**New Actions Required by This AD**

(e) For airplanes on which Modification No. 11454 was installed during production: Within 18 months after the date of manufacture of the airplane, or within 6 months after the effective date of this AD, whichever occurs later, accomplish the actions specified in paragraph (d)(2)(ii) of this AD.

(f) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

**Note 2:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

(g) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(h) Except as provided by paragraph (a) of this AD, the actions shall be done in accordance with the following Airbus service bulletins.

(1) The incorporation by reference of Airbus Service Bulletin A310–22–2036, dated December 14, 1993; and Airbus Service Bulletin A300–22–6021, Revision 1, dated December 24, 1993, was approved previously by the Director of the Federal Register, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, as of May 23, 1996 (61 FR 16873, April 18, 1996).

(2) The incorporation by reference of Airbus Service Bulletin A310–22–2044, Revision 1, dated January 8, 1997; Airbus Service Bulletin A300–22–6032, Revision 1, dated January 8, 1997; Airbus Service Bulletin A310–22–2047, dated July 16, 1996; and Airbus Service Bulletin A300–22–6035, dated July 16, 1996; as applicable; was approved previously by the Director of the Federal Register as of October 3, 1997 (62 FR 45710, August 29, 1997).

(3) Copies may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

**Note 3:** The subject of this AD is addressed in French airworthiness directive 97–373–237(B), dated December 3, 1997.

(i) This amendment becomes effective on September 17, 1998.

Issued in Renton, Washington, on August 6, 1998.

**Darrell M. Pederson,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 98–21655 Filed 8–12–98; 8:45 am]

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## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

**[Docket No. 98–SW–25–AD; Amendment 39–10712; AD 98–12–19]**

**RIN 2120–AA64**

## Airworthiness Directives; Robinson Helicopter Company (RHC) Model R44 Helicopters

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule; request for comments.

**SUMMARY:** This document publishes in the **Federal Register** an amendment adopting Airworthiness Directive (AD) 98–12–19 which was sent previously to all known U.S. owners and operators of RHC Model R44 helicopters by individual letters. This AD requires, within 5 hours TIS, a dye penetrant inspection of each main rotor blade skin (blade skin) around both inboard trim tab alignment rivet holes. Thereafter, a repetitive visual inspection of the blade skin around both inboard trim tab alignment rivet holes is required prior to the first flight of each day or at intervals not to exceed 5 hours TIS, whichever occurs first. This amendment is prompted by an incident in which a crack in the main rotor blade resulted in a forced landing. Subsequent investigations revealed that the manufacturing process utilized to drill the trim tab alignment rivet holes in the blade skin can allow a fatigue crack to originate at these holes and propagate in the skin. This condition, if not corrected, could result in failure of the main rotor blade and subsequent loss of control of the helicopter.

**DATES:** Effective August 28, 1998, to all persons except those persons to whom it was made immediately effective by priority letter AD 98–12–19, issued on June 2, 1998, which contained the requirements of this amendment.

Comments for inclusion in the Rules Docket must be received on or before October 13, 1998.

**ADDRESSES:** Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of the Regional Counsel, Southwest Region, Attention: Rules Docket No. 98–SW–25–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

**FOR FURTHER INFORMATION CONTACT:** Mr. Fred Guerin, Aerospace Engineer, FAA, Los Angeles Aircraft Certification Office, Airframe Branch, 3960 Paramount Blvd., Lakewood, California 90712, telephone (562) 627–5232, fax (562) 627–5210.

**SUPPLEMENTARY INFORMATION:** On June 2, 1998, the FAA issued priority letter AD 98–12–19, applicable to RHC Model R44 helicopters, which requires, within 5 hours TIS, a dye penetrant inspection of the blade skin around both inboard trim tab alignment rivet holes. Thereafter, a repetitive visual inspection of the blade skin around both inboard trim tab alignment rivet holes is required prior to the first flight of each day or at intervals not to exceed 5 hours TIS, whichever occurs first. If a crack is found, this AD requires replacing the main rotor blade with an airworthy main rotor blade before further flight. That action was prompted by an incident in which a pilot heard a loud noise and felt severe vibrations while hovering, resulting in a forced landing. Upon inspection, a crack was found in a main rotor blade that started at the mid-span inboard trim tab and ran chordwise to the spar where it turned along the spar for about an inch. The crack originated from a trim tab alignment rivet hole in the blade skin. Subsequent investigations revealed that the manufacturing process utilized to drill the trim tab alignment rivet holes in the blade skin can allow a fatigue crack to originate at these holes and propagate in the skin. This condition, if not corrected, could result in failure of the main rotor blade and subsequent loss of control of the helicopter.

Since the unsafe condition described is likely to exist or develop on other RHC Model R44 helicopters of the same type design, the FAA issued priority letter AD 98–12–19 to prevent failure of the main rotor blade and subsequent loss of control of the helicopter. The AD requires, within 5 hours TIS, a dye penetrant inspection of the blade skin around both inboard trim tab alignment rivet holes. Thereafter, a repetitive visual inspection of the blade skin around both inboard trim tab alignment rivet holes is required prior to the first flight of each day or at intervals not to exceed 5 hours TIS, whichever occurs first. If a crack is found, this AD requires replacing the main rotor blade with an airworthy main rotor blade before further flight. Installing a set of main rotor blades, P/N C016–2, constitutes terminating action for the requirements of this AD.

Since it was found that immediate corrective action was required, notice and opportunity for prior public comment thereon were impracticable and contrary to the public interest, and good cause existed to make the AD effective immediately by individual letters issued on June 2, 1998, to all

known U.S. owners and operators of RHC Model R44 helicopters. These conditions still exist, and the AD is hereby published in the **Federal Register** as an amendment to section 39.13 of the Federal Aviation Regulations (14 CFR 39.13) to make it effective to all persons.

The FAA estimates that 96 helicopters of U.S. registry will be affected by this AD, that it will take approximately 2 work hours per helicopter to inspect the blade skin and 10 work hours per helicopter to replace both main rotor blades and that the average labor rate is $60 per work hour. Required parts will cost approximately $10,000 per main rotor blade set. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $1,029,120, assuming one inspection and replacement of both main rotor blades on all helicopters with blades which would terminate the requirements of this AD.

### Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES.** All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 98–SW–25–AD.'' The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a ''significant regulatory action'' under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

### Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

## PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

### § 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

**98–12–19 Robinson Helicopter Company:** Amendment 39–10712. Docket No. 98–SW–25–AD.

*Applicability:* Model R44 helicopters, serial numbers (S/N) 0002 thru 0486, with main rotor blades, part number (P/N) C016–1, installed, certificated in any category.

**Note 1:** This AD applies to each helicopter identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (f) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any helicopter from the applicability of this AD.

*Compliance:* Required as indicated, unless accomplished previously.

To detect main rotor blade skin fatigue cracks which originate from the inboard trim tab alignment rivet holes, that could result in failure of the main rotor blade and subsequent loss of control of the helicopter, accomplish the following:

(a) Within the next five hours time-in-service (TIS), perform a dye penetrant inspection of the blade skin around both inboard trim tab alignment rivets as follows, referring to Figure 1.

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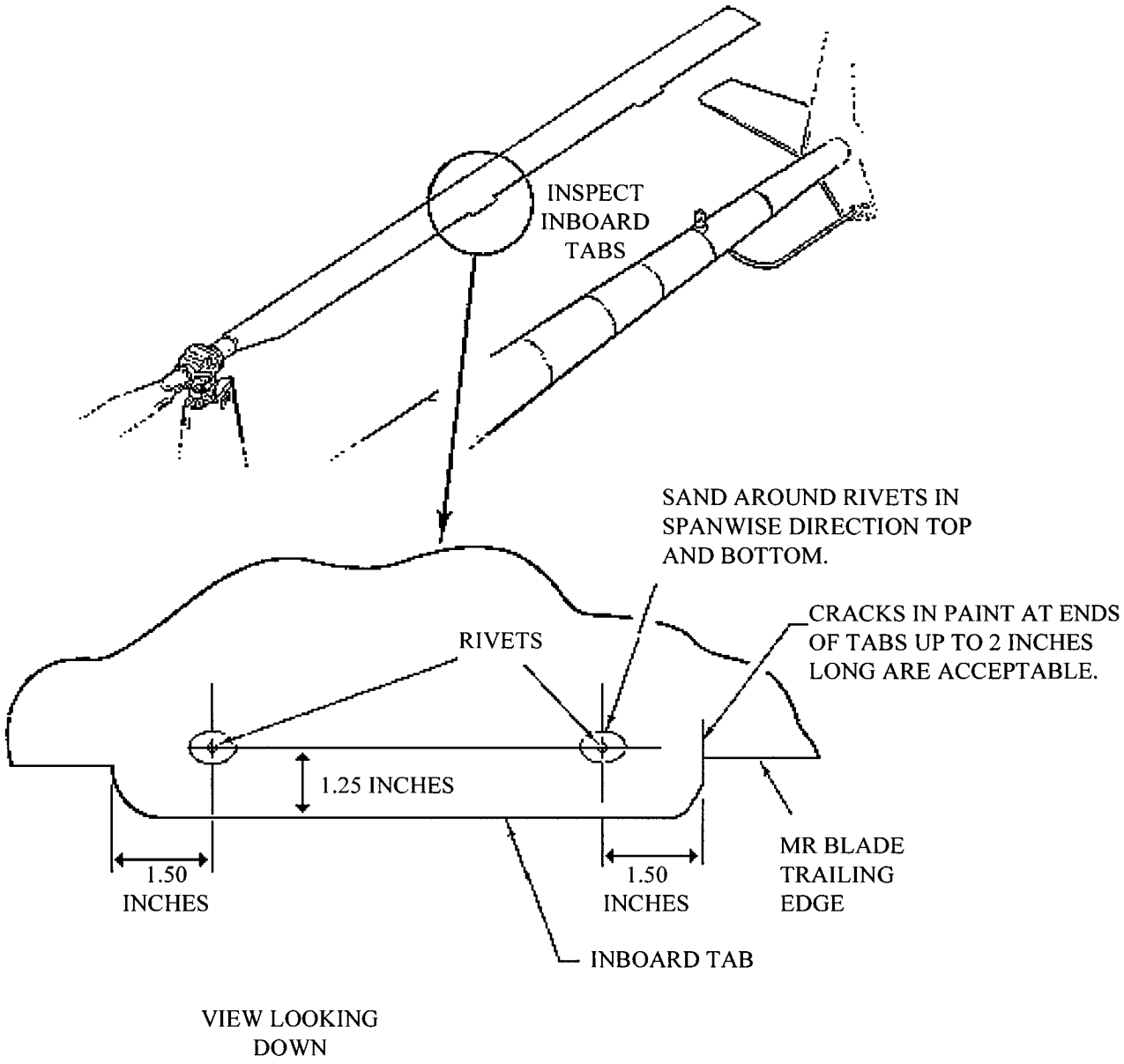


Figure 1

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(1) Remove all paint around both rivets, exposing an area of approximately ¾″ in diameter, at the inboard trim tab on top and bottom of each blade (4 places per blade). Use 180 grit or finer abrasive paper, followed by 600 grit or finer paper to eliminate course sanding marks. Sand only in a spanwise direction. Do not use chemical paint strippers.

(2) Inspect the blade skin around the rivets on the upper and lower surfaces (4 locations) using a dye penetrant method.

**Note 2:** Chordwise cracks in the paint up to 2 inches long which are located along either inboard or outboard edge of the trim tab are acceptable.

(b) Clean the sanded areas prepared in accordance with paragraph (a) of this AD with 111-Trichloroethane or methyl ethyl ketone (MEK) and then apply clear lacquer to seal the unpainted areas.

**Note 3:** Do not bend the inboard main rotor blade tabs from their present position or utilize them for any subsequent blade tracking adjustment.

(c) Thereafter, prior to the first flight of each day, or at intervals not to exceed 5 hours TIS, whichever occurs first, using a 5-power or higher magnifying glass, visually inspect the upper and lower blade skin surfaces around the inboard trim tab rivets (4 locations) for cracks.

(d) If a crack is found, replace the main rotor blade with an airworthy main rotor blade before further flight.

(e) Installation of a set of main rotor blades, P/N C016–2, constitutes terminating action for the requirements of this AD.

(f) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles Aircraft Certification Office, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Los Angeles Aircraft Certification Office.

**Note 4:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles Aircraft Certification Office.

(g) Special flight permits will not be issued.

**Note 5:** Robinson Helicopter Company R44 Service Bulletin SB–27A, revised May 29, 1998, pertains to the subject of this AD.

(h) This amendment becomes effective on August 28, 1998, to all persons except those persons to whom it was made immediately effective by Priority Letter AD 98–12–19, issued June 2, 1998, which contained the requirements of this amendment.

Issued in Fort Worth, Texas, on August 5, 1998.

**Henry A. Armstrong,**

*Manager, Rotorcraft Directorate, Aircraft Certification Service.*

[FR Doc. 98–21706 Filed 8–12–98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 358

**[Docket No. 81N–0201]**

**RIN 0910–AA01**

## Pediculicide Drug Products for Over-the-Counter Human Use; Final Monograph; Technical Amendment

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the regulation that established conditions under which over-the-counter (OTC) pediculicide drug products (products used for the treatment of head, pubic (crab), and body lice) are generally recognized as safe and effective and not misbranded. This final rule clarifies that the pediculicide active ingredient, pyrethrum extract, is to provide a specified concentration range of pyrethrins in a formulated product. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

**EFFECTIVE DATE:** September 14, 1998.

**FOR FURTHER INFORMATION CONTACT:** Michael T. Benson, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2245.

**SUPPLEMENTARY INFORMATION:**

### I. Background

In the **Federal Register** of December 14, 1993 (58 FR 65452), FDA issued a final monograph for OTC pediculicide drug products (part 358 (21 CFR part 358, subpart G)) establishing conditions under which the drug products that are subject to that monograph will be generally recognized as safe and effective and not misbranded. The effective date of that monograph was December 14, 1994. The active ingredients under § 358.610 of the monograph were described as the combination of pyrethrum extract (0.17 to 0.33 percent) with piperonyl butoxide (2 to 4 percent) in a nonaerosol dosage formulation.

On October 30, 1996, the Nonprescription Drug Manufacturers Association (NDMA) requested a technical amendment of the final monograph to clarify that pyrethrum extract in § 358.610 provides a concentration of 0.17 to 0.33 percent pyrethrins in the final product formulation (Ref. 1). NDMA stated that proposed § 358.610 of the tentative final monograph for OTC pediculicide drug products listed ''pyrethrins (0.17 to 0.33 percent)'' as the active ingredient (54 FR 13480 at 13487, April 3, 1989), and that there was no United States Pharmacopeia (USP) monograph for pyrethrins at that time. NDMA noted that a USP monograph entitled ''pyrethrum extract'' (Ref. 2) was in effect at the time of publication of the final monograph for OTC pediculicide drug products in 1993, and FDA used ''pyrethrum extract (0.17 to 0.33 percent)'' in § 358.610. The USP monograph (Ref. 2) stated that pyrethrum extract contains approximately 50 percent of the sum of Pyrethrins I and II. NDMA added that, subsequently, USP changed the concentration of Pyrethrins I and II in pyrethrum extract from 50 percent to 20 percent (Ref. 3). NDMA pointed out that a manufacturer following § 358.610 of the final monograph and the latest USP monograph for pyrethrum extract could produce a product containing one-fifth the desired concentration of pyrethrins. NDMA recommended that the agency publish a technical amendment to revise § 358.610 to state ''* * * pyrethrum extract (providing a concentration of pyrethrins of 0.17 to 0.33 percent) * * *'' instead of ''* * * pyrethrum extract (0.17 to 0.33 percent) * * *.'' NDMA indicated that this amendment would allow manufacturers flexibility in using pyrethrum extract containing either 50 or 20 percent pyrethrins to produce a pediculicide product with the desired concentration of pyrethrins.

### II. Description of the Technical Amendment

The agency concurs that amendment of § 358.610 is appropriate and is revising this section accordingly.

Publication of this document constitutes final action on this change under the Administrative Procedure Act (5 U.S.C. 553). This final rule institutes a change that is nonsubstantive in nature. The change does not alter the required range of pyrethrins for pediculicide active ingredients, but simply clarifies that the range was intended to apply to the pyrethrins in the active ingredients. Therefore, FDA finds that the notice and comment procedures are unnecessary and not in the public interest (5 U.S.C. 553(b) and (d)).

### III. References

The following references are on display in the Dockets Management Branch (HFA–305), Food and Drug