

79662-1

9/15/2011

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SEP 15 2011

Lewis & Harrison
c/o for A-dec, Inc.
122 C Street, N.W.
Suite 740
Washington, DC 20001

Attention: Georgia Anastasiou
Regulatory Specialist

Subject: ICX
EPA Reg. No. 79662-1
Notification Letter Dated August 16, 2011

This will acknowledge receipt of your notification submitted under the provisions of FIFRA Section 3(c) (9). Based on a review of the submitted material, the following apply:

- Adding the expiration date on the label.

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been made a part of your file.

If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely,

A handwritten signature in black ink, appearing to read "Marshall Swindell".

Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimicrobials Division (7510C)



United States
Environmental Protection Agency
 Washington, DC 20460

- Registration
 Amendment
 Other -Notification

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 79662-1	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) ICX	PM Team 33	
5. Name and Address of Applicant (Include ZIP Code) A-dec, Inc 2601 Crestview Drive Newberg, OR 97132 <i>NOTE: PLEASE SEND ALL CORRESPONDENCE TO "CONTACT POINT" LISTED BELOW</i> <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 _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application |
| <input checked="" type="checkbox"/> Notification – Explain below. | <input type="checkbox"/> Other – Explain below |

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

Notification to Add Expiration Date

Notification in Accordance With PR Notice 98-10

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 type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
*Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container	<input type="checkbox"/> Plastic
					<input type="checkbox"/> Glass
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.375 oz		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 checked="" type="checkbox"/> Lithograph – or- <input type="checkbox"/> Paper glued – or- <input type="checkbox"/> Stenciled – or- <input type="checkbox"/> Other _____					

Section - IV

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

Name Georgia Anastasiou, Lewis & Harrison 122 C Street, NW Ste. 740 – Washington DC 20001	Title Agent for A-dec	Telephone No. (Include Area Code) 202-393-3903 ext. 19
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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.

2. Signature <i>Georgia Anastasiou</i>	3. Title Agent for A-dec
4. Typed Name Georgia Anastasiou, Lewis & Harrison, LLC	5. Date August 16, 2011

6. Date Application Received

(Stamped)

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**LEWIS &
HARRISON**

Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001
telephone 202.393.3903
fax 202.393.3906

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August 16, 2011

HAND DELIVERED

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

**ATTENTION: Marshall Swindell
Product Manager (33)**

**SUBJECT: A-dec, Inc
ICX (EPA Reg. No. 79662-1)
Application for Notification per PR Notice 98-10**

Dear Mr. Swindell:

On behalf of A-dec, I am submitting a notification for the product **ICX (EPA Reg. No. 79662-1)**. The purpose of this notification is to add an expiration date of 28 months. The storage and stability data submitted for ICX supports the 28 month expiration date. Please note that Demson Fuller confirmed on 8/1/2011 that this submission can be done through the notification process.

In support of this submission I have enclosed the following documents:

- 1) Application for Pesticide Notification.
- 2) One (1) copy of the label with changes highlighted.
- 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,
A-dec, Inc

cc: Tom Louisell (A-dec)

cc: Tom Louisell (A-dec)

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A-dec®

ICX®

A-dec® ICX® tablets are specially formulated to maintain dental unit waterlines and prevent accumulation of odor and foul taste bacteria.

ACTIVE INGREDIENTS:

Sodium Percarbonate.....	6.96%
n-Alkyl(60% C ₁₄ 30% C ₁₆ 5% C ₁₂ 5% C ₁₈) dimethyl benzyl ammonium chloride	0.85%
n-Alkyl(68% C ₁₂ 32% C ₁₄) dimethyl ethylbenzyl ammonium chloride	0.85%
Silver Nitrate	0.14%
Other Ingredients.....	91.2%
Total.....	100%

[Note to reviewer: EPA approved the location of the active ingredients statement on the back panel of the label on 12/15/09 in order to accommodate the small container size]

Net weight of tablet: 212.4 mg / 0.008 oz (2L application), 80.5 mg / 0.003 oz (0.7L application)
Net weight of product: 10.62 g / 0.375 oz (2L application), 4.03 g / 0.142 oz (0.7L application) – 50 tablets per box

KEEP OUT OF REACH OF CHILDREN

WARNING

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Causes moderate eye irritation, wear protective eyewear. Avoid contact with eyes, skin or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

DIRECTIONS FOR USE:

ICX® is intended for use in general dental applications by providing water to the dental syringe, various handpiece ancillary devices, and cuspidor cupfill. When used according to these instructions for every bottle refill, optimum efficacy for control of odor and foul taste bacteria can be achieved.

1. Empty any remaining water left in the bottle.
2. Drop tablet into an empty dental unit water bottle (0.7L tablet in 0.7 liter bottle, 2 L tablet in 2 liter). Avoid touching the tablet with unprotected skin.
3. Fill bottle with water and connect to the dental unit.
4. Wait 120 seconds for the tablet to fully dissolve.

NOTE -This product is intended for use with potable water and in conjunction with regular dental unit water testing, following flush (shock) treatment with an antimicrobial product registered with the U.S.EPA and recommended by the manufacturer

FIRST AID:

If solid product gets in eyes, hold eye open and rinse slowly and gently with water 15 to 20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage disposal. Store at room temperature out of direct sunlight; **DO NOT** store above 30°C (86°F). Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available or dispose of empty outer foil pouch in the trash.

A-dec Inc., 2601 Crestview Drive, Newberg, Oregon 97132, USA
Phone: 1-800-547-1883 Fax: 503-537-2843
EPA Registration Number 79662-1
EPA Establishment Number:
Expiration Date: 28 months from manufacturing date
Made in USA

