8e98(1)EA

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[ ]

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August 7, 1998

Document Processing Center
(Attn: Section 8(e) Coordinator) Mail Code 7407
Office of Pollution Prevention and Toxic Substances
U.S. Environmental Protection Agency
401 "M" St., S.W.
Washington, D.C. 20460

COMPANY SANITIZED

Dear Section 8(e) Coordinator:

This letter is to notify the Agency of fish toxicity test data which suggest that [ ], is a substance of high concern in the aquatic environment.

This information was located during the process of revising the MSDS of the product, while reviewing reports of toxicological studies, provided by [ ] for the purpose, on August 5, 1998.

Chemical Description:

CASRN: 1541-67-9

CBI status: CONFIDENTIAL

Usage pattern:

This substance is not intended for large volume use or release to the environment. It is a non-ionic surfactant used as an [ ]

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Please find attached, the report for test performed [ ] by Huntingdon Laboratories.

Additional Information : Biodegradation
Assessment of Ready Biodegradability performed by the Modified Sturm Test (Huntingdon Laboratories) suggests that this product is inherently degradable. Test results showed >20% degradation after 29 days. The entire study will be made available upon request.

The submission of the attached information is part of [ ] good faith effort to comply with requirements under TSCA Section 8(e).

Sincerely,

[ ]

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SUBSTANTIATION OF CONFIDENTIALITY

[ ]

Substantiation Questions and Answers:

1. Is your company asserting this confidential business information (CBI) claim on its own behalf? If the answer is no, please provide company name, address and telephone number of entity asserting claim.

[

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2. For what period do you assert your claim(s) of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why such information should remain confidential until such point.
No time limit.

3. Has the information that you are claiming as confidential been disclosed to any other governmental agency, or to this Agency at any other time: Identify the Agency to which the information was disclosed and provide the date and circumstances of the same. Was the disclosure accompanied by a claim of confidentiality? If yes, attach a copy of said document reflecting the confidentiality agreement.

No, not in the U.S.

4. Briefly describe any physical or procedural restrictions within your company relating to the use and storage of the information you are claiming CBI.

In [ ] and the U.S., [ ] has strict security procedures regarding individuals entering the site where intellectual property records are maintained. Only individuals with proper identification and authorization are allowed to enter. Proprietary records are kept in restricted areas, which are kept locked. Computers are security protected.

5. If anyone outside your company has access to any of the information claimed CBI, are they restricted by confidentiality agreement(s). If so, explain the content of the agreement(s).

Not applicable.

6. Does the information claimed as confidential appear or is it referred to in any of the following:

a. Advertising or promotional material for the chemical substance or the resulting end product: No

b. Material safety data sheets or other similar materials (such as technical data sheets) for the substance or resulting end product (include copies of this information as it appears when accompanying the substance and/or product at the time of transfer or sale);
No

c. Professional or trade publications: No

d. Any other media or publications available to the public or to your competitors. No

If you answered yes to any of the above, indicate where the information appears, include copies, and explain why it should nonetheless be treated as confidential. Not applicable

7. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? If so, provide copies of such determinations.

No.

8. Describe the substantial harmful effects that would result to your competitive position if the CBI information is made available to the public? In your answer, explain the causal relationship between disclosure and any resulting substantial harmful effects. Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes and competitors access to your customers. Address each piece of information claimed CBI separately.

[ ] has made a significant investment in researching the substance and it's performance for the specific purpose. If competitors were to learn that [ ] a respected name in surfactant development, has found this substance to be effective for the stated purpose, the result would be that the competitors too would enter the market and [ ] would lose its intended market position.

9. Has the substance been patented in the U.S. or elsewhere? Is a patent or the substance currently pending?

No.

10. Is the substance/product commercially available and if so, for how long has it been available on the commercial market?

Yes. This substance is available in the U.S. market from various sources, and has been for many years. However the application developed by [ ] is innovative.

a. If on the commercial market, are your competitors aware that the substance is commercially available in the U.S.?

Yes, but not specifically identified under the Kao tradename.

b. If not already commercially available, describe what stage of research and development (R&D) the substance is in, and estimate how soon a market will be established.

Market is now being developed.

c. What is the substance used for and what type of product(s) does it appear in.

[ ]

11. Describe whether a competitor could employ reverse engineering to identically recreate the substance?

Not applicable . The concern is that [ ] would like to protect the fact that they are marketing this specific substance for this specific use.

12. Do you assert that disclosure of this information you are claiming CBI would reveal:

a. confidential processes used in manufacturing the substance;
No

b. If a mixture, the actual portions of the substance in the mixture; or
It would be used at a concentration of [ ]

c. information unrelated to the effects of the substance on human health or the environment? Yes.

If your answer to any of the above questions is yes, explain how such information would be revealed.

The information would be revealed on the MSDS developed for the product.

13. Provide the chemical Abstract Service Registry Number for the product, if know. is your company applying for a CAS number now or in the near future? If you have applied for a CAS number, include a copy of the contract with CAS.

CASRN: 1541-67-9

14. Is the substance or any information claimed CBI the subject of FIFRA regulation or reporting? If so explain.

No. But it is allowable for use as an inert substance for pesticides.

Material Name: [ ]

Material Safety Data Sheet

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* * * Section 1 - Chemical Product and Company Identification * * *

Chemical Name: Specific nonionic surfactant

Manufacturer Information

[ ]

Phone: [ ]

Emergency # CHEMTREC: 1-800-424-9300

Distributor/Contact Information

Resource Code: Not available

[ ]

Phone: US: [ ]

Emergency # CHEMTREC: 1-800-424-9300

* * * Section 2 - Composition / Information on Ingredients * * *

CAS #	Component	Percent
	Alkyl amine derivative	>70

Component Information/Information on Non-Hazardous Components

Component(s) of this product are considered to be hazardous by the manufacturer's determination. See Section 15 for other applicable regulations.

* * * Section 3 - Hazards Identification * * *

Emergency Overview

****

Corrosive, combustible, colorless, clear liquid with fatty amine odor. Causes damage to the skin and eyes. Prolonged exposure to eyes or skin can cause chemical burns. May be harmful if inhaled or swallowed.

FLASH POINT : 193°C (379.4°F)

HMIS Ratings : Health : 2 Fire : 0 Reactivity : 0

Personal Protection : (See Section 8) -Use a NIOSH approved respirator for bulk handling and small spills. Use a self contained breathing apparatus for large or uncontrolled spills.

See Section 5 for fire fighting measures.

****

Label Information

CORROSIVE

Potential Health Effects: Eyes

Product can cause eye damage. Prolonged exposure to eyes can cause chemical burns.

Potential Health Effects: Skin

Product can cause damage to the skin. Prolonged exposure to skin can cause chemical burns.

Potential Health Effects: Ingestion

Product may be harmful if swallowed.

Potential Health Effects: Inhalation

Product may be harmful if inhaled.

HMIS Ratings: Health: 2 **Fire:** 0 **Reactivity:** 0 **Pers. Prot.:** (See Section 8)

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe * = Chronic hazard

* * * Section 4 - First Aid Measures * * *

First Aid: Eyes

Flush eyes with plenty of water for a minimum of 15 minutes, and seek medical attention.

First Aid: Skin

Flush skin with plenty of water for a minimum of 15 minutes while removing all contaminated clothing. Seek medical advice. Dispose of contaminated clothing according to governmental regulations.

First Aid: Ingestion

If the material is swallowed, get immediate medical attention or advice.

First Aid: Inhalation

Remove person to fresh air and seek medical attention. If not breathing give artificial respiration. If breathing is difficult, give oxygen.

First Aid: Notes to Physician

This product is only slightly soluble in water and will adhere to skin. The manufacturer successfully uses 2% acetic acid in water to neutralize the product on SKIN ONLY. (NOTE: Higher concentrations of acetic acid may generate heat during neutralization, potentially giving thermal burns in addition to chemical burns.) Advise feasibility of use in specific situation. Symptoms of exposure may or may not be immediately apparent. They include burning sensation, coughing, laryngitis, shortness of breath, headache, nausea, and vomiting.

* * * Section 5 - Fire Fighting Measures * * *

Flash Point: 193°C (379.4°F)	**Method Used:** CLEVELAND open cup method
Upper Flammable Limit (UFL): Not available	**Lower Flammable Limit (LFL):** Not available
Auto Ignition: Not available	**Flammability Classification:** OSHA Class IIIB
Rate of Burning: Not available	

General Fire Hazards

Keep away from heat and fire.

Hazardous Combustion Products

Not available

Extinguishing Media

Foam, dry powder, and carbon dioxide.

Fire Fighting Equipment/Instructions

Cool fire exposed tank/container surfaces with water spray. Fight fire from upwind position. Wear self contained breathing apparatus and full protective equipment.

NFPA Ratings: Health: - Fire: - Reactivity: - Other: -

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe

* * * Section 6 - Accidental Release Measures * * *

Containment Procedures

Review FIRE FIGHTING MEASURES(Section 5) and EXPOSURE CONTROLS/ PERSONAL PROTECTION(Section 8) before proceeding with clean up. Use appropriate personal protective equipment during cleanup. Remove source of heat, sparks, flame, impact, friction, or electricity. Prevent discharge to natural waters and sewers.

Clean-Up Procedures

Small Spills: Absorb spills with suitable inert absorbent and dispose of in accordance with governmental regulations.

Large Spill: Dike spill. Contain spill by pumping (use an explosion proof or hand pump) or with suitable absorbent and place in covered container.

Evacuation Procedures

Isolate hazard area. Keep unnecessary and unprotected personnel from entering.

Special Procedures

Not provided

* * * Section 7 - Handling and Storage * * *

Handling Procedures

Prevent breathing vapors or mist. Prevent contact with eyes, skin, or clothing.

Storage Procedures

Keep containers tightly closed, and store it in a cool and well ventilated area.

* * * Section 8 – Exposure Controls / Personal Protection * * *

Exposure Guidelines

A: General Product Information

This product is hazardous. Handling this chemical without proper personal protection equipment and other exposure controls may result in injury.

B: Component Exposure Limits

ACGIH, OSHA, and NIOSH have not developed exposure limits for any of this product's components.

Engineering Controls

Use general ventilation and use local exhaust, where possible, in confined or enclosed spaces.

PERSONAL PROTECTIVE EQUIPMENT

Personal Protective Equipment: Eyes/Face

Wear chemical splash goggles in laboratory and for handling small quantities of the material.

Personal Protective Equipment: Skin

Use gloves made of PVC-coated rubber, butyl rubber, or neoprene. Use chemical resistant protective clothing or apron as appropriate to situation.

Personal Protective Equipment: Respiratory

In laboratory, use product in hood or properly ventilated area. Use a NIOSH approved full-face air-purifying apparatus with methylamine/ammonia cartridge for bulk handling of material or small spills. Use self-contained breathing apparatus for large or uncontrolled spills.

Personal Protective Equipment: General

ALWAYS use the appropriate personal protective equipment when handling this chemical.

* * * Section 9 - Physical & Chemical Properties * * *

Appearance:	Colorless, clear	**Odor:**	fatty amine odor
Physical State:	Liquid	**pH:**	10 (1% in water)
Vapor Pressure:	Not available	**Vapor Density:**	Not available
Boiling Point:	Not available	**Melting Point:**	13°C-18°C (55.4°F-64.4°F)
Solubility (H2O):	Slightly soluble: emulsified	**Specific Gravity:**	0.913 at 20°C (68°F) 0.907 at 40°C (104°F) 0.900 at60C (140F)
Viscosity:	143 mPa·s at 20°C (68°F) 78 mPa·s at 30°C (86°F) 46.5mPa·s at 40°C (104°F)		

Physical Properties: Additional Information

Solubility : Soluble in aromatic solvent, alcohol and chloroform.

* * * Section 10 – Chemical Stability & Reactivity Information * * *

Chemical Stability

Stable

Chemical Stability: Conditions to Avoid

Not available

Incompatibility

Not available

Hazardous Decomposition

Nitrogen oxides (NOx)

Hazardous Polymerization

Will not occur.

* * * Section 11 - Toxicological Information * * *

General Toxicity

A: General Product Information

Acute toxicity : Oral, Mouse LD50 : 19041mg/kg

Intraperitoneal, Mouse LD50: 2049mg/kg

B: Component Analysis - LD50/LC50

See above

Carcinogenicity

A: General Product Information

Negative

B: Component Carcinogenicity

None of this product's components are listed by ACGIH, IARC, OSHA, NIOSH, or NTP.

Epidemiology

Negative

Neurotoxicity

Negative

Mutagenicity

Ames test : TA98, TA100, TA1537, AK-1 ; negative

Micronucleus test : Negative

Teratogenicity

Negative

Other Toxicological Information

Corrosivity:

Manufacturer considers this product CORROSIVE under CESIO guidelines (EU risk phrase R35).

* * * Section 12 - Ecological Information * * *

Ecotoxicity

CO2 evolution test (OECD 301B): 64% (28 days)

Fish toxicity: Rainbow trout, 96hr, LC50: 0.57 mg/L

Environmental Fate

CODmn : 0.39 g/g (JIS K 0102)

BOD 5 : 0.026g/g (JIS K 0102)

TOD : 2.12 g/g

* * * Section 13 - Disposal Considerations * * *

US EPA Waste Number & Descriptions

A: General Product Information

Not applicable

B: Component Waste Numbers

No EPA Waste Numbers are applicable for this product's components.

Disposal Instructions

Dispose of in accordance with governmental regulations.

* * * Section 14 - Transportation Information * * *

US DOT Information

Shipping Name: Amines, Liquid, Corrosive,N.O.S. {contains Alkyl amine derivative}
Hazard Class: 8
UN/NA #: 2735
Packing Group: III
Required Label(s): Corrosive
Additional Info.: Not available

International Transportation Regulations

See above

* * * Section 15 - Regulatory Information * * *

US Federal Regulations

A: General Product Information

Not regulated

B: Component Analysis

None of this products components are listed under SARA Section 302 (40 CFR 355 Appendix A), SARA Section 313 (40 CFR 372.65), or CERCLA (40 CFR 302.4).

State Regulations

A: General Product Information

Not regulated

B: Component Analysis - State

None of this product's components are listed on the state lists from CA, FL, MA, MN, NJ, or PA.

Other Regulations

A: General Product Information

Product is registered on:

TSCA Inventory (USA)	: YES
DSL (CANADA)	: YES
NDSL (CANADA)	: Not applicable
EINECS (Europe)	: YES
ELINCS (Europe)	: Not applicable
AICS (Australia)	: YES
ECL (Korea)	: YES

B: Component Information (Canada)

No components are listed in the WHMIS IDL.

* * * Section 16 - Other Information * * *

Other Information

TO THE BEST OF THE MANUFACTURER'S KNOWLEDGE, THE INFORMATION CONTAINED HEREIN IS ACCURATE. HOWEVER, NEITHER THE MANUFACTURER, NOR ANY OF ITS AFFILIATES, MAKE ANY REPRESENTATIONS OR WARRANTIES (EXPRESSED OR IMPLIED), NOR ASSUMES ANY LIABILITY (INCLUDING LIABILITY FOR ANY DIRECT, INCIDENTAL, CONSEQUENTIAL, OR OTHER DAMAGES) WITH RESPECT TO THE ACCURACY OR COMPLETENESS OF THE INFORMATION CONTAINED HEREIN. SUCH INFORMATION MAY BE (WITHOUT LIMITATION) INVALID IF THE SPECIFIED MATERIAL IS USED IN COMBINATION WITH ANOTHER, IN A PARTICULAR PROCESS, OR UNDER UNUSUAL CONDITIONS. DETERMINATION OF SUITABILITY OF ANY MATERIAL FOR ANY GIVEN PURPOSE IS THE SOLE RESPONSIBILITY OF THE USER WHO ASSUMES ALL RISK AND RESPONSIBILITY THEREFOR. ALL MATERIALS MAY PRESENT UNKNOWN HAZARDS AND SHOULD BE USED WITH APPROPRIATE CAUTION. THE MANUFACTURER CANNOT AND DOES NOT GUARANTEE THAT THE HAZARDS DESCRIBED HEREIN ARE THE ONLY ONES THAT EXIST.

This MSDS corrects MSDS No.0598271 issued on May 14, 1998.
Changes to Sections 1, 2, 3, 5, 7,9, 11, 14 and 16.
Please replace all prior MSDSs for this product with the most recent issue.

Key/Legend

J.I.S.: Industry Standard test method
CESIO: European Committee of Organic Surfactants and their Intermediates

Contact:
Contact Phone:

SANITIZED VERSION

Schedule No : KAS/092
Report No : 96/KAS092/0216

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Acute toxicity to rainbow trout

(Preliminary toxicity screen)

FINAL REPORT

Study Director

C A Jenkins

To:

From:
Huntingdon Life Sciences Ltd
Eye
Suffolk IP23 7PX
England

Final: 22 April 1996

Huntingdon Life Sciences

[ ] ACUTE TOXICITY TO RAINBOW TROUT

(PRELIMINARY TOXICITY SCREEN)

FINAL REPORT

Schedule No : KAS/092
Report No : 96/KAS092/0216

I declare that the report following constitutes a true and faithful account of the procedures adopted and the results obtained in the performance of this study.

The study was conducted in accordance with the principles of Good Laboratory Practice but no formal quality assurance procedures were undertaken.

C.A. Jenkins, B.Sc, C.Biol, M.I.Biol, M.I.F.M.
(Study Director)

.....CAJenkins.....

Date: ....22 April 1996....

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1. SUMMARY

1.1 The acute lethal toxicity of [ ] to the rainbow trout was assessed under static exposure conditions over a period of 96 hours. Exposure concentrations were not verified by chemical analysis.

1.2 Groups of five fish were exposed to [ ] at nominal concentrations of 0.1, 0.32, 1, 3.2, 10, 32 and 100 mg/l. The test media were individually prepared by adding the test material directly to dilution water or by dilution of an aqueous stock solution. A control group of fish was placed into dilution water alone.

1.3 The test was conducted at 13.0 to 14.2°C in treated tap water of hardness 236 to 262 mg/l as $CaCO_3$ at pH values in the range 8.0 to 8.6. At 0.1 to 10 mg/l, the test media were clear and colourless; at 32 and 100 mg/l, they were off-white, hazy emulsions with a froth visible on their surfaces.

1.4 Observations of the fish were made at least at 24-hour intervals.

After 96 hours, the highest concentration at which no mortality had occurred was 0.32 mg/l and the lowest at which there was 100% mortality was 1 mg/l.

Sub-lethal, treatment-related effects were noted at 0.32 mg/l and higher concentrations and included hyperventilation, darkened pigmentation, lethargy and loss of co-ordination. At 32 and 100 mg/l, all of the fish were dead within twenty-five minutes of exposure. At 3.2 and 10 mg/l, all of the fish were adversely affected within fifteen minutes of exposure and dead within 24 hours. At 1 mg/l, all of the fish were adversely affected at fifteen minutes and died within 48 hours. At 0.32 mg/l, at most, three fish were adversely affected during the test.

The no-observed-effect concentration (NOEC) was 0.1 mg/l.

The 96-hour median lethal concentration (LC50) of [ ] to the rainbow trout was 0.57 mg/l.

2. TEST MATERIAL

A consignment of [ ] (approximately 300 g), was received at Huntingdon Life Sciences Ltd (Eye) 21 November 1995. It was identified by the batch number 2598 and was stored in the dark under ambient conditions until use.

Information supplied by the Sponsor indicated that the physical state of the test material was temperature dependent. On the day of receipt, it was a white, solid mass: after storage at ambient temperature it had changed to a clear, colourless liquid.

The identity, strength and purity of the test material received and its stability under the storage conditions were the responsibility of the Sponsor.

3. TEST PROCEDURES

The test was conducted between 27 February and 2 March 1996 according to the agreed Study Protocol (PTS12c).

The rainbow trout used in the test were supplied by Neil Hardy Aquatica, Surrey and arrived at Huntingdon Life Sciences (Eye) 19 January 1996. At the laboratory, they were held in an aerated supply of dilution water under flow-through conditions until removed for testing.

The fish were maintained and the study conducted in treated tap water (dechlorinated tap water which had been blended with reverse-osmosis, softened tap water).

No mortality occurred during the 14-day period before the test.

The mean wet-weight of the fish used in the test was 1.3 g; their mean fork length was 4.9 cm.

Groups of five fish were exposed to [ ] at nominal concentrations of 0.1, 0.32, 1, 3.2, 10, 32 and 100 mg/l. A control group comprising five fish was exposed to dilution water alone.

At 1 mg/l and higher concentrations, the test media were prepared by adding the appropriate weight of test material directly to the dilution water (14 litres); at 0.1 and 0.32 mg/l, they were prepared by dilution of an aqueous stock solution nominally containing 10 mg/l. The media were gently aerated during the test.

Chemical analysis of control and test media was not undertaken.

4. RESULTS

Table 1 lists the mortalities observed during the test. After 96 hours, the highest concentration at which no mortality had occurred was 0.32 mg/l and the lowest at which there was 100% mortality was 1 mg/l.

The 24- to 96-hour median lethal concentrations (LC50s) of [-] to the rainbow trout are listed below; the values were derived by non-linear interpolation between the two concentrations which bracket the 50% effect level, given in parenthesis below.

Observation intervals	LC50 values (mg/l)
24 hours	1.4 (1 & 3.2)
48 - 96 hours	0.57 (0.32 & 1)

At 32 and 100 mg/l, all of the fish were dead within twenty-five minutes of exposure. At 10 mg/l, all of the fish exhibited hyperventilation, loss of co-ordination and darkened pigmentation within fifteen minutes of exposure and were dead at 24 hours. At 3.2 mg/l, all of the fish exhibited hyperventilation and lethargy within fifteen minutes and were dead at 24 hours. At 1 mg/l, all of the fish exhibited hyperventilation within fifteen minutes of exposure; at 24 hours, one fish had died and the others displayed hyperventilation and darkened pigmentation; three fish also exhibited loss of co-ordination and one was lethargic. At 48 hours, all of the fish at this level had died. At 0.32 mg/l, no adverse effects were noted after fifteen minutes of exposure but at 24 hours, two appeared dark; from 48 hours onwards, three displayed darkened pigmentation.

The no-observed-effect concentration (NOEC) was 0.1 mg/l.

At 0.1 to 10 mg/l, the test media were clear and colourless; at 32 and 100 mg/l, they were off-white, hazy emulsions with froth visible on their surfaces.

The results of the water quality analysis conducted at the start of the test and at 24-hour intervals thereafter are summarised below.

- temperature, °C	13.0 - 14.2
- pH	8.0 - 8.6[#]
- dissolved oxygen, % ASV*	85 - 100
- total hardness, mg/l $CaCO_3$	236 - 262[s]

* Air saturation value

[#] At 96 hours, the pH values of the media (between 8.5 and 8.6) slightly exceed that recommended for this type of test (8.5 maximum); this is not thought to have affected the integrity of the test.

[s] At the end of the test, the water hardness of the dilution medium and test medium at the lowest level slightly exceeded that recommended for this type of test (250 mg/l $CaCO_3$ maximum); this is not thought to have affected the integrity of the test.

TABLE 1

Cumulative mortality

Observation times (hours)	Nominal concentrations, mg/l							
	0	0.1	0.32	1	3.2	10	32	100
0.5	0	0	0	0	0	0	5	5
24	0	0	0	1	5	5	5	5
48	0	0	0	5	5	5	5	5
72	0	0	0	5	5	5	5	5
96	0	0	0	5	5	5	5	5

Note : Five fish were exposed at each concentration.

ENTRY FORM

CAPNUM	LTR	DATE	CBI	CASNO	CONCERN	AI	SOLUBILITY
14238	a	0898	s	1541679	HIGH	NS	slightly

CHEMNAME

Ethanol, 2,2'-(dodecylimino)bis-, static

PHYSTATE

liquid

ORGANISM	DURATION	ENDPOINT	CODE	TOXVALUE	UNITS	MELTINGPT
Rainbow trout, O. mykiss	96h	LC50		0.57	mg/l	13C

COMMENTS

NOEC=0.1mg/l (abnorm. behavior)
nominal