Environmental Assessment

1. Date April 1, 2019

2. Name of Applicant/Notifier The Dow Chemical Company

3. Address

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4. Description of the Proposed Action

The action requested in this Notification is the establishment of a clearance to permit the use of 2-(dimethylamino)ethanol (DMEA), (CAS Reg. No. 108-01-0), a pH control agent, at a level not to exceed 0.9 g/m^2 in polyolefin dispersions used as coatings on paper and paperboard in contact with all types of food under Conditions of Use C through G, as set forth in Table 2 of 21 C.F.R. § 176.170(c). 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 DMEA will be present in the polyolefin dispersion which will be sold to manufacturers engaged in the production of food-contact materials. Food-contact materials produced with the use of the polyolefin dispersions will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. According to the US Environmental Protection Agency's (EPA) 2015 update regarding paper and paperboard waste, excluding corrugated boxes, in the United States, which is the most recent data available, 26.4% of paper and paperboard materials in MSW were recycled (2,270 thousand tons), leaving 59.1% (5,080 thousand tons) of paper MSW for disposal in landfills or elsewhere and 14.4 % (1,240 thousand tons) for combustion.[1]

[1] United States Environmental Protection Agency, *Advancing Sustainable Materials Management: 2015 Tables and Figures, Assessing Trends in Material Generation, Recycling, Combustion with Energy Recovery and Landfilling in the United States*, July 2018 (Page 5, Table 5). Available at the following website: https://www.epa.gov/sites/production/files/2018-07/documents/smm_2015_tables_and_figures_07252018_fnl_508_0.pdf.

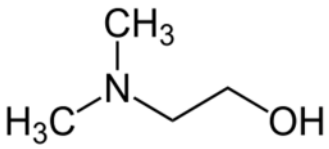
5. Identification of Substance[2] that Is the Subject of the Proposed Action

Chemical Name: 2-(dimethylamino)ethanol

CAS Registry Number: 108-01-0

Chemical Formula: $C_4H_{11}N\,O$

Chemical Structure:



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

Property	Value
MW	89.138 g/mol
Appearance	Clear colorless liquid
pH	10.5-11
Melting Point	-59 deg C
Boiling Point	134.1 deg C
Vapor Pressure	10 hPa at 28.1°C
Acid Dissociation Constant	pKa = 9.3
Water Solubility	Completely soluble
Octanol Water Partition Coefficient	Log K_{ow} -0,55 at 23°C

6. Introduction of Substances into the Environment

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. The FCS is not manufactured by the Notifier, but rather is purchased from a supplier. The FCS may be manufactured in plants both inside and outside of the United States.

To the best of the Notifier's knowledge, the plants that manufacture the FCS in the U.S. meet all applicable federal, state and local environmental regulations. The Notifier asserts that there are no extraordinary circumstances that would indicate the potential for adverse environmental impacts resulting from the manufacture of the FCS such as: 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 (40 C.F.R. § 1508.27(b)(10)); or 3) production associated with a proposed action may adversely affect a species or the critical habitat of a

[2] https://echa.europa.eu/registration-dossier/-/registered-dossier/14464/4/9.

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

Potential environmental exposure would occur during paper processing and when the paper and paperboard products themselves (as packaging) are disposed by the user. Coatings manufactured with the FCS will be applied following the sheet-forming phase of the paper manufacturing. Therefore, loss to processing waste-water and/or waste treatment sludge is not anticipated. As a conservatism, we address the potential introduction of the FCS into the environment via consumption of products packaged in paper and paperboard coated with DMEA.

Air: (Process)

The FCS is intended to be used as a pH control agent, in polyolefin dispersions, which will be used for coatings on paper and paperboard and thermally cured. The FCS is expected to volatize and be released to the air during the curing process.[3] The coating operation is an automated process carried out using appropriate engineering controls (ventilation systems) to mitigate environmental emissions. The coating facility must meet all applicable federal, state and local environmental regulations. Further, paper manufacturing facilities are EPA regulated industries (under 40 CFR 63, Subpart S). As such, the coating facility must meet all applicable federal environmental regulations under the Clean Air Act. These facilities must also comply with applicable state and local environmental regulations. Therefore, no significant environmental introduction of the FCS volatiles is anticipated. The potential release would be controlled by process enclosure, local exhaust, or personal protection equipment.

Air: (Combustion)

Paper and paperboard packaging waste, excluding corrugated board, including disposal of paper products generated with the FCS, are expected to be disposed of by either landfill or incineration if not recycled. The food contact substance 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 and that available nitrogen will be converted to nitrous oxide, and assumed that 14.4% of the market volume will be combusted.

The greenhouse gas (GHG) emissions resulting from the use and disposal of the FCS relate to 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 carbon dioxide equivalent (CO_2-e) emission

[3] *See* Confidential Environmental Assessment, Part B and C.

threshold for required reporting. To evaluate the significance of the environmental impact of these GHG emissions, we refer to CEQ regulations under 40 C.F.R. § 1508.27, which defines 'significantly' as it relates to assessing the intensity of an environmental impact in NEPA documents. 40 C.F.R. § 1508.27(b)(10) states that when evaluating intensity of an impact, one should consider "whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment." GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2. Based on confidential market volume data, the expected carbon dioxide equivalent (CO_2-e) emissions (*see* Attachment 11) are below 25,000 metric tons on an annual basis. As the estimated GHG emissions are well below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities.

Soil and Water:

Environmental introduction of the FCS to soil or water are not anticipated. Therefore, no significant effect on the concentrations of and exposure to the FCS in soil and water are anticipated due to the proposed production, use, and disposal of the FCS.

Landfill:

Only extremely small amounts, if any, of the FCS is expected to enter the environment as a result of the landfill disposal of food-contact articles, in light of the Environmental Protection Agency's (EPA) regulations governing municipal solid waste landfills. 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 groundwater and to take corrective action as appropriate. Even if a very small amount of substances leach from the landfilled food-packaging material into the landfill, we expect only extremely small amounts of substances, if any, to migrate from landfill leachate into the environment; this conclusion is based on EPA's regulations in 40 C.F.R. Part 258.

Introduction of the FCS into the Environment from Food:

The cumulative dietary exposure (CEDI) of DMEA, including all currently regulated uses and this proposed use, remains less than 150 µg/person/day (*see* Attachment 7). Once consumed, DMEA is absorbed from the small intestine (following oral exposure) and then undergoes metabolism in the liver. In humans, only 33% of an injected dose of DMEA was excreted, suggesting that the remaining dose is demethylated to form ethanolamine and directed to normal phospholipid biosynthetic pathways.[4] In male Wistar rats, only 13.5% of the orally administered dose was eliminated within 24 hours, suggesting most of the DMEA was routed

[4] *See* National Institute of Health, United States National Library of Medicine, Toxnet, Toxicology Data Network, available at https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/f?./temp/~0CFIHT:3.

toward phospholipid biosynthetic pathways. As no more than 33% of the cumulative DMEA is anticipated to be excreted (< 50 µg/day), the potential introduction of DMEA into the Publicly Owned Treatment Works (POTWs) would be minimal.

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 combustors or and Part 258 that pertain to landfills.

8. Environmental Effects of Released Substances

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

9. Use of Resources and Energy

As is the case with other food packaging materials, the production, use and disposal of the FCS involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the FCS in the fabrication of 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 packaging which will be used in place of similar paper and paperboard materials now on the market for use in food packaging applications. The partial replacement of these types of materials by products containing the FCS is not expected to have any adverse impact on the use of energy and resources.

Because the FCS is fully volatized during the curing process, no significant FCS residues are anticipated in recycled paper and paperboard. Therefore, the FCS also is not expected to have a significant effect on paper recycling programs. If DMEA used in the coating application were present in paper that is recycled, the DMEA would be expected to dissolve into the pulp slurry. In this event, any residual DMEA would be treated with other chemicals from the recycling process.

Recycled paper or cardboard food packaging material would be re-processed in paper mills to make paper pulp and then final paper/cardboard products. Paper mills are obligated to comply with pertinent stringent environmental regulations in terms of wastewater treatment and emission control.

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 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 marketed polyolefin coating materials; such action would have no environmental impact.

12. List of Preparers

Devon Wm. Hill, J.D. and Masters in Chemistry, 20 years of experience related to all aspects of preparing Food Additive Petitions and Food Contact Notifications, Partner at Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001.

Kristin Price Wiglesworth, Ph.D. in Chemistry, 2 years of experience related to all aspects of preparing Food Contact Notifications, 13 years of total experience in FDA regulated industries. Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001.

13. Certification

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

[redacted]

Date: April 1, 2019

Devon Wm. Hill, Partner
Counsel for The Dow Chemical Company

14. List of References

1. United States Environmental Protection Agency, *Advancing Sustainable Materials Management: 2015 Tables and Figures, Assessing Trends in Material Generation, Recycling, Combustion with Energy Recovery and Landfilling in the United States*, July 2018 (Page 5, Table 5). Available at the following website: https://www.epa.gov/sites/production/files/2018-07/documents/smm_2015_tables_and_figures_07252018_fnl_508_0.pdf.

2. https://echa.europa.eu/registration-dossier/-/registered-dossier/14464/4/9.

3. National Institute of Health, United States National Library of Medicine, Toxnet, Toxicology Data Network, available at https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/f?./temp/~0CFIHT:3.

15. List of Attachments

1. Confidential Environmental Assessment (Attachment 11).