Bio-Cide
INTERNATIONAL, INC.

October 21, 1999

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Rm. 1-23
12420 Parklawn Dr.
Rockville, MD 20857

**Request for Advisory Opinion**

The undersigned submits this request for an advisory opinion of the Commissioner of Food and Drugs with respect to the use of Oxine (stabilized chlorine dioxide) in sweetwater systems.

A. Issues involved.

Bio-Cide International is requesting an updated advisory opinion for the use of Oxine in a sweetwater system.

B. Statement of facts and law.

Oxine is an approved sanitizing solution and is regulated for use in 21 CFR 178.1010 (b)(34) and (c)(29).

It is unlikely that the stabilized chlorine dioxide will directly contact food because the sweetwater is in a closed loop system, separated from food. Sweetwater could only come into contact with food as a result of a leak in the system.

The department had previously issued an advisory opinion and concluded that the intended use of Oxine at 5 ppm is unlikely to come into contact with food. Therefore, its intended use in sweetwater systems would not represent a food additive use situation and would not be subject to the provisions of the FDCA.

The department goes on to further indicate that if Oxine was used at a sanitizing concentration in the sweetwater that the department does not believe that the inside surface of the sweetwater system is a typical food contact surface. As such, the department suggest that the use of Oxine fall within the limits of good manufacturing practices.

Bio-Cide wishes confirmation that the uses indicated in the October 7, 1987 FDA letter are still legitimate.

99A-4659

AP1

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Environmentally Friendly Products

The undersigned certifies that, to the best of his knowledge and belief, this request includes all data, information, and views relevant to the matter, whether favorable or unfavorable to the position of the undersigned, which is the subject of the request.

Signature

Theodore D. Head
R.P.E.S.,R.P.S.

Bio-Cide International, Inc.
2845 Broce Drive
Norman, OK 73070

Enclosure: October 7, 1987 FDA letter to
Bio-Cide International, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

OCT 7 1987

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Bio-Cide International, Inc.
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Norman, OK 73070

This is in response to your letter of September 9, 1987 to Mr. McCowin requesting an advisory opinion on the use of OXINE (stabilized chlorine dioxide) in "sweetwater" systems in dairy processing at concentrations of up to 5 ppm. You have indicated that it is unlikely that the stabilized chlorine dioxide will directly contact food because the "sweetwater" is in a closed looped system, separated from food, and that the "sweetwater" could only come in contact with food as a consequence of a leak in the system. In addition you have stated OXINE is an approved sanitizing solution and is regulated for use in 178.1010(b)(34) and (c)(29).

We have reviewed your request and conclude that your intended use of OXINE or other products in a sweetwater system is unlikely to come in contact with food. Therefore, your use of OXINE or other products in a "sweetwater" system does not represent a food additive use situation and would not be subject to the provisions of the Food, Drug and Cosmetic Act.

We would also like to point out that your use of OXINE would not be considered a sanitizer, because its use at 5 ppm does not conform to the concentration requirements of 178.1010(c)(29). In addition, if OXINE was used at a sanitizing concentration in the "sweetwater" we do not believe that the inside surface of the "sweetwater" system is a typical food contact surface. As such, we would only suggest that you use OXINE within the limits of good manufacturing practice and that quality control is exercised to prevent leaking so that you preclude the possibility of leaking "sweetwater" into milk.

If we can be of further assistance, please feel free to contact us.

Sincerely yours,

Hortense S. Macon

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Indirect Additives Branch, HFF-335
Division of Food and Color Additives
Center for Food Safety
and Applied Nutrition