Environmental Assessment

1.	**Date**	March 27, 2019
2.	**Name of Applicant/Notifier**	The Dow Chemical Company
3.	**Address**	All communications on this matter are to be sent to Ms. Alicia M Fitzpatrick, The Dow Chemical Company, 310 George Patterson Blvd, Suite 100, Bristol, PA 19007 Telephone: (215) 785-7033

4. Description of the Proposed Action

The action requested in this Notification is the establishment of a clearance to permit the use of 2-bromo-2-nitro-1,3-propanediol (CAS Reg. No. 52-51-7), known as Bronopol from here on, as a preservative in wet-end paper additives, at a level not to exceed 500 ppm in wet-end paper additives. The total use level of the FCS may not exceed 0.12 pounds per ton of dry weight fiber. The FCS is not for use in contact with infant formula and human milk.

The Notifier does not intend to produce finished food packaging materials from the subject food contact substance. Rather, the Bronopol will be sold to manufacturers, outside the United States, in the production of food-contact materials. The food contact substance will be sold to manufacturers engaged in the production of paper.

The FCS is a preservative that is normally regulated by the U.S. Environmental Protection Agency (US EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The Dow Chemical Company (TDCC) has not registered any products with the FCS, for this specific use, with the US EPA. TDCC intends to sell the FCS to customers outside the United States where a FIFRA registration is not necessary.

The paper production plants that purchase the FCS to use as a preservative are located outside of the United States. Any environmental impacts which should result from use of the FCS during production of food contact article will be under the jurisdiction of a foreign nation and are not occurring in the global commons. Therefore, an evaluation of the impacts is outside the scope of this environmental assessment (EA). Information on foreign production sites and compliance is not provided.

It is expected that food-contact articles that contain the FCS will ultimately be imported into the U.S. market and utilized in patterns corresponding to the national population density and widely distributed across the country. As explained in the confidential attachment, the FCS resulting from this notification will be used in the wet-end of the paper making process. It is expected that end consumers will either recycle or dispose of treated paper and paperboard products into the trash, which will ultimately end up in landfills or incinerated at a

municipal solid waste incineration (MSW) facility at current observed disposal patterns.[1] Preservatives are typical components of paper and paperboard products; there is nothing about this FCS in particular which would uniquely impact paper recycling operations. Therefore there is no likely impact of the use of this preservative on recycled paper.[2]

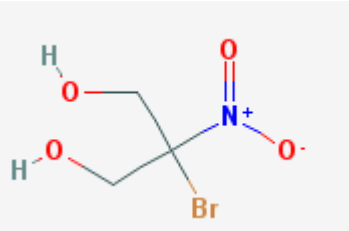
5. Identification of Substance that Is the Subject of the Proposed Action[3]

Chemical Name: 2-bromo-2-nitro-1,3-propanediol

CAS Registry Number: 52-51-7

Chemical Formula: $C_3H_6BrNO_4$

Chemical Structure:



The typical physical and environmental properties for Bronopol are as follows:

Property	Value
MW	198.9 g/mol
Appearance	Odourless white crystal
Density	1.1
Melting Point	266 to 271° F (NTP, 1992)
Boiling Point	305.1° F at 760 mm Hg (NTP, 1992)
Vapor Pressure	1.26×10^{-05} mm Hg at 68° F (NTP, 1992)
Water Solubility	2.5×10^{5} mg/L at 22 deg C
Octanol-Water Partition Coefficient	Log K_{ow} = - 0.64 (est)
Henry's Law Constant	1.33×10^{-11} atm • m^3/mol

6. Introduction of Substances into the Environment

a. Introduction of substances into the environment as a result of manufacture:

[1] EPA, 2018. *Advancing Sustainable Materials Management: 2015 Tables and Figures, Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States* http://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report

[2] https://www.epa.gov/facts-and-figures-about-materials-waste-and-recycling

[3] https://pubchem.ncbi.nlm.nih.gov/compound/bronopol

Under 21C.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 manufacture of the FCS. Furthermore, information available to the manufacturer does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of the food-contact substance.

Thus, 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**

Disposal by the end consumer of the FCS will be by landfill, incineration, and recycling facilities. Potential environmental impact of the FCS by each disposal scenario is discussed below.

1) Landfilling

Based on market volume estimates provided in a confidential attachment, the FCS will only account for a marginal amount of total MSW discards. EPA's regulations require new municipal 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). Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collections systems, they are required to monitor ground water and to take corrective action as appropriate. Therefore, based on MSW landfill regulations preventing leaching, the FCS is not expected to reach the aquatic or terrestrial environment when disposed of via landfill.

2) Incineration

Based on confidential market volume estimates provided in a confidential attachment to the EA, the proposed use of the FCS is expected to make up a very small portion of the total municipal solid waste (MSW). Therefore, incineration of food contact articles containing the FCS is not expected to cause MSW incineration facilities to threaten a violation of applicable emissions laws and regulations (under 40 C.F.R. Part 60 or relevant state and local laws). The incineration end products of the FCS are expected to be carbon dioxide, hydrobromic acid or its salt, and nitrogen oxide. Incineration facilities utilize emission abatement technologies and are required to comply with existing environmental regulations. The very small amount of FCS is not expected to alter the emission profile of the stack flue gas, ash residues or wastewater from incineration facilities.

In accordance with 40 CFR 1508.27, the analysis of significant 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, the greenhouse gas emissions (GHG) resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in municipal solid waste (MSW) incineration facilities. Such facilities are regulated by the U.S. Environmental Protection Agency (U.S. EPA) under 40 CFR 98, which "establishes

mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG." 40 CFR 98.2 describes the facilities that must report their GHG emissions under EPA's GHG reporting program (GHGRP), and sets an annual 25,000 metric ton carbon dioxide equivalent (CO_2-e) emission threshold for required reporting. Based on the confidential market volume, the expected carbon dioxide equivalent emissions are below 25,000 metric tons on an annual basis (refer to calculation in the attached Confidential Environmental Information for Bronopol).

Because the estimated GHG emissions are well below the threshold for mandatory reporting, no significant environmental impacts are anticipated to result from incineration of the FCS in MSW incineration facilities. Therefore, we have concluded that the FCS will make up a very small portion of the total municipal solid waste currently incinerated, the FCS will not significantly alter the emissions from properly operating municipal solid waste incinerators, and incineration of the FCS will not cause municipal waste incinerators to threaten a violation of applicable emissions laws and regulations and/or relevant state and local laws.

3) Recycling

Recycled paper or cardboard food packaging material would be re-processed in paper mills to make paper pulp and then final paper/cardboard products. The potential environmental impact of the wastewater from paper mills is beyond the scope of this environmental assessment because environmental regulations for paper mills wastewater will mitigate any potential impact of the FCS in the wastewater. Further, paper mills are obligated to comply with pertinent stringent environmental regulations in terms of wastewater treatment and emission control.

7. Fate of Emitted Substances in the Environment

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the FCS. Therefore, an evaluation of the environmental effects of the proposed use of the FCS is not required. In addition, the use and disposal of finished articles containing the FCS are not expected to threaten a violation of applicable laws and regulations, such as the EPA's regulations in 40 C.F.R. Part 60 that pertain to municipal solid waste incinerators and Part 258 that pertain to landfills.

a. Physical/chemical properties

Bronopol is highly water soluble and therefore would be expected to remain in water (rather than volatilize to the air). However, if in dry soil, the FCS could volatilize to air based partially on its vapor pressure and its low Log Kow, which indicates it is unlikely to sorb to soil or sediment. The low Log Kow also suggests bioaccumulation of the FCS is unlikely. Volatilization from moist soil surfaces is not expected to be an important fate process based upon an estimated Henry's Law constant of 1.3×10^{-11} atm • m^3/mol.

b. Environmental depletion mechanisms

Based on the use pattern of the FCS (as a component of food-contact articles recycled, landfilled or incinerated), the FCS is not expected to reach the environment. Additionally, based on the market volume information provided in the confidential attachment only extremely low levels of the FCS would be disposed of in MSW. If released into water, bronopol is not expected to adsorb to suspended solids and sediment.[4]

(a) Air

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the food-contact substance. The food-contact substance will make up a very small portion of the total MSW currently incinerated, the food-contact substance will not significantly alter the emissions from properly operating municipal solid waste incinerators (as it is composed of elements typical of MSW), and therefore not threaten a violation of applicable emissions laws and regulations (i.e., 40 CFR Part 60 and 40 CFR Part 98). Additionally, as indicated above the FCS is not expected to volatize into air from the aquatic environment. Although the FCS may volatize from terrestrial environment, it is not expected to reach the terrestrial environment (see below), and therefore this route of introduction is not considered further in the EA.

(b) Water

The preservative which is the subject of this notification is highly water soluble. A standard biodegradability study (OECD 301B) has shown that bronopol exhibits rapid primary biodegradation and extensive ultimate biodegradation [5]. Bronopol would be expected to biodegrade rapidly and extensively under environmental conditions, would be removed by wastewater-treatment facilities, and would not persist in the environment. Bronopol is not expected to bioaccumulate, due to its low octanol/water ratio and high solubility in water. The EPA estimated bioconcentration factor (BCF) for Bronopol is 3.54 L/kg.[6] In tested mammalian species metabolism is reported to be rapid and complete, and accumulation does not occur.[7] Therefore, the potential migration of the FCS into food would not have an environmental impact because the FCS would be completely metabolized in mammals. Volatilization from moist soil surfaces is not expected to be an important fate process based upon an estimated Henry's Law constant of 1.3×10^{-11} atm • m^3/mol.

(c) Land

---

[4] https://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+7195

[5] *Bronopol Registration Review,* United States Environmental Protection Agency, (www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2011-0421)

[6] EPA Chemistry Dashboard for Bronopol (https://comptox.epa.gov/dashboard/dsstoxdb/results?search=52-51-7)

[7] US E**PA –Pesticides – Fact Sheet for Bronopol; https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/fs_PC-216400_1-Oct-95.pdf**

Considering the factors discussed above (propensity to partition to water, unlikely to absorb to sediment or soil, marginal amount of FCS disposed and the regulations at 40 CFR Part 258 which prevent leaching from landfills), we do not expect the FCS to reach the terrestrial environment as a result of the proposed use of the food contact substance. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to the components of the food-contact substance as a result of the proposed use.

8. Environmental Effects of Released Substances

As discussed previously, the FCS is not expected to be introduced into the environment upon the use and disposal of food contact articles containing the FCS. At most, extremely small quantities of incineration products and FCS containing leachates might reach the environment. As no significant introductions of the FCS into the environment as a result of the proposed use of the FCS were identified under Item 6, and, as provided in Item 7 any residual amounts of the FCS entering the environment would have negligible potential for bio-accumulation. Therefore, no significant adverse environmental effects are expected as a result of the use and disposal of articles containing the food contact substance.

9. Use of Resources and Energy

The food contact substance is intended to replace other similar polymer preservatives such as 2-methyl-4-isothiazolin-3-one, 2-n-octyl-4-isothiazolin-3-one, and other anti-microbial preservatives currently allowed in Inventory of Effective Food Contact Notifications, and so no significant change in energy use is expected based on the approval of the requested use.

10. Mitigation Measures

As shown above, no potential significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials fabricated from the use of the FCS. 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 potential adverse environmental effects are identified herein which would necessitate alternative actions to that proposed in this Notification. The alternative of not clearing the action proposed herein would simply result in the continued use of the currently marked materials; such action would have no environmental impact.

12. List of Preparers

Alicia M. Fitzpatrick, B.S. in Biochemistry, EHS Regulatory Manager, 2 years of experience related to all aspects of preparing Food Contact Notifications, 10 years of total experience in FDA regulated industries The Dow Chemical Company, 310 George Patterson Blvd, Suite 100, Bristol, PA 19007

Yunzhou "Joe" Chai, Ph.D. in Chemical Engineering, Professional Engineer (P.E., licensed in the State of Louisiana). 5 years of experience related to environmental impact assessment supporting Food Contact Notifications in the U.S., 14 years of total experience in environmental research and consulting regarding the environmental fate, effects (ecotoxicology), risk assessment, and sustainability of chemical products, supporting global chemical registration, environmental remediation, and wastewater treatment. Environmental Scientist, Toxicology and Environmental Research and Consulting, The Dow Chemical Company. 1803 Building, Midland, MI 48674

Consultation with FDA Office of Food Additive Safety

13. Certification

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

Date: March 27, 2019

[redacted]

_____
Alicia M Fitzpatrick
EHS Regulatory Manager

[redacted]

_____
Yunzhou Chai
Environmental Research Scientist