Environmental Assessment

1.	**Date**	March 11, 2026
2.	**Name of Applicant**	Advancion Corporation
3.	**Address**	Agent for Notifier: Daniel C. Rubenstein, Partner Steptoe LLP 1330 Connecticut Avenue, N.W. Washington, D.C. 20036

4. Description of Proposed Action

a. Requested Action

The action identified in this Food Contact Notification (FCN) is to provide for the use of the food contact substance (FCS) identified as 3-amino-3-methyl-2-butanol (CAS Reg. No. 13325-14-9) as a dispersant for mineral pigment suspensions used as a component of fillers or coatings for paper and paperboard, except for use in contact with infant formula and human milk.

When used as a component of coatings, the FCS will be used at a level not to exceed 0.25% by weight of the mineral pigment. When used as a component of fillers, the FCS will be used at a level not to exceed 0.05% by weight of the mineral pigment. The finished paper and paperboard may contact all food types under Conditions of Use A through H, and J (microwave-only container applications).[1] The FCS is not for use in contact with human milk or infant formula; such uses were not included as part of the intended use of the substance in the FCN.

b. Need for Action

The FCS is intended for use as a dispersant used in the production of food-packaging materials. The FCS will be sold to manufacturers engaged in the production of mineral pigments; the mineral pigments, in turn, will be sold to other companies to manufacture paper and paperboard that is used as food contact materials. The FCS will provide various mineral pigment processing benefits, such as increased brightness, opacity and cost-efficiency of manufacture. The FCS has no ongoing technical function in the finished food contact paper or paperboard materials.

[1] *See* Food Types and Conditions of Use for Food Contact Substances, US Food and Drug Administration, *available at:* https://www.fda.gov/food/ingredientspackaginglabeling/packagingfcs/foodtypesconditionsofuse/default.htm.

c. Locations of Use/Disposal

The notifier does not manufacture the paper pulp, or paper and paperboard that could contain the FCS. Instead, the FCS is marketed to manufacturers of mineral pigments, who in turn, supply these pigments to paper and paperboard mills in the U.S. Finished articles containing the FCS are expected to be utilized in patterns corresponding to the national population density and widely distributed across the country. Therefore, it is anticipated that disposal will occur nationwide.

According to the U.S. Environmental Protection Agency's (EPA) 2018 update regarding municipal solid waste (MSW) in the United States, which is the most recent data available, 68.2% of paper and paperboard materials in MSW were recycled, leaving 25.6% of paper MSW for disposal in landfills or elsewhere and 6.2% for combustion.[2] More detailed data are provided by EPA on the recycling, combustion, and landfilling specifically of containers and packaging.[3] These data indicate that 20.8% are recycled; of the remaining generated waste, 15.5% (1,340 of 8,640 thousand tons generated) was combusted and 63.7% (5,500 of 8,640 thousand tons generated) was landfilled.[4]

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

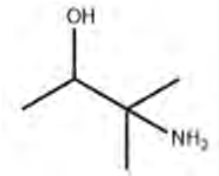
The FCS that is the subject of this Notification is 3-amino-3-methyl-2-butanol.

CAS Reg. No.: 13325-14-9

Molecular Formula: $C_5H_{13}NO$

Molecular weight: 103 g/mol

Structural Formula:



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[2] *See* U.S. Environmental Protection Agency (EPA), "Advancing Sustainable Materials Management: 2018 Fact Sheet Assessing Trends in Materials Generation and Management in the United States" (EPA530-F-20-009) December 2020, Table 1, *available at:* https://www.epa.gov/sites/production/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf

[3] *Id.*

[4] Advancing Sustainable Materials Management: 2018 Tables and Figures Assessing Trends in Materials Generation and Management in the United States, December 2020, Table 5, *available at:* https://www.epa.gov/sites/production/files/2021-01/documents/2018_tables_and_figures_dec_2020_fnl_508.pdf.

The typical physical and environmental properties of the FCS are as follows:

Property	Value[5]
Appearance	Colorless liquid
pH at 20°C	13
Melting point	16°C
Boiling point	160°C
Flash point	76°C (closed cup)
Vapor Pressure at 20°C	44.1 Pa
Density at 20°C	0.94 g/cm^3
Water Solubility	Miscible
Octanol-Water Partition Coefficient	Log K_{ow} 0.78
Acid Dissociation Constant	pKa 9.86 at 25°C
Freundlich Adsorption Coefficient	Log $K_{F,oc}$ 1.29 – 1.69 mL/g

6. Introduction of Substances into the Environment

a. Introduction of Substances into the Environment 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 manufacturer does not suggest that there are any extraordinary circumstances in this case indicative of any significant adverse environmental impact as a result of the manufacture of the food-contact substance. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

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

The FCS is intended for use as a dispersion agent for mineral pigments. The mineral pigments, in turn, are used as components of fillers and coatings during the paper manufacturing process. The notifier plans to market the FCS to pigment suppliers, who in turn market pigments to paper and paperboard mills in the U.S. Potential environmental exposure would occur during paper processing and when the paper and paperboard products themselves (as packaging) are disposed by the user.

1. Air (Combustion)

Solid wastes, including disposal by users of paper products generated with the FCS, are expected to be disposed of by either landfill or incineration.

[5] Advancion Chemical Company Safety Data Sheet for Food Contact Substance.

The FCS consists of carbon, hydrogen, nitrogen, and oxygen, elements commonly found in municipal solid waste. To calculate the potential environmental introduction of the FCS due to combustion of finished articles, we have assumed that available carbon in the FCS would be converted to carbon dioxide, that available nitrogen will be converted to nitrous oxide, and assumed that 15.5% of the market volume will be combusted.

There is the potential for greenhouse gas (GHG) emissions to result from the use and disposal of the FCS during the incineration of articles containing the FCS in MSW combustion facilities. Such facilities are regulated by the EPA under 40 C.F.R. Part 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG." Part 2 of this regulation (40 C.F.R. § 98.2), describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton CO2-e emission threshold for required reporting.

Because the food-contact substance will make up a very small portion of the total municipal solid waste currently combusted, the food-contact substance will not significantly alter the emissions from properly operating municipal solid waste contributors, and therefore not threaten a violation of applicable emissions laws and regulations (*i.e.*, 40 C.F.R. Part 60).

2. Wastewater

We will assume that all of the FCS used in the filler application 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.[6] This substance has high water solubility, a low vapor pressure, moderate Freundlich Adsorption Coefficient and low Log Kow, which indicates a low potential for adsorption to soil or sediments, and a low potential to volatilize from water or soil to the atmosphere. The FCS has been shown to be readily biodegradable, with degradation determined to be 85% after 28 days.[7]

The intended technical effect of the FCS is to aid with the dispersion of the mineral pigment added to food contact paper in order to increase brightness and opacity. A major application is in the production of bleached paper products.[8] Bryant, *et al*. have analyzed water use in paper and paperboard production based on process and product type.[9] Although this

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

[7] *See* Advancion Chemical Company Safety Data Sheet for Food Contact Substance.

[8] Grönfirs, J., *Use of Fillers in Paper and Paperboard Grades*, Final Thesis, Tampere University of Applied Sciences (May 2010), pp. 23-25, *available at:* https://theseus.fi/bitstream/handle/10024/16226/Gronfors_Jarkko.pdf?sequence=1, which discusses the types of cartonboard typically used in food contact applications and identifies them primarily as using bleached chemical pulp.

[9] Bryant, P.S., Malcolm, E.W., and Woitkovich, C.P., IPST Technical Paper Series Number 601 Pulp and Paper Mill Water Use in North America (December 1995), PDF p. 9, *available at:* https://repository.gatech.edu/server/api/core/bitstreams/28217569-3295-4692-8f4f-31ec80ce9b1e/content.

reference does not specifically address the production of food contact paper, it does report information on the water use in various types of mills, including integrated bleached and unbleached mills, paper mills producing more than 100 tons paper/day, and bleached market kraft pulp mills.[10] The reported median water use levels for these types of facilities (in thousand gallons per short ton) are 22.9, 23.0, 3.6, and 12.0, respectively.[11] The report notes that specialty grade mills may have very high water use relative to other mills in their category,[12] which would include some mills producing food contact papers. In describing the water consumption rate data for paper mills producing greater than 100 air-dried short tons (ADST) per day, Bryant, *et al*. states, "[of] the 11 categories analyzed, mills producing paper and board with production rates greater than 100 tons/day had the lowest median water use at 3,600 gallons/ton." The histogram for this mill category[13] shows that 14% of mills in this category (218 x 14% = 31 mills) use less than or equal to 1,000 gal/ton and 54% of these mills (218 x 45% = 118 mills) use less than or equal to 3,000 gal/ton per day. As summarized above, a reasonable conservative water consumption rate would be 1,000 gal/ton/day. Assuming 1,000 gal/ton, the calculated daily water use would be:

(1,000 gal/short ton paper) × (3.785 L/gal) × (1 kg water/L water) = 3,785 kg water/ton

The potential presence of the FCS in the wastewater is anticipated only as a result of the filling application. The coating is applied during the dry-end of production (*i.e.*, to the dried sheet). In our experience, the only loss of water containing the FCS from the coating application would be minor losses to evaporation, while excess coating is returned to the system for reuse. The use level requested for the FCS is 0.05% in the pigment; the mineral may comprise up to 72.5% of the pigment slurry; and the filler may be used at up to 30% in the finished paper. This equates, therefore, to 0.01% in the finished paper (or 100 mg FCS/kg paper).[14] The level of the FCS in the water is therefore calculated as follows:

(100 mg FCS/kg paper) × (907.185 kg/short ton) × (1 short ton/3,785 kg water) = 24.0 mg FCS/kg water per day

At an 85% biodegradation rate, the level of the FCS remaining after degradation would be 24.0 mg/kg × (100% – 85%) = 3.6 mg/kg. If we then use a 10-fold dilution factor for discharge to surface waters,[15] the estimated environmental concentration is 0.36 mg/kg (equivalent to 0.36 mg/L).

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10 *Id.* at Table 2.

11 *Id.*

12 *Id.* at page 2.

13 *Id.* at Figure 3.

14 0.05% × 72.5% × 30% = 0.01%.

15 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. Found online at: http://onlinelibrary.wiley.com/doi/10.1002/etc.5620070204/abstract.

3. Landfill

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). These requirements are enforced by state solid-waste management programs. Therefore, 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.

7. Fate of Emitted Substances in the Environment

a. Air

As described above, no significant quantities of any substances will be released to the atmosphere upon the use and disposal of finished articles manufactured with the FCS. Therefore, an assessment of the environmental fate of these substances is not required.

b. Water

As discussed above, the calculated EEC to surface waters is 0.36 mg/kg (equivalent to 0.36 mg/L). The FCS is highly water soluble, not volatile, and 85% biodegraded in 10 days by sewage sludge. With Freundlich Adsorption Coefficients in soil (log $K_{F,OC}$) ranging from 1.29 – 1.69 mL/g, the FCS is not likely to bind to soil particles and instead will be available for biodegradation. The measured log K_{OW} of 0.78 is low (less than 3), indicating a low potential for bioaccumulation. The predicted bioaccumulation factor (BAF)/ bioconcentration factor (BCF) is -0.033 log(L/kg), or 0.93 L/kg.[16] The BAF and BCF reflect the potential accumulation in aquatic organisms, with (BAF) and without (BCF) a dietary contribution.[17] Substances with a BAF/BCF < 1,000 L/kg are considered not bioaccumulative.[18] Therefore, the FCS is not expected to bioaccumulate in sediment or aquatic species.

The lowest reliable aquatic toxicity values are reported below:

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[16] Modeled using QSAR Toolbox Version 4.7, SMILES CC(C(C)(C)N)O

[17] U.S. Environmental Protection Agency. (2016). *Development of National Bioaccumulation Factors: Supplemental Information for EPA's 2015 Human Health Criteria Update* (EPA 822-R-16-001). Office of Water, Office of Science and Technology. *Available at:* https://www.epa.gov/sites/production/files/2016-01/documents/national-bioaccumulation-factors-supplemental-information.pdf [www.epa.gov].

[18] U.S. Environmental Protection Agency. (2025). *New Approach for Evaluating the Bioaccumulation Potential of Metals in the New Chemicals Division*. EPA Office of Pollution Prevention and Toxics. *Available at:* https://www.epa.gov/system/files/documents/2025-01/ncd_metal_bioaccumulation-approach_final_13jan2025_ncd-ref-library.pdf.

Test species **Acute Toxicity Tests**	Method	Endpoint (exposure time)	Value
Gobiocypris rarus (rare gudgeon)	Other guideline	LC_{50} (96h)	> 107 mg/L
Cyprinus carpio (carp)	OECD TG 203	LC_{50} (96 h)	> 100 mg/L
Cyprinus carpio (carp)	OECD TG 203	NOEC (96h)	100 mg/L
Daphnia magna (water flea)	OECD TG 202	EC_{50} (48h; immobilization)	> 100 mg/L
Raphidocelis subcapitata (freshwater green algae)	OECD TG 201	NOEC (72h; growth rate)	100 mg/L
Raphidocelis subcapitata (freshwater green algae)	OECD TG 201	ErC_{50} (72h; growth rate)	> 100 mg/L
Eisenia fetida (earthworm)	OECD TG 207	LC_{50} (14d)	> 1,000 mg/kg
Test species **Subchronic Toxicity Tests**	**Method**	**Endpoint** **(exposure time)**	**Value**
Gobiocypris rarus (rare gudgeon)	OECD TG 215	NOEC (28d)	12.5 mg/L

No effects were observed in acute and subchronic toxicity tests, up to the highest concentrations tested of 100 and 12.5 mg/L, respectively. No chronic ecotoxicity studies on the FCS were identified in the literature. Thus, the acute No Observed Effect Concentration (NOEC) for the FCS is 100 mg/L, and acute EC_{50}s / LC_{50}s for all species tested are > 100 mg/L. The subchronic NOEC in rare gudgeon for the FCS is 12.5 mg/L, and the LC_{50} > 12.5 mg/L.

The calculated EEC of 0.36 mg/L is 278-fold below the acute NOEC of 100 mg/L, and > 278-fold below the acute EC_{50}s / LC_{50}s for the aquatic species tested. The EEC of 0.36 mg/L is 35-fold lower than the subchronic NOEC of 12.5 mg/L. Thus, the FCS is not expected to have any significant effect on aquatic organisms.

c. Land

Considering the factors discussed above, no significant introductions of the FCS to terrestrial ecosystems are anticipated as a result of the proposed use and disposal of the subject FCS. As discussed above, EPA's regulations for new and expanding landfills require implementing preventive measures to significantly reduce or eliminate leachate. Furthermore, the low production of the FCS for use in food-contact applications precludes any substantial release to the environment of the components. Thus, there is no expectation of any

meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the FCS.

We respectfully submit, therefore, that there is no reasonable expectation of a significant impact on any substance in the environment due to the proposed use of the FCS in articles intended for use in contact with food.

8. Environmental Effects of Released Substances

No significant introductions of the substances into the environment as a result of the proposed use of the FCS were identified under Item 6. Therefore, a quantitative evaluation of the environmental effects of the proposed use of the FCS is not required.

9. Use of Resources and Energy

The use of the FCS in food-contact materials is not expected to result in a net increase in the use of energy and resources, since the FCS is intended to be used in place of similar substances now on the market.

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of the FCS. Therefore, mitigation measures of any kind are not required.

11. Alternatives to the Proposed Action

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

12. List of Preparers

Ms. Patricia Kinne, Environmental Specialist, Steptoe LLP, 1330 Connecticut Avenue, N.W., Washington, D.C. 20036, with over 10 years of experience with food contact compliance matters, including FCN submissions and chemical registration submissions.

Dr. Sarah Owen, DABT, Toxicology Specialist, Steptoe LLP, 1330 Connecticut Avenue, N.W., Washington, D.C. 20036, with over 20 years of experience in toxicology and risk assessment.

Daniel C. Rubenstein, Partner, Steptoe LLP, 1330 Connecticut Avenue, N.W., Washington, D.C. 20036, with 16 years of experience working in the food regulatory arena, including as an attorney working on 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 his knowledge.

Date: March 11, 2026



Daniel C. Rubenstein, Partner

14. References

Advancion Chemical Company Safety Data Sheet.

Bryant PS, Malcolm EW, Woitkovich CP. *Pulp and Paper Mill Water Use in North America*. IPST Technical Paper Series No. 601. December 1995:9. https://repository.gatech.edu/server/api/core/bitstreams/28217569-3295-4692-8f4f-31ec80ce9b1e/content

Grönfors J. *Use of Fillers in Paper and Paperboard Grades*. Final Thesis. Tampere University of Applied Sciences; May 2010:23–25. https://theseus.fi/bitstream/handle/10024/16226/Gronfors_Jarkko.pdf?sequence=1

US EPA Report: *Advancing Sustainable Materials Management: 2018 Fact Sheet*, December 2020.

US EPA Report: *Advancing Sustainable Materials Management: 2018 Tables and Figures*, December 2020.

US FDA, *Food Types & Conditions of Use for Food Contact Substances*, *available at*: https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances.

Rapaport RA. *Prediction of consumer product chemical concentrations as a function of publicly owned treatment works treatment type and riverine dilution.* Environmental Toxicology and Chemistry 1988;7(2):107–115. http://onlinelibrary.wiley.com/doi/10.1002/etc.5620070204/abstract

15. Attachments

Confidential Attachment to the Environmental Assessment