

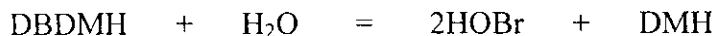
ENVIRONMENTAL ASSESSMENT

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4. Description of Proposed Action:

The action requested in this notification is the establishment of a clearance to permit the general use of 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) as an antimicrobial in water during red meat processing at a level not to exceed that needed to provide the equivalent of 300 ppm of available bromine in the water. The product will be introduced to facility process water and applied to animal hides, carcasses, heads, trim, parts, and organs to reduce the numbers of and inhibit the growth of pathogens and other bacteria

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



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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 (Br⁻). 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 300 ppm corresponds to a maximum DBDMH addition level of approximately 270 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 5 of this FCN.

This product is proposed for general use in red meat processing plants that may be located throughout the United States. DBDMH will be introduced to plant process water at the levels described above and applied as an antimicrobial to control the growth of pathogens on animal hides, carcasses, heads, trim, parts, and organs. Estimates of water usage in the meat processing industry vary. It has been reported that water usage, primarily from carcass washing and process clean-up during processing of beef, is in the range of 150 – 450 gal./animal processed.¹ The US Environmental Protection Agency (EPA) has reported the rate of wastewater generated at three hog and three cattle processing facilities ranged from 50 – 442 gal /1,000 lbs live weight killed.² Additionally, at 19 medium and large complex

¹ *Water Efficiency Manual for Commercial, Industrial, and Institutional Facilities Meat and Poultry Processing*; Division of Pollution Prevention and Environmental Assistance; Division of Water Resources of the North Carolina Department of Environment and Natural Resources, and Land-of-Sky Regional Council: Asheville, NC, Aug, 1998.
<http://www.p2pays.org/ref/01/00692.pdf>

² *Technical Development Document for the Final Effluent Limitations Guidelines and Standards for the Meat and Poultry Products Source Category (40 CFR 432) Volume 1 of 4*, EPA-821-R-

slaughterhouses, wastewater flows ranged from 435 – 1,500 gal /1,000 lbs live weight killed, with a mean value of 885 gal./1,000 lbs live weight killed.³ The International Finance Corporation has published industry benchmarks of 1.62 – 9 m³ water/ton slaughtered cattle. This corresponds to approximately 190 – 1077 gal./1,000 lbs live weight killed.³ Based on the above information, it is obvious that a wide range of water usage is possible in the beef processing industry. However, it is expected that the majority of water usage will occur in medium and large complex slaughterhouses. That is, those using in the range of 435 – 1,500 gal./1,000 lbs live weight killed (mean of 885 gal /1,000 lbs live weight killed). The United States Department of Agriculture (USDA) has reported that the average live weight of commercial cattle, calf, hog, sheep, and lamb slaughtered ranges from 137 – 1,275 pounds⁴ Based on an average water usage of 885 gal./1,000 lbs live weight killed and a worst case live weight of 1,275 lbs, a conservative estimate of water usage per carcass is calculated as follows:

$$885 \text{ gal./1,000 lbs live wt.} \times 1,275 \text{ lbs live wt.} = 1128 \text{ gallons water}$$

Therefore, it is estimated that a beef processing facility may utilize approximately 1128 gallons of water per processed carcass.

04-011, U.S. Environmental Protection Agency; Office of Water: Washington, D.C., Jul, 2004.
<http://www.epa.gov/guide/mpp/tdd/vol1.pdf>

³ *Environmental, Health, and Safety Guidelines for Meat Processing*, International Finance Corporation, World Bank Group. Apr 30, 2007.
[http://www.ifc.org/ifcext/enviro.nsf/AttachmentsByTitle/gui_EHSGuidelines2007_MeatProcessing/\\$FILE/Final+-+Meat+Processing.pdf](http://www.ifc.org/ifcext/enviro.nsf/AttachmentsByTitle/gui_EHSGuidelines2007_MeatProcessing/$FILE/Final+-+Meat+Processing.pdf) .

⁴ *Livestock Slaughter 2006 Summary*, Mt An 1-2-1(07), U.S. Department of Agriculture; National Agricultural Statistics Service: Washington, DC, Mar, 2007.
<http://usda.mannlib.cornell.edu/usda/current/LiveSlauSu/LiveSlauSu-03-02-2007.pdf> .

The primary route of disposal for water that has been treated with DBDMH is through the processing plant wastewater treatment facility. A majority of beef processors treat their wastewater on site and ultimately discharge directly into a receiving body of water or via land application. The plant process water (effluent) empties into drains and may contain fat and other solids which may be dislodged as the beef carcasses are washed, trimmed, and further processed. The effluent stream is screened or filtered to remove the solids and particulates prior to being sent to the Dissolved Air Flotation (DAF) cells. In the DAF area the water may be chemically treated and filtered further. The solids are sent to a rendering plant on site. The water from the pretreatment process is then pumped or sent to the wastewater treatment plant and/or to an anaerobic lagoon system where the fats, proteins, and waste products of slaughter and processing operations are digested. It is noted that although use of anaerobic treatment is common, it is not always utilized.² After the anaerobic lagoon system, the water is 1) sent to a waste activated sludge treatment facility where it is eventually released to a receiving stream, or 2) discharged directly into a large pond where it is fed through an irrigation system and applied over a large area of land. Only minor quantities are lost to evaporation into the air. A small amount of water containing these disinfectant by-products may be bound to solids and carried over to the rendering plant. However, the level of by-products carried over to the rendering plant on the fat and solids 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 as 0.35³. The magnitude of this number

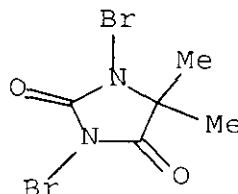
² 5,5-Dimethylhydantoin (DMH) High Production Volume (HPV) Chemical Challenge Test Plan, 201-14589A; American Chemistry Council Brominated Biocides Panel DMH Task Group;

indicates that DMH strongly prefers water than the oil phase. 3. A study was performed by Albemarle Corporation to determine if there is preferential uptake of DMH by beef meat sprayed with a water solution of DMH. The data showed that beef sprayed for 30 seconds, with water containing a known amount of DMH, did not result in a decrease of DMH from the water. The difference in concentration of DMH in the water before and after rinsing the beef meat was inconsequential. The final report from the above study is included in this FCN as attachment 11.

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



A confidential description of the product composition appears in 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 300 ppm available bromine in process water. As shown in Attachment 5 of this FCN, based on traditional industry usage of the term “available bromine,” this corresponds to a maximum DBDMH addition level of 270 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 red meat processing system given the high organic content of the water following contact with beef 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.⁶ The hypobromous acid will degrade far more rapidly in the aqueous systems present in the red meat processing plant.) Thus, it is fully expected that no hypobromous acid will be released from the processing facility. 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.

⁶ EPA Re-registration Eligibility Decision (RED), Inorganic Halides, September 1993

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As shown in Attachment 5 of this FCN and described in the following paragraphs, addition of DBDMH at the maximum level of 270 ppm results in a maximum DMH concentration of 121 ppm and a maximum bromide ion (Br^{-}) concentration of 151 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. 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 conservative estimate of the total amount of water used per processed carcass was calculated in section 4 as 1,128 gallons. Of course, not all of this water will contain DBDMH. Water consumption research indicates that much of the water used in beef processing is in the slaughtering and carcass washing process.¹ In an Australian survey, 44 to 60% of water consumption occurred in the slaughter, evisceration, and boning process.² Similar values have been reported in other publications.^{1,3,8,9} Water treated

¹ Hansen, P.; Christiansen, K.; Hummelose, B. *Cleaner Production Assessment in Meat Processing Chapter 2 Overview of Meat Processing*; United Nations Environment Programme, Division of Technology, Industry and Economics: 2000. http://www.agrifoodforum.net/publications/guide/m_chp2.pdf

with DBDMH is expected to be used primarily as a pre-evisceration carcass spray, a carcass wash, a head wash, parts wash, and as a mist or spray in the carcass aging rooms. It is estimated that approximately 18% of the total water used per head will be treated with DBDMH (see table below).¹⁰

Primary Use Areas	Application Rate (gal./min.)	Application Time (seconds)	Volume DBDMH-Treated Water/Carcass (gal./carcass)
Pre-Evisceration Carcass Spray	120	30	60 (120 x 0.5)
Carcass Wash	150	30	75 (150 x 0.5)
Head Wash	50	30	25 (50 x 0.5)
Parts Wash (represented by 30 carcasses)	20	30	0.33 (20 x 0.5/30)
Carcass Aging Room ^a	200	12	38.4
Total			198.7 gal./carcass (198.7/1128 = 17.6%)

^aNote that 4500 carcasses processed per day in 3 aging rooms = 1500 carcasses/room) Spray/mist is applied for 12 sec/min at the rate of 200 gal/min/room. So, 200 gal/min/room x 1 min/60 sec x 12 sec/min x 60 min/hr = 2400 gal/hr/room, 2400 gal/hr/room x 24 hrs x 1 room/1500 carcasses = 38.4 gal./carcass

Using a conservative estimate of 25%, the volume of DBDMH-treated water per head is calculated as follows:

$$1128 \text{ gal./head.} \times 0.25 = 282 \text{ gal. DBDMH-treated water/head}$$

⁸ Murphy, N. *Meat Processing Environmental Impacts*, Waste Reduction Resource Center: Jul 27, 2006. <http://wrre.p2pays.org/p2rx/subsection.cfm?hub=449&subsec=15&nav=15&CFID=1355636&CFTOKEN=24795527>

⁹ *Environmental Best Practice Guidelines for the Red Meat Processing Industry*; Meat and Livestock Australia: Apr, 2007. <http://www.mla.com.au/NR/rdonlyres/41275A51-823F-4A7A-B24E-8A0EE959EA58/0MLAEnvoBestPracManualsmall.pdf>

¹⁰ Tyson Fresh Meats, Inc., 800 Stevens Port Drive, Dakota Dunes, SD. 57049; Operating Plans, October, 2007.

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An Agricultural Marketing Report published in 2004, estimated that a small facility processed 20,000 head per year, a medium facility processed 480,000 head per year, and a large facility processed 1.5 million animals per year.¹¹ This results in approximately 77 head processed per day in a small facility (20,000 head/year x 1 year/52 weeks x 1 week/5 days), 1846 head per day in a medium facility (480,000 head/year x 1 year/52 weeks x 1 week/5 days), and 5769 head per day in a large facility (1,500,000 head/year x 1 year/52 weeks x 1 week/5 days). On this basis, we submit that 4500 head/day is a reasonable estimate for the number of cattle processed in a typical beef processing plant. For purposes of determining the level of by-products released into the environment, 282 gallons DBDMH-treated water/head will be used for calculations. The total amount of DBDMH used per day at the maximum approved level of 270 ppm (270 mg/kg) is calculated as:

$$\begin{aligned}
 &4500 \text{ head/day} \times 282 \text{ gal/head} = 1,269,000 \text{ gal water/day containing DBDMH} \\
 &1,269,000 \text{ gallons water/day} \times 3.785 \text{ L/gal.} = 4.8 \times 10^6 \text{ L/day} = 4.8 \times 10^6 \text{ kg water/day} \\
 &4.8 \times 10^6 \text{ kg water/day} \times 270 \text{ mg/kg} \times 1 \text{ kg}/10^6 \text{ mg} = 1297 \text{ kg DBDMH per day}
 \end{aligned}$$

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 5 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 1297 kg of DBDMH is calculated as follows:

$$\text{DMH formed} = 1297 \text{ kg DBDMH} \times (128.1 \text{ DMH} / 286 \text{ DBDMH}) = 581 \text{ kg DMH}$$

¹¹ Koontz, S. R.; Hoag, D. L. *community Development and the Profitability of Value-Added Meat Production and Processing*, February/No 99-01; Colorado State University; Cooperative Extension; Feb, 1999. <http://dare.colostate.edu/csusagecon/extension/docs/agmarketing/amr99-01.pdf>

Similarly, the amount of $\text{Br}^{(-)}$ produced from the addition of 1297 kg of DBDMH is calculated using the ratio of the weight of two bromide ions (159.8) to that of DBDMH, as follows

$$\text{Bromide ion formed} = 1297 \text{ kg DBDMH} \times (159.8 - 286) = 725 \text{ kg } \text{Br}^{(-)} \text{ ion}$$

Therefore, the maximum amounts of DMH and $\text{Br}^{(-)}$ ion present in process water applied directly to animal hides, carcasses, heads, trim, parts, and organs in a typical beef processing plant are approximately 581 kg and 725 kg per day, respectively.

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 filtered 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 the filtered solids into other usable products such as feed.

To calculate the maximum concentration at which DMH and $\text{Br}^{(-)}$ 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 $\text{Br}^{(-)}$ ion may be present in plant wastewater, it is necessary to consider the total volume of wastewater produced. This volume was previously estimated to be approximately 1128 gallons per processed carcass. On this basis, the maximum DMH and $\text{Br}^{(-)}$ ion concentrations in the wastewater are calculated as follows:

$$1128 \text{ gal./head} \times 4500 \text{ head/day} = 5,000,000 \text{ gal wastewater/day}$$

$$5,000,000 \text{ gal} \times 3.785 \text{ L/gal.} = 19.2 \times 10^6 \text{ L/day} = 19.2 \times 10^6 \text{ kg wastewater/day}$$

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$$581 \text{ kg DMH/day} - 19.2 \times 10^6 \text{ kg wastewater/day} = 3.0 \times 10^{-5} \text{ kg DMH/kg water} \\ = 30 \text{ ppm DMH}$$

$$725 \text{ kg Br}^{(-)}/\text{day} - 19.2 \times 10^6 \text{ kg wastewater/day} = 3.8 \times 10^{-5} \text{ kg Br}^{(-)}/\text{kg water} \\ = 38 \text{ ppm Br}^{(-)} \text{ ion}$$

7. Fate of Emitted Components in the Environment:

According to the calculations detailed above, DMH and Br⁽⁻⁾ ion may be present in wastewater at concentrations up to 30 ppm and 38 ppm, 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.¹² In an activated sludge biodegradation test, 94% of the DMH was removed in 19 days.⁵ On this basis, after 19 days in a wastewater or anaerobic lagoon environment, the DMH level in the effluent is expected to be much less and is calculated as follows:

$$30 \text{ ppm} \times (100\% - 94\%) = 1.8 \text{ ppm DMH remaining}$$

The actual concentrations at which the by-products may be present in receiving waters into which effluent is directly 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 Br⁽⁻⁾ ion in the receiving water will be 0.18 ppm and 3.8 ppm, respectively.

Therefore, the majority of DMH produced as a byproduct of the addition of DBDMH to water is expected to be degraded in the facility wastewater treatment and lagoon systems prior to

¹² See EA for FAP 4B4418, id.

being released into a receiving body of water. Thus, DMH is not expected to be present significantly in wastewater that is released directly from the plant

On the contrary, the Br⁽⁻⁾ ion may remain in the water released from the wastewater treatment facility, unless steps are taken to remove it from the effluent. As demonstrated by the data discussed in Section 8 below, however, it is unlikely that a facility 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 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 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)¹³ 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 minnows at 29 mg/L but not at 14 mg/L¹⁴ 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 0.18 mg/L, where the effluent concentration is only reduced by the standard dilution factor of 10, is more than 100

¹³ See EA for FAP 4B4418, 1d

¹⁴ High Production Volume Information System, <http://www.epa.gov/hpv/hpvjs/index.html> (accessed Oct. 16, 2007)

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.

Aquatic Toxicity Data on 5,5-Dimethylhydantoin⁵

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.¹⁵ (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 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.¹⁶ The studies in question report a 96-hour LC₅₀ of 0.18 ppm for opossum

¹⁵ Specifically, the database searched was the Environmental Protection Agency’s ECOTOX Ecotoxicology Database, located at <http://www.epa.gov/ecotox/>

¹⁶ 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.

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*¹⁷. 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.

¹⁷ 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

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.

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 EC₅₀ or LC₅₀ given in the table above is 500 mg/L, in Daphnia magna. Other EC₅₀ 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). Thus, relying on the lowest relevant EC₅₀ 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 1/100th of the lowest LC₅₀ (or acute EC₅₀). In this case, the lowest EC₅₀ 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 that receive effluent directly was estimated in section 7 as 3.8 ppm. This is approximately the TCC for bromide ion as derived above. This maximum bromide ion level is a conservative estimate and is not ever expected to occur. It is unrealistic to assume that a beef processor would add the maximum level of DBDMH to 25% of the process water in its establishment. Thus, we respectfully submit that the possible presence of bromide ion in waste water from red meat 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. 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.¹⁸

“As discussed earlier, EPA conducted a Tier 1c 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

¹⁸ RED Facts Inorganic Halides, EPA-738-F-93-015; U S Environmental Protection Agency: Washington, D.C , 2007 <http://www.epa.gov/oppsrrd1/REDs/factsheets/4051fact.pdf>

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 "

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).¹⁹ 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.²⁰ 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.

¹⁹ *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)

²⁰ 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

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 the beef 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 RED 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”*¹⁹

“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 ²¹ Active products include EPA Registration No's 3377-61, 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 beef processing industry, such action would have no environmental impact. In view of the excellent properties of DBDMH as an antimicrobial treatment for beef, 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.

²¹ National Pesticide Information Retrieval System,
<http://ppis.ceris.purdue.edu/htbin/ppismenu.com> (assessed Oct. 22, 2007)

13. Certification

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

Date: 11/26/07

Signature of Responsible Official:

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