

40391-10

10-26-2010

1/9



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 26, 2010

Ms. Sharon M. Johnston,
Regulatory Consultant for
Entech Systems Corporation
c/o RegGuide
509 Tower Valley Drive
Hillsboro, MO 63050-1216

**Subject: Amended Labeling, Updates for PR Notice 2007-4
ENTECH FOG-10, EPA Reg. No. 40391-10
Your Submission Dated July 23, 2010**

Dear Ms. Johnston:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable with the following provision(s):

General Statement:

1. Delete all text throughout the label marked with "strikethrough."

Marketing Statements section comment(s):

2. At the beginning of this section, replace the words "Effective in the control of the below-listed insects ..." with the words "To kill the following listed insects, ..."

Environmental Hazards section comment(s):

3. To facilitate inclusion of required language from the REDs for pyrethrins, piperonyl butoxide and MGK® 264 insecticide synergist (updated label tables for pyrethrins/piperonyl butoxide/MGK 264 insecticide synergist combination products), make the following changes within this section:
 - Within the 4th sentence of the 1st paragraph, replace the word "water" with the word "product," and replace the word "weeks" with the words "months or more."
 - Within the 1st sentence of the 3rd paragraph, revise the words "Do not apply to water, ..." to read "Do not apply directly to ..."

Directions for Use, General Precautions & Restrictions subsection comment(s):

4. Revise the subsection heading "General Precautions & Restrictions" to read "Use Restrictions."
5. To facilitate inclusion of required language from the REDs for pyrethrins, piperonyl butoxide and MGK® 264 insecticide synergist (updated label tables for pyrethrins/piperonyl butoxide/MGK 264 insecticide synergist combination products), make the following changes within this subsection:
 - Add the following statement immediately following the existing 3rd bulleted statement: "Do not wet plants to point of run-off or drip."
 - Within the 4th bulleted statement, replace the word "and" with the words "and/or."
 - Within the 6th bulleted statement, insert the words "(12 weeks of age or older)" immediately following the word "pets."
 - Revise the 13th bulleted statement to read "For indoor food handling/processing facilities: Do not make space spray applications when facility is in operation. Prior to space spray applications, cover or remove food. Prior to space spray applications, cover food processing surfaces or clean after treatment and before use. Do not apply more than 1 time per day."

Directions for Use section comment(s):

6. Revise the existing subsection heading "**General:**" to read "**Use Directions:**"
7. Within the 1st paragraph in the "**Indoor Use as a Space Spray Undiluted:**" subsection, replace the last 4 sentences with "Do not remain in treated areas. Leave the treated area closed off for at least 15 minutes. Thoroughly ventilate treated areas before re-occupying. Do not apply more than 1 time per day. Sweep up and destroy fallen insects."
8. Within the 1st sentence of the 2nd paragraph in the "**Indoor Use as a Space Spray Undiluted:**" subsection, replace the word "controls" with the word "kills."
9. Within the 1st sentence in the "**Dried Fruit Products:**" subsection, replace the words "for control of" with the words "to kill" and replace the last 3 sentences with "Leave the treated area closed off for at least 1 hour. Thoroughly ventilate treated areas before re-occupying. Do not apply more than 1 time per day. Sweep up and destroy fallen insects."
10. Within 1st sentence of the 1st paragraph in the "**Stored Food:**" subsection, replace the words "for control of" with the words "to kill."
11. Within 2nd paragraph in the "**Stored Food:**" subsection, replace the last sentence with "Leave the treated area closed off for at least 1 hour. Thoroughly ventilate treated areas before re-occupying. Do not apply more than 1 time per day. Sweep up and destroy fallen insects."
12. Within the "**Indoor Use as a Space Spray, Diluted:**" subsection, replace the last 3 sentences with "Do not remain in treated areas. Leave the treated area closed off for at least 15 minutes. Thoroughly ventilate treated areas before re-occupying. Do not apply more than 1 time per day."
13. Within the 1st sentence in the subsection starting with "**On Peanuts, Nuts, Beans, ...**," replace the words "For the control of" with the words "To kill."
14. Within the 1st sentence of the 1st paragraph in the "**Surface Spray:**" subsection, replace the words "To ensure maximum control of" with the words "To kill."
15. Within the 1st sentence of the 2nd paragraph in the "**Surface Spray:**" subsection, replace the word "control" with the word "kill."
16. Within the 3rd sentence of the 2nd paragraph in the "**Surface Spray:**" subsection, replace the words "As an aid in the control of" with the words "To kill."
17. Within the 1st sentence of the 1st paragraph in the "**Outdoor Ground Application, Undiluted:**" subsection, replace the word "control" with the word "kill."
18. Within the 3rd sentence of the 2nd paragraph in the "**Outdoor Ground Application, Undiluted:**" subsection, replace the words "laxer-based" with the words "laser-based."
19. Within the 1st sentence of the 1st paragraph in the "**For Use on Animals:**" subsection, replace the word "dog" with the words "dog (12 weeks of age or older)."
20. Within the 1st sentence of the 2nd paragraph in the "**For Use on Animals:**" subsection, replace the word "control" with the word "kill."

Storage and Disposal section comment(s):

- 21. Revise the "**Storage:**" subsection to read "**Pesticide Storage:** Store in a cool, dry place away from heat or open flame in an area that is inaccessible to children and animals."
- 22. To facilitate inclusion of language from PR Notice 2007-4, revise the non-dilutable "**Container Disposal:**" statement to read "{Containers with NO dilutable instructions.} Nonrefillable container. Do not reuse or refill this container. **If empty:** Offer for recycling if available. **If partially filled:** Call your local solid waste agency for disposal instructions."

A copy of your label stamped "Accepted with Comments" is enclosed for your records. Please submit two (2) copies of the final printed labeling, incorporating the above changes, before releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA. Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions.

If you have any questions about this label review, please contact Mr. Carmen Rodia at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov.

Sincerely yours,



Richard J. Gebken,
 Product Manager (10)
 Insecticide Branch,
 Registration Division (7504P)

Enclosure: Label stamped "Accepted with Comments"
 040391-00010 D438424

4

ENTECH FOG-10

For Use Only by Trained Personnel

Effective in the control of the below-listed insects if the applicator follows the directions for use as set forth in this label. Angoumois Grain Moths, Ants, Boxelder Bugs, Cadelles, Cheese Mites, Cheese Skippers, Cigarette Beetles, Clover Mites, Confused Flour Beetles, Dark Meal Worms, Deer Flies, Dried Fruit Beetles, Drugstore Beetles, Earwigs, Fruit Flies (*Drosophila*), Fungus Gnats, Gnats, Grain Mites, Granary Weevils, Horn Flies, Hornets, Horse Flies, House Flies, Indian Meal Moths, Lice, Mediterranean Flour Moths, Mosquitoes, Mushroom Flies, Red Flour Beetles, Rice Weevils, Roaches, Sawtoothed Grain Beetles, Small Flying Moths, Spider Beetles, Stable Flies, Tobacco Moths, Wasps, Yellow Meal Worms.

Active Ingredients:

Pyrethrins	1.00%
*Piperonyl butoxide, technical	2.00%
**N-octyl bicycloheptene dicarboximide	3.33%
Other Ingredients***	93.67%
Total	100.00%

*Equivalent to 1.60% (butylcarbityl)(6-propylpiperonyl) ether and 0.40% related compounds.

**MGK® 264, Insecticide Synergist

***Contains petroleum distillates.

MGK® - Registered trademark of McLaughlin Gormley King Co.

Lot # _____

EPA Reg. No. 40391-10

EPA Est. No. 40391-LA-1

Keep Out of Reach of Children

CAUTION

See side [back] panel for additional precautionary statements.

Formulated by

Entech Systems Corporation

607 Maria Street Kenner, LA 70062
(504) 469-6541

Net Contents: Gallons
 1 5 20 55

ACCEPTED
With COMMENTS
In EPA Letter Dated:
October 26, 2010
Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:
40391-10

{Side/back panel(s)}

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Harmful if swallowed or absorbed through the skin. Avoid breathing vapor or spray mist. Avoid contact with skin, eyes or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

5/2

First Aid

If Swallowed	<ul style="list-style-type: none"> • Immediately call a poison control center or doctor. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give any liquid to the person. • 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. • Immediately rinse skin with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
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.
Note to Physician: Contains petroleum distillate. Vomiting may cause aspiration pneumonia.	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. [You may also contact 1-800-{appropriate number} for emergency medical treatment information.]	

{Note: The first aid statements' grid format will be used if market label space allows; otherwise a paragraph format will be used.}

Environmental Hazards

This product is toxic to aquatic organisms, including fish and invertebrates. Drift and run-off may be hazardous to aquatic organisms in water adjacent to treated areas. This product may contaminate water through run-off. This water has a potential for run-off for several weeks after application. Poorly draining soils and soils with shallow water tables are more prone to produce run-off that contains this product.

This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area.

Do not apply to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash-waters or rinsate. See Directions for Use for additional precautions and restrictions.

{Only for containers 5 gallons or larger} 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 sewer treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Physical or Chemical Hazards

Do not use or store near heat or open flame. Exposure to temperatures above 130°F may cause bursting.

DIRECTIONS FOR USE

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

~~GENERAL PRECAUTIONS & USE RESTRICTIONS~~

- Apply this product only as specified on this label.
- Do not contaminate food or feedstuffs.
- Not for use in outdoor residential misting systems.
- Do not enter or allow others to enter until vapors, mists and aerosols have dispersed and the area has been thoroughly ventilated.
- Except when applying directly to pets (12 weeks of age or older), do not apply this product in a way that will contact adults, children or pets, either directly or through drift.
- Except when applying to pets, only protected handlers may be in the area during application.
- Do not remain in treated area. Exit area immediately and remain outside the treated area until aerosols, vapors and/or mists have dispersed.
- Do not apply directly to or near water, storm drains or drainage ditches. Do not apply when windy. To prevent product run-off, do not over water the treated area(s) or apply prior to heavy rainfall.
- Remove or cover exposed food and drinking water before application.
- Remove or cover dishes, utensils, food processing equipment and food preparation surfaces or wash them before use.
- For pet care: Do not apply to pets less than 12 weeks old. Consult a veterinarian before applying this product on medicated, debilitated, aged, pregnant or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.
- For food stored in bags: direct application to food contact surfaces is prohibited.
- For use in food handling and processing facilities: Do not make space spray applications when facility is in operation. During space spray applications, cover or remove exposed food. During space spray applications, cover food processing surfaces or clean after treatment with a suitable detergent, rinse with potable water before use. Do not apply more than 1 time per day.
- For indoor agricultural premises, commercial animal housing and equipment and direct application to non-domestic animals: Do not apply more than 1 time per day.
- For dairy barns or non-residential indoor facilities: Close milk bulk tank lids to prevent contamination from spray and from dead or falling insects. Remove or cover milking utensils before application. Wash teats of animals before milking.
- Remove pets, birds and cover fish aquariums before application.

General: This product is designed for use undiluted in mechanical sprayers that give particles of aerosol size. It may be diluted with kerosenes (that meet Food Additive Regulations as defined by CFR Title 21, 172.884) and applied in fogging equipment that give larger than aerosol particle size.

~~Do not apply directly to food. Do not apply space spray while food processing is underway. Cover food processing surfaces or clean after treatment with suitable detergent and rinse with potable water before use.~~

Indoor Use as a Space Spray Undiluted: ~~Confine the use of this product in food processing or food handling establishments to time periods when these plants or facilities are not in operation. Remove or cover foods during treatment. Cover all food processing surfaces during treatment or thoroughly clean before using.~~ Close windows and doors and shut off ventilating systems. Use a fogger or vaporizer adjusted to deliver an aerosol spray (no droplets over 50 microns in diameter and 80% less than 30 microns). Apply at a rate of 1 ounce per 1,000 cubic feet of space. Direct the spray toward the ceiling and upper corners of the area behind obstructions. Keep the area closed for at least 15 minutes. Vacate the treated area and ventilate before reoccupying. Repeat treatment as necessary. Sweep up and destroy fallen insects.

This method of application controls exposed, accessible stages of Flies (including Fruit Flies), Mosquitoes, Small Flying Moths, Gnats, Wasps, Hornets, Clover Mites, Cheese Mites, Cheese Skippers, Boxelder Bugs, Earwigs, Ants and the following common stored product pests: Granary Weevils, Rice Weevils, Confused Flour Beetles, Sawtoothed Grain Beetles, Spider Beetles, Cigarette Beetles, Drugstore Beetles, Angoumois Grain Moths, Mediterranean Flour Moths, Indian Meal Moths, Tobacco Moths, Yellow Meal Worms, Dark Meal Worms, Grain Mites, Cadelles and Red Flour Beetles.

Dried Fruit Products: In storage or being processed, for control of Confused Flour Beetles, Dried Fruit Beetles, Indian Meal Moths and Sawtoothed Grain Beetles: Remove and destroy infested products. As noted above disperse this product as a fine mist in the air above the trays and shelves. Do not apply directly to fruit. Use 1 ounce per 1,000 cubic feet of space. Repeat application at this dosage in any given month. Leave the room closed for one hour. Do not remain in treated areas and ventilate the area before reentry. Sweep up and destroy fallen insects.

Stored Food: (Stored in multiwall bags or cloth bags) in warehouses, storage rooms, flour mills, grain elevators, granaries for control of Angoumois Grain Moths, Cadelles, Confused Flour Beetles, Indian Meal Moths, Mediterranean Flour Moths, Rice Weevils, Sawtoothed Grain Beetles, Yellow Meal Worms, Cheese Mites, Cheese Skippers, Cigarette Beetles, Grain Mites, Granary Weevils, Dark Meal Worms, Red Flour Beetles: Remove and destroy infested products. As noted above, disperse this product first by directing spray into corners, under pallets and around stacks of packaged foods hitting as many insects as possible and then treat as a space spray.

Fumigate or treat infested stored products by other effective methods using a product intended and approved for this purpose. Use a dosage of 1 fluid ounce per 1,000 cubic feet of space. Do not remain in treated areas and ventilate area before reentry. This application kills accessible, exposed stages of those stored product pests listed above. Sweep up and destroy fallen insects.

Indoor Use as a Space Spray, Diluted: For use in conventional mechanical fogging equipment to kill Flies, Fruit Flies, Mosquitoes, Small Flying Moths and Gnats: ~~Cover or remove exposed food and food handling surfaces.~~ Close room and shut off all air conditioning or ventilating system equipment. Dilute 1 part concentrate in 9 parts oil and mix well. Apply at the rate of 1 to 2 fluid ounces per 1,000 cubic feet filling the room with mist. Keep area closed for at least 15 minutes. Vacate treated area and ventilate before reoccupying. Repeat treatment when reinfestation occurs.

On Peanuts, Nuts, Beans (including Cocoa), Seeds and Copra (in bags or other packaging): For the control of accessible stages of Almond Moths, Angoumois Grain Moths, Ants, Cadelles, Cereal Beetles, Cheese Mites, Cheeses Skippers, Chocolate Moths, Cigarette Beetles, Cockroaches, Confused Flour Beetles, Crickets, Dark Mealworms, Drugstore Beetles, Earwigs, Firebrats, Flies, Fruit Flies, Fungus Gnats, Grain Mites, Granary Weevils, Hide Beetles, Indian Meal Moths, Mediterranean Flour Moths, Mosquitoes, Red Flour Beetles, Rice Weevils, Sawtoothed Grain Beetles, Silverfish, Small Flying Moths, Spiders, Spider Beetles, Yellow Mealworms, Dried Fruit Beetles, Warehouse Beetles, Rusty Grain Beetles, Lesser Grain Beetles, Coffee Bean Weevils, Khapra Beetles and other listed insects. Apply to the surfaces of stored or bagged products. Also thoroughly spray walls, floors and other surfaces, storage and handling areas, being especially careful to treat cracks, crevices and similar hiding places. Then apply as a space spray at the rate of 1/2 to 1 ounce per 1000 cubic feet of space by directing the spray toward the ceiling and upper corners of the area and behind any obstructions.

Surface Spray: To ensure maximum control of crawling insects (Ants, Boxelder Bugs, Clover Mites, Drugstore Beetles, Earwigs, Lice, Spider Beetles) dilute 1 part concentrate in 9 parts oil, mix well and apply as a coarse wetting spray using approximately 1 gallon of spray mixture to 750 square feet of surface. Thoroughly spray walls, floors and other surfaces of bins and storage and handling areas, being especially careful to treat cracks, crevices and similar hiding places. Treat unloading, handling and processing areas and inside conveying, processing and handling equipment. Thoroughly spray around the base of heavy machinery and equipment. Directly spray insects when possible.

For in-transit protection, clean and spray truck beds, boxcars and ships holds before loading. Thoroughly treat walls and floors and lightly spray each layer of stacked cartons or containers.

To control Indian Meal Moths and Angoumois Grain Moths in stored grain, apply to the surface of binned grain at a rate of 1 gallon per 1,000 square feet. Apply at monthly intervals with the first appearance of moths and continuing until early fall. In case of severe infestation, break up webbing with rake before spraying and make a second application in two weeks.

9/8

As an aid in the control of Mosquitoes, Gnats, Wasps and Skippers: Treat walls, ceilings, moldings, screens, door and window frames, beams, light cords and similar resting places.

Animal Quarter Use: (Cattle barns, horse barns, poultry houses, swine houses, zoos). As a space spray diluted for use in conventional mechanical fogging equipment to kill Flies, Mosquitoes, Small Flying Moths and Gnats, dilute 1 part concentrate in 9 parts oil and mix well. Apply at the rate of 2 fluid ounces per 1,000 cubic feet of space above the animals. Direct spray towards the upper portions of the enclosure filling the room with mist. Keep area closed for at least 15 minutes. Vacate treated area and ventilate before reoccupying. Repeat treatment when reinfestation occurs.

Outdoor Ground Application, Undiluted: To control Adult Mosquitoes, Gnats and Small Flying Moths: For best results, apply when there is a light breeze of approximately 5 mph and temperature is cool (75°F or less). With a ULV spraying device spray at a dosage rate of 5 ounces per minute up-wind of the area to be controlled. If the equipment is truck mounted, keep the speed to approximately 5 mph with a swath width of no more than 300 feet.

For ground-based mechanical application equipment for ULV mosquito abatement programs: Spray equipment must be adjusted so that the volume median diameter is less than 30 microns ($Dv\ 0.5 < 30\ \mu m$) and that 90% of the spray is contained in droplets smaller than 50 microns ($Dv\ 0.9 < 50\ \mu m$). Directions from the equipment manufacturer or vendor, pesticide registrant or a test facility using a laser-based measurement instrument must be used to adjust equipment to produce acceptable droplet size spectra. Application equipment must be tested at least annually to confirm that pressure at the nozzle and nozzle flow rates(s) are properly calibrated.

Temporary Reduction of Annoyance from Flies, Mosquitoes and Small Flying Moths outdoors. The aforementioned application for outdoor ground application will afford temporary reduction of annoyance from these pests in public gathering places (drive-in restaurants, drive-in theaters, golf courses, municipalities, parks, playgrounds and recreational areas). Direct application into tall grass, shrubbery and around lawns where these pests may hover or rest. Apply while air is still. Avoid wetting foliage. Application should be made prior to attendance. Repeat as necessary.

In additional outdoor areas (corrals, feed lots, swine lots and zoos) cover water, drinking fountains and animal feed before use. Fill area with mist, directing application into tall grass, shrubbery and around lawns where these pests may hover or rest. Apply while air is still. Avoid wetting foliage. In zoos avoid exposure of reptiles to the product. Repeat as necessary.

For Use on Animals: To protect beef and dairy cattle, horse and dogs from Horn Flies, House Flies, Mosquitoes and Gnats, dilute 1 part of concentrate in 9 parts oil and mix well. Apply a light mist sufficient to wet the tips of the hair. To control Stable Flies, Horse Flies and Deer Flies on beef and dairy cattle and horses, apply 2 ounces per adult animal sufficient to wet the hair but not to soak the hide. Repeat treatment once or twice daily or at intervals to give continued protection.

To control the motile stages of Blood Sucking Lice on beef and dairy cattle, apply the spray to thoroughly wet the hair. Use 2 ounces or less per animal and repeat every 2 to 3 weeks as required.

9/2

Storage and Disposal

Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited.

Storage: Store in a cool, dry place. Keep container closed.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: {Containers with NO dilutable instructions} Non-refillable container. Do not reuse or refill this container. Triple rinse container (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.

{Containers that include dilutable instructions} Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. {Containers 5 gallons or less} Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with kerosene and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling if available, or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill or by other procedures as approved by state and local authorities. {Containers over 5 gallons} Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with kerosene. 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 if appropriate, or puncture and dispose of in a sanitary landfill or by other procedures as approved by state and local authorities.

IMPORTANT: READ BEFORE USE

To the extent consistent with applicable law, buyer assumes all risks of use, storage or handling of this material not in strict accordance with the directions given herewith.

[] Denotes alternate/optional language

{ } Denotes language that does not appear on market labeling