United States Department of Agriculture
Animal and Plant Health Inspection Service
Center for Veterinary Biologics
P. O. Box 844
Ames, IA 50010

1. Reagent Name: *Erysipelothrix rhusiopathiae* Reference Bacterin

2. Strain or Source: SE-9, serotype 2

3. Lot Number: IRP 529 (05)

4. Fill Date: December 15, 2005

5. Expiration Date: March 23, 2019

Precautions: This reagent does not present a hazard to laboratory personnel who work with it provided sound fundamental laboratory techniques are followed.

6. Intended Use: IRP 529 (05) serves as a reference bacterin for testing the potency of bacterins containing *Erysipelothrix rhusiopathiae.*

7. Instructions for Use: Dilute IRP 529 (05) 1:3 in 0.85% saline just prior to use. This shall be considered undiluted reference bacterin. Prepare 3-fold dilutions to bracket the 50% endpoint for use in the mouse potency test according to 9 CFR 113.119 and **SAM 611**. The mouse dose is 0.2 mL administered subcutaneously.

The swine dose is 2.0 mL administered subcutaneously.

8. Test of Reagent:

Mouse potency test - IRP 529 (05) was tested for potency using the mouse protection test as described in 9 CFR 113.119 and **SAM 611**.

Mouse safety test - IRP 529 (05) was tested for safety according to 9 CFR 113.33 with no unfavorable reactions being observed.

Sterility test - IRP 529 (05) was tested for sterility according to 9 CFR 113.26 and found to be free of viable bacteria and fungi.

Residual free formaldehyde test - IRP 529 (05) was tested for free formaldehyde content by the ferric chloride test and found to contain 0.15 g/L.

9. Container Size, Type, Weight, or Volume: 20-mL glass vials containing 10 mL of bacterin.

10. Storage Conditions: Store at 2°- 7°C.

11. CVB Technical Contact: Bacteriology Section, Center for Veterinary Biologics, (515) 337-6140 or FAX (515) 337-7673.

12. Origin and Passage History: The master seed was received from R. Wood, USDA-ARS-NADC, Ames, IA 50010. The number of passages is unknown.

13. Method of Preparation: Rehydrated master seed SE-9 was expanded 6 hours in flasks containing *E. rhusiopathiae* seed media, pH 7.2-7.4. The seed media culture was transferred to a 14-L fermenter vessel containing 10 L of production media, pH 7.2. The culture was incubated 7 hours at 35°- 37°C while being mixed and purged with sterile air. The culture was inactivated with 0.5% formaldehyde (v/v), and 1 part sterile AlH_3O_3 (Rehydragel-L-V aluminum hydroxide fluid gel) was added to 4 parts of formalinized culture.

14. Other: None

Reagent orders and feedback should be sent *including phone number* to the following email address: CVB@aphis.usda.gov

Reagent orders forms (APHIS 2018) are available from:
https://www.aphis.usda.gov/library/forms/pdf/APHIS_2018.pdf

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