

Est. 124

1541.00

**Erysipelothrix Rhusiopathiae Vaccine
Avirulent Live Culture**

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Code 1541.00

Prepared January 12, 2010

Complete Revision

Supersedes December 15, 2004
Inclusive of all previous versions

Boehringer Ingelheim Vetmedica, Inc.
St. Joseph, Missouri

U.S. Veterinary License No. 124

FILED WITH USDA-APHIS-VS
CENTER FOR VETERINARY BIOLOGICS

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V. Testing

A. Purity

revised { Ten final container samples of biological product from each serial and subserial are tested for purity in accordance with 9CFR 113.27 (b). The test to confirm the final product is free of extraneous bacteria is conducted by inoculating 0.2 mL of final product into each of the 10 bottles containing 150 mL of Fluid Thioglycollate Medium and incubating at 30 - 35°C for a minimum of 14 days. The test to confirm the final product is free of extraneous fungi is conducted by inoculating 0.2 mL of final product into each of the 10 bottles containing 150 mL of Soybean Casein Digest Medium and incubating at 20 - 25°C for a minimum of 14 days. The ratio of inoculum to medium was accepted by the CVB on (to be determined) in accordance with 9CFR 113.25 (d).

B. Safety

Final container samples from each serial or first subserial of completed product *added* are tested for safety in swine in accordance with 9CFR 113.44, except that five pigs, representing at least two different litters, are used instead of two, ensuring that the entire volume is ingested.

** - chgs not an Summary*

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V. (Continued)

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D. **Moisture, if Desiccated**

See section IV.H. Not applicable for frozen product serials.

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