1. Date: January 22, 2026

2. Name of Applicant: Laboratorios Argenol SL
3. Address: 50011 Zaragoza
Naves 1-11
Spain

All communications on this matter are to be sent in care of Submitter:

Leslie Patton, PhD, DABT Principal
ChemReg Compliance Solutions LLC 131 N. Donelson Street
Alexandria, VA 22304
Phone: 240-997-1644
email: leslie.patton@chemregcompliance.com

4. Description of the Proposed Action

A. Request for Action

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS), silver (CAS #7440-22-4) zinc-calcium-sodium-borate-polyphosphate glass.

The FCS is intended for use as an antimicrobial agent in all polymers at levels not to exceed 1.0% by weight of the finished article. The silver concentration of the FCS is 2.0 wt%, which equates to a silver concentration of 0.02% in the final polymeric article. Approved conditions of use will be A through H, as described in Table 2 in 21 CFR Part 176.170(c), in contact with all food types as described in Table 1 in 21 CFR Part 176.170(c). The FCS is not for use in contact with infant formula and human milk. Such uses were not included as part of the intended use of the substance in the FCN.

B. Need for Action

This FCS is an antimicrobial agent used in the production of food packaging materials. The food contact substance will be sold to manufacturers who produce such materials.

The FCS is an antimicrobial preservative that is also regulated by the U.S. Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and has been registered with the U.S. EPA (EPA Reg No. 94446-3). The current EPA label is appended to the cover letter of this FCN; it will be modified to add food uses upon approval by FDA of this FCN.

C. Location of Use/Disposal

The Notifier does not intend to produce finished food-contact articles from the FCS. Rather, the FCS will be sold to manufacturers engaged in the production of polymeric food-contact materials and articles. Food contact articles produced with the FCS in the U.S. will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal will occur nationwide.

According to U.S. EPA data for 2018, approximately 50.0% of municipal solid waste (MSW) is currently deposited in land disposal sites, 11.8% is combusted, 23.6% is recycled, 8.5% is composted, and 6.1% is directed to other food management pathways[1]. As the FCS is expected to be primarily disposed of through combustion and landfilling (i.e. not recycled, composted or handled through other food management pathways), to evaluate the most conservative environmental introduction of the FCS, we recalculate the disposal pattern based on only the quantities of MSW that are land disposed or combusted. On this basis, we estimate that 19.1% of food-contact materials containing the FCS will be combusted annually[2].

5. Identification of Substance that is the Subject of the Proposed Action

The FCS that is the subject of this Notification is silver (CAS RN 7440-22-4) zinc-calcium-sodium-borate-polyphosphate glass (P_2O_5 · CaO · B_2O_3 · ZnO · Na_2O). The active ingredients are silver ion, which comprises 2.0 wt% FCS, and zinc oxide (CAS RN 1314-13-2), which comprises 5.0% by wt of the FCS. The glass serves as an inert matrix in the FCS, which is a powder.

6. Introduction of Substances into the Environment

A. As a Result of Manufacture

Under 21 C.F.R. 25.40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances[3] in this case indicative of any adverse environmental impact as a result of the manufacture

---

[1] Table 35 of Advancing Sustainable Materials Management: 2018 Tables and Figures. Assessing Trends in Material Generation and Management in the United States, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, December 2020. Accessed 11/5/25. Available at: *https://www.epa.gov/sites/default/files/2021-01/documents/2018_tables_and_figures_dec_2020_fnl_508.pdf*

[2] This amount is calculated as follows: 11.8% combusted ÷ (11.8% combusted + 50.0% land disposed) = 19.1% combusted. The remaining 80.9% will be land-disposed.

[3] Such extraordinary circumstances would include: 1) unique emission circumstances not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State, or local environmental agencies where the emissions may harm the environment 2) the proposed action threatening a violation of Federal, State, or local environmental laws or requirements; or 3) production associated with a proposed action that may adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on Intentional Trade in Endangered Species of Wild Fauna to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

of the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

B. As a Result of Use and Disposal

No significant environmental release is expected upon the use of the FCS in the manufacture of food-contact articles. In these applications, the FCS will be entirely incorporated into the finished food-contact articles. Any waste materials generated in the process (e.g., plant scraps) are expected to be disposed as part of the manufacturer's overall non-hazardous solid waste in accordance with established procedures.

The FCS is expected to remain in the food-contact articles and, therefore, its disposal by the ultimate consumer will be by conventional rubbish disposal, and thus, primarily by sanitary landfill or incineration. For food-contact materials containing the FCS that are determined to be recyclable, recycling processes will compete with conventional rubbish disposal and, therefore, reduce the amount of the FCS that is landfilled or incinerated.

Air

No significant effect on the concentrations of and exposures to any substances in the atmosphere is anticipated due to the proposed use of the food contact substance. The FCS does not readily volatilize and will be entrained within food contact materials or articles. Furthermore, because the FCS will make up a very small portion of the total municipal solid waste currently combusted, it will not significantly alter the emissions from properly operating municipal solid waste combustors, and therefore not threaten a violation of applicable emissions laws and regulations (i.e., 40 CFR Part 60).

The FCS consists of silver (Ag_2O) and zinc-calcium-sodium-borate-polyphosphate glass (P_2O_5,CaO, B_2O_3, ZnO, Na_2O), all of which are inorganic. While reaction with oxygen may occur upon combustion, no greenhouse gases are expected to be produced. The FCS does not contain carbon and thus, will not form carbon dioxide. The resins used in the packaging (*e.g.*, LDPE) are already cleared for use in this type of application. We do not anticipate a significant increase in polymeric materials being introduced into market or waste streams as addition of the FCS to such materials would constitute a redirection of polymers not currently containing the FCS to those which do. Thus, no net increase in greenhouse gas generation is expected if these resins are combusted. Thus, the concentrations of greenhouse gases in the environment will not be significantly altered by the proper incineration of the FCS in the amounts utilized for food packaging applications.

Land

For substances present in food-packaging material, the principal route for potential environmental introduction results from their disposal in municipal solid waste combustors or landfills. Landfilled articles containing silver have the potential to release that metal into groundwater and at a certain concentration, silver will be considered a hazardous waste. For this FCS, a significant concentration of ionic silver is *not* expected to be released into the environment after disposal, but rather it is expected to remain with the finished food packaging because silver is incorporated into the glass matrix, which in turn is almost completely incorporated into food contact articles. The results of the migration study that is referenced in the confidential attachment to this EA support

the idea that there would be minimal introduction of silver into the environment resulting from the disposal of the FCS.

The potential for landfilled wastes to leach silver was evaluated using the EPA toxicity characteristic leaching protocol (TCLP) SW846-1311. Using EPA analytical method 6020B, silver was detected at a level well below 5 mg/L (referenced in the confidential attachment to this EA). Per 40 CFR 261.24 and the Resource Recovery and Conservation Act (RCRA), discarded silver is regulated as hazardous waste if detected at 5 mg/L in the TCLP. Therefore, the concentration of silver potentially introduced into the environment as a result of the disposal of this FCS will not be hazardous. The migration test and TCLP results also suggest that recycling articles containing this FCS will not result in the release of significant levels of silver.

Furthermore, the estimated production of finished food contact articles with the FCS, as discussed in the corresponding confidential attachment, precludes any substantial release to the environment of its components. Thus, there is no expectation of any meaningful exposure to terrestrial organisms of these substances as a result of the proposed use of the FCS.

Water

No significant effect on the concentrations of and exposure to any substances in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the FCS. No significant quantities of any substance will be added to these water systems upon the proper incineration of the FCS nor upon its disposal in landfills. Similarly, no significant effects on the concentrations of and exposures to any substances are anticipated as a result of the proposed use of the subject FCS. Further, we compared the maximum annual market volume of the food-contact polymers containing the FCS[4], to the annual municipal solid waste (292,360 thousand tons in 2018 from EPA) and concluded that the FCS and the food contact polymers containing the FCS will constitute a very small portion of the plastic containers and packaging waste in the MSW. Therefore, we do not expect there are any extraordinary circumstances that would otherwise suggest a significant environmental impact on the aqueous environment resulting from post-consumer disposal of food contact articles that contain the FCS due to the proposed use.

Considering the foregoing, we respectfully submit that there is no reasonable expectation of a significant impact on the concentration of any substance in the environment due to the proposed use of the FCS in the manufacture of food contact materials.

7. Fate of Emitted Substances in the Environment

As discussed in Section 6, no significant quantities of the FCS will be released upon manufacture, use and disposal of food contact articles containing the FCS. Considering the foregoing, we respectfully submit that there is no reasonable expectation of significant effects on the concentrations of and exposures to any substances in the atmospheric, aquatic, or terrestrial environmental compartments. Accordingly, because there is no

[4] The comparison is contained in the confidential attachment to the EA

expectation of the FCS being introduced into the environment as a result of the proposed use of the FCS, the environmental fate of the FCS does not need to be addressed.

8. Environmental Effects of Released Substances

As discussed previously, only extremely small and insignificant quantities of the FCS may be expected to be released to the environment during use and disposal of food-contact articles containing the FCS. Based on these considerations, no adverse effect on organisms in the environment, or the environment itself, is expected as a result of the disposal of articles containing the FCS. In addition, the use and disposal of the food-contact articles containing the FCS are not expected to threaten a violation of applicable laws and regulations, e.g., EPA's regulations in 40 CFR Parts 60 and 258.

9. Use of Resources and Energy

The proposed use of the FCS in this Notification will not require additional energy resources for the treatment and disposal of wastes as the FCS is expected to compete with, and to some extent replace similar substances already on the market. Food- contact materials and articles containing the FCS are expected to be disposed according to the same patterns when it is used in place of current materials. Therefore, there will be no anticipated impact on current or future recycling programs. The partial replacement of this type of material by the subject FCS is not expected to have any adverse impact on the use of energy and resources. Manufacture of the FCS, and its use in food-contact materials and articles, will consume energy and resources in amounts comparable to the manufacture and use of other similar antioxidants. Furthermore, packaging materials produced from resins containing the FCS are expected to be disposed of in the same manner when used in place of current materials. The raw materials that are used in the manufacture of the FCS are commercially manufactured chemicals that are produced for the use in various chemical reactions and used for production purposes. Thus, the energy used for the production of the FCS is insignificant.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials fabricated containing the FCS. This is primarily due to the minute levels of leaching of potential migrants from the finished item; the insignificant impact on environmental concentrations of combustion products of the FCS; and the close similarity of the FCS to the products it is intended to replace. Thus, the use of the FCS as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

No significant potential adverse environmental effects are identified herein that would necessitate alternative actions to those proposed in this Notification. The alternative of not approving the action proposed herein would simply result in the continued use of the materials that the subject FCS would otherwise replace; such action would have no environmental impact.

12. List of Preparers

Dr. Leslie Patton, principal scientist, ChemReg Compliance Solutions LLC; 131 N. Donelson Street; Alexandria, VA 22304. Dr. Patton is a board-certified toxicologist with over 18 years of experience drafting Food Contact Notification (FCN) submissions and environmental assessments.

13. Certification

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of her knowledge.

Date: January 22 , 2026

Leslie E. Patton, Ph.D., DABT
Consultant to Notifier

14. Confidential Attachment