

MAY 26 1995

Merlyn L. Jones, Ph.D.
DowElanco
9330 Zionsville Road
Indianapolis, IN 46268-1054

Dear Dr. Jones:

Subject: Revised Labeling
Profile 2SC
EPA Registration No. 62719-234
Your Submission Dated May 4, 1995

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

- In the In the General Precautions section specify:

"Ornamental trees not specifically identified...", or

"Trees not used for food production and not specifically identified..."

As written the statements imply that this product could be applied to food trees.

2. Submit one (1) copy of your final printed labeling before you release the product for shipment.

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

Sincerely yours,

James M. Stone
Acting Product Manager (22)
Fungicide Herbicide Branch
Registration Division (7505C)

Enclosure

1912

12

Profile* 2SC

Tree Growth Regulator

Current label text based on EPA-accepted copy dated June 29, 1992.

Proposed Revisions:

1. **Precautionary Statements:** Added use of protective eyewear while mixing and applying as basal drench.
2. **Environmental Hazards:** Added statement to allow application in "seasonally dry" wetland areas.
3. **Storage and Disposal:** "Storage" statement revised to include use of waste material as directed by label.
4. **General Information:** Added the following statement for tree species not listed on this label: "Trees not specifically identified on this label may be treated if all other label recommendations are followed."
5. **Directions for Use:** (1) Minor editing for clarity; (2) Expanded rate tables for treatment of larger trees; (3) Adjusted application rate for certain species of oak.

Note: EPA notified DowElanco that the amended label for Profile as submitted on January 23, 1995, was unacceptable. The Agency objected to amendments as indicated in items 1, 2, and 3 above. In this draft, the changes proposed in items 1, 2 and 3 above have been deleted and the following has been retained:

1. **General Information:** Added the following statement for tree species not listed on this label: "Trees not specifically identified on this label may be treated if all other label recommendations are followed."
2. **Directions for Use:** (1) Minor editing for clarity; (2) Expanded rate tables for treatment of larger trees; (3) Adjusted application rate for certain species of oak.

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[Editor's note: Added text is underlined and deleted text denoted by strike-through.]

ACCEPTED
with CDF REVISIONS
In EPA Letter Dated:

MAY 26 1995

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

62719-237

3513

(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-ethanol.....	21.8%
Inert Ingredients	78.2%
Total	100.0%

Contains 2 pounds of active ingredient/gallon

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

Shake Well Before Use

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.

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.

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

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.

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.

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

EPA Reg. No. 62719-234

EPA Est. 000-XX-00

*Trademark of DowElanco
DowElanco • Indianapolis, IN 46268 U.S.A.

Specialty Growth Regulator

Net Contents 1 Gal

512

(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:

paclobutrazol: (R*,R*)-(±)-β-[(4-chlorophenyl)methyl]-
α-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol..... 21.8%

Inert Ingredients 78.2%

Total 100.0%

Contains 2 pounds of active ingredient/gallon

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

Keep Out of Reach of Children

CAUTION

Shake Well Before Use

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.

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

EPA Reg. No. 62719-234

EPA Est. 000-XX-00

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DowElanco • Indianapolis, IN 46268 U.S.A.

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.

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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 vegetative growth retardation regulation. Profile 2SC demonstrates little or no phloem mobility. Activity occurs following root uptake and xylem translocation throughout the tree canopy. 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.

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.

Profile 2SC retards vegetative growth and thereby significantly reduces 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

Symptoms of growth regulation may not be visible for up to 18 months following application of Profile 2SC. Initial effects of Profile 2SC will 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 somewhat thickened. Smaller leaf size and enhanced flowering may also be observed in some species.

General Use Precautions

Apply only to trees that are healthy:

Apply at recommended rates and follow safety procedures.

Trees not specifically identified on this label may be treated if all other label recommendations are followed.

Do not apply to trees which are severely stressed due to moisture, temperature, low soil fertility, or mechanical or chemical injury.

Do not reapply Profile 2SC until symptoms from previous applications begin to disappear, or within 3 years of the last application, whichever comes first.

If soil is heavily compacted or a high water table exists, use trunk-injection of a registered tree growth regulator such as Cutless® Tree Implants FP may provide more effective control.

Basal drench and soil injection application of Profile 2SC may result in localized, temporary discoloration of turfgrass.

Avoid basal drench applications on slopes or other areas conducive to runoff from rainfall or irrigation.

Avoid treating trees bordered by shrubs and/or herbaceous ornamentals as non-target effects may occur.

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.

Application Timing

Applications can be made throughout the year, weather permitting, except when soil is frozen or saturated. Note: Profile 2SC will only be absorbed by the roots and translocated to the growing tissues during periods of active growth.

If dormant season applications are made, uptake of Profile 2SC will not occur until bud-break 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

Mix 300 ml (10.2 fl oz) of this product Profile 2SC with water to make one gallon of Ready-to-Use (RTU) solution. Eight gallons of this product Profile 2SC will make 100 gallons of RTU solution.

Approved Uses

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.

Soil Injection

Use equipment that will inject the RTU solution into the soil in 100 to 250 ml aliquots 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.

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:

<u>Common Name</u>	<u>Scientific Name</u>
red maple	<i>Acer rubrum</i>
Norway maple	<i>Acer plananoides</i>
silver maple	<i>Acer saccharinum</i>
sweetgum	<i>Liquidambar styraciflua</i>
Australian pine	<i>Casuarina equisetifolia</i>
laurel oak	<i>Quercus laurifolia</i>
water oak	<i>Quercus nigra</i>
live oak	<i>Quercus virginiana</i>

Chinese elm	<i>Ulmus parvifolia</i>
Siberian elm	<i>Ulmus pumila</i>
boxelder	<i>Acer negundo</i>
hackberry	<i>Celtis occidentalis</i>
littleleaf linden	<i>Tilia cordata</i>
American basswood	<i>Tilia americana</i>
slippery elm	<i>Ulmus rubra</i>
honey locust	<i>Gleditsia triacanthos</i>

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.

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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:

<u>Common Name</u>	<u>Scientific Name</u>
eucalyptus	<i>Eucalyptus</i> spp.
ash	<i>Fraxinus</i> spp.
sycamore	<i>Platanus occidentalis</i>
laurel oak	<i>Quercus laurifolia</i>
live oak	<i>Quercus virginiana</i>
pin oak	<i>Quercus palustris</i>
red oak	<i>Quercus rubra</i>
water oak	<i>Quercus nigra</i>
white oak	<i>Quercus alba</i>
willow oak	<i>Quercus phellos</i>
weeping willow	<i>Salix babylonica</i>

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	500 to 1500	2 to 6
9	500 to 1750	2 to 7
10	750 to 2000	3 to 8
11	750 to 2000	3 to 8
12	750 to 2250	3 to 9
13	750 to 2500	3 to 10
14	750 to 2750	3 to 11
15	1000 to 3000	4 to 12
16	1000 to 3000	4 to 12
17	1000 to 3250	4 to 13
18	1000 to 3500	4 to 14
19	1000 to 3750	4 to 15
20	1250 to 3750	5 to 15
21	1250 to 3750	5 to 15
22	1250 to 3750	5 to 15
23	1250 to 3750	5 to 15
24	1500 to 3750	5 to 15
25	1500 to 3750	5 to 15
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 18
27	2750 to 4000	11 to 18
28	2750 to 4000	11 to 18
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.

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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.

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, tornadoes, 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.

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