70060-30 11/6/2012 1/5

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

November 6, 2012

Georgia Anastasiou
Agent for BASF Corp.
Lewis & Harrison, LLC
122 C Street NW Ste. 505
Washington DC 20001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Subject: Aseptrol FC-Tab
EPA Reg.#: 70060-30
Notification Date: October 19, 2012
Receipt Date: October 25, 2012

Dear Ms. Anastasiou:

This acknowledges the receipt of your notification, submitted under the provision of PR Notice 98-10 and FIFRA section 3(c)9.

Proposed Notification:

Revise Storage and Disposal Statement in compliance with PR Notice 2007-4 for Aseptrol FC-Tab product (EPA Reg#70060-30). Initial submitted label dated 10/19/12 (pin punch 10/25/12) was revised and updated on 11/06/2012 (pin punch 11/06/12).

General Comment:

Based on the review of the material submitted, the following comments apply:

The submitted revised Storage and Disposal Statement is acceptable. This notification and a copy of this letter have been inserted in your file for future reference.

If you have any questions on this letter, please contact David Liem by email at liem.david@epa.gov or at 703-305-1284.

Sincerely,

Monisha Harris
Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)

2/5

Please read instructions on reverse before completing it. Form Approved, OMB No. 2070-0060, Approval expires 05-31-98

EPA United States Environmental Protection Agency Washington, DC 20460

☐ **Registration**
☐ **Amendment:**
☒ **Other**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
70060-30	**Monisha Harris**	X None ☐ Restricted
4. Company/Product (Name) **Aseptrol FC-Tab**	PM# **32**	

5. Name and Address of Applicant *(Include ZIP Code)*
BASF Corporation
100 Park Avenue
Florham Park, NJ 07932
PLEASE SEND ALL CORRESPONDENCE TO "CONTACT POINT" LISTED BELOW
☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

☐ Amendment – Explain below.
☐ Resubmission in response to Agency letter dated _____
☒ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application
☐ Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Notification to update storage and disposal and add mandatory advisory precautionary statements.

Notification of label change per PR Notice 2007-4 and 98-10. This notification is consistent with the guidance in PR Notice 2007-4 and 98-10 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C Sec. 1001 to willfully make any false statements to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§156.10, 156.140, 156.144, 156.146 and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes*	☐ Yes	☐ Yes	☐ Metal
☐ No	☐ No	☐ No	☐ Plastic
	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt. / No. per container	☐ Glass
***Certification must be submitted**			☐ Paper
			☐ Other (Specify)

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application)*

Name:	Title:	Telephone No. (Include Area Code):
Georgia Anastasiou, Lewis & Harrison, LLC, 122 C Street NW, Ste. 505, Washington, DC 20001	**Agent**	**202-393-2903 x19**

Certification

I certify that the statements I have made on this form and all attachments thereto 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.

6. Date Application Received: **(Stamped)**

2. Signature	3. Title
Georgia Anastasiou	**Agent for BASF Corporation**
4. Typed Name **Georgia Anastasiou**	5. Date **October 19, 2012**

3/5

LEWIS & HARRISON
Consultants in Government Affairs

122 C Street, N.W., Suite 505
Washington, D.C. 20001
telephone 202.393.3903
fax 202.393.3906

October 19, 2012

HAND DELIVERED

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard, Room S4900
2777 S. Crystal Drive
Arlington, VA 22202

ATTENTION: **Monisha Harris**
Product Manager (32)

SUBJECT: **BASF Corporation**
Aseptrol FC-Tab (EPA Reg. No. 70060-30)
Notification

Dear Ms. Harris:

On behalf of BASF Corporation, I am submitting a notification for the product **Aseptrol FC-Tab (EPA Reg. No. 70060-30).** The purpose of this submission is to correct the storage and disposal section to be in accordance with PR Notice 2007-4 and add mandatory advisory statements that were required per the sodium chlorite Reregistration Eligibility Decision (RED). This product is still under review for the RED.

Enclosed please find the following documents in support of this submission:

1. Application for Pesticide which includes a sign certification statements in accordance with PR Notices 2007-4 and 98-10;
2. One (1) copy of the revised label with changes highlighted; and,
3. Two (2) copies of the revised label.

If you have any questions, or require any additional information, please feel free to contact me by phone at 202-393-3903 ext. 19, by fax at 202-393-3906, or by email at georgia@lewisharrison.com.

Sincerely,

Georgia Anastasiou

Georgia Anastasiou
Agent for BASF Corporation

cc: Marie Paquette (BASF)
Janet Cerra (BASF)

Aseptrol FC-Tab is a new, product specially designed to control pathogenic viruses and bacteria in animal production facilities, and on farm premises.

A 200 ppm use-solution of Aseptrol FC-Tab is a broad spectrum disinfectant effective against Newcastle Disease virus, Norwalk virus, Canine Parvovirus, and the following gram negative and positive bacteria: Escherichia coli pathogenic strain 0157:H7, Pseudomonas aeruginosa, Staphylococcus aureus and Salmonella enterica after 10 minutes of contact. The 200 ppm use-solution is also effective against Staphylococcus aureus (MRSA) and Enterococcus faecalis (VRE) after 5 minutes of contact, and Virucidal against the Foot and Mouse Disease Virus after 30 minutes of contact.

Aseptrol FC-Tabs can be used as a disinfectant/virucide* in Animal Production Facilities (e.g. poultry, swine, cattle), Farm Premises and on Animal Transport Vehicles and Equipment.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

PREPARATION OF USE-SOLUTION:

In a clean plastic container or pail, place two (2) 6.0 gram **Aseptrol FC-Tab** or eight (8) 1.5 gram **Aseptrol FC-Tab** for every gallon (4 liters) of clean potable water. Prepare in a well ventilated area. Wait 10 minutes for the 1.5 gram tab and 15 minutes for the 6 gram tab to completely dissolve. Once dissolved, this will yield a working solution containing **200 ppm** of free chlorine dioxide. Prepare fresh solutions daily.

USE-INSTRUCTIONS

Poultry and Animal (swine, cattle, turkey, chicken) Houses and Related Facilities including kennels.

Remove all poultry and other animals and feeds from premises, trucks or other vehicles, coops, crates and other enclosures. Remove all litter droppings and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals. Empty all troughs, racks, and other feeding and water appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with the 200 ppm disinfecting solution for a period of 10 minutes (or 30 minutes for Foot and Mouth Disease Virus). Immerse all halters, ropes, and other types of equipment used in handling or restraining animals, as wells as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent and rinse with potable water before reuse.

Aseptrol FC-Tab

Disinfectant/ Virucidal*

For use in Cleaning and Disinfecting Animal Production Facilities and Farm Premises Effective Against Viruses*, including Animal Viruses, and Bacteria

Active Ingredients	
Sodium Chlorite	20.8%
Sodium Dichloroisocyanurate Dehydrate	7.0%
Other Ingredients	72.2%
Total	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

See side panel for first aid and precautionary statements.

EPA Reg. No. 70060-30
EPA Est. No. 70060-

Net Weight:

Manufactured by:
BASF Corporation
100 Campus Drive
Florham Park, NJ 07932

Patent: 6,699,404

[contains]

Aseptrol®

[Aseptrol and the Aseptrol logo are trademarks of BASF]

[Sodium Chlorite in this product is from Spain]

Fogging

The 200 ppm use-solution can also be used in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and as an adjunct to disinfecting operations. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use instructions. **Note:** The fog generated is irritating to eyes, skin and mucous membranes. Do not allow people to enter treated areas until [ten air exchanges] [2 hours of mechanical ventilation, i.e. fans] [4 hours of passive ventilation (i.e., windows, vents)] or [24 hours of no ventilation]. If the treated area must be entered before [insert the appropriate time period] then the individuals entering the area must wear a self contained respirator approved by NIOSH/MSHA, goggles, long sleeves and long pants.

Animal Transport Vehicles and Equipment

Use Aseptrol FC-Tab to control animal pathogens on vehicles and equipment that are used to transport live animals (poultry, swine, cattle). Prior to application of Aseptrol FC-Tab, remove all animals from the vehicle. Clean the vehicle with water to remove debris and dirt. Then apply, using a hand sprayer, a 200 ppm use-solution of Aseptrol FC-Tab to the interior and exterior of the vehicle, transport cages, crates and other related equipment. Allow at 10 minutes of contact time. Allow to air dry.

Shoe Bath Sanitizer

To prevent tracking of harmful organisms into animal areas, shoe baths containing one-inch of a freshly made 50 ppm sanitizing solution of Aseptrol FC-Tab must be placed at all entrances to buildings and hatcheries. Prepare the sanitizing use-solution by placing in the shoe bath, two (2) 1.5 grams of Aseptrol FC-Tab for every gallon of clean potable water. Shoes and work boots must remain in the shoe bath for at least 60 seconds. Change the solution in the batch at least daily or more often if the solution appears diluted or soiled.

ENVIRONMENTAL HAZARDS

This product is toxic to fish and aquatic organisms.

(If container size is greater than 50 lbs add the following statement:) Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National 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 to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

NOTIFICATION
Date Reviewed: 11-6-12
Reviewed By: D. Liem

FIRST AID

If in eyes:

- 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 swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have 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 by mouth to an unconscious person.

If on skin or clothing:

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

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

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

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if absorbed through skin. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses), protective clothing and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

Handlers applying in an occupation setting must wear gloves

People must vacate the premises during fogging treatments; a one-hour restricted entry interval (REI) is required.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store this product in a cool, dry area away from direct sunlight and heat to avoid deterioration and in an area inaccessible to children.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or 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 HANDLING AND DISPOSAL: Non-refillable [container] [pouch] [blister pack] [packet]. Do not reuse or refill this [container] [pouch] [blister pack] [packet]. Offer for recycling, if available. If recycling is not available, dispose [empty pouch] [blister pack] [container] in sanitary landfill or by incineration. If burned stay out of smoke.

Notice: Seller expressly warrants that the product conforms to its chemical description. There are no warranties associated with the sale of this product, either expressed or implied, including but not limited to the warranties of fitness for a particular purpose.