



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

October 1998

Pesticide Registration (PR) Notice 98-9

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS AND REGISTRANTS OF AGRICULTURAL PESTICIDES**Attention: Persons Responsible for Registration of Pesticide Products.****Subject: Modification of Respirator Statements for Pesticide Product Labels**

This PR Notice informs registrants of technology improvements for respirators and designation changes for certain respirator filters required in pesticide labeling statements. Because the National Institute of Occupational Safety and Health has revised respirator standards for particulate filters, references to filter classification types on pesticide labels are no longer accurate. Previously certified filters for pesticide users will no longer be available after fall 1998. EPA intends to modify the regulations governing respirator requirements for product labels. EPA is issuing this notice in order to allow registrants adequate time to make appropriate changes in product labels.

Registrants should modify the respirator designations on those product labels that contain language that requires pesticide handlers to wear dust/mist filtering respirators (TC-21C) or those respirators that require an organic vapor-removing cartridge respirator with a prefilter approved for pesticides (TC-23C).

Registrants should update the respirator language on each product label. A notification process may be used for this change if registrants do not combine this change with other changes that require Agency review.

This PR Notice is effective immediately. Registrants are required to remove old respirator language between April 1, 2001 and April 1, 2004, while adding new respirator language should begin as soon as possible so that the new language is in place by April 1, 2000.

I. Background

In June 1995, the National Institute for Occupational Safety and Health (NIOSH) published a Federal regulation for certifying nonpowered, air-purifying particulate respirators, Part 84; Part 84 was to replace the outdated certification standards in 30 CFR 11 (Part 11) regulations. In the new regulation, only nonpowered, air-purifying, particulate filter respirator classifications have been changed. The new Part 84 regulation creates a total of nine classes of particulate filters; these classes apply only to nonpowered, air-purifying, particulate filter respirators. NIOSH allowed manufacturers of respirators to continue selling and shipping Part 11 particulate filters as NIOSH-certified until July 10, 1998.

In reviewing the NIOSH certification changes, EPA has concluded that all 42 CFR 84 (Part 84) respirators meet or exceed all 30 CFR 11 (Part 11) requirements and that a respirator certified under Part 84 is an acceptable substitute for a respirator certified under Part 11.

II. Rationale for Respirator Classification Changes

Three categories exist for filter efficiency and each category has three possible oil degradation resistances that may be selected and matched with filter efficiency. Each of the nine resulting respirator categories is designated by a code in which a letter -- N, R or P -- represents its oil resistance and a

number -- 95, 99 or 100 -- represents filter efficiency.

The three levels of filter efficiency are:

- 95%,
- 99% and
- 99.97%.

The three categories of oil degradation resistance are based on the degree to which the filter performance is impaired by the deposition of oil. Examples of oils include: dioctyl phthalate oil, glycerine, and hydrocarbons used as lubricants. For Part 84 respirators, di-octyl phthalate (DOP) oil is utilized as a challenge material; this substance will act to neutralize the electrostatic charges present on the surface of filter fibers and reduce respirator efficiency. In this document the term "oil" will be used to represent any high-boiling point liquid hydrocarbon that will accumulate on the particulate filter of a respirator with minimal evaporation. Note that the accumulation of oil may lead to filter efficiency degradation. In assessing formulated products, registrants should work closely with respirator manufacturers to assure that the proper filter type is selected for the product.

- **N-series** (not resistant to oil) particulate filters may be used for solid particulate or liquid particulate hazards. During certification sodium chloride is used as a testing material and a very high particulate load (200 mg) is utilized for the test. Given the rigorosity of the testing regime, there is no recommended time limitation for an N-series filter.
- **R-series** (oil resistant) particulate filters may be used for solid and liquid particulate hazards. For those products containing oil, the R-series is to be used for only one work shift (an 8 hour work period) or per manufacturer's recommendations.
- **P-series** filters may be used for more than a single work period, but NIOSH has requested each respirator manufacturer to establish service time recommendations as part of their user instructions. It has been determined that long term oil exposure could reduce the efficiency of a P100 filter to levels below that of a P95 filter.

		Oil Resistance		
Filter Efficiency	N-series particulate filters Not resistant to oil.	R-series particulate filters Oil-resistant.	P-series filters Oil-proof.	
95%	<p>N95</p> <p>Not resistant to oil.</p> <p>May be used for solid particulate or liquid particulate hazards</p> <p>No time limitations</p> <p>Moderate filter efficiency</p>	<p>R95</p> <p>Oil-resistant.</p> <p>May be used for solid and liquid particulate hazards.</p> <p>Time limitation: 8 hours or manufacturer recommendation</p> <p>Moderate filter efficiency</p>	<p>P95</p> <p>Oil-proof.</p> <p>Time limitation: manufacturer recommendation, usually more than 8 hours.</p> <p>Moderate filter efficiency</p>	
99%	<p>N99</p> <p>Not resistant to oil.</p> <p>May be used for solid particulate or liquid particulate hazards</p> <p>No time limitations</p> <p>High filter efficiency</p>	<p>R99</p> <p>Oil-resistant.</p> <p>May be used for solid and liquid particulate hazards.</p> <p>Time limitation: 8 hours or manufacturer recommendation</p> <p>High filter efficiency</p>	<p>P99</p> <p>Oil-proof.</p> <p>Time limitation: manufacturer recommendation, usually more than 8 hours.</p> <p>High filter efficiency</p>	

99.97%.	N100 Not resistant to oil. May be used for solid particulate or liquid particulate hazards No time limitations Very high filter efficiency	R100 Oil-resistant. May be used for solid and liquid particulate hazards. Time limitation: 8 hours or manufacturer recommendation Very high filter efficiency	P100 Oil-proof. Time limitation: manufacturer recommendation, usually more than 8 hours. Very high filter efficiency NOTE: long-term exposure to oil can lower efficiency to 95%.
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III. What Label Supplements Should Be Revised?

The labeling revision applies to any product label that currently requires a dust/mist filtering respirator (TC-21C) and/or an organic vapor removing cartridge respirator with a prefilter approved for pesticides (TC-23C).

Registrants should modify such a label to add Part 84 respirator designations but should retain Part 11 respirator designations. This modification allows pesticide users to continue to use and deplete their existing supplies of Part 11 respirators; it also permits the use of the Part 84 respirators to satisfy Part 11 respirator requirements on product labels.

IV. When Should Labels Be Revised?

Registrants should modify labels according to the following schedule:

- Complete the process of adding references to Part 84 respirator designations beginning April 1, 2000.
- Retain current Part 11 respirator designations until April 1, 2001.
- Remove Part 11 respirator designations between April 1, 2001 and April 1, 2004.

Registrants will not be required to sticker, relabel, or retrieve product from the channels of trade that bears only Part 11 language. In a May 7, 1998 Federal Register Notice entitled "Labeling Requirements for Pesticides: Respirator Compliance Policy Statement" (63 FR 25168), the Agency has issued a policy statement allowing pesticide users to utilize a Part 84 respirator to satisfy Part 11 respirator statements on old product labels.

V. How to add new label language for dust/mist respirators?

Use the following procedure to determine the new respirator language that should be added to your product labels for dust/mist respirators.

IF your present label states:	AND...	THEN your new label must state:
"dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C)"	your product contains oil or has instructions that would allow application with an oil-containing material.	"dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH approved respirator with any R, P or HE filter."

"dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C"	your product does NOT contain oil and bears no instructions that will allow application with an oil-containing material, Examples include: granular formulations, dusts mixed with water, dry powders mixed with water	"dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH approved respirator with any N, R, P or HE filter."
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Note: If oil is not present, an additional filter type, N, can be used.

VI. How to add new language for organic vapor respirators?

Use the following procedure to determine the new respirator language that should be added to your pesticide product for organic vapor respirators.

IF your present label states:	AND...	THEN your new label must state:
"respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G)."	your product contains oil or has instructions that would allow concurrent application with an oil-containing material,	"respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any R, P or HE prefilter."
"respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G)."	your product does NOT contain oil and bears no instructions that will allow concurrent application with an oil-containing material, Examples include: granular formulations, dusts mixed with water, dry powders mixed with water	"respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any N, R, P or HE prefilter."

Clarification concerning HE prefilters in the preceding tables: Text entries for new label language in the column marked "THEN your new label must state" mention "HE prefilters". "HE" stands for "high efficiency particulate aerosol" and refers to a category of canister-type respirators with a particle filtering efficiency well above 99.97%. "HE" can be considered to be a fourth level of particle removal efficiency. EPA believes HE respirators will rarely be used in pesticide handling and application since they are more expensive than those in the 95%, 99% and 99.97% (which is sometimes called 100%) particle removal efficiency categories and since EPA does not require pesticide applicators and other handlers to use "HE" filters. However, the new label language mentions "HE" filters to make the new requirements clear in the infrequent situations where these filter types are incorporated by the respirator manufacturer in canister-type respirators.

VII. Procedure for Notification

A. Notification submission

For each product to be modified, the registrant should notify EPA. No changes other than

revision of the respirator statement should be included, otherwise the notification must be processed as an amended application. The registrant must submit the following items for each label modification:

1. An Application for Registration (EPA Form 8570-1), identified as a "Notification of Respirator Statement Change per PR Notice 98-9."
2. One copy of the labeling with changes highlighted in a way that can be photocopied. This may be draft labeling or final printed labeling.
3. The following certification statement:

"On behalf of _____ (insert Registrant's name) _____, I certify that this notification is consistent with the provisions of PR Notice 98-9 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 98-9 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."

Notifications should be sent to:

U.S. Postal Service Deliveries

Document Processing Desk (RESPIRATOR)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
401 M St., S.W.
Washington DC 20460-0001

Personal/Courier Service Deliveries

(Mon.-Fri., 8:00 a.m. to 4:30 p.m., except Federal Holidays)

Document Processing Desk (RESPIRATOR)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington VA 22202

VIII. Sale and Distribution of Pesticide Products with Revised Labeling

The notification must be received by the Agency before the registrant may distribute or sell the product with the revised labeling, as modified. A product distributed or sold with revised labeling before a notification and final printed labeling are received is in violation of FIFRA and may be subject to enforcement action.

This PR Notice does not require registrants to relabel products bearing only Part 11 respirator language already in channels of trade. EPA will permit pesticide users to use Part 84 respirators in place of Part 11 respirators; the Agency has determined that a respirator certified under Part 84 will meet or exceed all Part 11 requirements.

IX. Agency Determination to Revise the Respirator Statement

If, on the basis of information received from a registrant or other sources, the Agency determines that the respirator statement on a product label must be revised, the Agency will inform the registrant of that determination and of the new statement that should replace the existing respirator statement on the product label. The Agency will inform the registrant of actions, if any, that should be taken with respect to existing stocks of products labeled with an incorrect respirator statement. Reregistration decisions or decisions

resulting from other Agency review processes may supersede this notice.

X. Compliance


Registrants are responsible for the content and accuracy of labeling and for compliance with labeling requirements. The Agency will monitor notifications to verify that changes are accurate. Registrants who submit notifications which do not comply with this policy or EPA's requirements may be subject to enforcement action under FIFRA sections 12 and 14.

Registrants selling or distributing products bearing revised labeling are responsible for ensuring that the products bearing the proposed labels are not misbranded. In most cases, incorrectly modifying the respirator statement would be considered misbranding as defined under FIFRA section 2(q), and may result in the Agency issuing stop-sale orders or civil penalties. Such misbranding may create a potential for harm to workers, handlers, or other persons, or the environment, or may prevent the Agency from achieving the basic goals of the Worker Protection Standard or FIFRA.

All products released for shipment by registrants after April 1, 2000 should bear labeling that is consistent with this notice. It is the responsibility of the registrants to submit notifications in a timely manner. After this date, the Agency may either issue a notice of Intent to Cancel or bring enforcement action against products not bearing required labeling.

VIII. Further Information

Questions regarding this notice may be addressed to your Product Manager or Mr. Jim Tompkins (703-305-5697), e-mail: tompkins.jim@epamail.epa.gov.



James J. Jones, Director
Registration Division