EN

ENVIRONMENTAL ASSESSMENT

1. **Date:**
   October 25, 2000

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) as a preservative for mineral slurries (clay, kaolin clay, calcium carbonate or titanium dioxide) used as components of paper coatings that are used in the manufacture of food-contact paper and paperboard and as a preservative for calcium carbonate or titanium dioxide mineral slurries that are used as paper fillers in the manufacture of food-contact paper and paperboard.

The methylolhydantoins will be added to the mineral slurries at a minimum application rate of 400 ppm and a maximum rate of 1200 ppm. The methylolhydantoins will be used predominantly in the Southeastern United States by formulators of mineral slurries. The mineral slurries containing 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 methylolhydantoin degradates, dimethylhydantoin (DMH) and formaldehyde, may be released to water during the manufacture of paper containing preserved mineral slurries that are used as paper fillers. Conversely, 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 for 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)
- (trade name for a 40% aqueous solution of the methylolhydantoins)

CAS Reg. Nos.

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

Molecular Weights

- DMDMH - 188.18
- MMDMH - 158.16

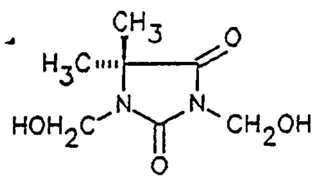
Chemical Formulas

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

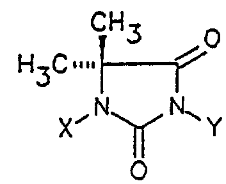
000067

Structures

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



Hydroxmethyl -5,5-dimethylhydantoin



X,Y = H or CH_2OH

Impurities

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

000068

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 this Environmental Assessment.

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

1) Market Volume

The estimated annual market volume for all FDA regulated uses of the methylolhydantoins is included in a confidential appendix for this notification. The FDA regulated uses comprising the market volume estimate are as follows:

- The current approved use (21 CFR Part 176.170) as a preservative for clay slurries that are used as fillers for paper.
- The proposed use (FCN-99) as an adjuvant in the bleaching of recycled paper fibers.
- The proposed use (FCN-104) as a preservative for mineral slurries (clay, titanium dioxide and calcium carbonate) that are used as components of paper coatings.
- The proposed use (FCN-104) as a preservative for mineral slurries (titanium dioxide and calcium carbonate) that are used as fillers for paper.

2) Environmental Releases

As noted above, the methylolhydantoins decompose 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 as mineral slurry preservatives, are DMH and formaldehyde.

- Paper Filler Use of Mineral Slurries

For this use of the mineral slurries, almost all the DMH and formaldehyde are expected to transfer to paper mill process water[1] since both substances are water soluble and are not substantive to paper. Approximately 55% of the estimated market volume for this use of the methylolhydantoins is released to the environment (water from plant effluent) as DMH and approximately 1.5% is released to water as formaldehyde. The remaining amount is biodegraded. Less than 1% of the estimated market volume for this use of the methylolhydantoins stays with paper and paperboard as DMH and formaldehyde[2].

---

[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 (less than 0.1 ppm) 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).

- Coating Use of Mineral Slurries

During the drying of the paper coating, only negligible, if any, amounts of DMH and formaldehyde are anticipated to be released to the environment since the drying step occurs at the dry end of the paper manufacturing process. In addition, it is expected that DMH and formaldehyde are bound up in the coating's resin. It should be noted that no violations of applicable regulations, including the OSHA Permissible Exposure Limit (PEL) for formaldehyde, is expected to occur.

Approximately 42% of the estimated total market volume for the methylolhydantoins is released to water as DMH and approximately 1.0% is released to water as formaldehyde. The remaining amount is biodegraded. In addition, approximately 25% of the estimated total market volume for the methylolhydantoins stays with paper and paperboard as DMH and formaldehyde.

3) Expected Introduction Concentration (EIC) and Estimated Environmental Concentration (EEC)

The EIC and EEC values for the current regulated use of the methylolhydantoins (as a preservative for clay slurries that are used as paper fillers) and the proposed use in other mineral slurries are the same since the application rates of the methylolhydantoins are identical. The worst-case situation is a paper mill that combines both clay and other mineral slurries as the filler material. However, paper mills do not typically use combinations of the mineral slurries and approximately 75% of paper mills use fillers based on clay while the remainder use calcium carbonate and titanium dioxide.

In addition, the current approval for use as a preservative for clay slurries that are used as paper fillers and the proposed uses as a preservative for clay, titanium dioxide and calcium carbonate mineral slurries that are used as components of paper coatings and for titanium dioxide and calcium carbonate mineral slurries that are used as paper fillers are all applied to the mineral slurry while the use as an adjuvant in the bleaching of recycled paper is applied directly to water. Moreover, the market estimate assumes that more paper mills will use mineral slurries preserved with the methylolhydantoins than will use them as adjuvants in the bleaching of recycled paper.

In our estimates of the EICs and the EECs, we assumed that most paper mills will use either clay slurries or other mineral slurries; however, for those few that might use both, the amount of the methylolhydantoins used for one use will be subtracted from the amount used for the other such that the total amount of the methylolhydantoins used will be the same. We also assumed that at any particular paper mill, the methylolhydantoins can used concurrently both as an adjuvant in the bleaching of recycled paper and as a preservative for mineral slurries that are used as paper fillers. Consequently, we estimated cumulative EICs and cumulative EECs as a result of these two uses.

4) Individual EICs

The EICs for DMH and formaldehyde, from the use of the methylolhydantoins as a preservative for calcium carbonate or titanium dioxide 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 EICs.

- The maximum application rate for the methylolhydantoins in the mineral slurry is 1200 ppm or 0.0012 lb/lb of clay filler.
- The DMH/formaldehyde ratio from the degradation of the methylolhydantoins is 70:30.
- The mineral slurry filler is approximately 10% of the weight of paper/paperboard.
- Daily production, per plant, of paper and paperboard 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 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-%Removal Rate) (Percentage of Methylolhydantoins that is DMH) ÷ (Plant Effluent in Gallons per Day) (lbs/gal)

(600 tons/day) (2000 lbs/ton) (0.0012 lbs/lb of mineral slurry) (0.1 lb of mineral slurry/lb of paper)(0.8)(0.7) ÷ (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) (0.0012 lbs/lb of mineral slurry) (0.1 lb of mineral slurry/lb of paper)(0.05)(0.3) ÷ (2 x 10^6 gallons/day) (8.33 lbs/gal) =

0.12 ppm

As noted above, the same EIC values for DMH and formaldehyde apply to the use of the methylolhydantoins as a preservative for clay slurries that are used as paper fillers since the application rate for all the mineral slurries is the same.

[1]The effluent value is from the following USEPA report: Development Document for Effluent Limitations, 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) shows that the overall effluent may be somewhat higher.

A slightly different and simplified equation is used to calculate the EICs for DMH and formaldehyde from the use of the methylolhydantoins as an adjuvant in the bleaching of recycled paper fibers since this use involves the direct application of the methylolhydantoins to water. The following inputs are used to derive these EICs:

- The maximum water application or dosing rate for the methylolhydantoins is 200 ppm.
- The DMH/formaldehyde ratio from the degradation of the methylolhydantoins is 70:30.
- For DMH, a 20% removal during wastewater treatment is assumed since DMH is ultimately biodegradable under acclimating conditions. For formaldehyde, a a 95% removal is assumed since formaldehyde is readily biodegradable.

Accordingly, the EIC for DMH is:

(140 ppm) (0.20) (0.80) = 22.4 ppm

and the EIC for formaldehyde is

(60 ppm) (0.20) (0.05) = 0.6 ppm

5) Cumulative EICs

The cumulative EICs for DMH and formaldehyde, presented in Table 1 below, are derived by adding together the individual EICs for both the use of the methylolhydantoins as a preservative in mineral slurries that are used as paper fillers and as an adjuvant in the bleaching of recycled paper. As noted above, the mineral slurries substitute for each other so that no matter which mineral slurry is used the EIC values are the same.

Table 1
Cumulative EICs for Methylolhydantoins

Methylolhydantoin Use	EIC (ppm)	
	DMH	Formaldehyde
Mineral Slurry Preservative	4.8	0.12
Bleaching Adjuvant for Recycled Paper	22.4	0.6
Total	27.2	0.72

000072

c). FATE OF SUBSTANCES RELEASED INTO THE ENVIRONMENT

1) 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 2.

2) 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].

3) Individual EECs

EECs for DMH and formaldehyde, from the use of the methylolhydantoins as a preservative for calcium carbonate and titanium dioxide mineral slurries that are used as paper fillers, are derived by applying a dilution factor for the receiving water body to the EECs. 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 the NCASI study[3]. This 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 mills, will further curtail effluent discharge.

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

Substance	EIC	Dilution Factor	EEC
DMH	4.8 ppm	20	0.24 ppm
Formaldehyde	0.12 ppm	20	0.006 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 2
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 Proteolysis	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, D.H. is considered ultimately biodegradable.

The EECs for DMH and formaldehyde, from the use of the methylolhydantoins as an adjuvant in the bleaching of recycled paper, are derived similarly, as shown in the chart below.

Substance	EIC	Dilution Factor	EEC
DMH	22.4 ppm	20	1.12 ppm
Formaldehyde	0.6 ppm	20	0.03 ppm

4) <u>Cumulative EECs</u>
The cumulative EECs for DMH and formaldehyde, presented in Table 3 below, are derived by adding together the individual EECs for both the use of the methylolhydantoins as preservatives in mineral slurries that are used as paper fillers and as an adjuvant in the bleaching of recycled paper. As noted above, the mineral slurries substitute for each other so that no matter which mineral slurry is used the EEC values are the same.

Table 3
Cumulative EECs for Methylolhydantoins

Methylolhydantoin Use	EEC (ppm)	
	DMH	Formaldehyde
Mineral Slurry Preservative	0.24	0.006
Bleaching Adjuvant for Recycled Paper	1.12	0.030
Total	1.36	0.036

000075

d). **Environmental Effects of Released Substances**

A comprehensive data base has been compiled on the aquatic toxicity of DMH. Tables 4 and 5 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 4
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.

000076

TABLE 5
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 that have been conducted with formaldehyde. A summary of the key studies is presented in Table 6 below. In addition, studies performed on a variety of fish and shrimp have shown that formaldehyde does not bioaccumulate.

TABLE 6
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

000077

Based on the results of the aquatic toxicity studies, the cumulative EEC value for DMH (1.36 ppm) is approximately 1/100 of the most sensitive acute LC_{50} study (>125 ppm) and approximately 1/20 of the MATC. For formaldehyde, the cumulative EEC (0.036 ppm) is approximately 1/300 of the most sensitive acute LC_{50} study (10 ppm). These values clearly indicate that the subject use of methylolhydantoins will not present any increased risks to aquatic organisms. It should 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 further biodegradation in water so the actual EEC's should be lower than the above estimates. 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 formaldehyde from paper mills using the methylolhydantoins as preservatives for paper fillers 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 *dazomet* (3,5-dimethyl-1,3,5-2H-tetrahydrothiadiazine-2-thione) and the *isothiazolones* (5-chloro-2-methyl-4-isothiazolone-3-one and 2-methyl-4-isothiazolin-3-one) that are already being used for preservatives mineral slurries used in the manufacture of paper and paperboard. Consequently, we do not expect the use of the methylolhydantoins will 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.

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.

000078

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 25, 2000

000079