ATTACHMENT 3
ENVIRONMENTAL ASSESSMENT

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1. **Date:**

   December 29, 2001

2. **Name of Notifier:**

   Lonza Inc.

3. **Address:**

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

4. **Description of Proposed Action:**

The notification requests the use of a mixture of methylolhydantoins (1,3-bis-hydroxymethyl-5,5-dimethylhydantoin and hydroxymethyl-5,5-dimethylhydantoin), at a ratio of approximately 1:1, as preservatives for mineral (pigment) slurries of clay, kaolin clay, calcium carbonate and titanium dioxide that are used as components of coatings and/or fillers employed in the manufacture of food-contact paper and paperboard. The methylolhydantoin mixture may contain up to 8.5% of dimethylhydantoin (DMH) on a dry basis (5.5% in the formulated product). The methylolhydantoin mixture will be marketed under the trade name Dantogard 2000.

The methylolhydantoins will be added to the mineral slurries at a minimum application rate of 400 ppm and a maximum rate of 1100 ppm. The mineral slurries containing the methylolhydantoins will be used nationwide by paper and paperboard mills.

The methylolhyantoin mixture (Dantogard 2000) covered by this notification is very similar to the methylolhydantoin mixture, known as Dantogard, that was the subject of Food-Contact Notification Number 104. The differences are that Dantogard 2000 contains less free formaldehyde (<0.1% vs. 2%) than Dantogard. In addition, the ratio of the methylolhydantoins in Dantogard 2000 is approximately 1:1 compared to 4:1 for Dantogard. However, since the application sites for Dantogard 2000 and Dantogard are the same and the use-rates are equivalent, this notification will not result in any increases in market volume or environmental releases for the methylolhydantoins or their degradates[1].

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[1] At a maximum application rate of 1100 total methylolhydantoins for Dantogard 2000, the environmental releases of the degradates (DMH and formaldehyde) are practically the same as the maximum application rate of 1200 ppm total methylolhydantoins for Dantogard.

The methylolhydantoins will be produced at the petitioner's manufacturing site identified below:

Lonza, Inc.
3500 Trenton Avenue
Williamsport, PA

The manufacturing site is located in an industrial park on the outskirts of Williamsport, PA. The Susquehanna River is approximately one mile from the manufacturing site. To the east of the manufacturing site is undeveloped land (railroad tracks and woods); an industrial park is south of the site and north of the site is a residential area.

Upon use, the methylolhydantoins decompose into dimethylhydantoin (DMH) and formaldehyde. These decomposition products, as well as "free" DMH associated with Dantogard 2000, may be released to water during the manufacture of paper containing preserved mineral slurries that are used as paper fillers. As noted above, both the nature and amount of these environmental releases will be the same as from currently approved methylolhydantoin mixtures. The use of the preserved mineral slurries as components of paper coatings is a "dry-end" use and, therefore, should also result in negligible environmental releases during the drying of the coating.

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

The subject additives are methylolhydantoins. Chemical identity information on these methylolhydantoins is presented below.

Chemical Abstract Service Names

- 2,4-imidazolidinedione, 1,3-bis(hydroxymethyl)-5,5- dimethyl
- 2,4-imidazolidinedione, hydroxymethyl-5,5-dimethyl

Common/Trade Names

- 1,3-bis (hydroxymethyl)-5,5-dimethylhydantoin
- Hydroxymethyl-5,5-dimethylhydantoin
- Dimethylol dimethylhydantoin (DMDMH)
- Monomethylol dimethylhydantoin (MMDMH)

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CAS Reg. Nos.

- 6440-58-0 (DMDMH)
- 27636-82-4 (MMDMH)

Molecular Weights

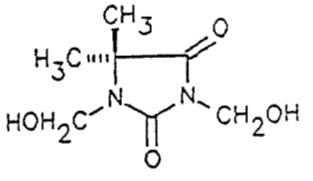
- DMDMH - 188.18
- MMDMH - 158.16

Chemical Formulas

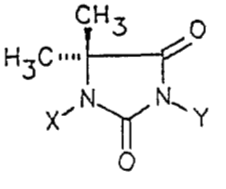
- DMDMH - $C_7H_{12}N_2O_4$
- MMDMH - $C_6H_{10}N_2O_3$

Structures

1,3-Bis(hydroxymethyl)-5,5-dimethylhydantoin



Hydroxymethyl-5,5-dimethylhydantoin



X,Y = H or CH_2OH

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Impurities (in the formulated product, Dantogard 2000)

Chemical Name	CAS Reg. No.	Typical Level	Max. Level

Chemical/Physical Properties

Properties	Values
Melting Point	DMDMH: 102-104°C MMDMH: 116-121°C
Solubility	DMDMH - Water: 77.3 g/100 cc - Ethanol: 56.4 g/100 cc - Hexane: 0.02 g/100 cc MMDMH - Water: 83.3 g/100 cc - Ethanol: 54 g/100 cc - Hexane: 0.11 g/100 cc

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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 the methylolhydantoins, as Dantogard 2000, and, therefore, information about environmental introductions resulting from the production of these substances 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 all FDA regulated uses of the methylolhydantoins is included in the confidential appendix for this notification. The FDA regulated uses comprising the market volume estimate are as follows:

- As a preservative for clay slurries that are used as fillers for paper (21 C.F.R. Part 176.170).
- As an adjuvant in the bleaching of recycled paper fibers (FCN-99 and FCN-168).
- As a preservative for mineral slurries (clay, titanium dioxide and calcium carbonate) that are used as components of paper coatings (FCN-104).
- As a preservative for mineral slurries (titanium dioxide and calcium carbonate) that are used as fillers for paper (FCN-104).

Since the use-sites and application rates for the methylolhydantoin mixture covered by this FCN are essentially the same as those currently approved, the total market volume will not change. In other words, the market volume for this notification will substitute for the market volume of methylolhydantoins currently being sold.

2) Environmental Releases

As discussed below, the environmental releases covered by this notice will be the same as those for methylolhydantoin mixtures previously approved, both in the nature of the substances released and their levels.

3) Expected Environmental Introduction Concentration (EIC)

The EIC's for DMH and formaldehyde, from the use of the methylolhydantoins (applied as Dantogard 2000), as preservatives for mineral slurries that are used as paper fillers, can be estimated by determining the amount of these substances transferred into water from mineral slurries and any removal from biodegradation in wastewater treatment. The following inputs are used to derive the EIC's:

- The maximum application rate for the methylolhydantoins in the mineral slurry is 1100 ppm or 0.0011 lbs/lb of filler.
- The DMH/formaldehyde ratio from the degradation of the methylolhydantoins and from "free" DMH in Dantogard 2000 is 76:24.
- The mineral slurry is approximately 10% of the paper weight.
- Daily production, per plant, of paper is 600 tons.
- Total effluent for a paper mill is approximately 2 million gallons per day[1]
- For DMH, a 20% removal during wastewater treatment is assumed since DMH is ultimately biodegradable under acclimating conditions. For formaldehyde, a 95% removal is assumed since formaldehyde is readily biodegradable.

Accordingly, the EIC for DMH is:

(Paper production/day) (lbs/ton) (Application rate of Methylolhydantoins) (Amount of Mineral Slurry per lb of paper) (1 - % of Removal Rate) (Percentage of Methylolhydantoins that are DMH) ÷ (Plant Effluent in Gallons Per Day) (lbs/gal)

(600 tons/day) (2000 lbs/ton) (0.0011 lbs/lb of mineral slurry) (0.1 lb of mineral slurry/lb of paper) (0.8) (0.76) (2 x 10^6 gallons/day) (8.33 lbs/gal) = 4.8 ppm

and the EIC for formaldehyde is:

(600 tons/day) (2000 lbs/ton) (0.0011 lbs/lb of mineral slurry) (0.1 lb of mineral slurry/lb of paper) (0.05) (0.24) (2 x 10^6 gallons/day) (8.33 lbs/gal) = 0.09 ppm

The corresponding DMH and formaldehyde EIC's for Dantogard usage, as indicated in FCN-104, are 4.8 ppm and 0.12 ppm, respectively. The formaldehyde EIC is lower since Dantogard 2000 contains contains less formaldehyde.

[1]The effluent value is from the following USEPA report: *Development Document for Effluent Limitation, Guidelines and Standards for Pulp, Paper and Paperboard* (1982). A survey of paper mills sponsored by the National Council for Air and Stream improvement (NCASI) indicates that the overall effluent may be somewhat higher.

c). FATE OF SUBSTANCES RELEASED INTO THE ENVIRONMENT

DMH 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 EA.

Formaldehyde Environmental Fate Studies

According to the published literature, formaldehyde is rapidly biodegraded in aqueous systems. In the die-away test using water from a stagnant lake, degradation was complete in 30 hours under aerobic conditions and 48 hours under anaerobic conditions. Another study showed formaldehyde is also degraded by activated sludge and sewage in 48-72 hours[1].

Estimated Environmental Concentrations (EEC's)

The EEC's for DMH and formaldehyde can be derived by applying a dilution factor of the receiving water body to the EIC's. Lonza believes a dilution factor of 20 is a reasonable "worst-case" value for paper mills. A 1995 report[2], 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)[3]. The NCASI study found that there has been a substantial reduction in effluent discharged from paper mills. Finally, recent environmental regulations, such as USEPA's effluent limitations for pulp and paper production, will further curtail effluent discharge from paper mills.

Using a dilution factor of 20, the EEC's for DMH and formaldehyde are as follows:

Substance	EIC	Dilution Factor	EEC
DMH	4.8 ppm	20	0.24 ppm
Formaldehyde	0.09 ppm	20	0.0045 ppm

[1]Kitchens, JF et. al., *Investigation of selected potential environmental contaminants; formaldehyde*, p 99-110, USEPA 560/2-76-009 (1976).

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

[3]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.

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	Photo degradation 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.

The corresponding DMH and formaldehyde EEC's for Dantogard usage, as indicated in FCN-104, are 0.24 ppm and 0.006 ppm, respectively.

d). Environmental Effects of Released Substances

A comprehensive data base has been compiled on the aquatic toxicity of DMH. Tables 2 and 3 summarize acute and long-term aquatic studies conducted with DMH.

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 FAP# 4B4418.

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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

Formaldehyde

According to the Hazardous Substances Data Base (HSDB), several acute aquatic studies have been conducted with formaldehyde. A summary of the key studies is presented in Table 4 below. In addition, studies performed on a variety of fish and shrimp have shown that formaldehyde does not bioaccumulate.

TABLE 4
ACUTE AQUATIC STUDIES CONDUCTED WITH FORMALDEHYDE

STUDY TYPE	TEST SUBSTANCE	RESULT
Acute LC50- Rainbow Trout	Formaldehyde	LC_{50}: 89- 440 ppm
96.hr-Acute LC50 - Bluegill Sunfish	Formaldehyde	LC_{50}: 100 ppm
96-hr.-Acute LC50 - Fathead Minnow	Formaldehyde	LC_{50}: 24.1 ppm
96-hr.-Acute LC50 - Striped Bass larvae	Formaldehyde	LC_{50}: 10 ppm

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The studies show that DMH, an acute basis, is practically non-toxic to freshwater fish and marine organisms and only slightly toxic to aquatic invertebrates and fish on a chronic basis and that formaldehyde is slightly toxic to freshwater fish and moderately toxic to marine organisms. Moreover, since the DMH exposure from Dantogard 2000 and Dantogard is the same and the formaldehyde exposure is slightly lower the potential environmental risks are not increased.

7. Use of Resources and Energy

As noted above, the methylolhydantoin mixture convered by this notification will substitute for a previous cleared methylolhydantoin mixture. Accordingly, this notification will lead to any changes in the use or resources of 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: December 29, 2001

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