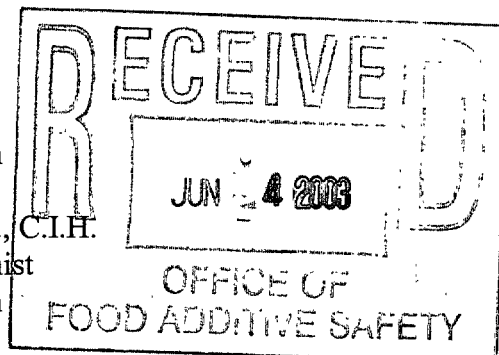




AMENDED ENVIRONMENTAL ASSESSMENT

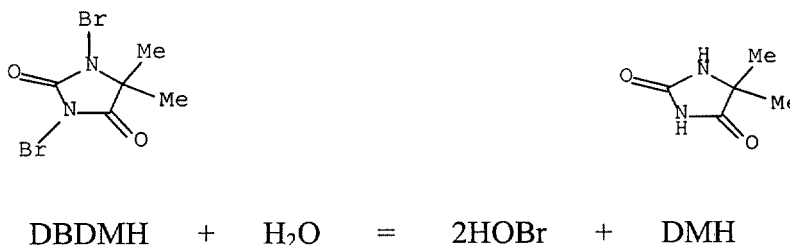
1. **Date:** June 2, 2003
2. **Name of Applicant/Petitioner:** Albemarle Corporation
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4. Description of Proposed Action:

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 chiller water during poultry processing at a level not to exceed that needed to provide the equivalent of 100 ppm of available bromine in the chiller water. The product will be used as an antimicrobial to control the growth of pathogens in chiller water and on chicken carcasses.

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



Hypobromous acid is the active antimicrobial agent, while the DMH byproduct serves no further function in the chiller water. After undergoing chemical oxidation during use (disinfection), the

hypobromous acid converts to bromide ion. DMH remains in the chiller 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 further discussed in Attachment 4 to this notification.

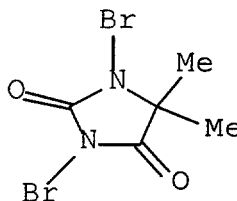
This product is for use in poultry processing plants that may be located throughout the United States. The expected route of disposal for chiller water that has been treated with DBDMH is the processing plant wastewater treatment facility. DBDMH is added at the levels described above to the front end of the chiller water. The defeathered, eviscerated carcasses are moved through the chiller bath by a paddle or auger-type conveyor, then exit the chiller bath for further processing. Waste chiller water ultimately runs into drains and enters the poultry processing plant water treatment facility. This water is collected and treated by the facility prior to being sent to a POTW. Only minor quantities are lost to evaporation into the air.

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

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A confidential description of the product composition appears in Form 3480 of this Notification.

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 is 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 poultry chiller water. As shown in Attachment 4 to this Notification, 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 chiller tank water and other aqueous waste streams. (The half-life of hypobromous acid in low-demand tap water has been estimated by EPA as 125 hours. The hypobromous acid will degrade far more rapidly in the aqueous systems present in the poultry plant.) Thus, it is fully expected that no hypobromous acid will be released from the poultry plant. 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 the proposed use of the FCS.

As shown in Attachment 4 to this FCN, addition of DBDMH at the maximum level of 90 ppm results in a maximum DMH concentration of 40 ppm and a maximum bromide ion concentration of 50 ppm in the treated chiller water.

Introduction of the decomposition products of DBDMH into the environment will take place primarily via release in wastewater treatment systems. The total amount of DBDMH used at a typical facility can be estimated as shown below, although the actual amounts used will vary, depending on the available bromine concentration needed to treat the contamination level on the poultry and the number of poultry carcasses processed.

The chiller bath is normally filled once per day with approximately 25,000 gallons of water. Fresh make-up water will be added to the bath at the rate of approximately 0.5 gallons/bird. About 200,000 birds are submersed in chiller water per day at a typical processing facility.

Based on the above information, an estimate of the daily use of DBDMH in a poultry processing plant can be calculated as follows:

Initial water volume = 25,000 gallons.

Make up water = 0.5 gal/carcass x 200,000 carcasses/day = 100,000 gal/day.

Thus, total water volume = 25,000 gal + 100,000 gal = 125,000 gal/day

125,000 gallons water x 3.785 L/gal = 473,125 L = 473,125 kg water

Assuming DBDMH is added to both initial water and make up water at maximum level of 90 ppm (or 90 mg/kg), the total amount of DBDMH used is:

$473,125 \text{ kg water} \times 90 \text{ mg DBDMH/kg} \times 1 \text{ kg}/10^6 \text{ mg} = 42.6 \text{ kg}$

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, the amount of DMH produced from a given amount of DBDMH is calculated using the ratio of the molecular weight of DMH (128) to that of DBDMH (286). Thus, the amount of DMH produced from the addition of a total of 42.6 kg of DBDMH is calculated as follows:

$\text{DMH formed} = 42.6 \text{ kg DBDMH} \times (128 \text{ DMH} \div 286 \text{ DBDMH}) = 19.1 \text{ kg DMH}$

Similarly, the amount of bromide ion produced from the addition of 42.6 kg of DBDMH is calculated using the ratio of the weight of two bromide ions (159.8) to that of DBDMH, as follows:

$\text{Bromide ion formed} = 42.6 \text{ kg DBDMH} \times (159.8 \div 286) = 23.8 \text{ kg Br}^{(-)} \text{ ion}$

Therefore, the total amounts of DMH and bromide ion that may be formed in poultry chiller water in a typical poultry processing plant are approximately 19.1 kg and 23.8 kg per day, respectively. To calculate the concentration at which DMH and $\text{Br}^{(-)}$ ion may be introduced into

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the environment, we will assume that the entire quantities of these byproducts will ultimately enter the drain and be discharged to the on-site treatment facility.

To calculate the concentration at which DMH and Br⁽⁻⁾ ion may be present in poultry plant waste water, it is necessary to consider the total volume of waste water produced, which includes water from, *e.g.*, rinsing of the evisceration trough, viscera carriage flume, etc., as well as the chiller water.¹ For this purpose, we will assume an average waste water volume of 7 gallons per bird.² On this basis, the maximum DMH and Br⁽⁻⁾ ion concentrations in the waste water are calculated as follows:

$$7 \text{ gal/bird} \times 200,000 \text{ birds/day} = 1.4 \text{ million gal waste water/day}$$

$$1.4 \text{ million gal} \times 3.785 \text{ L/gal} = 5.3 \text{ million L/day} = 5.3 \times 10^6 \text{ kg waste water/day}$$

$$19.1 \text{ kg DMH/day} \div 5.3 \times 10^6 \text{ kg waste water/day} = 3.6 \times 10^{-6} \text{ kg DMH/kg water} \\ = 3.6 \text{ ppm DMH}$$

$$23.8 \text{ kg Br}^{(-)}/\text{day} \div 5.3 \times 10^6 \text{ kg waste water/day} = 4.5 \times 10^{-6} \text{ kg Br}^{(-)}/\text{kg water} \\ = 4.5 \text{ ppm Br}^{(-)} \text{ ion}$$

Even assuming that none of the DMH were degraded in the on-site waste water treatment facility, the level of DMH in the plant effluent would be significantly diluted upon being released to the publicly owned treatment works (POTW). Assuming a typical POTW with a daily flow of 25 million gallons per day, the maximum DMH concentration in water entering the POTW is calculated as follows:

¹ Wesley, R.L. (1985). Water reuse and conservation in poultry processing. *Poultry Sci.* 64:476. The author identifies the primary sources of waste water in poultry processing as consisting of the scalding and chiller overflow; viscera carriage flume; handwash stations and evisceration trough rinse; and plant sanitation program.

² Wesley, 1985, *id.* The author cites an average of 7 gallons per bird for broilers and 11-23 gallons per bird for turkeys.

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$$25 \text{ million gal/day} \times 3.785 \text{ L/gal} = 9.46 \times 10^7 \text{ L/day}$$

$$3.6 \text{ ppm DMH} \times (5.3 \times 10^6 \text{ L/day} \div 9.46 \times 10^7 \text{ L/day}) = 0.20 \text{ ppm DMH}$$

Similarly, the maximum concentration of bromide ion in water entering the POTW is calculated as follows:

$$4.5 \text{ ppm Br}^{(-)} \text{ ion} \times (5.3 \times 10^6 \text{ L/day} \div 9.46 \times 10^7 \text{ L/day}) = 0.25 \text{ ppm Br}^{(-)} \text{ ion}$$

7. Fate of Emitted Components in the Environment:

According to the calculations detailed above, DMH and bromide ion may be present in waste water received by POTWs at concentrations up to 0.20 ppm and 0.25 ppm, respectively. These also represent the maximum concentrations in effluent exiting POTWs assuming, very conservatively, that none of the DMH or bromide is lost during processing at the POTW. The actual concentrations at which the byproducts may be present in receiving waters into which POTW effluent is discharged will be even lower due to the dilution effect of mixing effluent with the water flowing through the receiving river or other body. Assuming that the effluent concentrations are diluted by as little as 10-fold, the maximum concentrations of DMH and bromide ion in the receiving water will be 0.020 ppm (20 ppb) and 0.025 ppm (25 ppb), respectively.

Data previously submitted to FDA indicate that DMH is relatively stable in water, but that DMH degrades rapidly to yield carbon dioxide in activated sludge.³ Therefore, the DMH produced as a byproduct of the addition of DBDMH to poultry chiller water is expected to be

³ See Environmental Assessment for Food Additive Petition No. 4B4418 (dealing with the use of bromochloro-5,5-dimethylhydantoin (BCDMH) as a slimicide in the production of food-contact paper and paperboard).

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degraded by the biological treatment facility at the poultry processing plant. If any DMH remains in the effluent from the poultry plant, this residual is expected to be fully degraded at the POTW. Thus, DMH is not expected to be present in treated waste water that is released from the POTW.

On the contrary, the bromide ion may remain in the treated waste water released from the POTW unless special steps are taken to remove it from the POTW effluent. As demonstrated by the data discussed in Item 8 below, however, it is unlikely that a receiving POTW would need to put such special steps into place given the absence of any environmental concern regarding the possible aqueous release of bromide ion at the maximum level calculated.

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. LC₅₀ values reported for DMH range from 1300 mg/L in grass shrimp to 14,200 mg/L in fathead minnow. Aquatic static bioassays of DMH indicate that DMH is not toxic at levels of 12,700 to 14,200 mg/L (sheepshead minnow, grass shrimp, oysters) and 1300 to 8100 mg/L (water flea).⁴

FDA previously established a toxic concentration criterion (TCC) for DMH of 29 mg/L based on the lowest observed adverse effect level.⁵ The maximum concentration at which DMH may be released into the environment, assuming no degradation in biological waste water treatment systems, was calculated above to be 0.02 ppm, or 0.02 mg/L. This is three orders of

⁴ See EA for FAP 4B4418, id.

⁵ See Finding of No Significant Impact (FONSI) for FAP 4B4418.

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magnitude below the TCC. 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.

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.⁶ (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 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 LC₅₀ 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. 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.⁷ The studies

⁶ Specifically, the database searched was the Environmental Protection Agency’s ECOTOX Ecotoxicology Database, located at <http://www.epa.gov/ecotox/>.

⁷ 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.

in question report a 96-hour LC₅₀ of 0.18 ppm for opossum shrimp, a 96-hour LC₅₀ of 0.47 ppm for the Virginia oyster, and a 96-hour LC₅₀ 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 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*.⁸ 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.

88-5-2736; Study No. 1199.0188.6109.505. Unpublished studies prepared by Springborn Life Sciences, Inc.

⁸ 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.

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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. Note that, where more than one value is given for the same endpoint in the same species, we have included only the lowest relevant value.

**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	LC 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 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

The lowest LC₅₀ given in the table above is 500 mg/L, in Daphnia magna. Other LC₅₀ values cited in the database for sodium bromide in Daphnia range from 6100 mg/L to over 15,000 mg/L. Thus, relying on the lowest LC₅₀ 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, 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 POTW effluent.

In the past, FDA has calculated the toxic concentration criterion (TCC) for a test compound as either the lowest NOEC or 1/100th of the lowest LC₅₀. In this case, the lowest LC₅₀ divided by 100 is 5.0 mg/L; thus, the lower TCC is that derived from the minimum NOEC, or 3.0 mg/L. By contrast, the maximum concentration at which bromide ion may be present in rivers or other bodies of water that receive POTW effluent was estimated above as 25 ppb (0.025 mg/L). This is two orders of magnitude below the estimated TCC for bromide ion. 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 does not present any concern with regard to potential aquatic toxicity.

To further put into perspective the possible release levels of bromide ion as a result of the proposed use of DBDMH, we note that a survey of bromide levels in drinking water supplies indicates that bromide is commonly present at far higher levels than those calculated here. Specifically, a survey report set forth as Appendix 4 to this Environmental Assessment demonstrates average Br⁽⁻⁾ ion concentrations in randomly selected utility samples of 61 to 64

mg/L (ppm). The worst-case release concentration calculated here represents a minute fraction of this background level.

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 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 poultry chiller water, the use of DBDMH as described will not lead to a net increase in the consumption of resources and energy.

10. Mitigation Measures

Based on the foregoing, no significant adverse environmental impacts are expected to result from the intended use of DBDMH. Thus, 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

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13. Certification

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

Date: June 2, 2003

John B. Dubeck



Keller and Heckman LLP