OCT 17 2008

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



## SEPA United States Environmental Protection Office of Pesticide Programs Agency

A-dec, Inc. 2601 Cresiview Drive Newberg, OR 97132

Attention: Thomas H. Louisell

Subject: ICX

EPA Registration No. 79662-1 Amendment Dated October 2, 2008

The amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable.

The Agency has no objection to the company request to change the signal word from "Caution" to "Warning" based upon the State of California review and recommendation for the Primary Dermal Irritation study.

A. stamped copy of the "accepted" labeling is enclosed for your records.

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

Sincerely

Marshall Swindell **Product Manager 33** 

Regulatory Management Branch 1 Antimicrobials Division (7510P)

**Enclosure** 

#### afdee"

### 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 <sub>14</sub> 30% C <sub>16</sub> 5% C <sub>12</sub> 5% C <sub>18</sub> ) dimethyl benzyl ammonium chloride	0.85%
n-Alkyl(68% C <sub>12</sub> 32% C <sub>14</sub> ) dimethyl ethylbenzyl ammonium chloride	0.85%
Silver Nitrate	0.14%
Other Ingredients	91.2%
Total	100%

Net weight of tablet: 212.4 mg/(2L application), 80.5 mg/(0.71) Net weight of product: 10.62 g/2L application), 4.03 g/(0.7L) (2L application), 4.03 g/0.7L ap 0.31502

#### 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 60 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.

#### 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. Dispose of empty outer foil pouch in the trash. Store at room temperature out of direct sunlight; DO NOT store above 30°C (86°F).

A-dec Inc., 2601 Crestview Drive, Newberg, Oregon 97132, USA

Phone: 1-800-547-1883 Fax: 503-537-2843

EPA Establishment Number 84100

Made in USA

EPA Registration Number 79662-1

#### ICX®

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

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Silver Nitrate	0.14%	
Other Ingredients	91.2%	
Total	100%	
Not weight of tablet, 212.4 mg/0.000 ng/01 application), 90.5 mg/0.002 ng/0.71 ng/15	-4:- ·· \	

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

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- 3. Fill bottle with water and connect to the dental unit.
- 4. Wait 60 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.

#### FIRST AID:

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Phone: 1-800-547-1883 Fax: 503-537-2843

EPA Establishment Number 84100

Made in USA

EPA Registration Number 79662-1

Use with 2-liter bottle **50 TABLETS** 

a dec

formulated to maintain dental unit waterlines and prevent accumulation

Net weight of tablet: 212.4mg / 0.008 oz Net weight of product: 10.62g / 0.375 oz 50 tablets/box

EPA Registration No. 79662-1 EPA Establishment No. 084100-CT-001

Use with 2-liter bottle **50 TABLETS** 

a dec

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,

See insert for precautionary, first aid statements and storage and disposal.

LOT



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Authorized EU Representative: A-dec United Kingdom Austin House, 11 Liberty Way Nuneaton, Warwickshire CV11 6RZ England

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U.S. Patent No. 7,033,511

Order no. 90.1065.01

Use with 2-liter bottle a dec 50 TABLETS A-dec Inc. 2601 Crestview Drive Newberg, Oregon 97132 USA Phone: 1-800-547-1883, 1-503-538-9471, Fax: 1-503-538-5911 © 2008 A-dec inc. All rights reserved.

ICX **390** 

STALETS 2-liter bottle Use with

ACTIVE INGREDIENTS:	
Sodium Percarbonate	6.96%
n-Alkyl (60% C <sub>14</sub> , 30% C <sub>16</sub> , 5% C <sub>12</sub> , 5% C <sub>12</sub> ) dimethyl benzyl ammonium chloride .	0.85%
n-Alkyl (68% C <sub>32</sub> , 32% C <sub>14</sub> ) dimethyl ethylbenzyl ammonium chloride	0.85%
Silver Nitrate	0.14%
Other ingredients	91.2%
Total	100%
DIRECTIONS FOR USE	

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

Before Refilling Bottle:

Empty any remaining water left in the 2 liter bottle.

3. Fill bottle with water, connect to dental unit.

2. Drop tablet into empty dental

regular dental unit water testing.

Wait 60 seconds for tablet to fully

(Avoid touching the tablet with unprotected skin.)

NOTE -This product is intended for use with potable water and in conjunction with

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# |CX

Use with 0.7-liter bottle 50 TABLETS

Use with 0.7-liter bottle 50 TABLETS

# a dec

ICX

A-dec Inc. 2501 Crestview Drive

Newberg, Oregon 97132 USA

Phone: 1-800-547-1883, 1-503-538-9471, Fax: 1-503-538-5911

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#### ACTIVE INGREDIENTS:

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Silver Nitrate	0.14%
Other Ingredients	91.2%
Total	

#### DIRECTIONS FOR USE

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

## Before Refilling Bottle:

- Empty any remaining water left in the 0.7 liter bottle.
- Drop tablet into empty dental unit water bottle.
  - (Avoid touching the tablet with unprotected skin.)
- Fill bottle with water, connect to dental unit.
- Wait 60 seconds for tablet to fully dissolve.

NOTE -This product is intended for use with potable water and in conjunction with regular dental unit water testing.

Use with
0.7-liter bottle
50 TABLETS

a dec

ICX

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

Net weight of tablet: 80.5mg / 0.003 oz Net weight of product: 4.03g / 0.142 oz 50 tablets/box

EPA Registration No. 79662-1 EPA Establishment No. 084100-CT-001 Use with
0.7-liter bottle
50 TABLETS

a dec

KEEP OUT OF REACH OF CHILDREN WARNING

PRECAUTIONARY STATEMENTS

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See insert for precautionary, first aid statements and storage and disposal.

LOT

\*+D7189010640116\*

Authorized EU Representative: A-dec United Kingdom Austin House, 11 Liberty Way Nuneaton,Warwickshire CV11 6RZ England

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U.S. Patent No. 7,033,511

Order no. 90.1064.01