



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

June 10, 2016

Alicia Henk  
Director, Development and regulatory Affairs  
Ceva Animal Health, LLC  
8735 Rosehill Road  
Lenexa, KS 66215

Subject: Label Amendment – Clarification about package size and animal weight range  
Product Name: Imidacloprid and Pyriproxifen Spot-On Solution for Dogs  
EPA Registration Number: 83399-17  
Application Date: 4/13/2016  
Decision Number: 516634

Dear Ms. Henk:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. 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. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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

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516634

with FIFRA section 6. If you have any questions, please contact Rita Kumar by phone at (703) 308-8291, or via email at [kumar.rita@epa.gov](mailto:kumar.rita@epa.gov).

Sincerely,

A handwritten signature in cursive script that reads "Rita Kumar for". The signature is written in black ink and is positioned to the right of the word "Sincerely,".

Venus Eagle, Product Manager 01

Insecticide-Rodenticide Branch 3

Registration Division (7505P)

Office of Pesticide Programs

**“Master Label”**

This master label includes label text for different size packages and application rates specific to the pet’s age and body weight. Text that appears in parenthesis are informational to the EPA, but will not be printed. Text that appears in brackets are optional.

**(FRONT PANEL OF OUTER BOX)**

(Market Label-

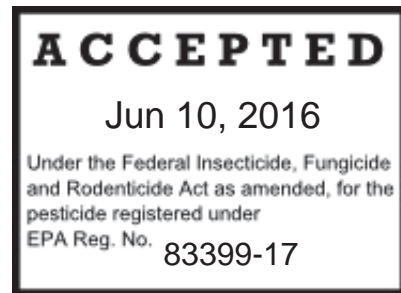
- The word Dog will be at least 40-75% in height of the largest letter in the primary brand name.
- A large clear picture of a dog in the respective weight range will be on the front panel of the label.)

**Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs**

Alternate Brand Names include:

**Combiva II For Dogs and Puppies**

**CrossBlock II For Dogs and Puppies**



(The above brand names will be packaged in the weight ranges below:)

**3-10 lbs, 7 weeks or older (0.014 fl oz)**

**11-20 lbs, 7 weeks or older (0.034 fl oz)**

**21-55 lbs, 7 weeks or older (0.085 fl oz)**

**Over 55 lbs, 7 weeks or older (0.135 fl oz)**

(Outer box will list only one weight range based on the package dose volume)

Imidacloprid and Pyriproxyfen Spot-on Solution for Dogs treats and prevents further flea infestation on dogs and puppies 7 weeks and older

(Optional marketing claims –see pages 9-10)

**ACTIVE INGREDIENTS:**

Imidacloprid..... 9.10%

Pyriproxyfen ..... 0.46%

**OTHER INGREDIENTS:** ..... 90.44%

**TOTAL** ..... 100.00%

**NET CONTENTS:** XXX fl oz [XXX mL]  
[XX Doses [each dose XXX fl oz]]

EPA Est. No. TBD

EPA Reg. No. 83399-17

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

See Back Panel / Package Insert for additional Precautionary Statements, First Aid and Directions for Use..

**Use only on dogs [and puppies] weighing (insert product weight range) lbs. and 7 weeks of age or older**



(“Do Not Use on Cats” icon 1.5cm x 1.5cm) (placed on front panel)

(BACK PANEL OF OUTER BOX)

## Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs

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(Outer box will list only one weight range based on the package dose volume)

(Optional marketing claims –see pages 9-10)

FIRST AID	
<b>IF SWALLOWED:</b>	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 the poison control center or doctor. Do not give anything to an unconscious person.
<b>IF IN EYES:</b>	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.
<b>IF ON SKIN OR CLOTHING:</b>	Wash with plenty of soap and water. Remove and wash contaminated clothing before reuse.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may contact 1-800-999-0297 weekdays between 9am and 6pm EST or 1-888-426-4435 for emergency medical treatment information.	

## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS

**CAUTION:** Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and warm water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Keep out of reach of children.

### HAZARDS TO DOMESTIC ANIMALS

**FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS.**

Do not use on puppies under 7 weeks of age or weighing less than (*minimum weight based on the package size*) [3 lbs (0.014 fl oz)][11 lbs (0.034 fl oz)][21 lbs (0.085 fl oz)][56 lbs (0.135 fl oz)]. As with any product, consult your veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing dogs. If your dog is exhibiting signs or is being treated for skin dermatitis, talk to your vet before applying any topical flea and tick control product.

**Side Effects:** Monitor your dog after application. Side effects, although rare, may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-999-0297. Have the product container or label with you when calling your veterinarian for advice.



Keep cats away from treated dog for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

[Product of]

[Distributed by:] [Manufactured for:]  
Ceva Animal Health, LLC  
8735 Rosehill Road  
Lenexa, KS 66215

[Made in Germany]

lot#, date &/or label code [UPC CODE]

[MWI, Boise, ID 83705]

[Combiva is a registered trademark of Ceva Santé Animale]

[Recyclable Packaging][recycling symbol]

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(SECTION UNDER FRONT PANEL- appears after lifting the front panel of the box)

## Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs

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**Over 55 lbs, 7 weeks or older (0.135 fl oz)**

(Outer box will list only one weight range based on the package dose volume)

1 Tear through perforation



2 Fold back the safety tab



3 Cut with scissors to open applicator



### RESTRICTIONS:

- Do not allow children to apply product.
- Do not apply more than one [1] tube per treatment.
- Do not split one tube between two dogs.
- Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death.

See package insert for complete directions for use.

(PACKAGE INSERT)

## Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs

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(Optional marketing claims –see pages 9-10)

### ACTIVE INGREDIENTS:

Imidacloprid..... 9.10%

Pyriproxyfen ..... 0.46%

**OTHER INGREDIENTS:** ..... 90.44%

**TOTAL** ..... 100.00%

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

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<b>IF SWALLOWED:</b>	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 the poison control center or doctor. Do not give anything to an unconscious person.
<b>IF IN EYES:</b>	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.
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### HAZARDS TO DOMESTIC ANIMALS

#### FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS.

Do not use on puppies under 7 weeks of age or weighing less than (*minimum weight based on the package size*) [3 lbs (0.014 fl oz)][11 lbs (0.034 fl oz)][21 lbs (0.085 fl oz)][56 lbs (0.135 fl oz)] As with any product, consult your veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing dogs. If your dog is exhibiting signs or is being treated for skin dermatitis, talk to your vet before applying any topical flea and tick control product.

**Side Effects:** Monitor your dog after application. Side effects, although rare, may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-999-0297. Have the product container or label with you when calling your veterinarian for advice.



Keep cats away from treated dog for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.  
**READ ENTIRE LABEL BEFORE EACH USE**

## CONSUMER INFORMATION

**Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs** kills fleas within 12 hours. **Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs** prevents flea infestation for four (4) weeks [1 month] [30 days].

OR

The active ingredients in Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs [this product] are formulated for control of fleas for 1 month [4 weeks] [30days] on dogs.

### RESTRICTIONS:

- Do not allow children to apply product.
- Weigh your dog to be sure you are using the right size product for your dog.
- For use only on dogs and puppies 7 weeks and older weighing [3-10 lbs (0.014 fl.oz.)] or [11-20 lbs (0.034 fl. oz.)] or [21-55 lbs (0.085 fl. oz.)] or [Over 55 lbs (0.135 fl. oz.)]
- Do not apply more than one [1] tube per treatment.



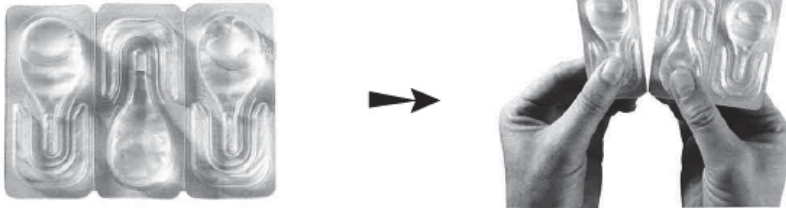
**EPA REG. NO. 83399-17**  
**LABEL AMENDMENT**  
**DATE: May 23, 2016**

- Do not split one tube between two dogs.
- Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death.
- Do not use on other animals.
- Do not have contact or allow children to have contact with treated area until completely dry.

TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS. DO NOT USE ON OTHER ANIMALS.

**OPENING INSTRUCTIONS:**

**1** Tear through perforation



**2** Fold back the safety tab

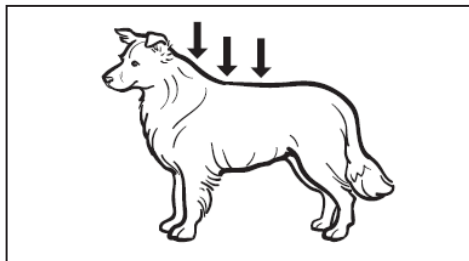


**3** Cut with scissors to open applicator



**HOW TO APPLY:**

1. The dog should be standing or in a comfortable position for easy application. Apply the entire contents of the applicator evenly to three spots along the dog's back, from the shoulder to the middle of the back.
2. At each spot, part the hair down to the level of the skin and gently squeeze the applicator to apply the product. [Avoid superficial application to the dog's hair.]



3. Do not apply an excessive amount of solution to any one spot. This could cause the product to run off the dog. Do not get the product in the dog's eyes or mouth or allow your dog to ingest the

- product. Do not use more than one tube on dogs greater than 55 lbs.
4. Discard the empty applicator as outlined in the Storage and Disposal section.
  5. Repeat every month, or as recommended by your veterinarian.

### **FREQUENCY OF APPLICATION**

Treatment of Imidacloprid and Pyriproxyfen Spot-on Solution for Dogs will kill fleas on dogs [and][puppies] within 12 hours and re-infesting fleas within 2 hours. It is possible pre-existing pupae in the environment may continue to emerge for six [6] weeks [or longer] depending on climatic conditions. Use Imidacloprid and Pyriproxyfen Spot-on Solution for Dogs monthly [every 30 days] [every 4 weeks] for the control and prevention of flea re-infestations.

OR

[Studies have shown that] Imidacloprid and Pyriproxyfen Spot-on Solution for Dogs kills fleas on dogs within 12 hours for up to four [4] weeks [1 month] [30 days]. To prevent flea re-infestation, apply monthly. Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs remains effective even after exposure to sunlight. Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs is water resistant and is still effective, after bathing or water immersion. Allow treated area to dry thoroughly.

### **STORAGE AND DISPOSAL**

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

**PESTICIDE STORAGE:** Store in a cool, dry place. Keep out of reach of children.

**PESTICIDE DISPOSAL AND CONTAINER HANDLING:** Non-refillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling, if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

### **LIMITED WARRANTY AND LIMITATION OF DAMAGES**

Seller warrants that the material conforms to the chemical parameters of the US EPA registration and the label. To the extent consistent with applicable law, seller makes no warranty, express or implied, other than indicated on the label. Buyer and user assume all risk of use and handling of this material. To the extent consistent with applicable law, any damages arising from use of this product or a breach of this warranty shall be limited to direct damages and shall not include consequential or incidental damages such as loss of profit or values.

[Made in Germany]

[Product of] [Distributed by:] [Manufactured for:]  
Ceva Animal Health, LLC  
8735 Rosehill Road  
Lenexa, KS 66215

EPA Reg. No. 83399-17  
EPA Est. No. TBD  
lot#, date &/or label code [UPC CODE]

[MWI, Boise, ID 83705]  
[Combiva is a registered trademark of Ceva Santé Animale]

[Recyclable Packaging][recycling symbol]

(OPTIONAL MARKETING CLAIMS)

(for use on the front, side, or back panels of the outer box or on the package insert)

**Fleas**

- [Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs] contains the active ingredient [imidacloprid],[and an/the] [insect growth regulator][IGR] [pyriproxyfen]
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs] contains an [insect growth regulator] [IGR] that effectively kills flea eggs
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs] prevents further flea infestation for four [4] weeks [1 month] [30 days]
- Protects against fleas for up to four [4] weeks [1 month] [30 days]
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs] helps prevent further flea infestation for up to four [4] weeks [1 month] [30 days]
- Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs [continually] works to prevent further flea infestation for up to four [4] weeks [1 month] [30 days]
- Effectively kills adult fleas and prevents further re-infestation
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs] treats, controls, and prevents further flea re-infestation
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs] treats for fleas within 12 hours on dogs
- Kills fleas within [in] 12 [twelve] hours [after application]
- Kills fleas before egg laying
- Kills fleas before eggs can be laid
- Kills fleas on dogs and puppies 7 weeks of age or older weighing at least [3 lbs (0.014 fl. oz.)] or [11 lbs. (0.034 fl. oz.)] or [21 lbs. (0.085 fl. oz.)] or [55 lbs. (0.135 fl. oz.)]
- Kills re-infesting fleas within 2 hours
- Kills fleas and their eggs
- Effectively kills flea eggs
- Disrupts the flea cycle and kills larval flea stages
- Breaks the flea life cycle and [prevents] [stops] flea eggs [and larvae] from developing into adult [biting] fleas
- Stops flea eggs from hatching [and] [developing into biting adults]
- Kills larval flea stages
- Kills re-infesting fleas within 2 hours [and protects against further flea re-infestation up to four [4] weeks [one month] [30 days]]
- Prevents further re-infestations by killing adult fleas within 12 hours for up to one month [4 weeks] [30 days]
- Controls fleas for dogs and puppies 7 weeks or older and weighing at least [3 lbs (0.014 fl. oz.)] or [11 lbs. (0.034 fl. oz.)] or [21 lbs. (0.085 fl. oz.)] or [55 lbs. (0.135 fl. oz.)]
- Treats flea infestations on dogs and puppies 7 weeks or older weighing at least [3 lbs (0.014 fl. oz.)] or [11 lbs. (0.034 fl. oz.)] or [21 lbs. (0.085 fl. oz.)] or [55 lbs. (0.135 fl. oz.)]
- Provides flea protection up to four [4] weeks [one month] [30 days]]
- Controls against [problematic] flea bites
- Kills fleas that may cause Flea Allergy Dermatitis [FAD]
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs] offers 3-way flea protection that [kills] [controls] [prevents] adults, larvae, and eggs
- [An effective] flea adulticide, larvicide, and ovicide [that [kills][prevents][,treats] [,and] [controls] fleas]
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs] offers effective multistage flea control
- Effective [once a month] [flea] [protection] [prevention and treatment]

- Effective flea treatment for your dog 7 weeks or older weighing at least [3 lbs (0.014 fl. oz.)] or [11 lbs. (0.034 fl. oz.)] or [21 lbs. (0.085 fl. oz.)] or [55 lbs. (0.135 fl. oz.)]
- Monthly topical treatment of Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs kills fleas and treats flea infestation for dogs and puppies 7 weeks or older weighing at least [3 lbs (0.014 fl. oz.)] or [11 lbs. (0.034 fl. oz.)] or [21 lbs. (0.085 fl. oz.)] or [55 lbs. (0.135 fl. oz.)]
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs] treats for fleas in 12 hours on dogs and puppies 7 weeks or older weighing at least [3 lbs (0.014 fl. oz.)] or [11 lbs. (0.034 fl. oz.)] or [21 lbs. (0.085 fl. oz.)] or [55 lbs. (0.135 fl. oz.)]
- Monthly treatment prevents further re-infestation and treats fleas on dogs 7 weeks or older weighing at least [3 lbs (0.014 fl. oz.)] or [11 lbs. (0.034 fl. oz.)] or [21 lbs. (0.085 fl. oz.)] or [55 lbs. (0.135 fl. oz.)]
- [Kills] [Treats] fleas which may serve as intermediate hosts for tapeworm

**All Others**

- For Dogs and puppies 7 weeks or older weighing at least [3 lbs (0.014 fl. oz.)] or [11 lbs. (0.034 fl. oz.)] or [21 lbs. (0.085 fl. oz.)] or [55 lbs. (0.135 fl. oz.)]
  - For Use on puppies 7 weeks or older weighing at least [3 lbs (0.014 fl. oz.)] or [11 lbs. (0.034 fl. oz.)] or [21 lbs. (0.085 fl. oz.)] or [55 lbs. (0.135 fl. oz.)]
  - For Use on Dogs Only 7 weeks or older weighing at least [3 lbs (0.014 fl. oz.)] or [11 lbs. (0.034 fl. oz.)] or [21 lbs. (0.085 fl. oz.)] or [55 lbs. (0.135 fl. oz.)]
  - Easy to Use Applicator
  - Easy to Apply Applicator
  - Applies Easily
  - Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs recommends monthly treatments
  - One Step Flea Prevention for up to four [4] weeks [one month][30 days]
  - For Best Results Apply Monthly [every 30 Days] [every [4] [four] weeks]
  - For year round protection apply monthly [every [[four] [4] weeks] [30 days]]
  - Use Monthly [Every [30 Days] [4] [Four] Weeks] for best results
  - Only one treatment needed every month [30 Days] [[4] [Four] Weeks]
  - One treatment remains effective for four [4] weeks [1 month] [30days]
  - Convenient
  - Water-resistant after application
  - Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs is waterproof after application
  - Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs is effective after [bathing] [shampooing]
  - Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs is effective [even] after exposure to rain or sunlight
  - Formulated for control of fleas for 1 month [4 weeks] on dogs
  - Contains the [same] active ingredients as in [Bayer] Advantage II for Dogs
  - Contains the active ingredients [imidacloprid, pyriproxyfen]found in [Bayer] Advantage II for dogs
  - Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs is not manufactured or distributed by Bayer [Animal Health]
  - Satisfaction guaranteed [or] Ceva Animal Health, LLC will provide new product or your money back
-

**EPA REG. NO. 83399-17**  
**LABEL AMENDMENT**  
**DATE: May 23, 2016**

*(APPLICATOR LABELING)*

**Imidacloprid and Pyriproxyfen Spot-on  
Solution For Dogs**

[insert wt range] lbs  
7 weeks or older

Imidacloprid 9.10%  
Pyriproxyfen 0.46%

**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**

Read entire label before use.  
[Use scissors to open.]

EPA REG. No. 83399-17  
Lot # *(designation will identify producing establishment)*  
XXX fl. oz.

[label code]