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OFFICE REGI	ONMENTAL PROTECTION AGENCY E OF PESTICIDES PROGRAMS	66927-1	MAR I U 1994	
	STRATION DIVISION <i>(TS-767)</i> VASHINGTON, DC 20460	TERM OF ISSUANCE		
NOTICE OF PESTICIDE: REGISTRATION		NAME OF PESTICIDE PRODUCT		
•	Under the Federal Insecticide, Fungicide, Pha and Rodenticide Act, as amended)		Pharmadine Whirlpool Solution	
NAME AND ADDRESS	OF REGISTRANT (Include ZIP code)		·	
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Novel Pharmaceutical, Inc. 6 E.V. Hogan Drive Hamlet, North Carolina 28345				
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NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.				
On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.				
A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.				
health and the envi icide in accordance	no way to be construed as an indorsement ironment, the Administrator, on his motio e with the Act. The acceptance of any na nstrued as giving the registrant a right to	n, may at any time suspend or me in connection with the reg	cancel the registration of a pest- istration of a product under this	
This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:				
 Submit/cite all data required for registration/ reregistration of your product under FIFRA sec. 3(c)(5) or sec. 4 when the Agency requires all registrants of similar products to submit such data. 				
2.	Develop efficacy data in accordance with the attached guidelines for the upcoming reregistration data callin.			
3.	Submit a revised Confidential Statement of Formula. Indicate 10.1% as upper limit and 9.1% as lower limit for the active ingredient. Indicate upper and lower limits for all inert ingredients. Refer to enclosed PR Notice 91-2 regarding nominal concentration.			
4.	Make the labeling chan release the product fo	ges indicated be r shipment:	low before you	

EPA Form 8570-6 (Rev. 5-76)

ATTACHMENT IS APPLICINET ingredients.

Add the phrase "EPA Registration No. 66927-1.

Revise the label ingredient declaration to read 9.65% for the active ingredient and 90.35% for the

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- c. Change the heading "Recommended Use" to read "Diractions for Use".
- d. Include the following statement immediately below the Directions for Use Heading:

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

- e. On back panel, change the "CAUTION" heading to read "Statement of Practical Treatment (First Aid)".
- f. On the front panel include "Keep Out of Reach of Children" immediately above the signal word "CAUTION".
- g. Include the EPA Establishment No. on the label or on the container.
- 5. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label in enclosed for your records.

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Sincerely,

Ruth G. Douglas, PM 32 Antimicrobial Program Branch

Registration Division



FUR DISINFECTION OF WHIRLPOOL BATH WATER

RECOMMEND USE:

ADDITINE DISINFECTION OF WHIRLPOOL BATH WATER, ADD APPROXIMATELY ONE (1) FLUID OUNCE (30cc.) OF PHARMADINE, WHIRLPOOL SOLUTION TO EACH TWENTY GALLONS OF WATER, DRAIN AND CLEAN TANK AFTER USE.

JAJII.S:

IF CONTACT COCURS, WASH SKIN WITH SOAP AND WATER.
IN CASE OF EYE CONTACT, FLUSH WITH WATER FOR AT FOR LEAST 15 MINUTES AND CONSULT A PHYSICIAN.

NOTE: THYROLD FUNCTION TESTS OF SOME PATIENTS MAY BE TO AFFECTED.

STORAGE AND DISPOSAL

STURAGE: STURE AT ROOM TEMPERATURE (59-86°F). AVOID EXCESS HEAT OR FREEZING. DO NOT STACK, CRUSH OR PUNCTURE.

PRODUCT DISPOSAL: WASTES RESULTING FROM THE USE OF THIS PRODUCT MAY BE DISPOSED OF ON SITE OR AT AN APPROVED WASTE DISPOSAL FACILITY. DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR LISPOSAL.

CONTAINER DISPOSAL: DO NOT REUSE EMPTY CONTAINER.

RINSE CONTAINER THOROUGHLY AND DISCARD IN
THASH.





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To Action WHIRLPOOL SO

FOR DISINFECTION OF WHIRL

ACTIVE INGREDIENT: POLYVINYLPYRR

INERT INGREDIENTS:

PROVIDES 1% TITRATABLE

CAUTION: AVOID CONTACT OF UNDI SKIN AND EYES. SEE BACK P

FOR PROFESSIONAL AND HOSPIT

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BEST AVAILABLE COPY