

71512-14

8/4/2010

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

AUG - 4 2010

Mr. Mark D. Gelin
ISK Biosciences Corporation
7470 Auburn Road, Suite A
Concord, OH 44077

Subject: Label Notification(s) for Pesticide Registration Notice 2007-4

Dear Registrant:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4 dated July 29, 2010 for:

EPA Registration 71512-14 Flonicamid 50WG for Manufacturing and Repacking

The Registration Division (RD) has conducted a review of this request for applicability under PRN 2007-4 and finds that the label change(s) requested falls within the scope of PRN-2007-4. The label has been date-stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on nonrefillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact me directly at 703-305-5335 or Banza Djapao of my staff at 703-305-7269.

Sincerely,

A handwritten signature in cursive script that reads "Paul J. Mastradone".

Paul Mastradone, Acting Leader
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number ISK Biosciences Corporation / 71512-14	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product Name Flonicamid 50WG for Manufacturing and Repacking	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) ISK BIOSCIENCES CORPORATION 7470 Auburn Road, Suite A Concord, OH 44077 <input type="checkbox"/> 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

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION AUG - 4 2010
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input checked="" type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.	

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

1. Notification - Revision of Container Disposal statement on label

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, 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:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input checked="" type="checkbox"/> Yes* <input type="checkbox"/> No	If "Yes" Unit Packaging wgt. No. per container		<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 80 kg		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other Adhesive			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Mark D. Gelin	Title Manager, Int'l Registrations	Telephone No. (Include Area Code) 440-357-4644
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
2. Signature 	3. Title Manager, Int'l Registrations	
4. Typed Name Mark D. Gelin	5. Date July 29, 2010	



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number ISK Biosciences Corporation / 71512-14	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product Name Flonicamid 50WG for Manufacturing and Repacking	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) ISK BIOSCIENCES CORPORATION 7470 Auburn Road, Suite A Concord, OH 44077 <input type="checkbox"/> 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

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated	NOTIFICATION AUG - 4 2010
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application.	
<input checked="" type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.	

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1. Notification - Revision of Container Disposal statement on label

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, 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:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input checked="" type="checkbox"/> Yes* <input type="checkbox"/> No	<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Unit Packaging wgt. No. per container		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input checked="" type="checkbox"/> Other Adhesive		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Premjit Halarnkar, Ph. D., MPA	Title Registration Manager	Telephone No. (Include Area Code) 440-357-4651
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
2. Signature 	3. Title Registration Manager	
4. Typed Name Premjit Halarnkar, Ph. D., MPA	5. Date October 30, 2009	



November 2, 2009

Ms. Linda Arrington
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

**Re: Technical Flonicamid Insecticide (EPA Reg. No 71512-7)
Flonicamid 50WG (EPA Reg. No 71512-9)
Beleaf 50SG Insecticide (EPA Reg. No. 71512-10)
Flonicamid 50WG for Manufacturing and Repacking (EPA Reg. No. 71512-14)
Notification - Labels Revision – Container Disposal Statement**

Dear Ms. Arrington:

Please find enclosed applications and labels for Technical Flonicamid Insecticide (EPA Reg. No 71512-7), Flonicamid 50WG (EPA Reg. No 71512-9), Beleaf 50SG Insecticide (EPA Reg. No. 71512-10) and Flonicamid 50WG for Manufacturing and Repacking (EPA Reg. No. 71512-14), as per the Notification process of PR Notice 98-10. Per EPA PR Notice 2007-4, the container disposal statement was revised on each label of the above products.


- 1. EPA Form 8570-1 for each of the above product
- 2. Three (3) revised labels and one (1) red-lined revised label for each product

If you have any questions, please contact me at (440) 357-4651 or by email halarnkarp@iskbc.com

Thank you,
Sincerely,

Premjit Halarnkar, Ph.D., MPA
Registration Manager

"Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 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 statement 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."



Mark Gelin
Manager, International Registrations
ISK Biosciences Corporation
7470 Auburn Road, Suite A
Concord, Ohio 44077 USA
tel: 440 357-4644
fax: 440 357-4661



NOTIFICATION
AUG - 4 2010

**FLONICAMID 50WG
FOR MANUFACTURING AND
REPACKAGING USE ONLY**

FIRST AID	
If in Eyes	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Call a poison control center or doctor for treatment 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 the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If Inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
If on Skin or Clothing	<ul style="list-style-type: none"> • 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.
Note to Medical Doctor: Treatment is controlled by removal of exposure followed by symptomatic and supportive care.	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
HOT LINE NUMBER	
For 24-Hour Medical Emergency Assistance call 1-888-484-7546 . For Chemical Emergency, Spill, Leak, Fire or Accident , call CHEMTREC 1-800-424-9300 .	

ACTIVE INGREDIENT: By Wt.
 *Flonicamid50.0%
 INERT INGREDIENTS.....50.0%
 Total.....100.0%
 *Contains 0.5 pounds active ingredient per pound of formulated product
 U.S. Patent No. 5360806

KEEP OUT OF REACH OF CHILDREN

WARNING

AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See side panel for additional precautionary statements.

Read entire label carefully and use only as directed.

ISK Biosciences Corporation
7470 Auburn Road, Suite A
Concord, Ohio 44077 U.S.A.

EPA Reg. No. 71512-14- EPA Est. No. 69029-ITA-001

Made in Japan

Net Contents: 176 pounds (80 kilograms)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through skin. Avoid contact with skin. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Avoid breathing dust or spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS

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.

DIRECTIONS FOR USE

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

THIS PRODUCT IS FOR MANUFACTURING AND REPACKAGING USE ONLY.

Only for formulation or repackaging into insecticides for use in commercial greenhouses, interior plantscapes, nursery and landscape ornamentals, cotton, cucurbit vegetables, fruiting vegetables and leafy vegetables (except Brassica), potato, pome fruit and stone fruit. This product may be used to formulate products for any additional uses not listed on this label if the formulator, user group, or grower has complied with USEPA data submission requirements regarding support of such uses.

STORAGE AND DISPOSAL

DO NOT contaminate water, food or feed by storage or disposal. Open dumping is prohibited.

STORAGE: Store in original container, in a secured, dry and cool place separate from other pesticides, fertilizer, food, and feed.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. 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 DISPOSAL: DO NOT reuse empty plastic bags. Completely empty plastic bags into formulation or repackaging equipment by shaking and tapping sides and bottom of the bags to loosen clinging particles. Then dispose of plastic bags in a sanitary landfill or by incineration if allowed by state and local authorities. If burned, stay out of smoke.

Steel drum: ~~Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.~~ Nonrefillable container. Do not reuse or refill this container. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full of water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

Offer for recycling, if available, or reconditioning or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

WARRANTY AND LIMITATION OF DAMAGES

Seller warrants to those persons lawfully acquiring title to this product that at the time of first sale of this product by Seller that this product conformed to its chemical description and was reasonably fit for the purposes stated on the label when used in accordance with Seller's directions under normal conditions of use, and Buyers and users of this product assume the risk of any use contrary to such directions. **EXCEPT AS PROVIDED ELSEWHERE IN WRITING CONTAINING AN EXPRESS REFERENCE TO THIS WARRANTY AND LIMITATION OF DAMAGES, SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OR GUARANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF**

AUTHORIZED TO DO SO. In no event shall Seller's liability for any breach of warranty or guaranty exceed the purchase price of the product as to which a claim is made. Buyers and users of this product are responsible for all loss or damage from use or handling of this product which results from conditions beyond the control of Seller, including, but not limited to, incompatibility with other products unless otherwise expressly provided in Directions for Use of this product, weather conditions, cultural practices, moisture conditions or other environmental conditions outside of the ranges that are generally recognized as being conducive to good agricultural and/or horticultural practices.