



United States  
Environmental Protection Agency  
Washington, DC 20460

 Registration  
 Amendment  
 Other

OPP Identifier Number

### Application for Pesticide - Section I

1. Company/Product Number 524-499	2. EPA Product Manager Jim Tompkins	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) MON 37500 Technical	PM # 25	
5. Name and Address of Applicant (Include ZIP Code) Monsanto Company 600 13 <sup>th</sup> St., N.W., Suite 660 Washington, DC 20005 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

### Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated	<b>NOTIFICATION</b> MAY 22 2003
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application.	
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.	

Explanation: Use additional page(s) if necessary. (For section I and Section II.)  
Submission of foreign language (Japanese) label.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

### Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) Plant Cells
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per Container	If "Yes" Package wgt. No. per Container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container Various	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Dr. Marsha C. Gray	Title Registration Manager	Telephone No. (Include Area Code) (202) 783-2460
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Registration Manager	
4. Typed Name Rhonda M. Mannion 314/694-8785	5. Date 9 April 2003	

Submitted in Support of the Registration of MON 37500 Technical  
EPA Reg. No. 524-499

**INTERNATIONAL LABEL CERTIFICATION STATEMENT**

I hereby certify that the attached Japanese label (TMK-19, MON 37500) does not add new uses or claims, nor does it conflict with the approved Section 3 labeling for MON 37500 Technical (Reg. No. 524-499).

The Japanese label contains additional advisory language for the safe handling of the material, as well as additional personal protective equipment and first aid instructions which have been deemed unnecessary by the U.S. EPA based upon the acute toxicity properties of MON 37500 Technical.

**NOTIFICATION**  
MAY 22 2003

Company Agent: Rhonda M. Mannion  
Title: Registration Manager  
Monsanto Company

Date: 9 April 2003

Signature: *Rhonda M. Mannion*

MONSANTO



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MONSANTO COMPANY  
600 13TH STREET, N.W.  
SUITE 600  
WASHINGTON, D.C. 20005  
<http://www.monsanto.com>

9 April 2003

**Hand Delivered**

Document Processing Center (NOTIF)  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2,  
1921 Jefferson Davis Highway  
Arlington, VA 22202-4501

Attention: Mr. Jim Tompkins (7505C)  
Product Manager (Team 25)

Subject: Sulfosulfuron (MON 37500) Technical (Reg. No. 524-499).  
Notification of Japanese Labeling Required for Export.

Dear Mr. Tompkins:

Monsanto imports MON 37500 Technical (Reg. No. 524-499) from Japan where it is currently manufactured by Sumiomo Chemical Takdea Agro Co., Ltd. Japanese regulations require that the MON 37500 Technical containers bear Japanese labeling during transit from the manufacturing site to the U.S.

Foreign language labeling is permitted under 40 CFR 156.10(a)(3), and Chapter 18 of the U.S. EPA Label Review Manual provides additional guidance on the provisions of foreign language (international) labeling. The Manual states that such labeling is permitted provided the foreign language label does not add any new uses or claims and does not contradict the current Section 3 label, and the registrant submits a certification statement.

To this end, Monsanto is herein submitting the Japanese label that is affixed to the MON 37500 Technical containers along with the approved Section 3 label, an English translation of the Japanese label, and the certification statement. The Japanese label does not contain language which contradicts the approved Section 3 labeling, rather the Japanese label merely incorporates additional advisory and precautionary statements which EPA deemed unnecessary based upon the acute toxicity and physical and chemical properties of MON 37500 Technical.

Should you have any questions, please contact Dr. Marsha Gray at our Washington office (202) 383-2460, or me directly at (314) 694-8785 or [rhonda.m.mannion@monsanto.com](mailto:rhonda.m.mannion@monsanto.com).

Sincerely,

Rhonda M. Mannion  
Registration Manager

cc: V. Walters / EPA  
M.Gray / DC Office  
File copy

Enclosure

NOTIFICATION  
MAY 22 2003

# TKM-19 原体 (MON 37500 Technical)

化審法 指定化学物質

NET 40 Kg Lot. No.

H195

成分	1-(4,6-ジメトキシピリミジン-2-イル)-3-(2-エチルスルホニルイミダゾ [1,2-a] ピリジン-3-イルスルホニル) 尿素
含有量	98.0%以上
注意事項	<p>指定化学物質の環境汚染防止のための注意事項</p> <ol style="list-style-type: none"> <li>1. 容器から製品を取り出す際は、こぼさないように作業して下さい。</li> <li>2. 固体の製品を加熱溶解して取り扱う場合、その作業には、捕集能のある局所廃棄装置を設けて下さい。</li> <li>3. 局所排気装置、除塵装置等の洗浄廃液及び廃棄容器等製品の付着物は、産業廃棄物処理の許可を有する業者に委託して処理するか、自社で適正に処理して下さい。</li> </ol>
製造社名 住所	<p>武田薬品工業株式会社 大阪市中央区道修町四丁目1番1号</p>

**△注意** 本化合物は指定化学物質（化審法）につき、取扱いには十分注意し、飲み込んだりしないで下さい。



- 取扱い中は換気を良くして下さい。
- 取扱いの際は、長袖の作業衣・保護手袋・保護マスク・保護眼鏡を着用し、吸い込んだり、目や皮膚に触れないよう注意して下さい。
- 直射日光を避け、適当な換気のある乾燥した場所に保管して下さい。
- 下水道・河川等、環境へ放出しないで下さい。

**【応急処置】**

- 火災の際は、水、粉末消火器、二酸化炭素等を用いて消火して下さい。
- 目に入った場合は、直ちに流水で15分以上洗眼した後、眼科医の手当を受けて下さい。
- 皮膚に付着した場合は、直ちに触れた部位を多量の水で十分に洗い流し、石けんでよく洗って下さい。
- 吸入した場合は、直ちに空気の新鮮な場所に移し、安静・保湿に努め、速やかに医師の手当を受けて下さい。
- 飲み込んだ場合は、多量の水を飲ませ、指をのどに差し込んで吐き出させ、直ちに医療処置を受けて下さい。

連絡先 武田薬品工業株式会社

アグロカンパニー

情報・安全グループ TEL 03-3278-2837


5/15

TKM-19 Technical (MON 37500 Technical)

Designated Chemical Substance

NET 40 kg Lot. No. H195

Active Ingredient	1-(4,6-dimethoxypyrimidin-2-yl)-3-(2-ethylsulfonylimidazo [1,2-a]pyridin-3-yl-sulfonyl) urea
Purity:	>98%
Precautionary Language	<p><b>Cautions to prevent environmental contamination</b> By designated chemical substance</p> <ol style="list-style-type: none"> <li>1. Take caution not to spill when removing the content from the container</li> <li>2. When handling solid product with heating to melt, use local ventilation apparatus with ability to collect the material</li> <li>3. The rinse solution or collected waste from the local ventilator or dust collector should be disposed by authorized industrial waste disposer or on site</li> </ol>
Manufacturer	Takeda Chemical Industries, Ltd. 1-1,4 chome, Doshomachi, Chuo-ku, Osaka

 **CAUTION** This compound is a designated chemical substance under chemical Substance Control Law and care should be taken not to ingest



*Protective Gear  
Gloves,  
Goggles,  
Mask*

- ◆ When handling, make sure the room is well ventilated
  - ◆ Wear long sleeve clothes, protective gloves, mask and goggles and take care not to inhale material, and avoid contact with eyes and skin
  - ◆ Store in ventilated dry place avoiding direct sunlight
  - ◆ Do not directly release to sewage, river and the environment
- FIRST AID**
- ◆ In case of fire, use water, dry extinguisher or CO<sub>2</sub>
  - ◆ If in eyes, wash eyes with running water for longer than 15 minutes and get ophthalmologist's attention
  - ◆ If on skin, wash the contacted skin with plenty of water and soap immediately
  - ◆ If inhaled, move the person to fresh air and calm and warm place and get medical attention immediately
  - ◆ If ingested, dilute with plenty of water and induce vomiting then get medical attention

Contact: Takeda Chemical Industries, Limited Agro Company. Information and Safety Group Tel. No. 03-3278-2837