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Reg # 62719-234

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

APR 28 1997

Steve A. McMaster
DowElanco
9330 Zionsville Rd.
Indianapolis, IN 46268-1054

SUBJECT: Label Amendment
Profile 2SC Tree Growth Regulator
EPA Registration No 62719-234
Your Submission Dated December 10, 1996

Dear Mr. McMaster:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below.

1. In the General Use Precautions Section modify the second bullet to read either "Trees not used for food production that are not specifically listed on this label may be treated if all other label directions are followed." or "Ornamental trees not specifically listed on this label may be treated if all other label directions are followed." See our letter dated May 26, 1995. (copy enclosed)
2. Add Storage and Disposal Directions to the base label.

Five (5) copies of the finished labeling must be submitted prior to releasing the product for shipment.

Sincerely yours,

/s/

Cynthia Giles-Parker
Team Leader (22)
Fungicide Branch
Registration Division (7505C)

Enclosure

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Profile* 2SC

Tree Growth Regulator

62719-234

Registration Notes:

Proposed label amendment: Current label text based on EPA-accepted text dated May 26, 1995.

Proposed Changes by Amendment:

Directions for Use Section:

1. General Information text edited for clarity.
2. "Approved Uses" section changed to "Application Methods".
3. Revised tree groupings relative to application rates and consolidated elms, maples and oaks to include all species.
4. Added guidance on when to use higher rate in rate range.
5. Added Figures 1 and 2 illustrating correct application techniques.
6. Revised application rate table and increased the number of injection sites per tree to improve uniformity of growth regulation.

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Editor's Note: Added text underlined, deleted text denoted by strike through.

ACCEPTED
with COMMENTS
In EPA Letter Dated
APR 28 1997

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

62719-234

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(Base Label)

(Logo) DowElanco

Profile* 2SC

Tree Growth Regulator

For the reduction of terminal growth and pruning volume in trees not used for food production on sites such as utility rights-of-way, urban environments, residential areas and non-crop areas.

Active Ingredient:

paclobutrazol: (R*,R*)-(±)-β-[(4-chlorophenyl) methyl]-α-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol21.8%

Inert Ingredients78.2%

Total100.0%

Contains 2 pounds of active ingredient/gallon

U.S. Patent No. 4,243,405

Precautionary Statements

Hazards to Humans and Domestic Animals

Keep Out of Reach of Children

CAUTION

Harmful If Swallowed Or Absorbed Through The Skin

Avoid contact with eyes, skin or clothing. Wear protective clothing, long-sleeved shirt, and rubber gloves. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling.

First Aid

If swallowed: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If on skin: Wash with plenty of soap and water.

If in eyes: Flush with plenty of water. Get medical attention if irritation persists.

Environmental Hazards

Do not apply directly 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 washwaters.

Physical or Chemical Hazards

Do not use or store near heat or open flame.

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Directions for Use

It is a violation of Federal law to use this product in manner inconsistent with its labeling.
Read all Directions for Use carefully before applying.

Notice: Read the entire label. Use only according to label directions. Before buying or using this product, read "Warranty Disclaimer" and "Limitation of Remedies" inside label booklet.

Refer to attached booklet for additional precautionary information and Directions for Use.

In case of emergency endangering health or the environment involving this product, call collect 517-636-4400.

Specialty Chemical: Do not ship or store with food, feeds, drugs or clothing.

Shake Well Before Use

Product Must be Diluted Before Use

EPA Reg. No. 62719-234

EPA Est. 1471-IN-5

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Specialty Growth Regulator

Net Contents 1 Gal

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(Label Booklet)

(Logo) DowElanco

Profile* 2SC

Tree Growth Regulator

For the reduction of terminal growth and pruning volume in trees not used for food production on sites such as utility rights-of-way, urban environments, residential areas and non-crop areas.

Active Ingredient:

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Inert Ingredients78.2%

Total100.0%

Contains 2 pounds of active ingredient/gallon

U.S. Patent No. 4,243,405

Keep Out of Reach of Children

CAUTION

Refer to inside of label booklet for additional precautionary information and Directions for Use including STORAGE AND DISPOSAL.

Notice: Read the entire label. Use only according to label directions. Before buying or using this product, read "Warranty Disclaimer" and "Limitation of Remedies" inside label booklet.

In case of emergency endangering health or the environment involving this product, call collect 517-636-4400.

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EPA Reg. No. 62719-234

EPA Est. 1471-IN-5

*Trademark of DowElanco.

DowElanco • Indianapolis, IN 46268 USA

Specialty Growth Regulator

Net Contents 1 Gal

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Precautionary Statements

Hazards to Humans and Domestic Animals**CAUTION****Harmful If Swallowed Or Absorbed Through The Skin**

Avoid contact with eyes, skin or clothing. Wear protective clothing, long-sleeved shirt, and rubber gloves. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling.

First Aid

If swallowed: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If on skin: Wash with plenty of soap and water.

If in eyes: Flush with plenty of water. Get medical attention if irritation persists.

Environmental Hazards

Do not apply directly 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 washwaters.

Physical or Chemical Hazards

Do not use or store near heat or open flame.

Directions for Use

It is a violation of Federal law to use this product in manner inconsistent with its labeling. Read all Directions for Use carefully before applying.

Storage and Disposal

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

Storage: Keep container closed when not in use. Do not store near food or feed. Protect from freezing. In case of spill or leak on floor or paved surfaces, soak up with sand, earth or synthetic absorbent. Remove to chemical waste area.

Pesticide Disposal: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these cannot be used 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.

Metal Container Disposal: 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.

Plastic Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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General Information

Profile* 2SC tree growth regulator is a xylem mobile plant growth regulator that slows vegetative growth by inhibiting gibberellin biosynthesis. Effects of Profile 2SC are expressed as internode compression and long-term reduces vegetative growth regulation thereby reducing the volume of woody growth that must be removed from trees when trimming occurs and may extend the trimming cycle. Profile 2SC demonstrates little or no phloem mobility. Activity occurs following root uptake and xylem translocation throughout the tree canopy. Profile 2SC is equally effective when applied as a basal soil drench or by soil injection.

Profile 2SC can be used on listed trees found in areas such as utility rights-of-way, urban environments, residential areas and other non-crop areas.

Profile 2SC retards vegetative growth thereby significantly reducing the volume of woody growth that must be removed from trees when trimming occurs. In some cases, the trimming cycle for treated trees can be extended. Profile 2SC is equally effective when applied as a basal soil drench or by soil injection.

Symptoms of Growth Retardation Regulation: Profile 2SC demonstrates little or no phloem mobility. Activity occurs following root uptake and xylem translocation throughout the tree canopy. Symptoms of growth regulation may not be visible for up to 18 months following application of Profile 2SC. Initial effects of Profile 2SC will may be observed as intense greening of foliage with no resulting phytotoxicity. At the time when normal vegetative growth extension should occur, trees treated with Profile 2SC will exhibit shortened internodes which are may be somewhat thickened. Smaller leaf size and enhanced flowering may also be observed in some species.

The degree and longevity of effect following application of Profile 2SC can be reduced by local soil and environmental conditions such as heavy clay soils and a shallow water table. Within the rate range given, adjust rates according to your local environmental and tree conditions.

General Use Precautions

- Apply at recommended rates and follow safety procedures.
- ~~Trees not specifically identified listed~~ on this label may be treated if all other label recommendations directions are followed.
- ~~Do not apply to trees~~ Trees which are severely stressed due to moisture, temperature, low soil fertility, or exhibit mechanical or chemical injury should not be treated.
- ~~Do not reapply Profile 2SC until symptoms from previous applications begin to disappear~~ subside, or within 3 years of the last application, whichever comes first.
- If soil is heavily compacted or a high water table exists, use of a registered tree growth regulator such as Cutless* Tree Implants may provide more effective control be more satisfactory.
- Basal drench and soil injection application of Profile 2SC may result in localized, temporary discoloration of turfgrass immediately adjacent to the treatment site.
- Avoid basal drench applications on slopes or other areas where Profile 2SC or treated soil may be washed away from the base of the tree by conducive to runoff from rainfall or irrigation.
- ~~Avoid treating~~ Treatment of trees bordered by shrubs and/or herbaceous ornamentals as nontarget may cause effects may occur these plants to be affected if their roots extend into the treatment zone.
- Do not treat sugar maple trees or any other trees that are or could be tapped for sugar.
- Do not treat nut or fruit trees that will be harvested within one year.

Chemigation: Do not apply this product through any type of irrigation system.

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Application Timing

Applications can be made throughout the year, weather permitting, except when soil is frozen or saturated with water. Note: Profile 2SC will only be absorbed by the plant roots and translocated to the growing tissues in response to evaporative water loss (transpiration) during periods of active growth. If dormant season applications are made after fall leaf drop, uptake of Profile 2SC will not occur until bud-break development of new leaves in the spring and resumption of evaporative water loss by plant leaves.

Profile 2SC may be applied by basal drench or soil injection techniques as described below:

Preparation of Ready-to-Use (RTU) Solution

Mixing Directions

Mix 300 317 ml (10.2 10.7 fl oz) of Profile 2SC with water to make one gallon of Ready-to-Use (RTU) solution diluted mixture. Eight gallons of Profile 2SC will make 100 gallons of RTU solution. One gallon of Profile 2SC will make 12 gallons of diluted mixture. To improve the handling characteristics of the diluted mixture, the addition of a suspension aid is recommended. Follow all label directions and precautions on the product label of the suspension aid.

Approved Uses

Application Methods

Profile 2SC may be applied as a basal drench or by soil injection. Treat only trees that are well established in their final location. Treatment of trees less than 4 inches in diameter is not recommended.

Basal Drench

Use the amount of RTU solution indicated in the table below per tree for soil injection treatments. Pour the indicated amount of RTU solution uniformly around the trunk base at the trunk/soil interface, using a graduated pitcher or similar vessel, or apply using an automatic dose measuring device. Application should be made in a shallow trench around the base of the tree if run-off is a concern. Refill trench after application.

Apply the required dose [total ml required for the application rate and tree size (DBH)] uniformly around the base of the tree at the point of contact between the soil and the tree trunk (Figure 1). The diluted mixture of Profile 2SC may be carefully poured around the tree or an applicator which provides a controlled rate of flow may be used. If there is potential for rainfall or irrigation to move surface applied product to non-target plants, apply Profile 2SC diluted mixture to the bottom of a shallow furrow around the base of the tree. After applying, refill the furrow with untreated soil.

Soil Injection

Use equipment that will inject the RTU solution into the soil in 100 to 250 ml units (3.4 to 8.5 fl oz) at 100 to 200 psi. The lower pressure range can be used on lighter soils.

Adjust the number of soil injection sites per tree so that no more than 250 ml of RTU solution is injected per injection site. To ensure uniform effectiveness on small trees, the use of at least 4 evenly spaced injection sites per tree is recommended and should be placed adjacent to buttress roots.

Injections sites should be spaced uniformly around the tree. RTU solution should be injected approximately 6 inches below the soil surface, and within 2 to 8 inches of the trunk base.

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The diluted mixture of Profile 2SC should be injected approximately 6 inches deep. Use soil injection equipment capable of delivery at 100 to 200 psi. Injection orifices should be oriented to release the diluted product horizontally at the point of injection. The required dose should be divided evenly among injection sites spaced as uniformly as possible around the tree trunk. The injection sites should be positioned to release Profile 2SC diluted mixture as close as possible to the point of contact between soil and unthickened bark beneath the soil so that the active ingredient may be readily absorbed by the tree (Figure 2). Injection sites should also be located next to buttress roots (Figure 2). For trees less than 6 inches DBH, use at least 4 evenly spaced injection sites per tree.

Application Rates

Application Rate Ranges for Diluted Mixture of Profile 2SC for Treatment of Various Tree Species†		
50 to 100 ml (1 to 2 grams a.i.) per inch DBH	100 to 150 ml (2 to 3 grams a.i.) per inch DBH	150 to 200 ml (3 to 4 grams a.i.) per inch DBH
Sweetgum Australian Pine	American Basswood Boxelder Elm(s) Eucalyptus Hackberry Littleleaf Linden	Locust, honey Maple(s) Oak(s) Sassafrass Ash Bradford Pear Sycamore Tuliptree Weeping Willow

†For acidic soils (low pH), soils with high organic matter content or soils with high clay content, use the higher rate in the rate range.

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Amount Of Profile 2SC Diluted Mixture Required For Specific Application Rates And Tree Sizes:

<u>Dia. of Tree at Breast Height (DBH) (Inches)</u>	<u>50 ml per inch DBH</u>	<u>100 ml per inch DBH</u>	<u>150 ml per inch DBH</u>	<u>200 ml per inch DBH</u>
	<u>Total ml Required</u>	<u>Total ml Required</u>	<u>Total ml Required</u>	<u>Total ml Required</u>
4	200	400	600	800
5	250	500	750	1000
6	300	600	900	1200
7	350	700	1050	1400
8	400	800	1200	1600
9	450	900	1350	1800
10	500	1000	1500	2000
11	550	1100	1650	2200
12	600	1200	1800	2400
13	650	1300	1950	2600
14	700	1400	2100	2800
15	750	1500	2250	3000
16	800	1600	2400	3200
17	850	1700	2550	3400
18	900	1800	2700	3600
19	950	1900	2850	3800
20	1000	2000	3000	4000
21	1050	2100	3150	4200
22	1100	2200	3300	4400
23	1150	2300	3450	4600
24	1200	2400	3600	4800
25	1250	2500	3750	5000
26	1300	2600	3900	5200
27	1350	2700	4050	5400
28	1400	2800	4200	5600
29	1450	2900	4350	5800
30	1500	3000	4500	6000
31	1550	3100	4650	6200
32	1600	3200	4800	6400
33	1650	3300	4950	6600
34	1700	3400	5100	6800
35	1750	3500	5250	7000
36	1800	3600	5400	7200

Table 1: For the following tree species, apply the amount of RTU solution indicated in the table below using either basal drench or soil injection application techniques:

- Common Name _____ Scientific Name
- red maple _____ *Acer rubrum*
- Norway maple _____ *Acer platanoides*
- silver maple _____ *Acer saccharinum*
- sweetgum _____ *Liquidambar styraciflua*
- Australian pine _____ *Casuarina equisetifolia*
- Chinese elm _____ *Ulmus parvifolia*
- Siberian elm _____ *Ulmus pumila*
- boxelder _____ *Acer negundo*
- hackberry _____ *Celtis occidentalis*
- littleleaf linden _____ *Tilia cordata*
- American basswood _____ *Tilia americana*
- slippery elm _____ *Ulmus rubra*
- honey locust _____ *Gleditsia triacanthos*

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Diameter of Tree at Breast Height (DBH) (Inches)	Total ml of RTU ¹ Solution per Tree ² (Soil Drench) or (Soil Injection)	Number of Soil Injection Sites per Tree ³
6	500	2 to 4
7	500	2 to 4
8	500 to 750	2 to 4
9	500 to 750	2 to 4
10	750 to 1000	3 to 4
11	750 to 1000	3 to 4
12	750 to 1000	3 to 4
13	750 to 1250	3 to 5
14	750 to 1250	3 to 5
15	1000 to 1500	4 to 6
16	1000 to 1500	4 to 6
17	1000 to 1500	4 to 6
18	1000 to 1750	4 to 7
19	1000 to 1750	4 to 7
20	1250 to 2000	5 to 8
21	1250 to 2000	5 to 8
22	1250 to 2000	5 to 8
23	1250 to 2250	5 to 9
24	1250 to 2250	5 to 9
25	1500 to 2500	6 to 10
26	1500 to 2500	6 to 10
27	1500 to 2750	6 to 11
28	1750 to 2750	7 to 11
29	1750 to 2750	7 to 11
30	1750 to 3000	7 to 12
31	2000 to 3000	8 to 12
32	2000 to 3250	8 to 13
33	2000 to 3250	8 to 13
34	2250 to 3500	9 to 14
35	2250 to 3500	9 to 14
36	2250 to 3500	9 to 14

¹RTU indicates "Ready-to-Use". There are approximately 5 grams of active ingredient in every 250 ml unit.

²For acidic soils (low pH), soils with high organic matter content or soils with high clay content, use the higher rate in the rate range.

³For trees less than 14 inches in diameter, uniformity of growth regulation may be improved by reducing the injection volume and increasing the number of injection sites. Do not exceed the total injection volume specified for the diameter of the tree to be treated.

Table 2: For the following tree species, apply the amount of RTU solution indicated in the table below using either basal drench or soil injection application techniques:

- Common Name _____ Scientific Name
- eucalyptus _____ *Eucalyptus* spp.
- ash _____ *Fraxinus* spp.
- sycamore _____ *Platanus occidentalis*
- laurel oak _____ *Quercus laurifolia*
- live oak _____ *Quercus virginiana*

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pin oak *Quercus palustris*
 red oak *Quercus rubra*
 water oak *Quercus nigra*
 white oak *Quercus alba*
 willow oak *Quercus phellos*
 weeping willow *Salix babylonica*

Diameter of Tree at Breast Height (DBH) (inches)	Total ml of RTU ¹ Solution per Tree ² (Soil-Drench) or (Soil Injection)	Number of Injection Sites per Tree ³
6	500 to 1000	2 to 4
7	500 to 1250	2 to 5
8	750 to 1500	3 to 6
9	750 to 1750	3 to 7
10	1000 to 2000	4 to 8
11	1000 to 2000	4 to 8
12	1000 to 2250	4 to 9
13	1250 to 2500	5 to 10
14	1250 to 2750	5 to 11
15	1500 to 3000	6 to 12
16	1500 to 3000	5 to 12
17	1500 to 3250	6 to 13
18	1750 to 3500	7 to 14
19	1750 to 3750	7 to 15
20	2000 to 3750	8 to 15
21	2000 to 3750	8 to 15
22	2000 to 3750	8 to 15
23	2250 to 3750	9 to 15
24	2250 to 3750	9 to 15
25	2500 to 3750	10 to 15
26	2500 to 4000	10 to 16
27	2750 to 4000	11 to 16
28	2750 to 4000	11 to 16
29	3000 to 4250	12 to 17
30	3000 to 4250	12 to 17
31	3000 to 4750	12 to 18
32	3250 to 4750	13 to 19
33	3250 to 5000	13 to 20
34	3500 to 5000	14 to 20
35	3500 to 5250	14 to 21
36	3500 to 5250	14 to 21

¹RTU indicates "Ready-to-Use". There are approximately 5 grams of active ingredient in every 250 ml-unit.

²For acidic soils (low pH), soils with high organic matter content or soils with high clay content, use the higher rate in the rate range.

³For trees less than 14 inches in diameter, uniformity of growth regulation may be improved by reducing the injection volume and increasing the number of injection sites. Do not exceed the total injection volume specified for the diameter of the tree to be treated.

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Warranty Disclaimer

DowElanco warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in strict accordance with the directions, subject to the inherent risks set forth below. DowElanco MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OR IMPLIED WARRANTY.

Inherent Risks of Use

It is impossible to eliminate all risks associated with use of this product. Plant injury, lack of performance, or other unintended consequences may result because of such factors as use of the product contrary to the label instructions (including adverse conditions noted on the label, such as unfavorable temperatures, soil conditions, etc.), abnormal conditions (such as excessive rainfall, drought, tomadoes, hurricanes), presence of other materials, the manner of application, or other factors, all of which are beyond the control of DowElanco or the seller. All such risks shall be assumed by the buyer.

Limitation of Remedies

The exclusive remedy for losses or damages resulting from the use of this product (including claims based on contract, negligence, strict liability, or other legal theories), shall be limited to, at DowElanco's election, one of the following:

- (1) Refund of purchase price paid by buyer or user for product bought, or
- (2) Replacement of amount of product used

DowElanco shall not be liable for losses or damages resulting from handling or use of this product unless DowElanco is promptly notified of such loss or damage in writing. In no case shall DowElanco be liable for consequential or incidental damages or losses.

The terms of the Warranty Disclaimer above and this Limitation of Remedies cannot be varied by any written or verbal statements or agreements. No employee or sales agent of DowElanco or the seller is authorized to vary or exceed the terms of the Warranty Disclaimer or this Limitation of Remedies in any manner.

*Trademark of DowElanco

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