

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. 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.

(g) This amendment becomes effective on November 4, 1997.

Issued in Renton, Washington, on September 17, 1997.

James V. Devany,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97-25167 Filed 9-29-97; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 96-CE-23-AD; Amendment 39-10109; AD 96-12-03 R1]

RIN 2120-AA64

Airworthiness Directives; Aviat Aircraft, Inc. Models S-1S, S-1T, S-2, S-2A, S-2S, and S-2B Airplanes (Formerly Known as Pitts Models S-1S, S-1T, S-2, S-2A, S-2S, and S-2B Airplanes); Correction

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; correction.

SUMMARY: This document corrects the airworthiness directive (AD) number of an amendment that was published in the **Federal Register** on August 22, 1997 (62 FR 44535), and concerns Aviat Aircraft, Inc. Models S-1S, S-1T, S-2, S-2A, S-2S, and S-2B airplanes. The referenced amendment revises AD 96-12-03, but was inadvertently assigned the number of AD 97-17-07 instead of AD 96-12-03 R1. The AD currently requires repetitively inspecting the aft lower fuselage wing attach fitting on both wings for cracks and modifying any cracked aft lower fuselage wing attach fitting. Modifying the aft lower fuselage wing attach fitting on both wings eliminates the repetitive inspection requirement of the AD. This action corrects the amendment to reflect the right AD number throughout the entire document.

EFFECTIVE DATE: October 3, 1997.

FOR FURTHER INFORMATION CONTACT: Mr. Roger Caldwell, Aerospace Engineer, FAA, Denver Aircraft Certification Office, 26805 E. 68th Avenue, Room

214, Denver, Colorado 80249; telephone (303) 342-1086; facsimile (303) 342-1088.

SUPPLEMENTARY INFORMATION:

Discussion

On August 13, 1997, the FAA issued Amendment 10109 (62 FR 44535, August 22, 1997), which applies to Aviat Models S-1S, S-1T, S-2, S-2A, S-2S, and S-2B airplanes. This action revises AD 96-12-03 by retaining the requirements of repetitively inspecting the aft lower fuselage wing attach fitting on both wings for cracks, and modifying any cracked aft lower fuselage wing attach fitting; except the action eliminates from the applicability those airplanes that were equipped with aft lower fuselage wing attach fittings, either P/N 76090, 2-2107-1, or 1-210-102, at manufacture. These aft lower fuselage wing attach fittings were incorporated at manufacture on the Model S-2B airplanes beginning with serial number 5349. AD 96-12-03 applied to all serial numbers of the Model S-2B airplanes.

Need for the Correction

The AD number of this action is incorrectly referenced as AD 97-17-07 instead of AD 96-12-03 R1 throughout the document. Referencing the action as AD 97-17-07 may not allow operators of the affected airplanes that accomplished the intent of AD 96-12-03 to realize that the AD contains the same actions as contained in the original AD. The operators may spend unnecessary time tracking down information and approvals for "unless already accomplished" credit for the AD action.

Correction of Publication

Accordingly, the publication of August 22, 1997 (62 FR 44535), of Amendment 39-10109; AD 97-17-07, which was the subject of FR Doc. 97-22046, is corrected as follows:

§ 39.13 [Corrected]

On page 44535, in the third column, 5th line from the top of the column, correct "AD 97-17-07" to "AD 96-12-03 R1".

On page 44536, in the third column, section 39.13, the sixth line in this section and the 19th line from the top of the column, correct "97-17-07" to "96-12-03 R1".

Action is taken herein to correct this reference in Amendment 39-10109 and to add this AD correction to section 39.13 of the Federal Aviation Regulations (14 CFR 39.13).

The effective date remains October 3, 1997.

Issued in Kansas City, Missouri on September 24, 1997.

Henry A. Armstrong,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97-25831 Filed 9-29-97; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97-CE-15-AD; Amendment 39-10148; AD 97-20-11]

RIN 2120-AA64

Airworthiness Directives; Socata—Groupe Aerospatiale Model TBM 700 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule

SUMMARY: This amendment adopts a new airworthiness directive (AD) that applies to certain Socata—Groupe Aerospatiale (Socata) Model TBM 700 airplanes. This AD requires removing the main landing gear (MLG) inboard doors and the door locking control mechanism (MOD 70-065-32). This AD is the result of an incident on one of the affected airplanes where the MLG inboard door locking hooks (hinges) corroded, caused the doors to jam, and prevented the MLG from extending. The Federal Aviation Administration's analysis reveals that removing the MLG inboard doors will not cause any airplane safety or performance problems. The actions specified by this AD are intended to prevent the MLG from failing to extend because of corroded MLG inboard locking hinges, which could result in loss of control of the airplane during landing operations.

DATES: Effective November 13, 1997.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of November 13, 1997.

ADDRESSES: Service information that applies to this AD may be obtained from Socata—Groupe Aerospatiale, Socata Product Support, Aeroport Tarbes-Ossun-Lourdes, B P 930, 65009 Tarbes Cedex, France; telephone 62.41.74.26; facsimile 62.41.74.32; or the Product Support Manager, Socata—Groupe Aerospatiale, North Perry Airport, 7501 Pembroke Road, Pembroke Pines, Florida 33023; telephone (954) 964-6877; facsimile (954) 964-1668. This information may also be examined at

the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket 97-CE-15-AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Karl Schletzbaum, Aerospace Engineer, FAA, Small Airplane Directorate, 1201 Walnut Street, suite 900, Kansas City, Missouri 64106; telephone (816) 426-6934; facsimile (816) 426-2169.

SUPPLEMENTARY INFORMATION:

Events Leading to the Issuance of This AD

A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would apply to Socata Model TBM 700 airplanes was published in the **Federal Register** as a notice of proposed rulemaking (NPRM) on April 9, 1997 (62 FR 17125). The NPRM proposed to require removing the MLG inboard doors and the door locking control mechanism (MOD 70-065-32). Accomplishment of the proposed actions as specified in the NPRM would be in accordance with the Technical Instruction of Modification OPT70 KO59-32, dated December 1995, as referenced in Socata Service Bulletin 70-073, Amdt. 1, dated June 1996.

The NPRM was the result of an incident on one of the affected airplanes where the MLG inboard door locking hooks (hinges) corroded, caused the doors to jam, and prevented the MLG from extending. The FAA's analysis reveals that removing the MLG inboard doors will not cause any airplane safety or performance problems.

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received by one commenter.

Comment 1: No Justification for AD Action

The commenter states that the FAA does not have substantiating engineering data to justify the unsafe condition proposed in the NPRM. This commenter believes that if the pilot-in-command is adequately accomplishing the preflight checks, then any corrosion in the MLG inboard door locking hooks (hinges) would be detected and then corrected. Thus, the MLG doors would not jam and prevent the MLG from extending.

The FAA does not concur that the commenter's determination that an unsafe condition does not exist is

justified. The FAA analyzed the preflight procedures of the Socata TBM 700 airplanes and the preflight procedures of similar design airplanes. From this analysis, the FAA has determined that inspecting this area for corrosion is considered action over and above normal preflight procedures that the pilot is authorized to perform. In addition, the FAA always tries to mandate modifications or replacements rather than repetitive inspections. Removing the MLG doors and the door locking control mechanism is a modification that would eliminate the need for repetitive inspections, eliminate the unsafe condition identified by this AD, and not cause any adverse operational effects on the affected airplanes. No changes have been made to the final rule as a result of this comment.

Comment 2: Proposed Alternative Method of Compliance

The commenter states that removing the MLG inboard doors as proposed in the NPRM results in approximately 3-4 knots of performance degradation, and raises the level of cabin noise in the aircraft. Socata has issued SB No. 70-076-32, which specifies actions to address the noise issue (the FAA does not mandate accomplishment of this SB through AD action). The commenter explains that accomplishing this noise modification imposes substantial expense on the affected airplanes owners. For these reasons, the commenter has submitted a proposed alternative method of compliance (AMOC) that includes procedures for lubricating the inner landing gear door hinges and repetitively inspecting the inner landing gear door hinges every 50 hours time-in-service (TIS). The proposed AMOC also includes preflight visual inspections of the main landing gear doors prior to each flight. The commenter would like the proposed AMOC approved as an alternative to the proposed requirement of removing the MLG inboard doors and door locking control mechanisms.

The FAA is currently in the process of reviewing the information contained in the proposed AMOC and is working with the commenter toward approving this AMOC. All owners/operators of Socata TBM 700 airplanes may contact the FAA at the address specified in paragraph (d) of the AD to receive this AMOC (when and if it is approved) and to obtain the necessary documents pertinent to this AMOC.

The FAA's Determination

After careful review of all available information related to the subject

presented above, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed except for minor editorial corrections. The FAA has determined that these minor corrections will not change the meaning of the AD and will not add any additional burden upon the public than was already proposed.

Compliance Time of This AD

The unsafe condition specified in this AD develops primarily because of slush/debris accumulating in the MLG inboard doors area while landing in certain runway environments. Corrosion could have already developed on an airplane previously operated in certain slush/debris runway environments, regardless of future operation of the airplane. For this reason, the FAA has determined that the compliance time of this AD should be specified in both hours time-in-service (TIS) and calendar time (whichever occurs first), in order to assure that corrosion is not allowed to go undetected over time.

Cost Impact

The FAA estimates that 47 airplanes in the U.S. registry will be affected by this AD, that it will take approximately 3 workhours per airplane to accomplish this AD, and that the average labor rate is approximately \$60 an hour. Socata will provide parts at no cost to the owners/operators of the affected airplanes. Based on these figures, the total cost impact of this AD on U.S. operators is estimated to be \$8,460. This figure is based on the presumption that no owner/operator of the affected airplanes has accomplished the required actions.

Socata has informed the FAA that parts have been distributed to equip approximately 30 of the affected airplanes. Presuming that each set of parts is incorporated on an affected airplane, the cost impact upon U.S. airplane owners/operators is reduced by \$5,400 from \$8,460 to \$3,060.

Regulatory Impact

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.

For the reasons discussed above, I certify that this action (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); and (3) 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. A copy of the final evaluation prepared for this action is contained in the rules docket. A copy of it may be obtained by contacting the rules docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, 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 USC 106(g), 40113, 44701.

§39.13 [Amended]

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

97-20-11 Socata—Groupe Aerospatiale: Amendment 39-10148; Docket No. 97-CE-15-AD.

Applicability: Model TBM 700 airplanes (serial numbers 1 through 109), certificated in any category, that do not have the main landing gear (MLG) inboard doors and the door locking control mechanism removed (MOD 70-065-32) in accordance with the Technical Instruction of Modification OPT70 KO59-32, dated December 1995, as referenced in Socata Service Bulletin (SB) 70-073, Amdt. 1, dated June 1996.

Note 1: This AD applies to each airplane 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 airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required within the next 100 hours time-in-service after the effective date of this AD or within the next 6 calendar months after the effective date of this AD, whichever occurs first, unless already accomplished.

To prevent the MLG from failing to extend because of corroded MLG inboard locking hinges, which could result in loss of control of the airplane during landing operations, accomplish the following:

(a) Remove the MLG inboard doors and the door locking control mechanism (MOD 70-065-32) in accordance with the Technical Instruction of Modification OPT70 KO59-32, dated December 1995, as referenced in Socata SB 70-073, Amdt. 1, dated June 1996.

(b) As of the effective date of this AD, no person may undo MOD 70-065-32 on any affected airplane, by reinstalling the MLG inboard doors and the door locking control mechanism.

(c) 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.

(d) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Small Airplane Directorate, FAA, 1201 Walnut, suite 900, Kansas City, Missouri 64106. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Small Airplane Directorate.

(e) The removal required by this AD shall be done in accordance with the Technical Instruction of Modification OPT70 KO59-32, dated December 1995, as referenced in Socata Service Bulletin 70-073, Amdt. 1, dated June 1996. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Socata—Groupe Aerospatiale, Socata Product Support, Aeroport Tarbes-Ossun-Lourdes, B P 930, 65009 Tarbes Cedex, France; or the Product Support Manager Socata—Groupe Aerospatiale, North Perry Airport, 7501 Pembroke Road, Pembroke Pines, Florida 33023. Copies may be inspected at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(f) This amendment (39-10148) becomes effective on November 13, 1997.

Issued in Kansas City, Missouri, on September 24, 1997.

Henry A. Armstrong,
Acting Manager, Small Airplane Directorate,
Aircraft Certification Service.

[FR Doc. 97-25832 Filed 9-29-97; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N-0119]

21 CFR Part 801

Natural Rubber-Containing Medical Devices; User Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule requiring labeling statements on medical devices, including device packaging containing natural rubber that contacts humans. The rule requires labeling of medical devices containing natural rubber latex that contacts humans to state: "Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions."; labeling of medical devices containing dry natural rubber that contacts humans to state: "This Product Contains Dry Natural Rubber."; labeling of medical devices containing natural rubber latex in their packaging that contacts humans to state: "Caution: The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions."; labeling of medical devices containing dry natural rubber in their packaging that contacts humans to state: "The Packaging of This Product Contains Dry Natural Rubber."; and that the claim of hypoallergenicity be removed from the labeling of medical devices that contain natural rubber. These requirements are being established in response to numerous reports of severe allergic reactions and deaths related to a wide range of medical devices containing natural rubber.

EFFECTIVE DATE: This final rule is effective September 30, 1998.

FOR FURTHER INFORMATION CONTACT: Donald E. Marlowe, Center for Devices and Radiological Health (HFZ-100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20850, 301-443-2444, FAX 301-443-2296.

SUPPLEMENTARY INFORMATION:

I. Background

Natural latex is a milky fluid obtained in commercial quantities primarily from the *Hevea brasiliensis* (rubber) tree. There is often confusion concerning the terminology used to describe the raw agricultural materials derived from rubber-producing plants; products made from various intermediate forms of the