Environmental Assessment for Food Contact Notification FCN 2428

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Environmental Assessment

1. Date: January 9, 2025

2. Name of Applicant/Notifier: Solenis LLC

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4. Description of the Proposed Action

The action requested in this Notification is to permit the use of the Notifier's food-contact substance (FCS), 5,5-dimethylhydantoin (DMH) (CAS Reg. No. 77-71-4). Specifically, the FCS will be used as a stabilizer for hypohalite slimicides used in the manufacture of paper and paperboard, at a level not to exceed 0.5 grams DMH per kilogram of dry fiber.

The FCS is a halogen stabilizer and is intended for use with hypohalite compounds to inhibit the growth of bacterial and fungal slime in paper mill systems and industrial process waters. DMH acts as a synergist for hypohalite slimicides that are used during the wet-end of the paper manufacturing process. DMH reversibly reacts with the hypohalite slimicide to form a halohydantoin. The reversibility of the reaction provides a stabilizing effect on the active biocide lifetime, thus improving homogeneous distribution in the wet-end process. The slimicide package (DMH and hypohalite) inhibits the growth of bacterial and fungal slime in paper mill systems and industrial process waters.

The FCS is not intended for use in contact with infant formula and human milk, as such uses were not included as part of the intended use of the substance in the FCN.

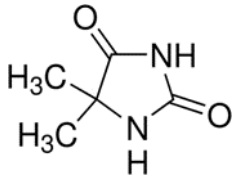
The Notifier does not intend to produce finished food-contact articles containing the FCS. Rather, the FCS that is the subject of this notification will be sold to manufacturers engaged in the production of food-contact materials. Food-contact materials containing the FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal of food-contact materials containing the FCS will occur nationwide, with the material being land disposed, combusted, or

recycled in quantities similar to those reported for municipal solid waste (MSW) generally.[1] According to the Environmental Protection Agency (EPA), it is estimated that, as of 2020, of the

292.36 million tons of MSW generated, approximately 50.0% of MSW is 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.[2] As food-contact materials made using the FCS are expected to be primarily disposed of through recycling, combustion, or land-filling (*i.e.*, not composted or handled through other food management pathways), we recalculate the disposal pattern based on only the quantities of MSW that are land disposed, recycled, or combusted. On this basis, we estimate that 13.8% of food-contact materials containing the FCS will be combusted annually.[3] The direct use of the FCS will be by paper and paperboard manufacturers and therefore the environmental release will be in discharge water as part of the existing plant effluent.

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

The FCS that is the subject of this Notification is 5,5-dimethylhydantoin (DMH). It is also alternatively identified as 2,4-imidazolidinedioine, 5,5-dimethyl-. The CAS Registry Number is 77-71-4. The molecular formula of DMH is $C_5H_8N_2O_2$ and it has a molecular weight of 128.1 g/mol. The structure of DMH is shown below.



6. Introduction of Substances into the Environment

Under 21 C.F.R. § 25.40(a) ("Environmental assessments"), an environmental assessment (EA) 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[4] in this case indicative of any significant adverse environmental impact as a result of the manufacture of the

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1 Environmental Protection Agency, Advancing Sustainable Materials Management: 2018 Fact Sheet: Assessing Trends in Materials Generation and Management in the United States (December 2020), available at: https://www.epa.gov/sites/default/files/2020- 11/documents/2018_ff_fact_sheet.pdf.

2 Id.

3 11.8% Combusted ÷ (11.8 % combusted + 23.6% recycled + 50% land disposed) = 13.8% combusted.

4 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 International Trade in Endangered Species of Wild Fauna and Flora to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other federal law.

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

A. As a Result of Use

No significant adverse environmental release is expected upon the use of the subject FCS in food-contact materials. The FCS will be used in paper and paperboard articles to fabricate food-contact materials or components thereof, and the FCS is expected to remain with these materials throughout use in the food-contact applications and use/disposal by the consumer. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as part of the food-contact article manufacturer's overall nonhazardous solid waste in accordance with established procedures. The annual projected market volume of the FCS for food-contact use in the U.S. is provided in the Confidential Environmental Information attachment.

The FCS is intended for use as a halogen slimicide stabilizer in the manufacture of food-contact paper and paperboard. Therefore, potential environmental exposure to the FCS would occur during the papermaking process and from the disposal of the finished paper and paperboard packaging by the end-user. Further, a portion of the FCS will enter the facility wastewater processing system. Effluent from the pulp and paper processing will be treated via wastewater treatment facilities before release into the environment.[5] In determining the environmental impact, we assume that all of the FCS enters the wastewater.

The intended technical effect of the FCS is to stabilize hypohalite slimicides during the wet-end of the papermaking process. During the wet-end phase of papermaking, the aqueous concentration of solids (fibers and fillers) typically varies between 0.5% and 1% by weight.[6] We consider a solids concentration of 1% in this assessment.

The use level of the FCS in the wet-end process is 0.5 grams DMH per kilogram of dry fiber, equivalent to an environmental introduction concentration (EIC) of 5.0 parts per million (ppm) of FCS in the process water.[7]

In lieu of specific data on the FCS with respect to removal efficiency in conventional wastewater treatment, we consider that the EIC may be fully distributed (*i.e.* 5.0 mg/L) in either sludge or in the treated wastewater as a worst-case. If we consider a 10-fold dilution factor for discharge to surface waters,[8] the estimated environmental concentration (EEC) in sludge and treated waters are 5.0 mg/L and 0.5 mg/L, respectively.

Sludge resulting from wastewater treatment may end up landfilled or land applied.

B. As a Result of Disposal

Disposal by the ultimate consumer of food-contact articles containing the subject FCS

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5 Water-discharging facilities producing pulp, paper, and paperboard are subject to the U.S. Environmental Protection Agency's effluent guidelines and standards under the Clean Water Act, at 40 C.F.R. Part 430.

6 Orlando J. Rojas and Martin A. Hubbe, The Dispersion Science of Papermaking, JOURNAL OF DISPERSION SCIENCE AND TECHNOLOGY, Vol. 25, No. 6, pp. 713-732, 2004.

7 0.5 kg ÷ (1000 kg/1%) = 0.5 kg ÷ 105 kg = 5.0 ppm.

8 Rapaport, Robert A., 1988. Prediction of consumer product chemical concentrations as a function of publicly owned treatment works treatment type and riverine dilution. Environmental Toxicology and Chemistry, 7(2), 107-115.

will be by conventional rubbish disposal, and, hence, primarily by sanitary landfill or incineration. For food-contact articles that contain 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.

The FCS consists of the elements carbon, hydrogen, oxygen, and nitrogen. Thus, the combustion products may include carbon dioxide, water, and nitrous oxide. The carbon and nitrogen content of the FCS have been calculated based on the elemental composition of the FCS (available in the Confidential Environmental Information attachment). Further, the carbon and nitrogen contents of the FCS have been used to calculate the potential greenhouse gas (GHG) emissions derived from combustion of the confidential annual market volume of the FCS for food-contact use in the U.S. (available in the Confidential Environmental Information attachment).

In accordance with 40 C.F.R. § 1508.27, the analysis of the significance of environmental impacts must include the degree to which the action threatens a violation of federal, state, or local laws imposed for the protection of the environment. In this context, 40 C.F.R. § 98.2(a)(3) requires stationary fuel combustion sources which emit 25,000 metric tons (MT) CO_2 equivalents (CO_2-e) or more per year to report their GHG emissions to the EPA. Municipal solid waste (MSW) combustion facilities are stationary fuel combustion sources pursuant to 40 C.F.R. § 98.30(a). The GHG emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in MSW combustion facilities.

Based on the confidential market volume, the expected carbon dioxide equivalent emissions, as shown in the Confidential Environmental Information attachment, are below 25,000 metric tons on an annual basis. As the estimated GHG emissions are below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Further, the FCS will not significantly alter the emissions from properly operating MSW combustors as the FCS contains carbon, hydrogen, oxygen, and nitrogen, elements that are commonly found in MSW. Therefore, incineration of the FCS will not cause MSW combustors to threaten a violation of applicable emission laws and regulations (*i.e.*, 40 C.F.R. Part 60 and/or relevant state and local laws).

Only extremely small amounts, if any, of the FCS constituents are expected to enter the environment as a result of the landfill disposal of food-contact materials, in light of the EPA regulations governing MSW landfills. EPA's regulations require new MSW landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water, to have ground water monitoring systems, and to take corrective action as appropriate (40 C.F.R. Part 258). These requirements are enforced by state solid-waste management programs.

7. Fate of Emitted Substances in the Environment

A. Air

No significant effects on the concentrations of and exposures to any substances in the

atmosphere are anticipated due to the proposed use of the FCS. The analysis discussed above in Item 6 demonstrates that no significant adverse environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact materials manufactured with the FCS.

B. Water

No significant effects on the concentrations of and exposures to any substance in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the FCS. Although 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, the fate of finished food-contact materials containing the FCS in the aqueous environment is addressed below due to the use of DMH by paper and paperboard manufacturers which may discharge water as plant effluent.

A set of environmental fate laboratory studies on DMH have been conducted, with copies of some studies provided in full under Food Additive Petition (FAP) No. 3B4367. These studies were also noted in prior FCNs for DMH, where the identity and intended use of the FCS are the same (*i.e.*, FCN 308). For reference, we reprint a summary table of the environmental fate studies in Table 1 below, from the publicly available environmental information for FCN 308.[9]

DMH has a low bioaccumulation potential and is ultimately biodegradable under acclimated conditions.

[9] See https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=FCN&id=308&sort=Sort_FCS&order=DESC&startrow=1&type=basic&search=308.

Table 1. Laboratory Environmental Fate Studies with DMH (*Reprinted*)

Test	Test Description	Result
Hydrolysis	Hydrolysis of DMH was determined at pH 5, 7 and 9.	DMH is hydrolytically stable at all pH's.
Aqueous Photolysis	Photodegradation of DMH was evaluated by exposing DMH to a light source simulating natural sunlight for 30 clays.	DMH is photolytically stable.
Aerobic Aquatic Metabolism	Microbial degradation of DMH was evaluated under non-acclimating aerobic conditions.	Minimal degradation of DMH was observed; half-life for degradation, under the conditions of the study, is 1170 days.
Anaerobic Aquatic Metabolism	Microbial degradation of DMH was evaluated under non-acclimating anaerobic (flooded sediment) conditions.	Minimal degradation of DMH was observed; under the conditions of the study the half-life is 1144 days.
Soil/ Sediment Adsorption / Desorption	Leaching potential of DMH was evaluated in several representative (clay loam, sandy loam and sand) soils.	DMH is highly mobile in all soil types.
Modified OECD Screening Test	DMH was exposed to a mixed microbial population (garden soil, secondary effluent and surface water) under minimal acclimating conditions	By day 28, average percent removal of DMH was 10.1%, indicating low level of biodegradation.
Modified SCAS Test Method	DMH was exposed to enriched microbial population (secondary activated sludge and raw sewage) and acclimated for a 16-day period.	After a 16-day acclimation period, biodegradation of DMH proceeded rapidly. From test day 18 until study completion, average percent removals were greater than 95%. Consequently, under the conditions of the study, DMH is considered ultimately biodegradable.

C. Land

Considering the factors discussed above, no significant effects on the concentrations of and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject FCS. The low use level of the FCS in the wet-end of the

papermaking process and the estimated low production volume anticipated for the FCS in food-contact applications 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.

Sludge containing adsorbed FCS may be landfilled or used as agricultural fertilizer. In the latter case, the concentration of the FCS in sludge is calculated to be no greater than 5.0 mg/kg. Accounting for dilution with base soils, the environmental concentration of the FCS is expected to be significantly lower than 5 mg/kg. Discounting that under the conditions of the biodegradability studies DMH is considered to be ultimately biodegradable amongst enriched microbial populations (secondary activated sludge and raw sewage), available summary data on the toxicity endpoints for terrestrial subjects suggest no realistic concern at the < 5.0 mg/kg concentration considered from the proposed use. Specifically, end points in a soil microorganism nitrogen transfer assay (OECD 216), an acute toxicity study in earthworms (OECD 207), and terrestrial plant toxicity assay (OECD 208) were all orders of magnitude higher than 5.0 mg/kg.[10]

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.

8. Environmental Effects of Released Substances

Information on the environmental impacts of the FCS in wastewater is provided to demonstrate that the FCS does not present any environmental risks of concern. Based on the described intended use as a stabilizer for hypohalite slimicides in the manufacture of paper and paperboard, the primary pathway for the FCS to reach the environment is through the disposal and treatment of plant processing wastewater. As shown in Section 7 above, the concentration of DMH in treated wastewaters will be < 0.5 mg/kg. The use and disposal of the subject substance in landfills or by combustion are not expected to threaten a violation of applicable laws and regulations, *e.g.*, EPA's regulations in 40 C.F.R. Part 60 ("Standards of performance for new stationary sources") that pertain to municipal solid waste combustors and Part 258 that pertain to landfills.

Acute and long-term aquatic studies on DMH are summarized below in Tables 2 and 3. The studies referenced below were previously summarized in FCN 308 and full copies of certain studies are available in FAP Nos. 3B4367 and 4B4418.

[10] See Terrestrial toxicity endpoint summary for Cas Reg. No. 77-71-4, at https://echa.europa.eu/registration-dossier/-/registered-dossier/13155/6/4/1.

Table 2. Acute Aquatic Studies Conducted with Dimethylhydantoin (DMH) (Some *Reprinted*)

Study	Test Substance	Result
96-hr. Acute LC50- Rainbow Trout	DMH	LC50 > 972.2 ppm
96 hr-Acute LC50 - Bluegill Sunfish	DMH	LC50 > 1017 ppm
96-hr.-Acute LC50 - Fathead Minnow	DMH	LC50 > 1085 ppm
48-hr.-Acute LC50 - *Daphnia magna*	DMH	LC50 > 1070 ppm
96-hr.-Acute LC50 - Mysid Shrimp	DMH	LC50 > 921.7 ppm
96-hr.-Acute LC50 - Sheepshead Minnow	DMH	LC50 > 1006 ppm
96-hr.- Acute LC50- Eastern Oyster	DMH	EC50 > 125 ppm
96-hr. - *Raphidocelis subcapitata* [11]	DMH	EC50 > 1000 ppm

Table 3. Long-Term Aquatic Toxicity Studies Conducted with DMH (*Reprinted*)

Study	Test Substance	NOEC [12]	MATC [13]	LOEC [14]
Life-Cycle Toxicity Test in *Daphnia magna*	DMH	70.9 ppm	90 ppm	116 ppm
Early Life-Cycle Toxicity Test in the Fathead Minnow	DMH	14 ppm	20 ppm	29 ppm

The conservative estimate of 0.5 mg/kg DMH in process wastewater is well below all relevant aquatic toxicity endpoints for the compound. Therefore, no significant effects on the concentrations of and exposures to any substances in freshwater, estuarine, or marine ecosystems are anticipated due to the proposed use of the subject FCS when used in the making of food-contact paper and paperboard.

[11] See https://echa.europa.eu/registration-dossier/-/registered- dossier/13155/6/2/6/?documentUUID=680d239d-f2fc-41c5-adaa-5b8f079ab9dd.

[12] NOEC: No-Observable Effect Concentration

[13] MATC: Maximum Allowable Toxicant Concentration

[14] LOEC: Lowest-Observable Effect Concentration

9. Use of Resources and Energy

As is the case with other food-contact materials, the production, use, and disposal of the FCS involves the use of natural resources. However, the use of the subject FCS in the fabrication of food-contact materials is not expected to result in a net increase in the use of energy and resources because the FCS will be used in place of similar slimicide stabilizers that are already on the market for use in the same or similar applications.

Manufacture of the FCS and the final conversion to finished food-contact materials will consume energy and resources in amounts comparable to the manufacture of chemically related stabilizers. Packaging materials produced using the FCS are expected to be disposed of according to the same patterns when used in place of currently marketed paper and paperboard. Thus, there will be no impact on current recycling programs. For these reasons, no significant adverse impacts on the use of natural resources and energy are expected as a result of this Notification becoming effective.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials containing the subject FCS. This is primarily due to the minute levels, if any, of leaching of components of the FCS from finished articles employing the FCS, the insignificant impact on environmental concentrations of combustion products of the FCS, and the similarity of the subject FCS to the material it is intended to replace (*i.e.*, competitive slimicide stabilizers). Thus, no significant adverse impacts were identified that require mitigation measures.

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 anticipated environmental impact.

12. List of Preparers

Pamela L. Langhorn, Partner, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington DC 20001. Ms. Langhorn has over 25 years of experience counseling and representing corporate entities on food additive petitions and FCNs, including Environmental Assessments.

Steven J. Manning, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington DC 20001. Dr. Manning has over eight years of experience drafting 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 9, 2025

Pamela L. Langhorn
Counsel for Solenis LLC

14. References

1. Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Fact Sheet: Assessing Trends in Materials Generation and Management in the United States* (December 2020), *available at*: https://www.epa.gov/sites/default/files/2020-11/documents/2018_ff_fact_sheet.pdf.

2. Orlando J. Rojas and Martin A. Hubbe, The Dispersion Science of Papermaking, JOURNAL OF DISPERSION SCIENCE AND TECHNOLOGY, Vol. 25, No. 6, pp. 713-732, 2004.Rapaport, Robert A., 1988. *Prediction of consumer product chemical concentrations as a function of publicly owned treatment works treatment type and riverine dilution.* Environmental Toxicology and Chemistry, 7(2), 107-115.

3. *See* https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=FCN&id=308&sort=Sort_FCS&order=DESC&startrow=1&type=basic&search=308.

4. *See* Terrestrial toxicity endpoint summary for CAS Reg. No. 77-71-4, at https://echa.europa.eu/registration-dossier/-/registered-dossier/13155/6/4/1.

5. *See* https://echa.europa.eu/registration-dossier/-/registered-dossier/13155/6/2/6/?documentUUID=680d239d-f2fc-41c5-adaa-5b8f079ab9dd.

15. Attachment

1. Confidential Environmental Information.