

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-226

B. Sponsor

Western Chemical, Inc.
Western Chemical, Inc.
1269 Lattimore Road
Ferndale, WA 98248

C. Proprietary Name

Tricaine-S

D. Established Name

tricaine methanesulfonate

E. Dosage Form

Soluble powder

F. Dispensing Status

OTC

G. Route of Administration

The route of administration is immersion of the animal at levels ranging from 10 to 1,000 mg/liter.

H. Indication

TRICAINE-S is intended for the temporary immobilization of fish, amphibians, and other aquatic, cold-blooded animals. It has been recognized as a valuable tool for the proper handling of these animals during manual spawning (fish stripping), weighing, measuring, marking, surgical operations, transport, photography, and research.

II. EFFECTIVENESS

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act, (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. Instead, the ANADA sponsor must show that the generic product is bioequivalent to the pioneer. For certain dosage forms, the agency will grant a waiver from conducting an *in*

vivo bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, April 1996).

Based on the formulation characteristics of the generic product (single pure active ingredient), Western Chemical, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product TRICAINE-S (tricaine methanesulfonate). The generic product is administered as an solution and contains the same active ingredients in the same concentration as the pioneer product.

III. TARGET ANIMAL SAFETY

Because this drug is a generic copy of the brand name drug whose safety has been established, no safety studies have been required for this application.

IV. HUMAN FOOD SAFETY

Withdrawal Time

When a waiver from the requirement of an *in vivo* bioequivalence study is granted, the withdrawal times established for the pioneer product apply to the generic product.

Do not use within 21 days of harvesting fish for food.

When used in food fish, use should be restricted to Ictaluridae, salmonidae, Esocidas, and Percidae and water temperature should not exceed 10°C (50°F).

Expiry Time

24 months.

V. AGENCY CONCLUSIONS

This ANADA submitted under section 512(b) of the Federal Food, Drug, And Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrates that TRICAINE-S, when used under its proposed conditions of use, is safe and effective for the labeled indications.

The format of this FOI Summary document has been modified from its original form to conform with Section 508 of the Rehabilitation Act (29 U.S.C. 794d). The content of this document has not changed.