UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV - 9 1992

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YM13 55947-104 1046

Mrs. Donna M. Hillebold **Registration Specialist II Regulatory Affairs** SANDOZ AGRO, INCORPORATION 1300 East Touhy Avenue Des Plaines, Illinois 60018

Dear Mrs. Hillebold:

Subject: Revised Cov fidential Statement of Formula (CSF) PR Notice 91-2 and Label Revision FLUVALINATE Technical EPA Registration Number 55947-104 Your Amended Application Dated October 15, 1991

The revised CSF and labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act as amended is acceptable, provided that you make the following labeling changes listed below before you release the product for shipment bearing the amended labeling:

1. In accordance with PR Notice 91-8, under the heading "Directions For Use" replace the first paragraph with following paragraph:

"Only For Formulation Into An Insecticide For The Following Use (s): (fill in blank with only those uses that are being supported by you the MP registrant.) Use For Which U.S. Environmental Protection Agency Has Accepted The Required Data And/Or Citations Of Data That The Formulator Has Submitted In Support Of Registration; And Uses For Experimental Purposes That Are In Compliance With U. S. Environmental Protection Agency Requirements."

Based on your application for pesticide registration 2. dated April 30, 1983, this product is being stored in metal drums or containers. Therefore your container disposal statement must be revised to read as follows:

"Metal Containers: 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."

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EPA Form 1320-1A (1/90)			Printed on Recursied Pener				OFFICIAL FILE COPY	

Printed on Recycled Paper

3. In regard to your revised CSF, the variations appears to be larger than normal for the limits of nominal concentration, which is 87.2%. The Lower Certified Limits can not be lower than 84.6%.

Submit five (5) copies 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,

George T. LaRocca Product Manager (13) Insecticide-Rodenticide Branch Registration Division (H7505C) 2046

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Enclosure:

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FLUVALINATE TECHNICAL

PM 13 55941-104

AN INSECTICIDE-ACARICIDE FOR MANUFACTURING USE ONLY

ACTIVE INGREDIENT:

(<u>R</u>)-2	2 <u>R)-fluvalinate [(RS-a-cyano-3-phenoxybenzyl</u> -[2-chloro-4-(trifluoromethyl)anilino]-3-methyl- pate]*
INERT	INGREDIENTS:

TOTAL.....100.0%

20H6

***U.S. Pat. 4,260,633 & 4,411,912**

EPA Reg. No. 55947-104 EPA Est. No. 55947-TX-1

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS WARNING

OPEN CONTAINER IN WELL VENTILATED AREA. DO NOT BREATHE FUMES

REFER TO ANALYTICAL LABEL ON THIS DRUM FOR EXACT ANALYSIS OF THIS LOT.

May be fatal if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash thoroughly before reuse. Sensitive persons may temporarily experience an itching, burning sensation, with or without a rash, following exposure. Avoid hand- or sleeveto-face exposure.

> SANDOZ CROP PROTECTION CORPORATION 1300 East Touhy venue Des Plaines, Illinoi 60018

NET CONTENTS: 245 Kg (540 lbs.) Lot No.: Specific gravity: 1.29

> ACCEPTED with COMMENTS in EPA Letter Dated

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Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticule registered under EPA Heg. No. 55047-104

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STATEMENT OF PRACTICAL TREATMENT

- <u>IF IN EYES:</u> Flush eyes with plenty of water. Get medical attention if irritation persists.
- 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.

ENVIRONMENTAL HAZARDS

This product is highly toxic to fish or other aquatic organisms. Do not discharge effluent containing this product directly into lakes, streams, estuaries, oceans or public waters unless this product is specifically addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your Regional Office of the Environmental Protection Agency.

PHYSICAL AND 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 a manner inconsistent with its labeling. Refer to the Formulators Manual for formulating instructions and other technical information. Formulators using this product are responsible for obtaining EPA Registration of their formulated product.

This product may not be used or referenced as a source of ingradient in the formulation, manufacture or registration of any products without prior written authorization from Sandoz Crop Protection Corporation.

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STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. In case of spill or leak, ventilate area well, then soak up with soil or other absorbent material.

- **STORAGE:** Store away from direct sunlight or heat. Pesticides must be stored in a secured area away from other products, food or feed.
- **DISPOSAL:** Wastes resulting from the use of Fluvalinate Technical may be disposed of on site or at any approved waste disposal facility.

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

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LIMITATION OF WARRANTY AND LIMITATION OF LIABILITY

NOTICE: Read this Limitation of Warranty and Limitation of Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness, or other unintended consequence. may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Sandoz or seller. All such risks shall be assumed by buyer or user.

Sandoz warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, under normal use conditions, subject to the risks described above. SANDOZ MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY OR ANY OTHER EXPRESS OR IMPLIED WARRANTY.

In no event shall Sandoz or seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SANDOZ OR SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SANDOZ OR SELLER, THE REPLACEMENT OF THE PRODUCT.

Sandoz and seller offer this product, and buyer and user accept it, subject to the foregoing limitations of warranty and limitation of liability, which may not be modified by any oral or written agreement.

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