11/04/2011





# U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Antimicrobials Division (7510P) 1200 Pennsylvania Avenue NW Washington, D.C. 20460

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x Registration Reregistration

(under FIFRA, as amended)

EPA Reg. Number:

Date of Issuance:

84526-4

NOV - 4 2011

Term of Issuance:

#### Conditional

Name of Pesticide Product:

Sanosil C34

Name and Address of Registrant (include ZIP Code):
Sanosil International LLC
c/o
Georgia Anastasiou, Lewis & Harrison
122 C Street NW, Suite 740
Washington, DC 20001

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(a) provided that you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
- 2. Make the labeling changes listed below before you release the product for shipment:
  - a. Revise the "EPA Registration Number to read, "EPA Reg. No. 84526-4".

Signature of Approving Official:

Marshall Swindell

Product Manager Team-33

Regulatory Management Branch I Antimicrobials Division (7510P) Date:

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- b. To satisfy OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics) requirements, results for a minimum of 1 year from a GLP-compliant storage stability and corrosion characteristics study must be provided as a condition of registration within a year of registration or as soon as the study is completed.
- The Agency encourages registrants to include a company telephone number or toll-free hotline number for emergency information in the first aid section. If registrant does not have its own number, the registrant may use the National Pesticides Information Center (NPIC) 800 number, 1-800-858-7378.
- d. Should you wish to retain a reference to the company's website on your label, then please be aware that such a reference transforms the website into labeling under the Federal Insecticide Fungicide and Rodenticide Act sec 2 (p) (2) and then the website is subject to review by the Agency. If the website content is false or misleading, the product would be misbranded and its sale or distribution unlawful to sell or distribute under FIFRA section 12(a)(1)(E). In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Although EPA has not yet determined the extent to which it will routinely review company websites, if the Agency finds or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from claims approved through the registration process, the website may be referred to the EPA's Office of Enforcement and Compliance Assurance.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records. Submit one (1) copy of your final printed labeling prior to release of this product for shipment. If you have any questions concerning this letter, please contact Abigail Downs at 703-307-5259.

> arshall Sainalell Sincerely,

Marshall Swindell

Product Manager Team-33

Regulatory Management Branch I Antimicrobials Division (7510P)

Enclosure: [Stamped Label]

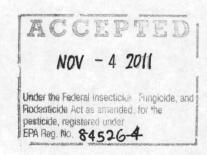
Enclosed in CBI envelope: [Acute Toxicity Review dated October 18, 2011], [Product Chemistry Review

dated August 25, 2011]

(Note: Bold, italicized text is information for the reader and is not part of the label).

# Sanosil® C34

For Microbial Control in Recirculating Cooling Water Systems



#### KEEP OUT OF REACH OF CHILDREN

#### DANGER

See [back] [side] [right] [left] panel for additional precautionary statements.

Net Contents: (as indicated on container)

EPA Reg. No. 84526-

EPA Est. No. (as indicated on container)

[See bottom or side for Lot/Data code]

Questions? Comments? [symbol of telephone]

Call: (1-877-726-6745)

[or] Visit us at (www.sanosilglobal.com)

Made in USA

Distributed by: Sanosil International, LLC, 91 Lukens Drive, New Castle, Delaware

19720

[or an authorized Sanosil International, LLC distributor (insert name)]

Sanosil® is a licensed trademark of Sanosil Ltd. Switzerland

ACCEPTED | + (7

Under the Federal Insecticity Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. \$4526-4

#### PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Danger. Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed. Do not get in eyes, on skin or on clothing. If fogged, avoid breathing spray mists. Wear protective eyewear such as goggles, face shield or safety glasses and protective clothing (long-sleeved shirt and long pants, socks, rubber gloves and chemical resistant footwear). Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. After product is diluted in accordance with directions for use, protective eyewear and protective clothing is not required. Wash thoroughly with soap and water after handling and before eating, drinking, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

#### **FIRST AID**

<u>If in eyes</u>: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a Poison Control Center or doctor for treatment advice.

If on skin: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment.

If swallowed: Call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything to an unconscious person. If product diluted in accordance with the directions for use, gets on skin, medical attention is not required.

**NOTE TO PHYSICIAN:** Probably mucosal damage may contraindicate the use of gastric lavage.

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor or going for treatment.

(If container size is 5 gallons or larger, use the following Environmental Hazards statement).

**ENVIRONMENTAL HAZARDS** 

Do not discharge effluent containing this product into lakes, streams, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination system (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your state water board or Regional Office of the EPA.

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## PHYSICAL AND CHEMICAL HAZARDS

This product is incompatible with oxidizing and reducing agents.

Under the Federal Insecticity Fungicide, and Rodenficide Act as amended, for the pesticide, registered under EPA Reg. No. \$4526-4

Optional Marketing Claims: (note that these claims may or may not appear on the commercial label; in addition, the claims may be used as bullet points or in a paragraph format)

## Miscellaneous Claims

Introductory

New (this claim will only be used for the first six months after commercial introduction)

Fast, Easy, Effective

Modern (Classic)

Controls Biofilm in Cooling Water Systems

Versatile Formula

Controls bacteria, algae, fungi, and slime in cooling water systems.

<u>DIRECTIONS FOR USE</u>: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read the entire label before using the product. Sanosil C34 must be applied to water systems using a closed dosing system, such as a dosing pump which connects the Sanosil 25 container to the water system. Do not open pour Sanosil 25 into water systems.

# Air Washers and Recirculating Cooling Water Systems

- 1. Severely fouled systems must be cleaned prior to treatment.
- 2 Add Sanosil C34 at a point in the system where uniform mixing can be achieved. Addition may be intermittent or continuous.
  - Intermittent (Slug Dose): For severely fouled systems, add 7 to 22 fl. oz of Sanosil C34 per 1000 gallons of water in the system (60 to 180 ppm). Repeat until control is achieved. When control is evident, add 3 to 9 fl. oz. of Sanosil C34 per 1000 gallons in the system (20 to 70 ppm) as needed to maintain control.
  - Continuous feed Initial Dose: If the system is noticeably fouled use, slug dose
    procedure for the initial treatment. Once control is achieved, continuously feed
    of 3 to 9 fl. oz of Sanosil C34 per 1000 gallons of water (20 to 70 ppm) per day
    in the system. Dosage rates should be increased or decreased depending on
    the extent of biofouling and control achieved.

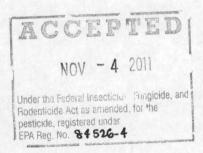
# **Pasteurizer Cooling Water Systems**

Sanosil C34 may be used for control of slime, bacteria, fungi, and other microorganisms in brewery and other pasteurizer systems and warmers at the same application rates and in same manner as described above. The solution should be added to be the closed recirculating system at a point where uniform mixing can be achieved, e.g., basin, sump, or collection areas.

### **Biofouling Control in Pulp and Paper Mill Systems**

For use in the manufacture of paper and paperboard intended for non-food contact only. Not for use in the manufacture of paper and paperboard intended for food contact. This product may be used to control bacterial, fungal and yeast growth in pulp, paper and paperboard mills.

- Severely fouled systems must be cleaned prior to treatment with Sanosil C34. Add Sanosil C34 directly to the system; don't mix with other chemicals or additives without first testing for compatibility. Contamination with other chemicals could result in product decomposition.
- 2. Add Sanosil C34 at a point in the system where it can be mixed uniformly with the pulp, e.g. the beater, hydropulper, fan pump, broke pump, etc.
- Apply 2 to 76 fl oz of Sanosil C34 per ton of pulp (dry basis) in paper produced, (15 to 750 ppm). Addition may be continuous or intermittent depending on the type of system and severity of the biofouling.



### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

<u>Pesticide Storage:</u> Keep out of direct sunlight and away from heat. Do not freeze. Store in original container in areas inaccessible to small children and pets.

<u>Pesticide Disposal:</u> Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray or mixture of rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

#### Container Disposal:

(Note to Reviewer: One of the following statements will be used)

Nonrefillable container. Do not reuse or refill this container unless the directions for use allow to refill empty container with this product.

Nonrefillable container. Do not reuse or refill this container.

If product leaking or spills should occur, dilute with water and dry with absorbent material, or dilute with water as it is flushed into waste water drain. Offer for recycling, if available or (replace cap and) discard in trash. (Contains no phosphorous.)

