1. Date June 19, 2023

2. Name of Notifier

Sun Chemical
Colors & Effects Switzerland AG
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3. Address

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4. Description of the Proposed Action

a. Requested Action

The action requested in this food contact notification (FCN) is to establish a clearance for the food contact substance (FCS) identified as 2,5-Dihydro-3,6-bis(4-methylphenyl)pyrrolo[3,4-c]pyrrole-1,4-dione, CASRN 84632-66-6, C.I. Name P.R.272, to be used as a colorant for all polymers for use in contact with all foods at levels not to exceed 0.2 percent by weight of the food-contact polymer in single and repeated use in contact with aqueous, alcoholic and acidic foods[1]. The FCS is not intended for use in contact with infant formula and human milk.

b. Need for Action

The FCS is used as a component of finished food contact articles. The FCS adds color to the finished article. The food contact articles include food packaging (e.g. plastic container boxes), repeat-use articles (e.g. bottle crates) and articles such as bottle caps, utensils, plastic cups and plastic plates.

c. Location of Use/Disposal

The Notifier does not intend to produce finished plastic food contact articles containing the FCS. Rather, the FCS will be sold to manufacturers engaged in the production of food contact polymers. Food contact articles manufactured with 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 will occur nationwide[2].

According to the U.S. Environmental Protection Agency's (EPA) report, *Advancing Sustainable*

[1] https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsofUse/default.htm
[2] https://www.epa.gov/sites/production/files/2021-01/documents/2018_tables_and_figures_dec_2020_fnl_508.pdf

Material Management: 2018 Tables and Figures, December 2020, Table 8 - Total Plastics in Containers and Packaging, a total of 14,530 thousand tons of plastics in containers and packaging were generated. Of this amount, 1,980 thousand tons (13.6 percent) was recycled, 2,460 thousand tons (16.9 percent) was combusted, and 10,090 thousand tons (69.4 percent) was landfilled. We expect disposal of articles containing the FCS to occur in this pattern.

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

The identity of the FCS is summarized below:

a. Chemical Abstract Service Name:

2,5-Dihydro-3,6-bis(4-methylphenyl)-pyrrolo[3,4-c]pyrrole-1,4-dione

b. CAS Number

84632-66-6

c. Other Chemical Names

3,6-bis-(4-methylphenyl)pyrrolo[3,4-c]pyrrole-1,4-dione
Pyrrolo[3,4-c]pyrrole-1,4-dione, 2,5-dihydro-3,6-bis(4-methylphenyl)-

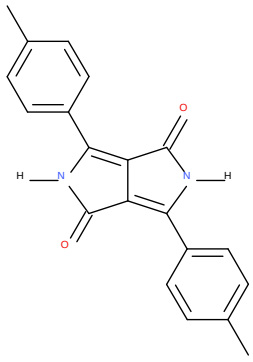
d. Empirical Formula

$C_{20}H_{16}N_2O_2$

e. Molecular Weight

316.12 Daltons

f. Structure



g. Physical Description

- Red powder
- Specific Density: 1.38 - 1.51 g/cm^3
- Melting Point/Decomposition: > 380°C

6. Introduction of Substances into the Environment

a. Introduction of the Substance into the Environment as a Result of Manufacture

Under 21 CFR 25.40(a), an environmental assessment should focus on relevant environmental issues relating to the use and disposal after use of the FCS, rather than the production, of FDA-regulated articles. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances indicative of adverse environmental impact that may result from the manufacture of the FCS. Consequently, information on manufacturing site and compliance with relevant emissions requirements is not provided herein.

b. Introduction of the Substance into the Environment as a Result of Use/Disposal

No environmental release is expected upon the use of the subject FCS to fabricate plastic food packaging, repeat-use articles or utensils like plastic cups and plastic plates. In these applications, the FCS will be entirely incorporated into the finished plastic food contact articles. Any waste materials generated in this process, e.g. plant scraps, are expected to be recycled by the manufacturer or disposed as part of the manufacturer's overall non-hazardous solid waste in accordance with established procedures.
Disposal by the ultimate consumer of food contact articles manufactured with the FCS will be by conventional trash disposal and, hence, primarily by incineration or sanitary landfill. The FCS consists of carbon, oxygen, hydrogen and nitrogen - elements that are commonly found in municipal solid waste. The products of complete combustion would be carbon dioxide, water and nitrous oxide or nitrogen oxides. Since carbon dioxide and nitrous oxide are greenhouse gases (GHG), a GHG Analysis has been provided in a confidential attachment to the EA to determine whether the GHGs contributing components emitted from incineration of the FCS at MSW combustion facilities will significantly impact the environment. Background information and a summary follow:

The GHG emissions of MSW combustion facilities are regulated by the EPA under 40 CFR 98, which “establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG”. Part 2 of this regulation (40 CFR 98.2), describes the facilities that must report GHG emissions and sets an annual 25,000 metric tons carbon dioxide equivalents (CO2-e) emission threshold for required reporting. GHG emissions from MSW combustion facilities are regulated under 40 CFR 98.2. Based on projected market volume information provided in the confidential attachment to the EA and information about the operation of MSW combustion facilities in the US, the expected CO2-e emissions resulting from the disposal FCS by combustion will not result in significant environmental impacts.
As the subject FCS consists of carbon, oxygen, hydrogen and nitrogen - elements that are commonly found in municipal solid waste - the action requested in this FCN is not expected to significantly alter the emission from properly operating MSW combustors.

Based on the confidential market volume, the expected annual carbon dioxide equivalent emission, as shown in the confidential attachment to the EA, is below 25,000 metric tons on an annual basis. As the estimated GHG emissions are below the threshold for mandatory reporting regulated under 40 C.F.R. Part 98 and because the operation of and emissions from MSW combustion facilities are regulated under 40 C.F.R. Part 60, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities.

In sum, incineration of the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations (40 CFR 98.2, 40 CFR part 60 under/or relevant state and local laws).

EPA regulations require all solid-waste 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 and to have ground-water monitoring systems (40 C.F.R. Part 258 and Appendix 2). These requirements are enforced by state solid-waste management programs. Therefore, based on MSW landfill regulations preventing leaching and state enforcement of these requirements, the food contact substance is not expected to reach the aquatic or terrestrial environment when disposed of via landfill.

Based on the proposed use and use level of the FCS, it can be concluded that the FCS will not significantly alter emissions from properly operating MSW combustion facilities, nor threaten violation of applicable Federal, State, or local emission laws and regulations (40 CFR part 60, and/or relevant state and local laws). Additionally, no significant quantities of the FCS or combustion products will be added to the environment.

ASTM standard number D7611, *Standard Practice for Coding Plastic Manufactured Articles for Resin Identification*[3] provides a guide for plastics manufacturers to mark the final plastic article with an identification code that informs users/recyclers of the identity of the resin with which the final plastic article is made. We therefore anticipate the articles manufactured with the FCS would be so marked and thus sortable for recycling. As such, impacts to recycling would not be anticipated.

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 FCS. The FCS with melting point/decomposition > 380°C (see above Item 5.g.), does not readily volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of plastic food contact articles manufactured with the FCS.
As stated above in item 6, the FCS will make up a very small portion of the total municipal solid waste currently combusted and will not significantly alter the emission from properly operating municipal waste combustors, and incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations.

b. Water

No significant effect on the concentrations of and exposures to the FCS or its constituents in fresh-water, estuarine, or marine ecosystems are anticipated due to the proposed use of the FCS or the disposal of plastic food contact articles manufactured with the FCS. No significant quantities of the FCS will be added to these systems upon the proper incineration of the food contact articles manufactured with the FCS, nor upon its disposal in landfills equipped with composite liners and leachate monitoring protocols.

As noted under Section 6 above, even if small amounts of the FCS or its constituents were to transfer from a disposed food contact article into landfill leachate, EPA's regulations governing landfills (40 CFR Part 258) will minimize migration of the leachate into the natural environment. MSW landfills must comply with the federal regulations in 40 CFR Part 258 or equivalent state regulations.
The federal standards include composite liner requirements, leachate collection and removal systems, ground water monitoring requirements and closure and post closure requirements. The

[3] ASTM International, Active Standard ASTM D7611/D7611M-20

environmental fate of substances in the aquatic environment does not need to be addressed because no significant introduction of substances into the aquatic environment as a result of the proposed use of the FCS is identified.

c. Land

Considering the factors discussed above, no significant effect on the concentrations of and exposure to any substances in terrestrial ecosystems are anticipated as result of the proposed use of the FCS and proper disposal of food contact articles manufactured with the FCS. Only very small amounts of leaching of the FCS may be expected to occur under normal environmental conditions when finished food contact articles are disposed of. Furthermore, as noted above, if the FCS were to migrate from the discarded food contact articles, the leachate will be prohibited from entering adjacent eco-systems by proper environmental controls in place at landfill sites.
Thus, there is little expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the FCS.

8. Environmental Effects of Released Substances

No significant adverse environmental effects are expected as a result of the anticipated release of substances into the environment. No significant quantities of any substance are expected to be released to the environment as a result of the proposed use of the subject FCS. As discussed previously, the only substances that may be expected to be released to the environment upon the use and disposal of food contact articles fabricated with the FCS consist of small quantities of combustion products and leachables, if any.
Accordingly, no significant adverse effect on organisms in the environment is expected as a result of the disposal of articles manufactured with the FCS. In conclusion, no information needs to be provided on the environmental effects of substances released into the environment as a result of use and/or disposal of the FCS because, as discussed under item 6, only extremely small quantities of substances, if any, will be introduced into the environment as a result of use and/or disposal of the FCS. Therefore, the use and disposal of the food contact substance are not expected to threaten a violation of applicable laws and regulations, e.g., the EPA’s regulation in 40 CFR parts 60 and 258.

9. Use of Resources and Energy

The notified use of the FCS will not require additional energy resources for the treatment and disposal of wastes as the FCS is expected to compete with, and to some degree replace similar substances already on the market. The manufacture of the FCS will consume comparable amounts of energy and resources as similar products, e.g., Irgazin Red 3840 and Irgazin Red K 3840 SQ, and the raw materials used in the production of the FCS are commercially manufactured materials that are produced for use in a variety of chemical reactions and processes. Thus, the additional energy used for the production of the FCS is not significant.

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of the food contact articles containing the FCS. This is primarily due to the minute levels, if any, of leaching of potential migrants from finished articles containing the FCS; the insignificant impact on the environmental concentrations of combustion products of the FCS and the similarity of the subject FCS to the articles it is intended to replace. Thus, the use of the FCS as proposed is not expected to result in any significant environmental impact requiring mitigation.

11. Alternatives to the Proposed Action

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

12. List of preparers

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13. Certification

The undersigned official certifies that the information presented is true accurate and complete to the best of his knowledge.

Date: June 19, 2023

Dr. Thomas Ruch