EN

ENVIRONMENTAL ASSESSMENT

1. Date: November 19, 2007 (Revised)

2. Name of Applicant/Petitioner: Albemarle Poultry Sciences, LLC

3. Address:

George M. Ricks, M.S., C.I.H
Senior Industrial Chemist
Albemarle Corporation
451 Florida Street
Baton Rouge, LA 70801-1765
Telephone: 225-388-7943
Fax: 225-388-7023
E-mail: george_ricks@albemarle.com

4. Description of Proposed Action:

The action requested in this notification is the establishment of a clearance to permit the use of 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) as an antimicrobial in ice. The food contact substance will be added to water that is supplied to ice machines to make "bromine-ice." The primary purpose of applying bromine-ice to poultry products is to reduce bacterial numbers. This action will provide a safer product with an extended shelf-life. The bromine-ice is proposed for use on poultry meat, its parts and organs as follows:

1. Within a Poultry Processing Plant

   - Anywhere within a facility where poultry products may be subjected to ice. Possible areas include. Salvage, Aging, Combo Packs (holding), Tray Packs (pre-packaging), and Chiller systems.

2. Outside a Poultry Processing Plant

   -Work In Progress (WIP) – during transfer of poultry products from one poultry processing location to another poultry processing location for further processing

   - Poultry packaged in totes/cartons destined for distribution in the marketplace.

DBDMH will be added to the supply water prior to entering the ice machine at a level not to exceed that needed to provide the equivalent of 100 ppm of available bromine in the water. As the ice melts, the active ingredient (hypobromous acid) is released and acts to kill pathogens and other bacteria present on the poultry product. This action reduces bacterial numbers, therefore providing safer, better quality poultry products. In addition, bacterial reduction during transit will provide an extended product shelf-life.

In water, DBDMH breaks down to form hypobromous acid and 5,5-dimethylhydantoin (DMH), as shown below.

DBDMH + H_2O = 2HOBr + DMH

Hypobromous acid is the active antimicrobial agent, while the DMH by-product serves no further function in the water. After undergoing chemical oxidation during use (disinfection), the hypobromous acid converts to bromide ion. DMH remains in the water and does not react further.

Based on the chemistry of DBDMH and the traditional usage of the term "available bromine" in the disinfection industry, the maximum available bromine level of 100 ppm corresponds to a maximum DBDMH addition level of approximately 90 ppm. The chemistry of DBDMH, including pertinent chemical reactions and calculations showing how the DBDMH level corresponds to equivalent available bromine, is provided in Attachment 4 of this FCN

The FCS is proposed for use in ice in poultry processing plants that may be located throughout the United States. DBDMH will be introduced to plant water at the levels described above and supplied to ice machines to produce "bromine-ice." The bromine-containing-ice, upon melting, will provide antimicrobial effects and serve to enhance the quality and safety of the poultry food products. The end result will benefit both the supplier and the consumer.

In FCN 453, it was estimated that total water usage in a poultry processing plant was approximately 2,000,000 gallons per day. This was based on the assumption that 10 gallons water would be used per bird and a plant processed 200,000 birds daily. In 2001, the average gallon per bird processed ranged between 4.5 and 8.8, with an average of 6.2 gallons per bird.[1] For a facility processing 200,000 birds, approximately 900,000 gallons per day to 1,760,000 gallons per day with an average of 1,240,000 gallons per day may be used in a processing facility. This estimate would cover water usage from all processing areas, including ice. For purposes of this environmental assessment, it is estimated as a worst case, that a poultry facility will treat approximately 50,000 gallons of water with DBDMH per day and convert it to ice.[2] Seventy-five percent (75%) or approximately 37,500 gallons of this water is expected to stay within the processing facility where the ice was produced or it may be used on poultry that is transferred to another processing facility for further processing. In either case, the ice and resulting water will enter the plant wastewater treatment system and become part of the estimated 1,240,000 gallons of effluent water produced daily. The remaining 25% or 12,500 gallons is expected to leave the poultry plant altogether since it is used on poultry products that

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[1] Kiepper, B. A survey of wastewater treatment practices in the broiler industry, http://www.engr.uga.edu/service/outreach/WEF%20PAPER.pdf (accessed May 15, 2007).

[2] Loren Williams (Consultant; President and CEO, Solution BioSciences, Inc., 414 Main Street, Suite 2, Chatham, NJ 07928)

are being distributed to the marketplace This ice and resulting water is expected to ultimately enter the environment via storm water runoff.

As described above, processing plant wastewater treatment systems or storm water runoff are the two expected routes of disposal for ice/water that has been treated with DBDMH All bromine-ice used within a poultry processing plant, including WIP, is expected to enter the "Offal" stream. Generally, the Offal stream consists of all effluent prior to the chiller system(s). The Offal stream contains the waste solids (heads, intestines, fat, feathers) which are filtered and removed and sent to a rendering plant where they are further processed into poultry feed and litter. The remaining filtered water from the Offal stream is sent to the Dissolved Air Flotation Generator (DAF) where it may be chemically treated and filtered further. The resulting water is sent to the wastewater treatment plant. The chiller waters (overflow and end-of-day contents) empty to the Wastewater stream. The chiller waters contain fat and other solids which may be dislodged as the carcasses are agitated and pass through the chiller system. This stream may be chemically treated and filtered in the DAF area and sent to the wastewater treatment plant Solids from the DAF area are also sent to the rendering plant. After the solids are removed, all wastewater are sent to the wastewater treatment plant where it is collected and treated by the facility prior to being discharged to a POTW, other receiving waters or land application. Only minor quantities are lost to evaporation into the air. The primary route of disposal for water that has been treated with DBDMH is through the processing plant wastewater treatment facility A small amount of water containing these disinfectant by-products may be bound to Offal solids and carried over to the rendering plant However, the level of by-products carried over to the rendering plant on the Offal solids and on poultry fat are considered insignificant since these compounds are water soluble and are expected to remain in the wastewater streams.

Additionally, DMH is not considered fat soluble to any appreciable extent. There are three reasons that support this assertion. 1. DMH is very water soluble. 2. The Log K_{ow} for DMH has been measured at 0.35.[3] The magnitude of this number indicates that DMH strongly prefers water over the oil phase. 3. A study was performed by Albemarle Poultry Sciences, LLC to determine if there is preferential uptake of DMH by poultry carcasses submerged in poultry chiller water treated with DBDMH. The data showed that poultry immersed for an extended time period into water containing a known amount of DMH did not result in a decrease of DMH from the water. The differential concentrations of DMH in the chiller water before and after submerging the carcasses were inconsequential to the extent that changes could be measured. The final report from the above study can be found in Attachment 10 of FCN 000334.

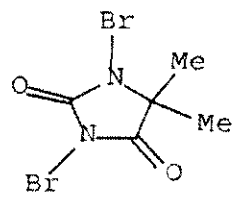
Bromine-ice that is used on poultry products during transit to the marketplace will ultimately melt and be discharged directly into the environment, via storm water runoff

5. Identification of Substances that are the subject of the Proposed Action:

The substance that is the subject of this Notification is 1,3-dibromo-5,5-dimethyl hydantoin (DBDMH). The CAS Registry Number is 77-48-5 The FCS may also be identified as 1,3-dibromo-5,5-dimethyl-2,4-imidazolidinedione.

The molecular structure for DBDMH is given below The molecular formula is $C_5H_6Br_2N_2O_2$, and the molecular weight is 286. DBDMH is a white, crystalline solid.

[3] *5,5-Dimethylhydantoin (DMH) High Production Volume (HPV) Chemical Challenge Test Plan*; 201-14589A; American Chemistry Council Brominated Biocides Panel DMH Task Group; Toxicology/Regulatory Services, Inc : July 3, 2003. http://www.epa.gov/oppt/chemrtk/pubs/summaries/55dmth/c14589tp.pdf (accessed May 29, 2007).



A confidential description of the product composition appears in Part II of Form 3480 of this FCN.

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 substances Moreover, information available to the Notifier 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 DBDMH. Consequently, information on the manufacturing site and compliance with relevant emissions requirements are not provided here.

b. Introduction of substances into the environment as a result of use/disposal:

DBDMH will be used at a level not to exceed that needed to provide the equivalent of 100 ppm available bromine in the water used to make ice As shown in Attachment 4 of this FCN, based on traditional industry usage of the term "available bromine," this corresponds to a maximum DBDMH addition level of 90 ppm. In water, the DBDMH breaks down into hypobromous acid and DMH. After disinfection, hypobromous acid converts to bromide ion DMH remains in the water and does not react further.

Due to its instability in water, there will be no release of DBDMH, *per se*, as a result of its use as intended. Moreover, the hypobromous acid is highly reactive and is not expected to survive transit through the poultry processing system given the high organic content of the water following contact with poultry carcasses and after mixing with other aqueous waste streams. (The half-life of hypobromous acid in low-demand tap water has been estimated by EPA as 125 hours.[4] The hypobromous acid will degrade far more rapidly in the aqueous systems present in the poultry processing plant.) Thus, it is fully expected that no hypobromous acid will be released from the processing facility or via storm water runoff. For these reasons, this Environmental Assessment focuses on the DMH and bromide ion as the principal, and ultimate, byproducts that may be released as a result of use of the FCS.

As shown in Attachment 4 of this FCN and described in the following paragraphs, addition of DBDMH at the maximum level of 90 ppm results in a maximum DMH concentration of 40 ppm and a maximum bromide ion ($Br^{(-)}$) concentration of 50 ppm in the dosed water.

Introduction of the decomposition products of DBDMH into the environment will take place primarily via release in wastewater treatment systems and through storm water runoff. The introduction of decomposition products to the environment from a rendering plant and downstream from a rendering plant is not considered a significant pathway. The decomposition products are water soluble and are expected to remain in the wastewater streams (See section 4 of this EA) and discharged directly into the environment via a receiving body of water such as a river, stream or land application. To determine the environmental introduction concentrations (EIC) of these by-products, we must first make an estimate of the DBDMH maximum use level. A typical poultry plant processes approximately 200,000 birds per day. As noted in section 4, water usage per bird was estimated at 6.2 gallons. This range represents water usage from all

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[4] EPA Reregistration Eligibility Decision (RED), Inorganic Halides, September 1993.

areas of processing including ice usage Assuming that DBDMH is added to all of this water, at the maximum approved level of 90 ppm (or 90 mg/kg), the total amount of DBDMH used is:

200,000 birds/day x 6.2 gal. water/bird = 1,240,000 gal. water/day containing DBDMH

1,240,000 gallons water/day x 3 785 L/gal. = 4.7×10^6 L/day = 4.7×10^6 kg water/day

4.7×10^6 kg water/day x 90 mg/kg x 1 kg/10^6 mg = 422.4 kg DBDMH per day

The amount of DMH that is produced as a result of the addition of this maximum amount of DBDMH may then be calculated As shown in Attachment 4 of this FCN, the amount of DMH produced from a given amount of DBDMH is calculated using the ratio of the molecular weight of DMH (128.1) to that of DBDMH (286). Thus, the amount of DMH produced from the addition of a total of 422.4 kg of DBDMH is calculated as follows:

DMH formed = 422.4 kg DBDMH x (128.1 DMH ÷ 286 DBDMH) = 189.2 kg DMH

Similarly, the amount of $Br^{(-)}$ produced from the addition of 422.4 kg of DBDMH is calculated using the ratio of the weight of two bromide ions (159.8) to that of DBDMH, as follows

Bromide ion formed = 422.4 kg DBDMH x (159.8 ÷ 286) = 236.0 kg $Br^{(-)}$ ion

Therefore, the maximum amounts of DMH and $Br^{(-)}$ ion present in all poultry process water, including ice, from all uses of DBDMH are approximately 189 2 kg and 236.0 kg per day, respectively. These maximum calculated levels of DMH and $Br^{(-)}$ are based on worst-case assumptions. It must be pointed out that it is unrealistic that any poultry processor would add DBDMH at its maximum level to all process water It would not be realistic to do this and would be cost prohibitive

An estimate of the environmental introduction concentrations (EIC) of DMH and $Br^{(-)}$ ion can now be calculated. As previously noted in section 4, within a poultry processing plant, there are two effluent streams; the Offal and the Wastewater Streams. Generally, the Offal stream consists of all effluent prior to the chill system(s). The Offal stream contains the waste solids (heads, intestines, fat, feathers) which are filtered and removed from the water and sent to a rendering plant where they are further processed into poultry feed and litter. The remaining filtered water from the Offal stream is sent to the Dissolved Air Flotation Generator (DAF) where it may be chemically treated and filtered further. The resulting water is sent to the wastewater treatment plant. The chiller waters (overflow and end-of-day contents) empty to a separate wastewater stream which may also be chemically treated and filtered in the DAF area The chiller waters contain fat and other solids which are dislodged from the carcasses as they are agitated and moved through the chiller system All solids removed are sent to the rendering plant After the solids are removed, all wastewater discharged from the DAF area are sent to the wastewater treatment plant where it is collected and treated by the facility prior to being discharged to a POTW, other receiving waters or land application. Only minor quantities are lost to evaporation into the air. The primary route of disposal for water that has been treated with DBDMH is through the processing plant wastewater treatment facility A small amount of water containing disinfectant by-products is expected to be carried over to the rendering plant from the Offal and DAF generated solids However, the level of by-products carried over to the rendering plant is expected to be insignificant since they are water soluble and will remain in the wastewater stream (See section 4 of this EA). Consequently, no environmental effects are expected by further processing poultry Offal into other usable products such as poultry feed.

To calculate the maximum concentration at which DMH and $Br^{(-)}$ ion may be introduced into the environment from the effluent streams entering the wastewater treatment plant, we will assume that the entire quantities of these by-products will ultimately be discharged to the on-site wastewater treatment plant

To calculate the concentration at which DMH and $Br^{(-)}$ ion may be present in poultry plant wastewater, it is necessary to consider the total volume of wastewater produced In section 4, it was estimated that total water usage in a poultry processing plant averaged approximately 1,240,000 gallons per day. This includes water from, *e g* , rinsing of the evisceration trough, viscera carriage flume, scalder and chiller overflow, handwash stations, and plant sanitation program.[5] For purposes of this environmental assessment, it is estimated as a worst case, that a poultry facility will treat approximately 50,000 gallons of water with DBDMH per day and convert it to ice. Seventy-five percent (75%) or approximately 37,500 gallons of this water is expected to stay within the processing facility where the ice was produced or it may be used on poultry that is transferred to another processing facility for further processing. In either case, the ice and resulting water will enter the plant wastewater treatment system and become part of the estimated 1,240,000 gallons of effluent water produced daily The remaining 25% or 12,500 gallons is expected to leave the poultry plant altogether, since it is used on poultry products that are being transported away from the processing plant and to the marketplace. This ice and resulting water is expected to ultimately enter the environment via storm water runoff. To calculate the maximum DMH and $Br^{(-)}$ concentrations in the wastewater, we will assume an average wastewater volume of 6.2 gallons per bird

6.2 gal./bird x 200,000 birds/day = 1,240,000 gal. waste water/day

1,240,000 gal. x 3.785 L/gal = 4.7×10^6 L/day = 4.7×10^6 kg waste water/day

189.2 kg DMH/day ÷ 4.7×10^6 kg waste water/day = 4.0×10^{-5} kg DMH/kg water

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[5] Wesley, R.L. (1985) Water reuse and conservation in poultry processing. *Poultry Sci* 64:476.

= 40 ppm DMH

236.0 kg $Br^{(-)}$/day ÷ 4.7 x 10^6 kg waste water/day = 5 0 x 10^{-5} kg $Br^{(-)}$/kg water

= 50 ppm $Br^{(-)}$ ion

Therefore, as a worst-case, wastewater containing 40 ppm DMH and 50 ppm bromide ion, may be directly introduced into the environment

7. Fate of Emitted Components in the Environment:

The direct discharge of poultry process wastewater or storm water runoff containing DMH and $Br^{(-)}$ into the environment represents a worst-case scenario. As previously noted, a maximum DBDMH level of 90 ppm corresponds to maximum DMH and $Br^{(-)}$ levels of 40 and 50 ppm respectively. This represents the maximum levels of these by-products that would be directly discharged into a receiving body of water such as a river or stream Using a dilution factor of 10, the environmental effect concentration (EEC's) would be 4 ppm for DMH and 5 ppm for $Br^{(-)}$.

8. Environmental Effects of Released Substances:

Testing previously provided to FDA indicates that DMH does not have a tendency to bioaccumulate in fish. A large volume of toxicological data on DMH in aquatic organisms also has been submitted LC_{50} values reported for DMH range from 1300 mg/L in grass shrimp to 14,200 mg/L in the fathead minnow. Aquatic static bioassays of DMH indicate that DMH is not acutely toxic at levels of 12,700 to 14,200 mg/L (sheepshead minnow, grass shrimp, oysters) and 1300 to 8100 mg/L (water flea)[6] The lowest No Observable Effect Concentration (NOEC) reported for chronic aquatic toxicity of DMH was 14 mg/L for the fathead minnow This value is based on changes in the measurement of length, wet weight, and dry weight of fat head

[6] *See* EA for FAP 4B4418, id.

minnows at 29 mg/L but not at 14 mg/L.[7] A maximum acceptable toxicant concentration (MATC) of 20 mg/L was reported by the Environmental Protection Agency (EPA) for this study.[7] The most conservative estimated environmental concentration of 4 mg/L, where the effluent concentration is only reduced by the standard dilution factor of 10, is five times below the lowest measured MATC and below the lowest NOEC. While we are not able to evaluate possible toxicity to algae or aquatic plants, because we do not have data for these organisms, we do not anticipate that toxicity to aquatic organisms will occur due to exposure to DMH when DBDMH is used as described This is also the case when you combine possible introductions from the uses approved in FCN 453 because the estimated introduction concentration for DMH is below toxicity endpoints even when it is assumed that all water is treated

Thus, we respectfully submit that there will be no adverse effect on organisms in the environment as a result of the postulated release of DMH at the maximum level calculated.

[7] High Production Volume Information System, http://www.epa.gov/hpv/hpvis/index.html (accessed Oct 16, 2007)

Aquatic Toxicity Data on 5,5-Dimethylhydantoin[3]

Test Organism	Endpoint	Duration	Concentration (mg/kg)
Rainbow trout	NOAEL	96h	>972.2
Fathead minnow	NOAEL	96h	>1085
Sheepshead minnow	NOAEL	96h	>1006
Bluegill sunfish	NOAEL	96h	>1017
Fathead minnow	LC50	96h	14200
Sheepshead minnow	LC50	96h	8100
Rainbow trout	LC50	96h	12700
Fathead minnow	NOEC	5d	14
Fathead minnow	LOEC	5d	29
Fathead minnow	NOEC	5d	116
Fathead minnow	LOEC	5d	>116
Fathead minnow	MATC	5d	20
American oyster	LC50	96h	13300
Water flea	LC50	96h	6200
Grass shrimp	LC50	96h	1300
Saltwater mysid	LC50	96h	921 7
Water flea	NOEC	5f	70 9
Water fles	LOEC	5d	116
Water flea	MATC	5d	90.7

MATC is the maximum concentration at which the chemical can be present and not be toxic to the test organism. LC50 is the concentration which kills ½ of the test species NOEC is the highest concentration at which the chemical has no observable effect on the test species. LOEC is the lowest concentration at which the chemical has an observable effect on the test species.

Bromide ion also is of low toxicity to aquatic organisms Attached to this Environmental Assessment, as Appendix 1, is a printout of the results of a search of an EPA ecotoxicity database for the compound sodium bromide.[8] (A search of the same database for "bromide ion," CAS Reg No. 24959-67-9, did not yield any hits.) Since sodium bromide dissociates in water to

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[8] Specifically, the database searched was the Environmental Protection Agency's ECOTOX Ecotoxicology Database, located at http://www.epa gov/ecotox/

yield the free sodium and bromide ions, the data on sodium bromide serve to provide useful information on the toxicity of the bromide ion, itself.

As indicated by the printout in Appendix 1, a large amount of data is available on the toxicity of sodium bromide to both fresh water and salt water organisms. The data include both LC_{50} values obtained from acute toxicity testing, as well as no-observed effect concentrations (NOECs) for a variety of toxicity endpoints from long-term exposures

It should be noted from the outset that, although the search term used was "sodium bromide," the data outputted from the database include the results of certain studies that actually were designed to investigate the toxicity of hypobromous acid generated by activated sodium bromide. In particular, these studies include three acute toxicity assays conducted by an industry task force to support a pesticide re-registration effort for sodium bromide used in the generation of hypobromous acid.[9] The studies in question report a 96-hour LC_{50} of 0.18 ppm for opossum shrimp, a 96-hour LC_{50} of 0.47 ppm for the Virginia oyster, and a 96-hour LC_{50} of 0.19 ppm for sheepshead minnow. The reference given in the ECOTOX database (reference 344) for all three studies is to an EPA Pesticide Ecotoxicity Database in the Environmental Fate and Effects Division of the Office of Pesticide Programs. The studies in question are not currently in the public domain. However, the Notifier, Albemarle Corporation, was a participant in the task force that carried out the studies and confirms that the actual test compound in the noted studies

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[9] Surprenant, D. (1988) *Acute Toxicity of Hypobromous Acid to Mysid Shrimp (Mysidopsis bahia) Under Flow-through Conditions*: SLS Report, No. 88-5-2722; Study No. 1199.0188.6109 515; Surprenant, D. (1988) *Acute Toxicity of Hypobromous Acid to Eastern Oysters (Crassostrea virginica) Under Flow-through Conditions*: SLS Report No 88-5-2726; Study No 1199.0188.6109.504; Surprenant, D (1988) *Acute Toxicity of Hypobromous Acid to Sheepshead minnow (Cyprinodon variegatus) Under Flow-through Conditions*: SLS Report, No. 88-5-2736; Study No. 1199.0188.6109 505. Unpublished studies prepared by Springborn Life Sciences, Inc.

was hypobromous acid, as suggested by the titles of the studies provided in the footnote above. Specifically, the studies were conducted by combining sodium bromide with sodium hypochlorite in a mole ratio of 1 2 to 1.0 to yield hypobromous acid. Thus, the data obtained in these studies are not directly relevant to the current environmental assessment as hypobromous acid is not expected to be released as a result of the proposed use of DBDMH.

Additional data included in the printout are from a 1999 paper by Fisher, et al. (reference number 6320 in the ECOTOX database) (copy attached as Appendix 2) in which sodium bromide again was tested in the presence of an activator (sodium hypochlorite) designed to generate hypobromous acid. Thus, this testing also was intended to examine the toxicity of bromine oxidants, not bromide ion, *per se* [10] Therefore, the various toxicity datapoints ascribed to the Fisher paper also are of no direct relevance to the present evaluation of the aquatic toxicity of bromide ion

Once these data are excluded from consideration, it is evident from Appendix 1 that bromide ion is not acutely toxic to freshwater or marine organisms, and that the NOECs from extended exposure also are comparatively high. A sampling of the relevant data is provided in the following table

[10] Indeed, as noted on page 766 of the paper, although excess sodium bromide was used in this testing, the toxicity observed was considered by the authors to be due to the oxidants and not to the sodium bromide

Representative Aquatic Toxicity Data on Sodium Bromide

Test Organism	Endpoint	Duration	Concentration
Daphnia magna	NOEC (behavior)	21 days	91 mg/L
Rotifer	NOEC (reproduction)	48 hours	1000 mg/L
Green algae	NOEC (population growth)	3-4 months	>500 mg/L
Daphnia magna	EC_{50}	24 hours	500 mg/l
Daphnia magna	NOEC (reproduction viability)	21 days	7 5 mg/L
Daphnia magna	NOEC (general reproduction)	19 days	< 3.0 to 19 mg/L*
Bluegill	LC_{50}	96 hours	> 1000 ppm
Rainbow trout	LC_{50}	96 hours	>1000 ppm
Medaka, high eyes	LC_{50}	34 days	1500 mg/L
Medaka, high eyes	LC_{50}	72 hours	24,000 mg/L
Medaka, high eyes	NOEC (multiple)	34 days	250 mg/L
Fathead minnow	LC_{50}	96 hours	16479 mg/L
Guppy	LC_{50}	124 days	7800 mg/L
Guppy	LC_{50}	96 hours	16,000 mg/L
Guppy	NOEC (reproduction)	124 hours	7 8 mg/L

* See discussion of this study below

The lowest acute toxicity EC_{50} or LC50 given in the table above is 500 mg/L, in Daphnia magna Other EC_{50} values cited in the database for sodium bromide in Daphnia range from 6100 mg/L to over 15,000 mg/L. A reported 24 hour EC50 in daphnid neonates of 1.4 mg/l was discounted because we believe the toxicity reported in this study was not due to sodium bromide. This value is inconsistent with values seen in Daphnia ring tests where sodium bromide was a standard reference substance. We do not have an actual copy of this study (Reference 7054 ECOTOX data base, See Appendix 4). Thus, relying on the lowest relevant EC_{50} value of 500 mg/L clearly represents a conservative estimate of the toxicity of bromide ion to this species.

A wide range of NOEC values for bromide ion in Daphnia also have been published. The value shown in the above table, < 3 0 mg/L, is the lowest NOEC established in a study by Soares, et al. (1992; ref. 5857 on ECOTOX database, see Appendix 3) in which nine different clones were tested to evaluate interclonal and environmental variation in the results obtained in the assay. For four of the clones, the NOEC was reported as <3 mg/L, for two clones the NOEC was 3 mg/L, and for the remaining clones the NOEC varied from 7.5 to 19 mg/L. These results suggest a fairly wide range of sensitivity in the different organisms tested. Moreover, 21-day or 23-day NOECs for reproduction in Daphnia of 7.5, 7.8, 16, and 91 mg/L are referenced elsewhere in the ECOTOX printout Based on the entirety of the data available, and given the variability as to daphnid clone, we respectfully submit that the use of a NOEC of 3.0 mg/L is sufficiently conservative for purposes of establishing a safe level of bromide ion in bodies of water receiving effluent.

In the past, FDA has calculated the toxic concentration criterion (TCC) for a test compound as either the lowest NOEC or $1/100^{th}$ of the lowest LC_{50} (or acute EC50). In this case, the lowest EC_{50} divided by 100 is 5.0 mg/L. Thus, the lower TCC is that derived from the minimum NOEC, or 3 0 mg/L. The maximum concentration at which bromide ion may be present in rivers or other bodies of water as a result of direct discharge of poultry wastewater or storm water runoff was estimated above as 5 ppm or 5 mg/L. This maximum bromide ion level is based on worst-case assumptions which are not expected to ever occur. It is unrealistic to assume that a poultry processor would add the maximum level of DBDMH to all process water in its establishment, therefore the actual environmental concentrations of bromide ion are expected to be lower. Thus, we respectfully submit that the possible presence of bromide ion in waste water from poultry processing facilities as a result of the proposed use of DBDMH is not expected to present any concern with regard to potential aquatic toxicity.

As stated previously, neither DBDMH per se nor the active microbial agent (hypobromous acid) from use of DBDMH in this application will be released from the processing facility or via storm water runoff. This is due to the fact that the hypobromous acid is highly reactive and not expected to survive transit through the facility because of the high organic content However, EPA has assessed ecological effects risk assessment for hypobromous acid from activated sodium bromide used in once through cooling systems in freshwater and estuarine environments. Although this application is not directly comparable to the application of this submission, the summary from the Inorganic Halide Re-registration Eligibility Decision (RED) Facts, is included for information:[11]

> *"As discussed earlier, EPA conducted a Tier Ic EEC screening model for hypobromous acid to estimate the maximum concentration that occurs immediately downstream from an industrial point source discharge site. The results for the high exposure case are comparable to the amounts detected in the two Potomac River aquatic residue studies, one of which showed high concentrations of hypobromous acid as far downstream as 80 meters. Based on these studies, the Agency presumes risk to freshwater and estuarine fish and invertebrates at the point of discharge and downstream to 80 meters. However, the modeling results for "typical" sites are well below the levels of concern for fish and invertebrates. These results indicate that (activated) sodium bromide can be used at typical sites without impact most of the time. Since the discharge of hypobromous acid is limited by the NPDES permit program administered by EPA's Office of Water, the Agency will be able to control the discharge of hypobromous acid on a site-by-site basis so that toxic levels are avoided.*
>
> *Based on this modeling, EPA also presumes a risk to endangered freshwater and estuarine/marine organisms in "worst case" situations. However, "typical" discharge levels are below those of concern for endangered species."*

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[11] *R.E.D. Facts, Inorganic Halides*, EPA-738-F-93-015, U. S. Environmental Protection

Use of inorganic halides in non food-contact poultry processing is listed as a use pattern subject to re-registration with use levels ranging from 150 – 300 parts per million (see page 25 of the RED document).[12] The EPA also recently published a Tolerance Reassessment Decision Document on sodium bromide. The Ecological Risk Characterization was based on that published in the RED for Inorganic Halides.[13] The EPA concluded,

> *"The current uses of sodium and potassium bromide have been evaluated and it is concluded that there is reasonable certainty that use of products as sanitizers will not pose harm to the general population or any population subgroup. It is further acknowledged that additional uses for these products do exist and that the RED for bromide should be consulted for additional information on the quantitative risks associated from the use of other bromide-containing products."*

We believe that when used in accordance with the RED for inorganic halides and with an NPDES permit, no adverse environmental impacts will occur

9. Use of Resources and Energy

The use of DBDMH will not require additional energy resources for treatment and disposal of waste water, as the DMH byproduct readily degrades. The raw materials used in the production of the compound are commercially manufactured materials that are produced for use

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Agency: Washington, D.C., 2007. http://www.epa.gov/oppsrrd1/REDs/factsheets/4051fact.pdf

[12] *Re-registration Eligibility Decision. Inorganic Halides, List D, Case 4051*, U.S Environmental Protection Agency: Washington, D.C., 2007 http://www.epa.gov/oppsrrd1/REDs/old_reds/inorganic_halides.pdf (assessed Oct 18, 2007).

[13] Morrow, M. S. *Potassium Bromide and Sodium Bromide Tolerance Reassessment Decision Document (CAS numbers 7758-02-3 and 7647-15-6, DP Barcode 321794)*; Docket Number EPA-HQ-OPP-2006-0143-004; U. S. Environmental Protection Agency: Washington, D.C., Sep 20, 2005

in a variety of chemical reactions and production processes. Energy used specifically for the production of the proposed use of DBDMH is not significant. Moreover, as DBDMH will be used in place of other antimicrobial treatments that currently are permitted for use in the poultry industry, the use of DBDMH as described will not lead to a net increase in the consumption of resources and energy.

10. Mitigation Measures

According to the RFD for Inorganic Halides, *"All manufacturing-use or end-use products that may be contained in an effluent discharged to waters of the United States or municipal sewer systems must bear the following revised effluent discharge labeling statement."*[12]

> *"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."*

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) labels for products containing DBDMH also include this statement (see all active labels for DBDMH products registered by Albemarle Corporation.[14] Active products include EPA Registration No's 3377-61,

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[14] National Pesticide Information Retrieval System, http://ppis.ceris.purdue.edu/htbin/ppismenu.com (assessed Oct. 22, 2007).

3377-62, 3377-63, and 3377-71). The precautionary statement will also be on the label for the proposed use and will help to mitigate any possible environmental effects.

The use of the subject food-contact substance 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 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 other products by the poultry processing industry; such action would have no environmental impact In view of the excellent properties of DBDMH as an antimicrobial treatment for poultry, the improvements in food safety that will result from its use, and the absence of any identified significant environmental impact that would result from its use, the clearance of the use of DBDMH as described herein appears to be environmentally safe and desirable in every respect.

12. List of Preparers

George M Ricks, M.S., C.I.H., Senior Industrial Hygiene Chemist, Albemarle Corporation, 451 Florida Street, Baton Rouge, LA 70801-1765.

13. Certification

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

Date: 11/19/07

Signature of Responsible Official:

Name and Title of Responsible Official: George M. Ricks, M.S., CIH
Senior Industrial Hygiene Chemist
Albemarle Corporation