Environmental Assessment

1. **Date:** November 27th, 2013
2. **Name of Applicant/Notifier:** Clordisys Solutions, Inc.
3. **Address:** PO Box 549
   Lebanon, NJ 08833

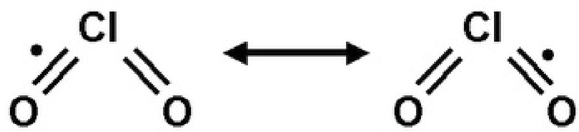
4. **Description of Proposed Action:**

The requested action is for the safe use of chlorine dioxide, generated by the reaction between chlorine gas and a solid matrix of sodium chlorite ("Gas:Solid process"[1]), for use as an antimicrobial agent in water used to process poultry and wash fruits and vegetables that are not raw agricultural commodities in an amount not to exceed 3 parts per million (ppm). Treatment of the fruits and vegetables in this way shall be followed by a potable water rinse or by blanching, cooking, or canning. Chlorine dioxide gas produced by this manner will also contain at least 90 percent by weight of chlorine dioxide in the effluent stream.

5. **Identification of Substances that are the Subject of the Proposed Action**

   a. Chemical Name: Chlorine dioxide
   b. Common or Trade Names: Chlorine (IV) oxide,
   c. CAS #: 10049-04-4
   d. Chemical formula: ClO_2
   e. Structural formula:
   f. Properties:
      i. Molecular weight: 67.5
      ii. Color: Gas phase – Yellow green
      iii. Melting point -59°C
      iv. Boiling point 11°C
      v. Odor chlorine-like
      vi. Density 1.64 g/mL (0°C; liquid)
      vii. Solubility 3.01 g/L at (25°C, 34.5 mm Hg)
      viii. Structure:

[1] US Patent No. 6,824,756 B2, Rosenblatt et al., "Process for manufacturing and using a more stable formulation of sodium chlorite," Nov. 30, 2004



g. Use Rates

The Notifier of this Food Contact Notice is proposing that chlorine dioxide can be applied as an aqueous solution to fruits and vegetables that are not raw agricultural commodities and in poultry processing water in an amount not to exceed 3 ppm residual chlorine dioxide. Since the FCS is produced in the gas form as described above in Section 4, Description of Proposed Action, but desired in the liquid form, it may be necessary to first dissolve the gas into liquid at a higher concentration than will be used in processing water. This solution would range from approximately 0.02-0.3% chlorine dioxide by weight. This solution would then be further diluted to the required dosage strength needed in processing water to maintain the targeted residual level of 3 ppm. Alternatively, gas could be fed directly into a processing water stream and controlled to maintain a residual chlorine dioxide level at 3ppm. See Figure 1 below.

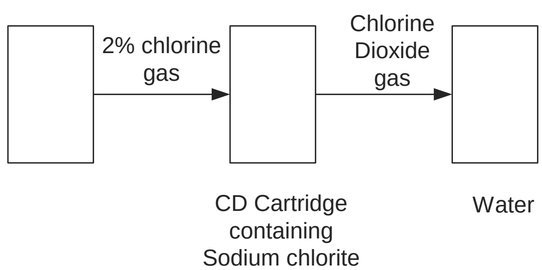


Figure 1.

In either case, the amount of solution or gas fed to maintain this level will be dependent on the microbiological and organic demand of the water. The Notifier estimates that application rates will be in the range of 4 ppm to 10 ppm. Application timing and holding periods of chlorine dioxide contained in processing water will be dependent on the level of organic demand in the water as well as level of antimicrobial reduction desired. It is estimated that the combined application and hold time can range from seconds to hours depending on volumes and flow rates of processing water, organic demand of water and antimicrobial reduction desired. After application of the FCS, fruits and vegetables will undergo a potable water rinse or blanching, cooking, or canning.

h. Impurities

There will be a negligible amount of impurities in the processing water from use of chlorine dioxide produced under this Food Contact Notice. The chlorine dioxide gas produced under the method proposed produces extremely high purity (at least 99.7%) chlorine dioxide gas and the only impurity from the method is solid sodium chloride which will remain in the reaction cartridge as well as any impurities originally in the solid technical grade sodium chlorite matrix. The only reaction product reaching the processing water is going to be dissolved chlorine dioxide. The reaction cartridge is not part of the FCS application process and only serves as a precursor to producing the FCS that is the subject of this FCN. Certificates of Analysis can be found in the Confidential Appendix, Cross Reference 3.

6. Introduction of Substances into the Environment

a. Manufacturing Process

The Food Contact Substance (FCS) that is the subject of this FCN will be produced on site at the point of application. The Notifier does not expect there to be any release of the FCS into the environment under normal manufacturing conditions. Under 21 CFR 25.40(a), an environmental assessment should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. Information available to the Notifier suggests no extraordinary circumstances suggesting an adverse environmental impact as a result of the manufacture of the antimicrobial agent. Consequently, information on the manufacturing site and compliance with the relevant emissions requirements is not provided here.

b. Use Releases

The release of chlorine dioxide as a result of this use is estimated to be similar to the release from methods that are already currently approved and in use (FCN 1011, 445, 644, 645, 1052). In addition to chlorine dioxide, generator effluent streams from currently approved methods can also contain sodium chlorite, chlorine, sodium chlorate, acidified sodium chlorite, etc. These byproducts are a function of the generation chemistry. In the method proposed by this FCN, the generation chemistry of chlorine dioxide production is as follows:

$$2NaClO_{2(s)} + Cl_{2\,(g)} \rightarrow 2ClO_{2\,(g)} + NaCl_{(s)}$$

Chlorine gas is passed through a matrix of solid sodium chlorite flakes to produce a high purity chlorine dioxide gas which will then be diluted by a water stream to produce the target residual amount of chlorine dioxide. The only byproduct formed as a result of this generation chemistry is solid sodium chloride (NaCl) which will not be present in the

gaseous stream as it will stay as a solid in the reaction cartridge. Releases from the use of this Food Contact Substance to both water and air are discussed below.

c. *Water Releases*

It is not expected that chlorine dioxide will be released to aquatic environments to any large extent. Processing water treated with chlorine dioxide as described in this Food Contact Notice must be treated by an onsite wastewater treatment facility and/or discharged to a Publicly Owned Treatment Works (POTW) and will not be discharged to any water body without treatment. Chlorine dioxide reacts with organic matter to chlorite, chlorate and chloride[2]. Ultraviolet (UV) light will also reduce chlorine dioxide to chlorine and oxygen[3]. These oxychlorine species will also be further be reduced to chloride upon contact with organic material. Chlorine dioxide will either be destroyed by organic matter, exposure to UV light and by the wastewater treatment system at the facility using this FCS. When poultry or food processors discharge their wastewater to a Publicly Owned Treatment Works (POTW), the chlorine dioxide will further be reduced by the dilution faction and the high receiving organic load of these facilities. The production of the FCS using the method described in this FCN will replace existing methods of generation and is not expected to result in an increased use of natural resources for production of this FCS.

An estimate of chlorite and chlorate to be found in water is given with parameters as can be found in already submitted and accepted Environmental Assessments for Food Contact Notices 668 (Drew Industrial Division, Ashland Specialty Chemical Company) and 1011 (CDG Environmental, LLC) as these estimates are believed to be identical for the FCS that is the subject of this Food Contact Notice.

Wastewater concentration assumptions:

1. The maximum application rate of chlorine dioxide is 10 ppm
2. Chlorine dioxide is converted to chlorite and chlorate in a 70:30 ratio[4].
3. There is no unreacted chlorite in the generator stream

The maximum concentration of chlorite in the wastewater is:

$$10 \text{ ppm} * 0.7 = 7 \text{ ppm}$$

[2] Toxicological Profile for Chlorine Dioxide and Chlorite, Agency for Toxic Substances and Disease Registry, http://www.atsdr.cdc.gov/toxprofiles/tp160.pdf

[3] Gordon, G., Kieffer, R.G., and Rosenblatt, D. H., "The Chemistry of Chlorine Dioxide, Progress in Inorganic Chemistry," Vol. 15, 1972.

[4] Werdehoff, K.S., and Singer, P.C., Chlorine Dioxide Effects on THMPP, TOXFP, and the Formation of Inorganic By-Products. Journal AWWA, September, 1987.

The maximum concentration of chlorate in the wastewater is:

10 ppm * 0.3 = 3 ppm

As stated above, it is estimated that when this water is discharged to either an onsite wastewater treatment facility and/or to a POTW as is required by usage of this FCS, the high organic loads and microorganisms present in either would be more than enough to consume the chlorate and chlorite present in the food or poultry processing water down to negligible levels. The large dilution factor of these facilities would further contribute to a reduction in these numbers.

Estimated environmental concentrations (EEC) for facilities that pre-treat wastewater and still discharge to a POTW use the following assumptions:

1. Approximately 50% of the total water discharged from a food processing plant is treated with chlorine dioxide[5,6].
2. The receiving stream dilution factor is 10[7].
3. Chlorite removal by the wastewater treatment at the food processing facility is 99%[2].

The EEC for chlorite would be as follows:

7 ppm * 0.5 * (1-0.99) * (1/10) = 0.0035 ppm

The EEC for chlorate would be as follows:

3 ppm * 0.5 * (1/10) = 0.15 ppm

After treated or untreated wastewater is then sent to a POTW, it is estimated that the EEC numbers would be much lower due to the organic load and the additional dilution factor upon treatment at these facilities.

d. Air Releases

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[5] United States-Asia Environmental Partnership; Civil Engineering Research Foundation. Clean Technologies in US Industries:Focus on Food Processing. www.p2pays.org/ref/09/08853.htm

[6] Graham, M.D., Strasser, J., Mannapperuma, J.D., Application of Ozonation and Membrane Treatment in Poultry Processing; 400-02-023F; California Energy Commission, 2002

[7] The stream dilution factor of 10 is based on a survey of poultry processing plants, which showed that 96% had a dilution factor of 20 or greater. Therefore, a dilution factor of 10 for all food-processing facilities should be considered a "worst-case" estimate. The EPA provided Drew Industrial Division, FCN 668 with a "7Q10" dilution factor of 24 for POTW's.

Since chlorine dioxide will exist as a dissolved gas in water for this application, air releases will occur primarily due to agitation of the solution. A Permissible Exposure Limit (PEL) as set by the Occupational Safety and Health Association (OSHA) for chlorine dioxide gas is 0.1 ppm (0.3 mg/m3). A Short Term Exposure Limit as set by the National Institute for Occupational Safety and Health (NIOSH) is 0.3 ppm (0.9 mg/m3)[8]. Both of these limits are not expected to be exceeded during normal use of the FCS. If limits are exceeded during use, all handlers or workers in the immediate surrounding area are instructed to wear a respirator capable of filtering chlorine dioxide from the breathable air. As stated in the Environmental Assessment for Food Contact Notice 445 (Selective Micro Technologies, LLC) in which a Finding of No Significant Impact (FONSI) Decision was made by the FDA, "The EA from FAP No. 4A4408 (poultry) showed that the possible air concentration of ClO_2 from a ClO_2 aqueous solution of chiller water is 0.03 ppm. This level would rapidly decrease by decomposition processes active in the outside environment. Appendix 4 of FAP No. 4A4408 provides the complete calculation for estimating air concentration of chlorine dioxide. The generation system for fruit and vegetable processing is similar; consequently, the air releases of ClO_2 will be similarly negligible." It is believed that chlorine dioxide for use as is described by the Notifier in this FCN will have identical air release potential as stated above. (The production of the FCS using the method described in this FCN will replace existing methods of generation and is not expected to result in an increased use of natural resources for production of this FCS.

7. Environmental Fate of Substances Released into the Environment

a. Air

Upon rapid agitation of water containing the Notifier's FCS, chlorine dioxide gas can be released to the atmosphere. In open environments, the chlorine dioxide gas will be rapidly diluted by the surrounding air. In applications where chlorine dioxide will be released to the open atmosphere, chlorine dioxide will undergo photodecomposition to chlorine and oxygen due to the sun's UV light[3]. Chlorine will be further reduced to chloride. Therefore it is estimated that chlorine dioxide releases to air will ultimately result in the formation of chloride and oxygen. As stated in the Final Risk Assessment for Chlorine dioxide Case 4023 as conducted by the U.S. Environmental Protection Agency, "Chlorine dioxide has a short half-life and in the presence of sunlight and will break down into chloride and chlorate ions (between pH 4 and 7). At pH lower than 4, its breakdown products are

[8] NIOSH Pocket Guide to Chemical Hazards. http:// www.cdc.gov/niosh/npg/npgd0116.html

chlorite and chlorate. Chlorite is the dominant breakdown product. Ultimately, oxygen is formed. Sodium chlorite dissolves in water, breaking down into chloride and chlorate ions under similar conditions as chlorine dioxide. Chemical degradation of sodium chlorite commonly occurs in water as well as in the presence of suspended soil particles containing ions, like Fe(II), Mn(II), I-, and S-2, through redox reactions. The final breakdown products are chloride and oxygen. These same end products are obtained when sodium chlorite is heated. Chlorate and chlorite ions tend to only undergo biodegradation only under anaerobic conditions. Biodegradation of chlorate and chlorite have been observed in anoxic groundwater, sediments and some soils. The end products are the same as stated above: chloride and oxygen." Additionally, as stated in the Environmental Assessment for Food Contact Notice 949 (ICA TriNova, LLC) in which the FDA issued a Finding of No Significant Impact (FONSI), "chlorine dioxide…present in the atmosphere in the gas phase…will photolyze rapidly, with a tropospheric half-life of a few seconds. The terminal by-product is chloride ion."

b. *Water Releases*

Chlorine dioxide, chlorite, and chlorate will be reduced by organic material, inorganic reactions, and exposure to ultraviolet light. It is estimated that all the oxychlorine species will ultimately be reduced to chloride. The environmental fate of chlorine dioxide has been well documented by the Re-registration Eligibility Decision (RED) published by the US EPA as well as the Final Risk Assessment published by the EPA and by Food Contact Notices submitted to the FDA. As stated in the Final Risk Assessment for Chlorine dioxide Case 4023 as conducted by the U.S. Environmental Protection Agency, "Chlorine dioxide has a short half-life and in the presence of sunlight and will break down into chloride and chlorate ions (between pH 4 and 7). At pH lower than 4, its breakdown products are chlorite and chlorate. Chlorite is the dominant breakdown product. Ultimately, oxygen is formed. Sodium chlorite dissolves in water, breaking down into chloride and chlorate ions under similar conditions as chlorine dioxide. Chemical degradation of sodium chlorite commonly occurs in water as well as in the presence of suspended soil particles containing ions, like Fe(II), Mn(II), I-, and S-2, through redox reactions. The final breakdown products are chloride and oxygen. These same end products are obtained when sodium chlorite is heated. Chlorate and chlorite ions tend to only undergo biodegradation only under anaerobic conditions. Biodegradation of chlorate and chlorite have been observed in anoxic groundwater, sediments and some soils. The end products are the same as stated above: chloride and oxygen."

8. Environmental Effects of Released Substances

a. *Air*

It is estimated that there will be no significant environmental impact for an air release of chlorine dioxide. This is due to a relatively low potential for release of chlorine dioxide into the air by use of the FCS in the way as stated in this FCN as well as the photodecomposition of chlorine dioxide in air.

Table 1 ***Acute toxicity profile for Sodium chlorite and Chlorine dioxide****

Date	Study Type/Test Substance	MRID	Species	Results	Toxicity Category
1982	Acute oral (79% chlorine dioxide)	43558601	Rat	LD50 = 292 mg/kg (males) LD50 = 340 mg/kg (females)	II
1985	Acute dermal (80% sodium chlorite)	40168704	Rabbit	LD50 > 2000 mg/kg	III
1992	Acute inhalation (80.6% sodium chlorite)	42484101	Rat	LC50 = 0.29 mg/L	II
1994	Primary eye irritation (2% chlorine dioxide)	43441903	Rabbit	Mild irritant	III
1985	Primary dermal irritation (80% sodium chlorite)	40168704	Rabbit	Primary irritant	II

*Table reprinted from USEPA Reregistration Eligibility Decision (RED) for Chlorine Dioxide and Sodium Chlorite case 4023

As estimated in Section 6 of this Environmental Assessment, the EEC value for chlorine dioxide in air was 0.03 ppm. As shown in the table above, the acute inhalation (ecotoxicity value) LC50 for rats is 0.29 mg/L which is equivalent to 105 ppm as shown below.

PPM calculation for 1 mg/L of Chlorine Dioxide Gas

PPM = (mg/m^3) (24.45^*) / Molecular Weight of Chlorine Dioxide

PPM = (mg/L) (1000) (24.45) / Molecular Weight of Chlorine Dioxide

CD ppm = (mg/L) ($1000 L/m^3$) (24.45) / 67.5
CD ppm = 362.2 *1 mg/L

For 0.29 mg/L:
CD ppm = 362.2*0.29 mg/L = 105 ppm
*The number 24.45 in the equations above is the volume (liters) of a mole (gram molecular weight) of a gas at 1 atmosphere and at 25°C.

Thus it can be estimated that potential air releases do not pose a threat at the levels estimated to be released.

b. *Water*

Toxicity information for chlorine dioxide, chlorite, and chlorate are well documented in the available literature. The USEPA RED for Chlorine Dioxide/Sodium chlorite provides extensive information on the topic as well as the following Food Contact Notices submitted to the FDA, (Food Contact Notice 668, 1011, 445). The following table summarizes the environmental toxicity for chlorite.

Table 2: Summary of Environmental Toxicity for Chlorite

Organism	Test	ClO_2^-	ClO_3^-
Freshwater fish			
Rainbow trout	LC50	203-360 ppm	>1000 ppm
Bluegill sunfish	LC50	244-420 ppm	>1000 ppm
Freshwater invertebrates			
Daphnia magna	EC50	0.027-0.39 ppm	920 ppm
Estuarine/Marine Fish			
Sheepshead minnow	LC50	75 ppm	>1000 ppm
Estuarine/Marine Invertebrates			
Eastern oyster	EC50 (96 hr.)	21.4 ppm	>1000 ppm
Mysid shrimp	LC50 (96 hr.)	0.576 ppm	>1000 ppm
Aquatic Plants			
Green Algae	EC50	1.32 ppm	133 ppm
Avian			
Mallard duck	LC50	>5000 ppm	5620 mg/kg-feed
Mallard duck	LD50	>31.25 mg/kg	2510 mg/kg
Northern bobwhite	LC50	>5000 ppm	5620 mg/kg-feed

Northern bobwhite	LD50	382-797 mg/kg	No data

**Table reproduced from Chlorine Dioxide Environmental Hazard and Risk Assessment (EPA-HQ-OPP-2006-0328-0020) and Environmental Fate and Ecological Risk Assessment for the Reregistration of Sodium Chlorate as an Active Ingredient in Terrestrial Food/Feed and Non-food/Non-feed Uses. Registration Case Number 4049. (EPA-HQ-OPP-2005-0507-0012)*

As stated in the Final Risk Assessment for Chlorine dioxide Case 4023 as conducted by the US Environmental Protection Agency, "Studies have been submitted, which fulfill the requirements of several EPA ecotoxicity guidelines. For terrestrial animals, the results of studies to examine the toxicity of chlorine dioxide/sodium chlorite to birds indicate these chemicals range from slightly to highly toxic to birds on an acute oral basis and from slightly toxic to practically non-toxic on a subacute dietary basis. For freshwater aquatic animals, the results of studies examining the toxicity of chlorine dioxide/sodium chlorite to freshwater fish indicate these chemicals range from slightly toxic to practically non-toxic on an acute basis. For aquatic invertebrates, the studies indicate that chlorine dioxide and sodium chlorite range from very highly toxic for technical grade sodium chlorite a.i. to practically non-toxic for the formulated product on an acute basis. Results of toxicity studies indicate that chlorine dioxide/sodium chlorite are slightly toxic to estuarine/marine fish on an acute basis and range from highly toxic to slightly toxic to estuarine/marine invertebrates on an acute basis. For terrestrial plants, results of toxicity studies indicate that chlorine dioxide/sodium chlorite are moderately toxic to terrestrial plants."

Additionally, as stated in the "Environmental Fate and Ecological Risk Assessment for the Reregistration of Sodium Chlorate as an Active Ingredient in Terrestrial Food/Feed and Non-Food/Non-feed Uses, Reregistration Case Number 4049, "Chlorite has been shown to more toxic than chlorate to fish and aquatic invertebrates." A "practically non-toxic" designation was given to aquatic plants according to the aforementioned document. And chlorate also received a "practically non-toxic to birds after acute oral gavage or subacute dietary exposures."

It is with this above data in mind that it is estimated that any releases of chlorine dioxide, or the chlorite and chlorate ion to the environment through the use of this FCS would be in an amount as to not pose any threats to aquatic systems. All process water treated with this FCS will be handled by onsite wastewater treatment and/or by treatment at a POTW which would significantly reduce the amount of chlorine dioxide, chlorite, or chlorate being discharged.

As estimated in Section 6 of this Environmental Assessment, the calculated EEC values for chlorite and chlorate are 0.0035 ppm and 0.15 ppm, respectively. When compared to the ecotoxicity values for most sensitive species

as shown in Table 2 above, the EEC values are far below these endpoints and should therefore pose no adverse effects to aquatic life.

9. Use of Resources and Energy

The production of the FCS using the method described in this FCN will replace existing methods of generation and is not expected to result in an increased use of natural resources.

10. Mitigation Measures

Since no environmental effects are anticipated with respect to use of this FCS, mitigation measures are not required.

11. Alternatives to the Proposed Action

Alternatives to this proposed action are not required since no potential adverse environmental impacts have been identified.

12. List of Preparers

This EA was prepared by Paul Lorcheim, Director of Operations, B.S., Electrical Engineering, Professional Engineer; Daniel Paznek, Engineer, B.S., Biochemical Engineering, Mark Czarneski, Director of Technology, B.S. Electrical Engineering.

13. Certification

The undersigned certifies that the information presented is true, accurate and complete to the best knowledge of all preparers.

Name:
Title: Director of Operations
Signature:
Date:

Name:
Title: Director of Technology
Signature:
Date:

Name:
Title: Engineer
Signature:
Date:

References

1. US Patent No. 6,824,756 B2, Rosenblatt et al., "Process for manufacturing and using a more stable formulation of sodium chlorite," Nov. 30, 2004.

2. Toxicological Profile for Chlorine Dioxide and Chlorite, Agency for Toxic Substances and Disease Registry, http://www.atsdr.cdc.gov/toxprofiles/tp160.pdf

3. Gordon, G., Kieffer, R.G., and Rosenblatt, D. H., "The Chemistry of Chlorine Dioxide, Progress in Inorganic Chemistry," Vol. 15, 1972.

4. Werdehoff, K.S., and Singer, P.C., Chlorine Dioxide Effects on THMPP, TOXFP, and the Formation of Inorganic By-Products. Journal AWWA, September, 1987.

5. United States-Asia Environmental Partnership; Civil Engineering Research Foundation. Clean Technologies in US Industries:Focus on Food Processing. www.p2pays.org/ref/09/08853.htm

6. Graham, M.D., Strasser, J., Mannapperuma, J.D., Application of Ozonation and Membrane Treatment in Poultry Processing; 400-02-023F; California Energy Commission, 2002

7. Environmental Assessment for Food Contact Notice 668, Drew Industrial Division, Ashland Specialty Chemical Company, Ashland, Inc. November 2006.

8. NIOSH Pocket Guide to Chemical Hazards.
http:// www.cdc.gov/niosh/npg/npgd0116.html

9. Environmental Assessment for Food Contact Notice 445, Selective Micro Technologies, LLC. July 2004. Available at:
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10. Chlorine Dioxide Final Risk Assessment Case 4023, August 2006. EPA Docket Number EPA-HQ-OPP-2006-0328-017 available at
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11. Environmental Assessment for Food Contact Notice 949, ICA TriNova, LLC. December 2009. Available at http://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/EnvironmentalDecisions/UCM207364.pdf

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http://www.epa.gov/oppsrrd1/REDs/chlorine_dioxide_red.pdf

13. Chlorine Dioxide Environmental Hazard and Risk Assessment Case 4023, July 2006. EPA Docket Number EPA-HQ-OPP-2006-0328-0020, available at:
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16. Environmental Assessment for Food Contact Notice 644, JohnsonDiversey, Inc. August 2006. Available at http://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/EnvironmentalDecisions/UCM143319.pdf

17. Environmental Assessment for Food Contact Notice 645, Selective Micro Technologies, LLP. August 2006. Available at http://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/EnvironmentalDecisions/UCM143320.pdf

18. Environmental Assessment for Food Contact Notice 1052, CDG Environmental LLC. November 2010. Available at http://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/EnvironmentalDecisions/UCM249781.pdf