



*"The Chlorine Dioxide People"*

## **Application Note #39**

### **Food Contact Notices**

Chlorine dioxide's use is allowed under U.S. Food and Drug Administration's (FDA) jurisdiction as given in the following regulations:

**21 CFR PART 173** -- SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

**21 CFR PART 178** -- INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

**21 CFR PART 137** -- CEREAL FLOURS AND RELATED PRODUCTS

**GRAS Notice 062, GRAS Notice 161**

These incorporate a variety of applications including chlorine dioxide's use as an antimicrobial agent in water used in both poultry processing and for washing fruits and vegetables, including raw agricultural commodities. It is also allowed as a sanitizing solution on food-processing equipment and utensils, to bleach whole wheat flour and can be used in packaging materials for fresh fruits, vegetables, meats, poultry and seafood.

Food Contact Notices (FCN) are required for any new food contact substance and uses which do not fall under the scope of the regulations above. A FCN is effective for the manufacturer, the Food Contact Substance (FCS), and the conditions of use identified in the notification and not effective for a similar or identical substance produced or prepared by another manufacturer.

Clordisys has the following food contact notices in place:

1. **FCN 1665** – Chlorine dioxide as an antimicrobial agent used to fumigate fruits and vegetables, including raw agricultural commodities.
2. **FCN 1634** – Chlorine dioxide as an antimicrobial agent in water used in poultry processing and to wash fruits and vegetables, including raw agricultural commodities (RAC).
3. **FCN 1421** – Chlorine dioxide as an antimicrobial agent in air to treat fruits and vegetables.
4. **FCN 1400** – Chlorine dioxide as an antimicrobial agent in water used in poultry processing and to wash fruits and vegetables that are not raw agricultural commodities.

1. [https://www.accessdata.fda.gov/scripts/fdcc/?set=FCN&id=1665&sort=FCN\\_No&order=DESC&startrow=1&type=basic&search=clordisys](https://www.accessdata.fda.gov/scripts/fdcc/?set=FCN&id=1665&sort=FCN_No&order=DESC&startrow=1&type=basic&search=clordisys)
2. [https://www.accessdata.fda.gov/scripts/fdcc/?set=FCN&id=1634&sort=FCN\\_No&order=DESC&startrow=1&type=basic&search=clordisys](https://www.accessdata.fda.gov/scripts/fdcc/?set=FCN&id=1634&sort=FCN_No&order=DESC&startrow=1&type=basic&search=clordisys)
3. [https://www.accessdata.fda.gov/scripts/fdcc/?set=FCN&id=1421&sort=FCN\\_No&order=DESC&startrow=1&type=basic&search=clordisys](https://www.accessdata.fda.gov/scripts/fdcc/?set=FCN&id=1421&sort=FCN_No&order=DESC&startrow=1&type=basic&search=clordisys)
4. [https://www.accessdata.fda.gov/scripts/fdcc/?set=FCN&id=1400&sort=FCN\\_No&order=DESC&startrow=1&type=basic&search=clordisys](https://www.accessdata.fda.gov/scripts/fdcc/?set=FCN&id=1400&sort=FCN_No&order=DESC&startrow=1&type=basic&search=clordisys)



October 24, 2016

Paul Lorcheim  
Director of Operations  
Clordisys Solutions, Inc.  
PO Box 549  
Lebanon, NJ 08833

RE: Food Contact Substance Notification (FCN) 001665  
**Final Letter**

Dear Mr. Lorcheim:

This letter is in reference to the notification for the food contact substance and use described as follows:

**Food Contact Substance (FCS)**  
Chlorine dioxide (CAS Reg. No. 10049-04-4)

**Notifier**  
Clordisys Solutions, Inc.

**Manufacturer/Supplier**  
Clordisys Solutions, Inc.

**Intended Use**  
As an antimicrobial agent used to fumigate fruits and vegetables, including raw agricultural commodities.

**Limitations/ Specifications**  
The FCS will be applied only in unlit areas and shall not exceed 3 ppm residual in the air. In raw agricultural commodities, the FCS will be applied in the preparing, packing, or holding of the food for commercial purposes, consistent with the FD&C Act section 201(q)(1)(B)(i) but not applied for use under 201(q)(1)(B)(i)(I), (q)(1)(B)(i)(II), or (q)(1)(B)(i)(III).

This is to inform you that as of November 2, 2016, FCN 001665 will become effective. It will be added to the list of effective notifications for FCNs which is available on our website at [www.fda.gov](http://www.fda.gov).

The agency has determined that allowing this notification to become effective will not have a significant impact on the quality of the human environment and therefore an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, will be publicly available after the effective date of the notification.

This effective notification is applicable only to chlorine dioxide (CAS Reg. No. 10049-04-4) manufactured by Clordisys Solutions, Inc., and is limited to the use identified above. You should inform the Agency of any modification to the FCS, the limitations/specifications given in the notification, or of any alteration in the manufacturing process that would result in a change in the impurities or impurity level in the FCS. Such changes may require the submission of a new notification.

FDA's review of this notification was limited to Section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA). The existence of an effective notification for a FCS does not relieve use of the subject substance from compliance with any other provision of the Act or with §174.5 (General provisions applicable to indirect food additives). For example, in accordance with section 402(a)(3) of the Act (21 U.S.C. 342), use of the FCS should not impart odor or taste to food rendering it unfit for human consumption.

Section 301(II) of the FFDCA prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FFDCA, a biological product licensed under section 351 of the Public Health Service Act or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(II)(1)-(4) applies. In our review of this notification, FDA did not consider whether section 301(II) or any of its exemptions apply to the intended use of the FCS. Accordingly, allowing this FCN to become effective should not be construed as a statement that the intended use of the FCS would not violate section 301(II).

If new data or information becomes available to FDA demonstrating that the intended use of the FCS is no longer safe, the Agency will inform you of its determination that the intended use of the FCS is unsafe. In addition, if you become aware of data that raise questions about the safety of the intended use of the FCS, you should notify the Agency immediately and be prepared to supply the necessary data to resolve any questions.

If you have any further questions concerning this matter, please do not hesitate to contact us.

Sincerely,

Elizabeth S.  
Furukawa -S

Digitally signed by Elizabeth S.  
Furukawa -S  
DN: cn=US, o=U.S. Government,  
ou=HHS, ou=FDA, ou=People,  
ou=2342.1920900.100.1.1=1300,  
212219, cn=Elizabeth S.  
Furukawa -S  
Date: 2016.10.24 11:13:09 -0400

Elizabeth S. Furukawa, Ph.D.  
Consumer Safety Officer  
Division of Food Contact Notifications HFS-275  
Office of Food Additive Safety  
Center for Food Safety  
and Applied Nutrition

Attachment (1)



Attachment 1

**Definitions of Food Types and Conditions of Use for Food Contact Substances**

*These tables were created for easy reference for notifications relating to a food contact substance.*

**Table 1--Types of Raw and Processed Foods**

- I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).
- II. Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
- III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
- IV. Dairy products and modifications:
  - A. Water-in-oil emulsions, high- or low-fat
  - B. Oil-in-water emulsions, high- or low-fat.
- V. Low-moisture fats and oil.
- VI. Beverages:
  - A. Containing up to 8 percent of alcohol.
  - B. Nonalcoholic.
  - C. Containing more than 8 percent alcohol.
- VII. Bakery products other than those included under Types VIII or IX of this table:
  - A. Moist bakery products with surface containing free fat or oil.
  - B. Moist bakery products with surface containing no free fat or oil
- VIII. Dry solids with the surface containing no free fat or oil (no end test required).
- IX. Dry solids with the surface containing free fat or oil.

**Table 2--Condition of use**

- A. High temperature heat-sterilized (e.g., over 212 deg. F).
- B. Boiling water sterilized.
- C. Hot filled or pasteurized above 150 deg. F.
- D. Hot filled or pasteurized below 150 deg. F.
- E. Room temperature filled and stored (no thermal treatment in the container).
- F. Refrigerated storage (no thermal treatment in the container).
- G. Frozen storage (no thermal treatment in the container).
- H. Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use:
  - 1. Aqueous or oil-in-water emulsion of high- or low-fat.
  - 2. Aqueous, high- or low-free oil or fat.
- I. Irradiation
- J. Cooking at temperatures exceeding 250 deg. F



June 22, 2016

Paul Lorcheim  
Clordisys Solutions, Inc.  
PO Box 549.  
Lebanon, New Jersey 08833

RE: Food Contact Substance Notification (FCN) 001634

**Final Letter**  
**Replaces FCN 1400**

Dear Mr. Lorcheim:

This letter is in reference to the notification for the food contact substance and use described as follows:

**Food Contact Substance (FCS)**

Chlorine dioxide (CAS No. 10049-04-4)

**Notifier**

Clordisys Solutions, Inc.

**Manufacturer/Supplier**

Clordisys Solutions, Inc.

**Intended Use**

As an antimicrobial agent in water used in poultry processing and to wash fruits and vegetables, including raw agricultural commodities (RAC)

**Limitations/ Specifications**

The FCS will be used in an amount not to exceed 3 ppm residual chlorine dioxide as determined by Method 4500-ClO<sub>2</sub>-D<sup>1</sup>, modified for use with the Hach Spectrophotometer, or equivalent. The FCS will be generated by the reaction between chlorine gas and a solid matrix of sodium chlorite. When used on RAC, the FCS will be applied as a spray or dip in the preparing, packaging, or holding of food for commercial purposes, consistent with the FD&C Act section 201(q)(1)(B)(i) but not applied for use under 201(q)(1)(B)(i)(I), (q)(1)(B)(i)(II) or (q)(1)(B)(i)(III). Treatment of fruits and vegetables, including raw agricultural commodities, shall be followed by a potable water rinse, blanching, cooking, or canning.

This is to inform you that as of June 21, 2016, FCN 001634 became effective. It will be added to the list of effective notifications for FCNs which is available on our website:

<http://www.fda.gov/food/ingredientspackaginglabeling/packagingfcs/notifications/default.htm>

The Agency has determined that allowing this notification to become effective will not have a significant impact on the quality of the human environment and, therefore, an environmental impact statement is not

<sup>1</sup> Method 4500-ClO<sub>2</sub> : Amperometric Method from Standard Methods for the Examination of Water and Wastewater, by the American Water Works Association (AWWA); The information can be found at <https://law.resource.org/pub/us/cfr/ibr/002/apha.method.4500-cio2.1992.html>

required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, will be publicly available after the effective date of the notification.

This effective notification is applicable only to the subject FCS, manufactured by Clordisys Solutions, Inc., and is limited to the uses of the FCS as identified above. You should inform the Agency of any modification to the FCS limitations/ specifications given in the notification or of any alteration in the manufacturing process that would result in a change in the impurities or impurity levels in the FCS. Such changes may require the submission of a new notification.

FDA's review of this notification was limited to Section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA). The existence of an effective notification for a FCS does not relieve use of the subject substance from compliance with any other provision of the Federal Food, Drug, and Cosmetic Act or with §174.5 (General provisions applicable to indirect food additives). For example, in accordance with section 402(a)(3) of the Act, use of the FCS should not impart odor or taste to food rendering it unfit for human consumption.

Section 301(l) of the FFDCA prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FFDCA, a biological product licensed under section 351 of the Public Health Service Act or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(l)(1)-(4) applies. In our review of this notification, FDA did not consider whether section 301(l) or any of its exemptions apply to the intended use of the FCS. Accordingly, allowing this FCN to become effective should not be construed as a statement that the intended use of the FCS would not violate section 301(l).

If new data or information becomes available to FDA demonstrating that the intended use of the FCS is no longer safe, the Agency will inform you of its determination that the intended use of the FCS is unsafe. In addition, if you become aware of data that raise questions about the safety of the intended use of the FCS, you should notify the Agency immediately and be prepared to supply the necessary data to resolve any questions.

If you have any further questions concerning this matter, please do not hesitate to contact us.

Sincerely,

Anita Chang  
Consumer Safety Officer  
Division of Food Contact Notifications HFS-275  
Office of Food Additive Safety  
Center for Food Safety and Applied Nutrition



June 27, 2014

Paul Lorcheim  
Director of Operations  
Clordisys Solutions, Inc.  
PO Box 549.  
Lebanon, NJ 08833

RE: Food Contact Substance Notification (FCN) 001421  
**Final Letter**

Dear Mr. Lorcheim:

This letter is in reference to the notification for the food contact substance and use described as follows:

**Food Contact Substance (FCS)**

Chlorine dioxide (CAS Reg. No. 10049-04-4)

**Notifier**

Clordisys Solutions, Inc.

**Manufacturer/Supplier**

Clordisys Solutions, Inc.

**Intended Use**

As an antimicrobial agent used to fumigate fruits and vegetables that are not raw agricultural commodities.

**Limitations/ Specifications**

The FCS gas shall not exceed 3 ppm total residual in the air. Treated fruits and vegetables will be followed by air flush or by blanching, cooking, or canning.

This is to inform you that as of July 1, 2014, FCN 001421 will become effective. It will be added to the list of effective notifications for FCNs which is available on our website:

<http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/Notifications/default.htm>.

The agency has determined that allowing this notification to become effective will not have a significant impact on the quality of the human environment and therefore an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, will be publicly available after the effective date of the notification.



This effective notification is applicable only to Chlorine dioxide (CAS Reg. No. 10049-04-4) manufactured by Clordisys Solutions, Inc., and is limited to the use identified above. You should inform the Agency of any modification to the FCS, the limitations/specifications given in the notification, or of any alteration in the manufacturing process that would result in a change in the impurities or impurity level in the FCS. Such changes may require the submission of a new notification.

FDA's review of this notification was limited to Section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA). The existence of an effective notification for a FCS does not relieve use of the subject substance with any other provision of the Act or with §174.5 (General provisions applicable to indirect food additives). For example, in accordance with section 402(a)(3) of the Act (21 U.S.C. 342), use of the FCS should not impart odor or taste to food rendering it unfit for human consumption.

Section 301(ll) of the FFDCA prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FFDCA, a biological product licensed under section 351 of the Public Health Service Act or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(ll)(1)-(4) applies. In our review of this notification, FDA did not consider whether section 301(ll) or any of its exemptions apply to the intended use of the FCS. Accordingly, allowing this FCN to become effective should not be construed as a statement that the intended use of the FCS would not violate section 301(ll).

If new data or information becomes available to FDA demonstrating that the intended use of the FCS is no longer safe, the Agency will inform you of its determination that the intended use of the FCS is unsafe. In addition, if you become aware of data that raise questions about the safety of the intended use of the FCS, you should notify the Agency immediately and be prepared to supply the necessary data to resolve any questions.

If you have any further questions concerning this matter, please do not hesitate to contact us.

Sincerely,

Elizabeth S. Furukawa, Ph.D.  
Consumer Safety Officer  
Division of Food Contact Notifications, HFS-275  
Office of Food Additive Safety  
Center for Food Safety  
and Applied Nutrition

Attachment (1)

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Attachment 1

**Definitions of Food Types and Conditions of Use for Food Contact Substances**

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**Table 1--Types of Raw and Processed Foods**

- I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).
- II. Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
- III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
- IV. Dairy products and modifications:
  - A. Water-in-oil emulsions, high- or low-fat
  - B. Oil-in-water emulsions, high- or low-fat.
- V. Low-moisture fats and oil.
- VI. Beverages:
  - A. Containing up to 8 percent of alcohol.
  - B. Nonalcoholic.
  - C. Containing more than 8 percent alcohol.
- VII. Bakery products other than those included under Types VIII or IX of this table:
  - A. Moist bakery products with surface containing free fat or oil.
  - B. Moist bakery products with surface containing no free fat or oil
- VIII. Dry solids with the surface containing no free fat or oil (no end test required).
- IX. Dry solids with the surface containing free fat or oil.

**Table 2--Condition of use**

- A. High temperature heat-sterilized (e.g., over 212 deg. F).
- B. Boiling water sterilized.
- C. Hot filled or pasteurized above 150 deg. F.
- D. Hot filled or pasteurized below 150 deg. F.
- E. Room temperature filled and stored (no thermal treatment in the container).
- F. Refrigerated storage (no thermal treatment in the container).
- G. Frozen storage (no thermal treatment in the container).
- H. Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use:
  - 1. Aqueous or oil-in-water emulsion of high- or low-fat.
  - 2. Aqueous, high- or low-free oil or fat.
- I. Irradiation
- J. Cooking at temperatures exceeding 250 deg. F



March 17, 2014

Paul Lorcheim  
Clordisys Solutions, Inc.  
PO Box 549.  
Lebanon, NJ 08833

RE: Food Contact Substance Notification (FCN) 001400  
**Final Letter**

Dear Mr. Lorcheim:

This letter is in reference to the notification for the food contact substance and use described as follows:

**Food Contact Substance (FCS)**

Chlorine dioxide (CAS Reg. No. 10049-04-4)

**Notifier**

Clordisys Solutions, Inc.

**Manufacturer/Supplier**

Clordisys Solutions, Inc.

**Intended Use**

As an antimicrobial agent in water used in poultry processing and to wash fruits and vegetables that are not raw agricultural commodities.

**Limitations/ Specifications**

The FCS will be used in an amount not to exceed 3ppm residual chlorine dioxide as determined by Method 4500-ClO<sub>2</sub>-D, modified for use with the Hach Spectrophotometer, or equivalent. The FCS will be generated by the reaction between chlorine gas and a solid matrix of sodium chlorite. Treatment of the fruits and vegetables shall be followed by a potable water rinse, blanching, cooking, or canning.

This is to inform you that as of April 1, 2014, FCN 001400 will become effective. It will be added to the list of effective notifications for FCNs which is available on our website:

<http://www.accessdata.fda.gov/scripts/fdcc/?set=FCN>. The agency has determined that allowing this notification to become effective will not have a significant impact on the quality of the human environment and therefore an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, will be publicly available after the effective date of the notification.

This effective notification is applicable only to Chlorine dioxide (CAS Reg. No. 10049-04-4) manufactured by Clordisys Solutions, Inc., and is limited to the use identified above. You should inform the Agency of any modification to the FCS, the limitations/specifications given in the notification, or of any alteration in the manufacturing process that would result in a change in the impurities or impurity level in the FCS. Such changes may require the submission of a new notification.

FDA's review of this notification was limited to Section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA). The existence of an effective notification for a FCS does not relieve use of the subject substance from compliance with any other provision of the Act or with §174.5 (General provisions applicable to indirect food additives). For example, in accordance with section 402(a)(3) of the Act (21 U.S.C. 342), use of the FCS should not impart odor or taste to food rendering it unfit for human consumption.

Section 301(ll) of the FFDC A prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FFDC A, a biological product licensed under section 351 of the Public Health Service Act or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(ll)(1)-(4) applies. In our review of this notification, FDA did not consider whether section 301(ll) or any of its exemptions apply to the intended use of the FCS. Accordingly, allowing this FCN to become effective should not be construed as a statement that the intended use of the FCS would not violate section 301(ll).

If new data or information becomes available to FDA demonstrating that the intended use of the FCS is no longer safe, the Agency will inform you of its determination that the intended use of the FCS is unsafe. In addition, if you become aware of data that raise questions about the safety of the intended use of the FCS, you should notify the Agency immediately and be prepared to supply the necessary data to resolve any questions.

If you have any further questions concerning this matter, please do not hesitate to contact us.

Sincerely,

Elizabeth S. Furukawa, Ph.D.  
Consumer Safety Officer  
Division of Food Contact Notifications HFS-275  
Office of Food Additive Safety  
Center for Food Safety  
and Applied Nutrition

(b) (5)

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