irritation	40385201-St	Denied/Def.
	Comments: Summary of MRID 40385201 previously submitted and		

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Chemical: 107401
Company: 034292

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION

MRID Comments Continued:
reviewed by the Agency, and core graded Supplementary. The Agency requested, "...clarification as to the method of application prior to coming to a conclusion with regard to this study." Also from the summary a number of deviations from the guideline were noted and this study cannot be ungraded.

81-5 Primary dermal irritation 41157801-St Denied/Def.

Comments: Summary of MRID 411157801 previously submitted to the Agency. A number of deviations were noted: 1) only one animal per dose level; 2) amount applied was between three sites (Guidelines: dosing, single dermal); 3) duration of exposure was 14 days (Guidelines: dosing duration 4 hours);and 4) test material was not removed nor washed with water. This study is Supplementary and not upgradable.

81-5 Primary dermal irritation 41157802-St Denied/Def.

Comments: Summary of MRID 411157802 previously submitted to the Agency. A number of deviations were noted: 1) only one animal per dose level; 2) amount applied was between three sites (Guidelines: dosing, single dermal); 3) duration of exposure was 14 days (Guidelines: dosing duration 4 hours);and 4) test material was not removed nor washed with water. This study is Supplementary and not upgradable.

81-5 Primary dermal irritation 42456513-St Pending

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Chemical: 107401
Company: 034292

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION
	Comments: This study is tentatively acceptable for review.		
81-6	Dermal sensitization	42197401-St	Pending
	Comments: This study is tentatively acceptable for review.		
82-3	90-day dermal-rodent	41339403-St	Pending
	Comments: This study is tentatively acceptable for review.		
83-3(a)	Teratogenicity - rat		Data Gap
83-3(a)	Teratogenicity - rat	41438002-St	~~Upgradable~~ NOT UPGRADABLE
	Comments: This is a rangefinding study. See comments for MRID # 41438003.		
83-3(a)	Teratogenicity - rat	41438003-St	NOT UPGRADABLE ~~Upgradable~~
	Comments: Summary of MRID 41438003 previously submitted and reviewed by the Agency, was graded core Supplementary. This study is upgradable by identification of compound purity.		
83-3(a)	Teratogenicity - rat	42456514-St	Upgradable
	Comments: MRID# 42456514 is a revision of MRID# 41438002.		

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Chemical: 107401
Company: 034292

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION
	MRID Comments Continued:		
83-3(a)	Teratogenicity - rat	42456515-St	Upgradable
	Comments: MRID# 42456515 is a revision of MRDI# 41438003.		
84-2(a)	Gene mutation-~~ames~~	41296801-St	Pending
	Comments: MRID's 42456518, 41353302, 41353301, 41296801 Mouse Lymphoma. This study is tentatively ready for review. FORWARD MUTATION ASSAY		
84-2(a)	Gene mutation-~~ames~~	41353301-St	Pending
	Comments: MRID's 42456518, 41353302, 41353301, 41296801 Mouse Lymphoma. This study is tentatively ready for review.		
84-2(a)	Gene mutation-~~ames~~	42456516-St	Pending
	Comments: MRID's 42456516, 42456519 BACTERIAL Reverse Mutation. This study is tentatively ready for review.		
84-2(a)	Gene mutation-~~ames~~	42456519-St	Pending
	Comments: MRID's 42456516, 42456519 BACTERIAL Reverse Mutation. This study is tentatively ready for review.		
84-2(a)	Gene mutation-~~ames~~	42465618-St	Pending

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Chemical: 107401
Company: 034292

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION
	Comments: MRID's 42456518, 41353302, 41353301, 41296801 Mouse Lymphoma. This study is tentatively ready for review.		
84-2(a)	Gene mutation-ames	93218039-Re	Pending
84-2(a)	Gene mutation-ames	28990-St	Pending
84-2(a)	Gene mutation-ames	93218040-Re	Pending
84-2(a)	Gene mutation-ames	41353302-St	Pending
	Comments: MRID's 42456518, 41353302, 41353301, 412976801 Mouse Lymphoma. This study is tentatively ready for review.		
84-4 ~~84-2(a)~~	Other Genotoxic Effects ~~Gene mutation-ames~~	93218045-Re	NOT ACCEPTABLE (for REVIEW) Pending
84-4 ~~84-2(a)~~	Other Genotoxic Effects ~~Gene mutation-ames~~	40385213-St	~~Pending~~ UNACCEPTABLE
84-2(b)	Struct. chrom. aberration	41296802-St	Pending
	Comments: This study is tentatively acceptable for review.		
84-2(b)	Struct. chrom. aberration	42456517-St	Pending
	Comments: This is a revision of MRID 41296803 02?, IN VIVO mouse micronucleus. This study is tentatively acceptable for review.		
84-4	Other genotoxic effects	41296804-St	Pending

NOT in Phase 4 review

DRAFT - Phase 3 Submission 08/03/93

Chemical: 107401
Company: 034292

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION

Comments: This study is tentatively acceptable for review. (unscheduled DNA Synthesis Assay in Rat Hepatocyte)

84-4 Other genotoxic effects 93218039-Re UNACCEPTABLE for Review

84-4 Other genotoxic effects 40385212-St Denied/Def.

Comments: Reformat of 00028990 (40385212) previously submitted and reviewed by the Agency, and graded Not Acceptable. The following deficiencies were noted in the original review: 1) actual doses not provided; 2) number of replicate plating at each level does not represent an adequate statistical sample; 3) exposure time of 24 hours to short (3 days recommended); 4) procarcinogen instead of a direct acting agent should have been used; and 5) a quality assurance/GLP form was missing. The reformat does not adequately address these issues. This study is unacceptable for review.

84-4 Other genotoxic effects 93218045-Re unacceptable for review

84-4 Other genotoxic effects 40385213-St Denied/Def.

Comments: Reformat of MRID No. 40385213 previously submitted and reviewed by the Agency, and core graded Not Acceptable. The following deficiencies existed in the original report: 1) exposure time of 2 hours is smaller than the normal 3 days; and 2) Actual doses not reported. The reformat does not adequately address these issues. The study is unacceptable for review.

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Chemical: 107401
Company: 034292

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION

MRID Comments Continued:

85-1 General metabolism

Comments: This study is currently not required. It is reserved and may be triggered depending on ~~Teir~~ Tier 1 study results.

85-1 General metabolism 93218041-Re Denied/Def.

85-1 General metabolism 57346-St Denied/Def.

Comments: Although submitted as a summary (93218031) of MRID No. 00057346, this is actually a dermal absorption study (see 85-2). In addition, a reformat (93218041) of MRID No. 00057346 was submitted. A number of deficiencies were noted in the supplied summary, including: 1) 3 animals per sex per group; 2) only one dose for dermal (66.5 ug) and intravenous (69.4 ug). This study is not acceptable for review as a 85-1 Metabolism study. The study was requested by Toxicology Branch to determine the percutaneous absorption of the active agent in rabbits. The study is actually a dermal absorption study. Currently not required.

85-2 Dermal penetration

Comments: This study is currently not required. It is reserved and may be triggered depending on ~~Teir~~ Tier 1 study results.

85-2 Dermal penetration 57346-St? Upgradable

93218023, 40385216, 00057346

DRAFT - Phase 3 Submission 08/03/93

Chemical: 107401
Company: 034292

GDLN #	DESCRIPTION	REGISTRANT'S COMPLIANCE/MRID	EPA DECISION

Comments: Summary of Accession No. 244089 previously reviewed by the Agency, and graded core Supplementary. The following information was requested at the time of the review:
1) control animal tissue backgrounds will be necessary to evaluate possible ^{14}C activity in the p. cut. and i. v. group tissues; 2) additional control tissue background needed; and 3) untreated cloth collar digestant background should be submitted. The study may be upgradable with the requested information. However, this study is currently not required.

^{14}C (carbon 14)

161-1 Hydrolysis Data Gap

Comments: The Agency requires a hydroloysis study because this is an industrial microbiocide covered by a National Pollutant Discharge Elimination System permit.

171-4(c) Res. analyt. method - plant

Comments: These studies and their reformats are on the durabilty of this product on textiles. This data will be reviewed in Phase 5.

171-4(c)	Res. analyt. method - plant	93218042-Re	Pending
171-4(c)	Res. analyt. method - plant	40385214-St	Pending
171-4(c)	Res. analyt. method - plant	93218043-Re	Pending

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-9

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary

1. Company name and Address	2. Case # and Name 3148 Trimethoxysilyl quats Chemical # and Name 169160 Didecyl-N-methyl-3-(trimethoxysilyl) propanaminium chloride	3. Date and Type of DCI GENERIC

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
62-1	Preliminary Analysis					all		12 mos.	
62-2	Certification of limits					all		12 mos.	
63-8	Solubility					all		12 mos.	
63-13	Stability					all		12 mos.	
72-1(d)	Fish toxicity rainbow trout-TEP					MNO		12 mos.	
72-2(a)	Invertebrate toxicity					MNO		12 mos.	
83-3(a)	Teratogenicity - rat		Y			MNO		24 mos.	
84-2(a)	Gene mutation-ames					MNO		12 mos.	
84-2(b)	Struct. chrom. aberration					MNO		12 mos.	
161-1	Hydrolysis							12 mos.	

10. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

Page ___ is not included in this copy.

Pages 20 through 32 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

X The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

R109743

13544

R109743

Chemical:	**1-Octadecanaminium, N,N-dimethyl-N-(3-(t**
PC Code:	**107401**
HED File Code	**13000 Tox Reviews**
Memo Date:	**08/05/1993**
File ID:	**00000000**
Accession Number:	**412-05-0095**

HED Records Reference Center
06/13/2005