ATTACHMENT 3
ENVIRONMENTAL ASSESSMENT

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1. **Date:**

   July 27, 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 adjuvants in the bleaching of recycled paper. The methylolhydantoin mixture may contain up to 8.5% of dimethylhydantoin (DMH) on a dry basis. The methylolhydantoin mixture will be marketed under the trade name Catagard 2000.

Upon aqueous dilution, the methylolhydantoins release formaldehyde, which binds and inactivates the enzyme catalase. Since catalase decomposes the bleaching agent hydrogen peroxide, the methylolhydantoins serve to maintain the bleaching activity of hydrogen peroxide.

The methylolhydantoins will be applied to process water during the bleaching of recycled paper at application rates ranging from 60-180 ppm. The bleaching process water, which contains the recycled paper fibers, will then be mixed with the pulp slurry (virgin fibers) to produce food-contact paper and paperboard. The notifier anticipates that the methylolhydantoins will be used nationwide by paper and paperboard mills.

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

The manufacturing site is located in an industrial park on the outskirts of
The 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.

The only potential significant environmental release anticipated from the use of the methylolhydantoins is discharge to water, as part of plant effluent, of the methylolhydantoin degradates, dimethylhydantoin (DMH) and formaldehyde. Since the estimated environmental concentrations (EECs) for DMH and formaldehyde are substantially lower than the levels expected to be toxic to non-target (aquatic) organisms the petitioner does not expect any adverse effects on non-target organisms.

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 Names

- 1,3-bis (hydroxymethyl)-5,5-dimethylhydantoin
- Hydroxymethyl-5,5-dimethylhydantoin

Common/Trade Names

- Dimethylol dimethylhydantoin (DMDMH)
- Monomethylol dimethylhydantoin (MMDMH)
- Catagard (trade name for a ~65% aqueous solution of the methylolhydantoins)

CAS Reg. Nos.

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

Molecular Weights

- DMDMH - 188.18
- MMDMH - 158.16

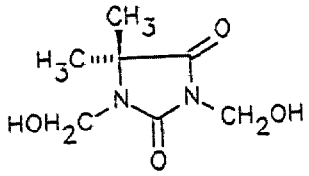
Chemical Formulas

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

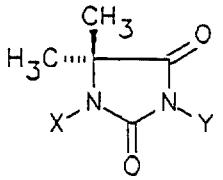
000030

Structures

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



Hydroxymethyl-5,5-dimethylhydantoin



X,Y = H or CH_2OH

X ≠ Y

Impurities

Chemical Name	CAS Reg. No.	Typical Level	Max. Level
Formaldehyde	50-00-0	0.45%	0.6%
Methanol	67-56-1	0.25%	0.3%
Dimethylhydantoin	77-71-4	5.2%	5.5%
Sodium Hydroxide	1310-73-2	<0.1%	<0.1%

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

000031

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, 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

As noted above, the methylolhydantoins decompose upon appreciable dilution yielding DMH and formaldehyde. Accordingly, the substances that will be introduced into the environment, or remain with paper and paperboard, from the use of the methylolhydantoins in bleaching process water are DMH and formaldehyde.

Almost all the DMH and formaldehyde are expected to remain with paper mill process water[1] since both substances are water soluble and are not substantive to paper. Based on an estimated maximum annual market volume of (**this information is considered Confidential Business Information and has been removed to a Confidential Appendix**) for the methylolhyantoins when used in the bleaching of recycled paper approximately 99% or (**Removed to Confidential Appendix**) of DMH and formaldehyde will either be released to the environment (or biodegraded prior to release) and less than 1% (or **Removed to Confidential Appendix**) of DMH and formaldehyde will stay with paper and paperboard[2].

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[1]Releases of formaldehyde to air are expected to be insignificant since the Henry's Law Constant for formaldehyde, as reported in the Hazardous Substances Database, is 3.27×10^{-7} atm-cum/mole.

[2]Based on the minimal amounts of DMH and formaldehyde in food-packaging material the environmental introduction of DMH and formaldehyde, from the disposal of food packaging material containing these substances, in municipal solid waste combustors or landfills are not environmentally significant. Therefore, we do not expect that any limited increases in environmental introductions resulting from the proposed action will violate EPA's regulations for either combustors (40 CFR Part 60) or landfills (40 CFR Part 258).

For all FDA regulated uses of the methylolhydantoins, the estimated maximum annual market volume is (**Removed to Confidential Appendix**). Based on this volume, approximately (**Removed to Confidential Appendix**) of DMH and formaldehyde will be released to the environment (or biodegraded prior to release) and approximately (**Removed to Confidential Appendix**) of DMH and formaldehyde will remain with paper and paperboard.

The expected introduction concentration (EIC) of DMH and formaldehyde into water, as a result of methylolhydantoin use in the bleaching of recycled paper, can be estimated by using the following equation:

EIC = (Maximum Dosing Rate in Bleaching Process Water) (1/Dilution in Paper Mill Process) (1- %Biodegradation/Removal in Wastewater Treatment)

For DMH, the maximum dosing rate is 152 ppm (137 ppm from the DMH component of the methylolhydantoins, 76% X 180 ppm, and 15 ppm from free DMH). The dilution in paper mill process water is roughly five-fold since the pulp concentration is reduced from approximately 3% in the bleaching process water (for recycled paper) to approximately 0.6% at the headbox. Since DMH is ultimately biodegradable under acclimating conditions (refer to next section) a 20% biodegradation/removal value is anticipated for DMH during wastewater treatment.

Based on the above, the EIC for DMH is:

(152 ppm) (0.20)(0.80) = 24.3 ppm

For formaldehyde, the maximum dosing rate is 24% of 180 ppm or 43 ppm. As with DMH, the dilution in paper mill process water is five-fold. Since formaldehyde is readily biodegradable in water systems, it is anticipated that 95% of formaldehyde is degraded during wastewater treatment.

Accordingly, the EIC for Formaldehyde is:

(43 ppm) (0.20) (0.05) = 0.43 ppm

Although there are other FDA regulated uses of the methylolhydantoins, cumulative EIC's are not being addressed in this EA since the use of the methylolhydantoins as adjuvants in the bleaching of recycled paper is currently permitted pursuant to Food-Contact Notification (FCN) No. 99 and the EIC's derived in this EA and the EIC's associated with the EA for FCN Number 99 are practically the same.

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.

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)

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	24.3 ppm	20	1.21 ppm
Formaldehyde	0.43 ppm	20	0.02 ppm

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

000035

[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.

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. The studies show that DMH on an acute basis is practically non-toxic to freshwater and marine organisms and 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 FAP# 4B4418.

000036

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.

000037

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

Based on the results of the aquatic toxicity studies, the EEC for DMH is greater than 1/100 of the acute LC_{50} or EC_{50} and approximately 1/20 of the MATC. For formaldehyde, the EEC is approximately 1/300 of the acute LC_{50}. These values clearly indicate that the subject use of the methylolhydantoins will not present any increased risks to aquatic organisms. It should also be noted that the EEC values assume no further degradation of DMH or formaldehyde in the receiving water body. Both substances are expected to undergo biodegradation in these water bodies so the actual EEC's should be lower than estimated. Finally, it should also be noted that effluent discharges from paper mills are regulated, by the Environmental Protection Agency, under Section 402 of the Clean Water Act and 40 CFR Part 122. These discharges are regulated through a permitting process called the National Pollution Discharge Elimination System (NPDES). Accordingly, discharges of DMH and formaldehdye from paper mills using the methylolhydantoins as bleaching agents for recycled paper will need to be in accordance with the applicable NPDES permit.

7. Use of Resources and Energy

The methylolhydantoins will replace or substitute for other substances, such as glutaraldehyde, that are already being used for bleaching of recycled paper and paperboard fibers. Consequently, we do not expect that the use of the methylolhydantoins will to lead to a significant change in the use of resources and 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.

000038

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: July 27, 2001

000039