ATTACHMENT 7:

Environmental Assessment For
Dimethylhydantoin (DMH) Food-Contact Notification (FCN)

000091

ENVIRONMENTAL ASSESSMENT FOR DIMETHYLHYDANTOIN (DMH) FOOD-CONTACT NOTIFICATION (FCN)

1. **Date:**

   October 21, 2002

2. **Name of Notifier:**

   Lonza Inc.

3. **Address:**

   c/o Lewis & Harrison, 122 C Street, NW, Suite #740, Washington, DC 20001

4. **Description of Proposed Action:**

This FCN requests the use of 5,5-dimethylhydantoin (DMH) as a halogen stabilizer for use with hypohalite compounds, such as sodium hypochlorite, that are used as slimicides in the manufacture of food-contact paper and paperboard. The maximum use-rate of DMH is 0.5 kg per 1,000 kg of dry weight fiber. DMH will be co-applied to paper mill process water with the hypohalite slimicide. In process water, DMH will rapidly combine with active halogen to form a halohydantoin. The reaction forming the halohydantoin is reversible so the halohydantoin is converted back into DMH and halogen. The stabilizing activity of DMH serves to prolong the lifetime of active halogen, which results in an even distribution, throughout process water, of active halogen. Accordingly, microbial control in paper mill process water is significantly enhanced.

The trade name for the formulated product containing DMH is Equinox.

The combination of DMH and hypohalites is an alternative to the halohydantoins, which are approved, pursuant to 21 C.F.R. §176.300, as slimicides in the manufacture of food-contact paper and paperboard. The DMH/hypohalite system is designed for users who desire a liquid system; the halogenated hydantoins are solids that require specialized feeders. It should be noted that this FCN will not result in any increases in environmental releases of DMH since the maximum amount of DMH added to paper mill process water, as either a halogen stabilizer or from the halohydantoins, is the same.

DMH will be used nationwide by paper and paperboard manufacturers. The only environment release is discharge to water as part of plant effluent.

5. **Identification of Chemical Substances that are Subject to the Proposed Action:**

Chemical Name

2,4-imidazolidinedione, 5,5-dimethyl-

Common/Trade Names

5,5-dimethylhydantoin (DMH)

CAS Reg. No.

77-71-4

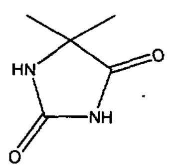
Molecular Weight

128

Chemical Formula

$C_3H_8N_2O_2$

Structure



000093

Impurities Associated with DMH

Chemical Name	CAS Reg. No.	Maximum Level

Chemical/Physical Properties

Properties	Values
Specific Gravity	1.25 @ 25°C
Solubility (aqueous)	135 g/l
pH	6.0-7.5

6. Environmental Consequences of the Proposed Action:

a) Production of the Food-Contact Substance

There are no extraordinary circumstances that apply to the manufacture of DMH and, therefore, information about environmental introductions resulting from the production of this substance need not be included in the Environmental Assessment.

b) Introduction of Substances into the Environment as a Result of Use/Disposal

1) Market Volume

The estimated market volume for the use of DMH as a stabilizer for hypohalite compounds, used as slimicides in the manufacture of paper and paperboard, can be found in Confidential Attachment for this Environmental Assessment.

2) Environmental Releases/Disposal

For the reasons given above in Section 4 of the Environmental Assessment, this FCN will not result in any increases in environmental releases of DMH including, releases from the disposal of paper packaging containing DMH.

3) Expected Environmental Introduction Concentration (EIC)[1]

The EIC for DMH discharge into water, from its use as a halogen stabilizer, can be determined using the following equation:

EIC = (Maximum Dosing Rate in Process Water) (1- % Biodegradation/Removal Rat in Wastewater Treatment)

The maximum dosing rate for DMH is 0.5 kg per 1,000 kg of dry weight fiber, which is equivalent to 5.0 ppm[2] of DMH in process water. Since DMH is ultimately biodegradable under acclimating conditions, a 20% biodegradation/removal value is anticipated for DMH during wastewater treatment.

Accordingly, the EIC for DMH is:

(5.0 ppm) (0.80) = 4.0 ppm

---

[1]Although no increases in environmental releases of DMH will result from this FCN, EIC (and EEC) estimates are being provided to demonstrate that the FCN does not present any environmental risks of concern.

[2]The 5.0 ppm value was derived by assuming that the paper slurry, into which DMH is applied, is approximately 1% pulp. Since the maximum application rate of DMH is 0.5 kg/1000 kg of dry paper, the parts-per-million (ppm) level in the slurry is:

0.5 kg ÷ 1000kg/0.01 = 0.5 kg/100,000 kg or 5.0 ppm

c) Fate of Substances Released Into the Environment

1) Environmental Fate Studies

The standard USEPA environmental fate laboratory studies have been conducted with DMH. The studies show that DMH is hydrolytically and photolytically stable, mobile in soil, resistant to aquatic degradation under non-acclimating conditions but ultimately biodegradable under acclimating conditions. In addition, DMH has a low potential to bioaccumulate since the octanol/water partition coefficient is 0.35. The DMH environmental fate studies are summarized in Table 1 (on the proceeding page) of this Environmental Assessment.

2) Estimated Environmental Concentration (EEC)

The EEC for DMH can be derived by applying a dilution factor (from the receiving water body) to the EIC. Lonza believes a dilution factor of 20 is a reasonable "worst-case" value for paper mill effluent. A 1995 report[1], by the Swedish National Chemical Inspectorate, evaluating environmental risks and hazards of slimicides used in Sweden, employed a dilution factor of 100 (the report did note that there is considerable variation of dilution factors between different water recipients). Additional support for a dilution factor of 20 is provided in a 1991 study of discharges from paper mills sponsored by the National Council for Air and Stream Improvement (NCASI)[2]. The NCASI study found that there has been, since 1980, a substantial reduction in effluent discharged from paper mills. Finally, recent environmental regulations, such as USEPA's effluent restrictions for pulp and paper production, will further curtail water discharge from paper mills.

Using a dilution factor of 20, the EEC for DMH is as follows:

Substance	EIC	Dilution Factor	EEC
EMH	4.0 ppm	20	0.20 ppm

[1]Eriksson, U., et. al., *Risk Assessment of Slimicides*, Kemi Report No. 9/95, Swedish National Chemicals Inspectorate (1995).

[2]Miner, R. and J. Unwin, *Progress in Reducing Water Use and Wastewater Loads in the U.S. Paper Industry*, p 127-131, TAPPI Journal, August, 1991.

000096

TABLE 1
Laboratory Environmental Fate Studies with DMH

Test	Test Description	Result
Hydrolysis	Hydrolysis of DMH was determined at pH 5, 7 and 9.	DMH is hydrolytically stable at all pH's.
Aqueous Photolysis	Photodegradation of DMH was evaluated by exposing DMH to a light source simulating natural sunlight for 30 days.	DMH is photolytically stable.
Aerobic Aquatic Metabolism	Microbial degradation of DMH was evaluated under non-acclimating aerobic conditions.	Minimal degradation of DMH was observed; half-life for degradation, under the conditions of the study, is 1170 days.
Anaerobic Aquatic Metabolism	Microbial degradation of DMH was evaluated under non-acclimating anaerobic (flooded sediment) conditions.	Minimal degadation of DMH was observed; under the conditions of the study the half-life is 1144 days.
Soil/Sediment Adsorption/Desorption	Leaching potential of DMH was evaluated in several representative (clay loam, sandy loam and sand) soils.	DMH is highly mobile in all soil types.
Modified OECD Screening Test*	DMH was exposed to a mixed microbial population (garden soil, secondary effluent and surface water) under minimal acclimating conditions	By day 28, average percent removal of DMH was 10.1%, indicating low level of biodegradation.
Modified SCAS Test Method*	DMH was exposed to enriched microbial population (secondary activated sludge and raw sewage) and acclimated for a 16-day period.	After a 16-day acclimation period, biodegradation of DMH proceeded rapidly. From test day 18 until study completion, average percent removals were greater than 95%. Consequently, under the conditions of the study, DMH is considered ultimately biodegradable.
*Full copies of these studies can be found in Food Additive Petition (FAP) No 3B4367		

d) Environmental Effects of Released Substances

A comprehensive data base has been compiled on the aquatic toxicity of DMH. Acute and long-term aquatic studies are summarized below in Tables 2 and 3. The studies show that, on an acute basis, DMH is practically non-toxic to freshwater and marine organisms and is only slightly toxic to aquatic invertebrates and fish on a chronic basis.

TABLE 2
ACUTE AQUATIC STUDIES CONDUCTED WITH DMH*

STUDY TYPE	TEST SUBSTANCE	RESULT
96-hr. Acute LC50- Rainbow Trout	Dimethylhydantoin	LC50 >972.2 ppm
96 hr-Acute LC50 - Bluegill Sunfish	Dimethylhydantoin	LC50 >1017 ppm
96-hr.-Acute LC50 - Fathead Minnow	Dimethylhydantoin	LC50 >1085 ppm
48-hr.-Acute LC50 - *Daphnia magna*	Dimethylhydantoin	LC50 >1070 ppm
96-hr.-Acute LC50 - Mysid Shrimp	Dimethylhydantoin	LC50 >921.7 ppm
96-hr.-Acute LC50 - Sheepshead Minnow	Dimethylhydantoin	LC50 >1006 ppm
96-hr.- Acute LC50- Eastern Oyster	Dimethylhydantoin	EC50 >125 ppm
*The referenced studies are associated with F AP# 4B4418.		

TABLE 3
LONG-TERM AQUATIC TOXICITY STUDIES CONDUCTED WITH DMH*

STUDY TYPE	TEST SUBSTANCE	RESULT
Life-Cycle Toxicity Test in *Daphnia magna*	Dimethylhydantoin	NOEC[1]: 70.9 ppm MATC[2]: 90 ppm LOEC[3]: 116 ppm
Early Life-Cycle Toxicity Test in the Fathead Minnow	Dimethylhydantoin	NOEC: 14 ppm MATC: 20 ppm LOEC: 29 ppm

*Full copies of the referenced studies can be found in FAP No. 3B4367.
[1]No-Observable Effect Concentration
[2]Maximum Allowable Toxicant Concentration
[3]Lowest-Observable Effect Concentration

Based on the results of the aquatic toxicity studies, the EEC for DMH is less than 1/500 of the acute LC_{50} and/or EC_{50} and less than 1/50 of the MATC. It should also be noted that the EEC assumes no further biodegradation of DMH in the receiving water body. Since DMH is expected to undergo biodegradation in water the actual EEC value should be lower. In addition, effluent discharges from paper mills are regulated by EPA under Section 402 of the Clean Water Act and 40 CFR Part 122. The regulatory mechanism to control point-source discharges is a permitting process formally known as a NPDES (National Pollutant Discharge Elimination System) permit. Accordingly, discharges of DMH from paper mills will need to be in accordance with the applicable NPDES permit.

7. Use of Resources and Energy

Since DMH, in conjunction with hypohalite compounds, will substitute for the halohydantoins, this FCN will not result in any significant increases in resources or energy.

8. Mitigation Measures

Mitigation measures need not be considered because no potential adverse effects have been identified.

9. Alternatives to Proposed Action

Alternatives to the proposed action need not be considered because no potential adverse effects have been identified.

10. List of Preparers

This EA was prepared for Lonza Inc., by Christina Swick and Eliot Harrison of Lewis & Harrison. Ms. Swick's training and background is in environmental health sciences and Mr. Harrison's background is in biology and chemistry.

11. Certification

The undersigned official certifies that the information presented is true, accurate, and complete to the best knowledge of Lonza Inc.

Name: Eliot I. Harrison

Title: Agent for Lonza

Signature:

Date: October 21, 2002