

Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

### Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect 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.

For the reasons discussed above, I certify that this AD:

- (1) Is not a "significant regulatory action" under Executive Order 12866,
- (2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),
- (3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and
- (4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

### Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

**2016-22-05 Pratt & Whitney Division:**  
Amendment 39-18694; Docket No.

FAA-2016-5423; Directorate Identifier  
2016-NE-09-AD.

#### (a) Effective Date

This AD is effective December 6, 2016.

#### (b) Affected ADs

None.

#### (c) Applicability

- This AD applies to Pratt & Whitney (PW):
- (1) PW4164, PW4168, and PW4168A model engines that have incorporated PW Service Bulletin (SB) PW4G-100-72-214, dated December 15, 2011, or PW SB PW4G-100-72-219, Revision No. 1, dated October 5, 2011, or original issue, and have fuel nozzles, part number (P/N) 51J345, installed;
  - (2) PW4168A model engines with Talon IIA outer combustion chamber assembly, P/N 51J100, and fuel nozzles, P/N 51J345, with serial numbers CGGUA19703 through CGGUA19718 inclusive or CGGUA22996 and higher, installed;
  - (3) PW4168A-1D and PW4170 model engines with engine serial numbers P735001 thru P735190 inclusive and fuel nozzles, P/N 51J345, installed; and
  - (4) PW4164-1D, PW4168-1D, PW4168A-1D, and PW4170 model engines that have incorporated PW SB PW4G-100-72-220, Revision No. 4, dated September 30, 2011, or earlier revision, and have fuel nozzles, P/N 51J345, installed.

#### (d) Unsafe Condition

This AD was prompted by nine instances of fuel leaks on PW engines with the Talon IIB combustion chamber configuration installed. We are issuing this AD to prevent failure of the fuel nozzles, which could lead to engine fire and damage to the airplane.

#### (e) Compliance

Comply with this AD within the compliance times specified, unless already done.

- (1) Within 800 flight hours after the effective date of this AD, and thereafter within every 800 flight hours accumulated on the fuel nozzles, do the following:
  - (i) Inspect all fuel nozzles, P/N 51J345. Use Part A of PW Alert Service Bulletin (ASB) PW4G-100-A73-45, dated February 16, 2016, to do the inspection.
  - (ii) For any fuel nozzle that fails the inspection, before further flight, remove and replace it with a part that is eligible for installation.
- (2) At the next shop visit after the effective date of this AD, and thereafter at each engine shop visit, remove all fuel nozzles, P/N 51J345, unless fuel nozzles were replaced within the last 100 flight hours. Use Part B of PW ASB PW4G-100-A73-45, dated February 16, 2016, to replace the fuel nozzles with parts eligible for installation.

#### (f) Definitions

- (1) For the purpose of this AD, an "engine shop visit" means the induction of an engine into the shop for any maintenance.
- (2) For the purpose of this AD, a part that is "eligible for installation" is a fuel nozzle, with a P/N other than 51J345, that is FAA-approved for installation or a fuel nozzle, P/N 51J345, that meets the requirements of Part

A, paragraph 4.B., or Part B, paragraph 1.B. of PW ASB PW4G-100-A73-45, dated February 16, 2016.

#### (g) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request. You may email your request to: [ANE-AD-AMOC@faa.gov](mailto:ANE-AD-AMOC@faa.gov).

#### (h) Related Information

For more information about this AD, contact Besian Luga, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA 01803; phone: 781-238-7750; fax: 781-238-7199; email: [besian.luga@faa.gov](mailto:besian.luga@faa.gov).

#### (i) Material Incorporated by Reference

- (1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.
- (2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.
  - (i) Pratt & Whitney (PW) Alert Service Bulletin PW4G-100-A73-45, dated February 16, 2016.
  - (ii) Reserved.
- (3) For PW service information identified in this AD, contact Pratt & Whitney Division, 400 Main St., East Hartford, CT 06108; phone: 860-565-8770; fax: 860-565-4503.
- (4) You may view this service information at FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781-238-7125.
- (5) You may view this service information at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Burlington, Massachusetts, on October 25, 2016.

**Colleen M. D'Alessandro,**  
Manager, Engine & Propeller Directorate,  
Aircraft Certification Service.

[FR Doc. 2016-26183 Filed 10-31-16; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2016-6990; Directorate Identifier 2016-NE-14-AD; Amendment 39-186990; AD 2016-22-10]

RIN 2120-AA64

### Airworthiness Directives; Turbomeca S.A. Turbohaft Engines

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** We are adopting a new airworthiness directive (AD) for certain Turbomeca S.A. Arriel 1, 1A, 1A1, 1A2, 1B, 1B2, 1C, 1C1, 1C2, 1D, 1D1, 1E, 1E2, 1K1, 1S, and 1S1 turboshaft engines. This AD requires removing the centrifugal impeller and replacing with a part eligible for installation. This AD was prompted by an anomaly that occurred during the grinding operation required by modification TU376, which increases the clearance between the rear curvic coupling of the centrifugal impeller and the fuel injection manifold. We are issuing this AD to prevent failure of the centrifugal impeller, uncontained centrifugal impeller release, damage to the engine, and damage to the helicopter.

**DATES:** This AD becomes effective December 6, 2016.

**ADDRESSES:** See the **FOR FURTHER INFORMATION CONTACT** section.

#### Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2016–6990; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the mandatory continuing airworthiness information (MCAI), the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

**FOR FURTHER INFORMATION CONTACT:** Philip Haberlen, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7770; fax: 781–238–7199; email: [philip.haberlen@faa.gov](mailto:philip.haberlen@faa.gov).

**SUPPLEMENTARY INFORMATION:**

#### Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to the specified products. The NPRM was published in the **Federal Register** on July 28, 2016 (81 FR 49575). The NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

Turbomeca reported an anomaly that was generated during the grinding operation

associated to the application of modification TU376, which increases the clearance between the rear curvic coupling of the centrifugal impeller and the fuel injection manifold.

This condition, if not corrected, could lead to crack initiation and propagation in the centrifugal impeller bore area, possibly resulting in centrifugal impeller failure, with consequent damage to, and reduced control of, the helicopter. To address this potential unsafe condition, the life of the affected centrifugal impellers was reduced and Turbomeca published Mandatory Service Bulletin (MSB) 292 72 0848 to inform operators about the life reduction and to provide instructions for the replacement of the affected centrifugal impellers.

For the reasons described above, this AD requires replacement of each affected centrifugal impeller before it exceeds the applicable reduced life limit.

You may obtain further information by examining the MCAI in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2016–6990.

#### Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM (81 FR 49575, July 28, 2016) or on the determination of the cost to the public.

#### Conclusion

We reviewed the available data and determined that air safety and the public interest require adopting this AD as proposed.

#### Related Service Information

Turbomeca S.A. has issued Mandatory Service Bulletin (MSB) 292 72 0848, Version B, dated April 13, 2016. The MSB describes procedures for reducing the life limit of the centrifugal impellers affected by an anomaly that occurred during the grinding operation required by modification TU376. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

#### Costs of Compliance

We estimate that this AD affects 3 engines installed on helicopters of U.S. registry. We also estimate that it would take about 22 hours per engine to comply with this AD. The average labor rate is \$85 per hour. Required parts cost about \$96,518 per engine. Based on these figures, we estimate the cost of this AD on U.S. operators to be \$295,164.

#### Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

#### Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect 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.

For the reasons discussed above, I certify this AD:

- (1) Is not a "significant regulatory action" under Executive Order 12866,
- (2) Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),
- (3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and
- (4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

#### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

#### Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

**2016–22–10 Turbomeca S.A.:** Amendment 39–186990; Docket No. FAA–2016–6990; Directorate Identifier 2016–NE–14–AD.

**(a) Effective Date**

This AD becomes effective December 6, 2016.

**(b) Affected ADs**

None.

**(c) Applicability**

This AD applies to certain Arriel 1, 1A, 1A1, 1A2, 1B, 1B2, 1C, 1C1, 1C2, 1D, 1D1, 1E, 1E2, 1K1, 1S, and 1S1 turboshaft engines, with modification TU376 installed.

**(d) Reason**

This AD was prompted by an anomaly that occurred during the grinding operation required by modification TU376, which increases the clearance between the rear curvic coupling of the centrifugal impeller and the fuel injection manifold. We are issuing this AD to prevent failure of the centrifugal impeller, uncontained centrifugal impeller release, damage to the engine, and damage to the helicopter.

**(e) Actions and Compliance**

Comply with this AD within the compliance times specified, unless already done.

(1) Remove from service, any centrifugal impeller listed in Table 1 to paragraph (e) of this AD, before exceeding the applicable cycles since new (CSN) and replace with a centrifugal impeller not listed in Table 1 to paragraph (e) of this AD.

TABLE 1 TO PARAGRAPH (e)—  
CENTRIFUGAL IMPELLER CSNS

Part No.	Serial No.	CSN
0292254040 .....	44	5,129
0292254040 .....	1762FT	11,476
0292254050 .....	1676CAR	6,281
0292254050 .....	5333OTT	5,495
0292254050 .....	5017OTT	5,491
0292254050 .....	1136CAR	8,734
0292254050 .....	3655OTT	4,600
0292254050 .....	1757CAR	7,913
0292254050 .....	1738CAR	10,640
0292254050 .....	1149CAR	12,273
0292254050 .....	2677OTT	11,145
0292254050 .....	3109OTT	10,662
0292254050 .....	3496OTT	5,562
0292254050 .....	2074CAR	7,423
729225293A .....	290CAR	6,326
729225293A .....	1227FT	8,139
729225293A .....	504FB	4,600
729225293A .....	2517OTT	9,732
729225293A .....	2165OTT	6,163
729225293A .....	2194FT	11,461
729225293A .....	1331OTT	12,513
729225293A .....	1301FT	7,262
729225293A .....	1567FT	6,305
729225293A .....	783FB	8,307
729225293A .....	98OTT	9,492

(2) Reserved.

**(f) Alternative Methods of Compliance (AMOCs)**

The Manager, Engine Certification Office, FAA, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request. You may email your request to: ANE-AD-AMOC@faa.gov.

**(g) Related Information**

(1) For more information about this AD, contact Philip Haberlen, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7770; fax: 781–238–7199; email: philip.haberlen@faa.gov.

(2) Refer to MCAI, European Aviation Safety Agency AD 2016–0090, dated May 10, 2016, for more information. You may examine the MCAI in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating it in Docket No. FAA–2016–6990.

**(h) Material Incorporated by Reference**

None.

Issued in Burlington, Massachusetts, on October 24, 2016.

**Colleen M. D'Alessandro,**

Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2016–26184 Filed 10–31–16; 8:45 am]

**BILLING CODE 4910–13–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 73 and 74**

[Docket No. FDA–2016–F–0821]

**Listing of Color Additives Exempt From Certification; Titanium Dioxide and Listing of Color Additives Subject to Certification; [Phthalocyaninato (2-)] Copper**

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA or we) is amending the color additive regulations to provide for the safe use of titanium dioxide and [phthalocyaninato (2-)] copper to color orientation marks for intraocular lenses. This action is in response to a petition filed by Milton W. Chu, M.D.

**DATES:** This rule is effective December 2, 2016. See section IX for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing by December 1, 2016.

**ADDRESSES:** You may submit objections and requests for a hearing as follows:

*Electronic Submissions*

Submit electronic objections in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on <http://www.regulations.gov>.

- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper objections submitted to the Division of Dockets Management, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA–2016–F–0821 for “Listing of Color Additives Exempt From Certification; Titanium Dioxide and Listing of Color Additives Subject to Certification; [Phthalocyaninato (2-)] Copper.” Received objections will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper