

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

BALLOT VOTE SHEET

DATE: OCT 03 2006

TO: The Commission
Todd A. Stevenson, Secretary

THRU: Patricia M. Semple, Executive Director *PS*

FROM: Page C. Faulk, General Counsel *PCF*
Jeffrey R. Williams, Assistant General Counsel
Barbara E. Parisi, Attorney *BEP*

SUBJECT: Technical Amendment to the Flammability Standards for Carpets and Rugs:
Legal Memorandum and Staff Briefing Package

OCT 10 2006

BALLOT VOTE DUE: _____

The Office of General Counsel recommends that the Commission instruct the staff to prepare a draft notice of proposed rulemaking (NPR) for Commission consideration concerning a technical amendment to the flammability standards for carpets and rugs in accordance with the staff recommendation. The legal memorandum and staff briefing package are attached.

Please indicate your vote:

- I. Instruct the staff to prepare a draft NPR in accordance with the staff recommendation for consideration by the Commission.

Signature

Date

- II. Instruct the staff to prepare a draft NPR in accordance with the staff recommendation with changes for consideration by the Commission. (Please specify.)
- _____
- _____

Signature

Date

III. Do not instruct the staff to prepare a draft NPR.

Signature

Date

IV. Take other action. (Please specify.)

Signature

Date



**TECHNICAL AMENDMENT TO THE
FLAMMABILITY STANDARDS
FOR CARPETS AND RUGS
16 C.F.R. PART 1630 AND 16 C.F.R. PART 1631
BRIEFING PACKAGE**

For further information contact:

Patricia K. Adair, Project Manager
Directorate for Engineering Sciences
Consumer Product Safety Commission
(301) 504-7536

**NOTE: This document has not been
reviewed or accepted by the Commission.**
Initial JS Date 10/3/06

10/3/06
EXCEPTED FROM
RULEMAKING

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EXECUTIVE SUMMARY

The U.S. Consumer Product Safety Commission (CPSC) administers two flammability standards for carpets and rugs: 16 Code of Federal Regulations (C.F.R.) Part 1630 – *Standard for the Flammability of Carpets and Rugs* and 16 C.F.R. Part 1631 – *Standard for the Surface Flammability of Small Carpets and Rugs*. The standards establish minimum acceptance criteria for the surface flammability of carpets and rugs when exposed to a standard small source of ignition under prescribed conditions (the “pill test”). The pill test was designed to determine the surface flammability of carpets and rugs when exposed to a small ignition source and to keep dangerously flammable products from distribution in commerce.

Both standards require a timed burning tablet as the standard ignition source for flammability performance testing. The standards define the ignition source as a methenamine tablet, weighing approximately 0.149 grams (2.30 grains), sold as Product No. 1588 in Catalog No. 79, December 1, 1969, by the Eli Lilly Company, or an equal tablet.

In April 2002, Commission staff learned that the Eli Lilly Company was no longer producing the methenamine tablets specified in the carpet and rug standards. Although the standards allow for the use of “an equal” methenamine tablet and give parameters for chemical composition and weight of the tablet, they do not provide any guidance on determining whether tablets from alternative sources are “equal” to those manufactured by the Eli Lilly Company. In an effort to make such a determination, the Commission staff conducted research designed to evaluate the weight, chemical composition, and combustion characteristics of presently available brands of methenamine tablets relative to each other and to those produced by the Eli Lilly Company. The outcome of this research indicates that tablets consisting of essentially pure methenamine and weighing approximately 0.149 grams may be considered equivalent to the tablets formerly produced by the Eli Lilly Company.

On July 29, 2004, the Office of Compliance issued a letter to industry in response to inquiries received by the CPSC staff regarding the equivalency of the methenamine tablets formerly manufactured by the Eli Lilly Company and similar tablets currently produced by other manufacturers. The letter stated that Commission staff determined that tablets consisting of pure methenamine and weighing approximately 0.149 grams may be considered equivalent to the tablets formerly produced by Eli Lilly Company. Several additional specifications that will help ensure this equivalency are now recommended by the staff.

Under the 2005 Program for Systematic Review of Commission Regulations (70 *Federal Register* 18338; April 11, 2005), staff reviewed the carpet and rug standards to identify areas for possible future Commission actions in regard to these regulations. Several technical issues, in addition to the one discussed in this briefing package, were identified. These other issues could not be addressed in a two-step rulemaking because they are potentially more substantive than “technical amendments.” They could be addressed separately in a future project, beginning with an advance notice of proposed rulemaking. Staff believes it is appropriate to amend the standards at this time to address the issue of an “equal” methenamine tablet and to address other aspects of the carpet and rug standards separately.

The staff recommends that the Commission issue a notice of proposed rulemaking to amend 16 C.F.R. Parts 1630 and 1631 to remove the reference to the Eli Lilly Company's Product No. 1588 in Catalog No. 79, December 1, 1969, as the standard ignition source and provide a specification defining the ignition source (§1630.1(f) and §1631.1(f)). The staff's proposed specification for the standard ignition source is a timed burning tablet, consisting of pure methenamine, with a nominal heat of combustion value of 7180 calories/gram, a mass of 150 mg \pm 5 mg, flat, and a nominal diameter of 6 mm. An immediate effective date is also recommended.



UNITED STATES
 CONSUMER PRODUCT SAFETY COMMISSION
 WASHINGTON, DC 20207

Memorandum

Date: **SEP 14 2006**

TO : The Commission
 Todd Stevenson, Secretary

THROUGH: Page C. Faulk, General Counsel *PCF*
 Patricia M. Semple, Executive Director *MS*

FROM : Jacqueline Elder, Assistant Executive Director
 Office of Hazard Identification and Reduction
 Patricia K. Adair, Project Manager *PKA*
 Directorate for Engineering Sciences

SUBJECT : Technical Amendment to the Flammability Standards for Carpets and Rugs, 16 C.F.R. Part 1630 and 16 C.F.R. Part 1631

I. INTRODUCTION

This memorandum presents information on the staff's draft proposed technical amendment to the flammability standards for carpets and rugs, 16 C.F.R. Part 1630 and 16 C.F.R. Part 1631 and supporting materials.

II. BACKGROUND

The standards for surface flammability of carpets and rugs appear at 16 C.F.R. Parts 1630 and 1631. They were codified and published in 1975, 40 *Fed. Reg.* 59931 and 59935 (December 30, 1975). The standards were originally issued in 1970 by the Department of Commerce under the authority of the Flammable Fabrics Act (FFA). Subpart A of 16 C.F.R. Parts 1630 and 1631 set forth the standards. Subpart B contains the implementing regulations of the standards. Subpart C contains alternative washing procedures for hide carpets and rugs and wool flokati carpets and rugs. Subpart D of 16 C.F.R. 1630 contains the staff interpretations and policies.

16 C.F.R. Parts 1630 and 1631 establish minimum acceptance criteria for the surface flammability of carpets and rugs when exposed to a standard small source of ignition, a burning methenamine tablet, under prescribed conditions (the "pill test"). These standards reduce the risks of death, personal injury, and property damage associated with fires that result from the surface ignition of carpets and rugs.

NOTE: This document has not been reviewed or accepted by the Commission.
 Initial *JE* Date *10/3/06*

10/3/06
 NO LIFELINE PRODUCTS
 EXCEPTED BY RULEMAKING ADMINISTRATION
 WITH PORTIONS REMOVED

Both standards require a timed burning tablet as the standard ignition source for flammability performance testing. The standards define the ignition source at §1630.1(f) and §1631.1(f) as a methenamine tablet, weighing approximately 0.149 grams (2.30 grains), sold as Product No. 1588 in Catalog No. 79, December 1, 1969, by the Eli Lilly Company, or an equal tablet.

In April 2002, Commission staff learned that the Eli Lilly Company was no longer producing the methenamine tablets specified in the carpet and rug standards. Although the standards allow for the use of “an equal” methenamine tablet and give parameters for chemical composition and weight of the tablet, they do not provide any guidance on determining whether tablets from alternative sources are “equal” to those manufactured by the Eli Lilly Company. In July 2003, CPSC staff met with representatives of the Carpet and Rug Institute (CRI) to discuss evaluation of alternative methenamine tablets for use in 16 C.F.R. Part 1630 and Part 1631. CRI members were experiencing differing test results using the old Eli Lilly tablets and currently available tablets. CRI members had begun to study the various characteristics of the current tablets. In one case, about 50% of one manufacturer’s tablets were found broken in the bottle, with others breaking later. This problem was attributed to the tablets having a domed top. The problem has since been corrected by the manufacturer with a flat tablet.¹

CRI urged the Commission to clearly specify the characteristics of the “equal” tablets that should be used for determining compliance to the carpet and rug standards. In an effort to make such a determination, the Commission staff conducted a comparison study to evaluate the weight, chemical composition, and combustion characteristics of presently available brands of methenamine tablets relative to each other and those produced by the Eli Lilly Company. The outcome of the study indicated that tablets consisting of essentially pure methenamine, having a heat of combustion value of approximately 7180 calories/gram and weighing approximately 0.149 grams may be considered equivalent to the tablets produced by the Eli Lilly Company and referenced in the regulation. (TAB A)

On July 29, 2004, the Office of Compliance issued a letter to industry in response to inquiries received by the CPSC staff regarding the equivalency of methenamine tablets formerly manufactured by the Eli Lilly Company and similar tablets currently produced by other manufacturers. The letter stated that the Commission staff determined that tablets consisting of pure methenamine and weighing approximately 0.149 grams may be considered equivalent to the tablets formerly produced by the Eli Lilly Company. Therefore, tablets meeting these criteria may be used for purposes of determining conformance with the carpet and rug standards. (TAB B)

III. RELATED STANDARDS

ASTM D2859-04 *Standard Test Method for Ignition Characteristics of Finished Textile Floor Covering Materials* is very similar to the federal carpet and rug standards. 16 C.F.R.

¹ Meeting log; *Methenamine tablets for Carpet and Rug Flammability Standard*; CPSC staff and representatives of the Carpet and Rug Institute, CPSC Headquarters, July 15, 2003.

Part 1630 and Part 1631 are referenced in ASTM D2859-04. The ignition source is a methenamine tablet; a footnote in the standard states, "Methenamine Reagent Tablet #1588 (0.149-g weight), Eli Lilly Inc., 307 East McCarty St., Indianapolis, IN 46206, has been found satisfactory." Note 2 in the standard states, "The normal variation in the weight of different tablets will not affect the test results."²

Carpets and rugs sold in Canada must meet the requirements of Health Canada's Hazardous Products Act, *Test Method for Evaluating Carpets and Textile Floor Coverings for Flame Resistance*, which references Method 27.6, of Canadian General Standards Board (CGSB) Standard 4-GP-2, *Flame Resistance – Methenamine Tablet Test*. This test method specifies the Eli Lilly Company's Product No. 1588 as the ignition source. In the Canadian test method it is noted that the normal variation in weight of the specified ignition source, a Timed Burning Tablet, Product No. 1588, manufactured by the Eli Lilly Company, will not affect the test results.³

ISO 6925 *Textile floor coverings – Burning behaviour – Tablet test at ambient temperature*, first published in 1982, specifies a method for assessing the burning behavior of textile floor coverings in a horizontal position when exposed to a small source of ignition under controlled laboratory conditions. The ignition source, a methenamine tablet, is described as "tablets of hexamethylenetetramine, flat, having a mass of 150 ±5 mg and a diameter of 6 mm."⁴

IV. TECHNICAL RATIONALE (TAB A)

In 2002, CPSC staff learned that the Eli Lilly Company was no longer producing the methenamine tablets specified as the ignition source in the carpet and rug standards. Defined at §1630.1(f) and §1631.1(f), the "Timed Burning Tablet" (pill) means the "methenamine tablet, weighing approximately 0.149 gram (2.30 grains) sold as Product No. 1588 in Catalog No. 79, December 1, 1969, by the Eli Lilly Company of Indianapolis, Ind. 46206, or an equal tablet."

The carpet standards do not provide guidance on how to determine if methenamine tablets from different sources are "equal" to the Eli Lilly tablet. However, the standards do provide two parameters for the ignition source: chemical composition and weight (§1630.1(f) and §1631.1(f)). In 2003 the staff conducted a study to determine if one or more methenamine tablets from several manufacturers meet the intent of the "or an equal" provision of the standards. The staff evaluated the combustion characteristics of currently available methenamine tablets and compared their characteristics with samples of the "old" Lilly tablets with 1977 and 1981 expiration dates. In addition, samples were analyzed to determine their chemical components.

² ASTM D2859-04 *Standard Test Method for Ignition Characteristics of Finished Textile Floor Covering Materials*, section 6.9 Methenamine Tablet. ASTM International, Philadelphia, PA.

³ Test Method for Evaluating Carpets and Textile Floor Coverings for Flame Resistance, Health Canada, Appendix II, Note 2, Method 27.6, of CGSB Standard 4-GP-2, *Flame Resistance – Methenamine Tablet Test*, published in February, 1973.

⁴ ISO 6925-1982 *Textile floor coverings – Burning behaviour – Tablet test at ambient temperature*, section 4.9 *Methenamine tablet*. International Organization for Standardization, Geneva, Switzerland.

Chemical analysis conducted by the staff found no differences in chemical composition among the currently manufactured tablets; all are essentially pure methenamine (hexamethylenetetramine), $(\text{CH}_2)_6\text{N}_4$, having a heat of combustion value of approximately 7180 calories/gram. The average heat of combustion for the tablets tested ranged from 7113 to 7146 calories/gram, a deviation of less than 1.0%.

A comparison of the weights of currently manufactured tablets with the Eli Lilly tablets showed each weighing approximately 0.149 grams, with an average tolerance within .005 grams. The tablets included in the study were flat, with a nominal diameter of 6 mm.

Production tolerances provided by two manufacturers indicate the generally accepted standard for the methenamine tablet is as defined in ISO 6925 *Textile floor coverings – Burning behaviour – Tablet test at ambient temperature*, which allows a ± 5 mg tolerance for 150 mg mass.⁵

V. PRELIMINARY REGULATORY ANALYSIS (TAB C)

The staff has determined that the staff's proposed amendments will not have a significant economic impact on manufacturers, consumers or other parties, including small entities. This is because "equal" methenamine tablets are already being used as allowed by the current standards. The staff's proposed amendment will not make any change to the scope, apparatus, test method, or pass/fail criterion of the standards, thus no significant economic impact is expected. In addition, the amendment will not have any potential to produce significant environmental effects.

VI. CONCLUSIONS

The staff believes it is appropriate to amend the standards to: (1) remove the reference to the Eli Lilly Company's Product No. 1588 as the standard ignition source (*16 C.F.R. 1630 §1630.1(f) and §1630.4(a)(3) and 16 C.F.R. 1631 §1631.1(f) and §1631.4(a)(3)*) since this product is no longer produced or sold by the Eli Lilly Company; and (2) describe the ignition source more precisely in *16 C.F.R. §1630.1(f) and §1630.4(a)(3) and 16 C.F.R. §1631.1(f) and §1631.4(a)(3)* as a methenamine tablet, flat, with a nominal heat of combustion value of 7180 calories/gram, a mass of 150 mg \pm 5 mg and a nominal diameter of 6 mm.

VII. OPTIONS

1. Make no change to amend 16 C.F.R. Part 1630 *Standard for the Surface Flammability of Carpets and Rugs* and 16 C.F.R. Part 1631 *Standard for the Surface Flammability of Small Carpets and Rugs*.

⁵ <http://www.vestapharm.com/industrial.html>; personal communication with Sam Kwon, Vesta Pharmaceuticals and Ronda Ziegenfus, Advanced Testing Instrument Corporation, August 8, 2005.

2. Issue a Notice of Proposed Rulemaking to solicit public comment on the recommended changes.

VIII. RECOMMENDATION

The staff recommends that the Commission issue a notice of proposed rulemaking in the *Federal Register* for a 75 day public comment period to remove the reference to the Eli Lilly Company's Product No. 1588 and reflect the parameters defining the timed burning tablet as the standard ignition source. The staff also recommends an immediate effective date upon publication of the amendments because the equivalent tablets are already in use.


TAB A

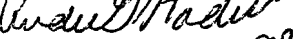





UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: May 22, 2006

TO : Patricia Adair, Project Manager, Carpets and Rugs 
Directorate for Engineering Sciences

THROUGH: Andrew G. Stadnik, AED Laboratory Sciences 
 Edward W. Krawiec, Director, Division of Electrical Engineering 

FROM : Linda Fansler, Division of Electrical Engineering 

SUBJECT : Evaluation of Methenamine Tablets

INTRODUCTION

The U.S. Consumer Product Safety Commission (CPSC) administers two flammability standards for carpets and rugs. These standards are codified in *16 C.F.R. Parts 1630 and 1631, Standard for the Surface Flammability of Carpets and Rugs* and *Standard for the Surface Flammability of Small Carpets and Rugs*. These standards identify the Eli Lilly Company as the manufacturer for a methenamine tablet (a timed burning tablet) used as an ignition source. Eli Lilly no longer manufactures the methenamine tablet. The standards also allow for the use of an “equal” tablet. However, complete specifications and flammability performance parameters for the tablet are not defined or provided in either standard. This memorandum discusses the results of a study to determine if one or more methenamine tablets from several manufacturers meet the intent of the “or an equal” provision in the standards. This memorandum also defines some parameters that could be used to define an “equal” tablet.

BACKGROUND

The ignition source specified in the carpet and rug standards is defined in sections §1630.1 and §1631.1 *Definitions (f) Timed Burning Tablet*, as a methenamine tablet, weighing approximately 0.149 grams, sold as Product No. 1588 in Catalog No. 79, December 1, 1969 by the Eli Lilly Company, or an equal tablet. In April 2002, Commission staff learned that Eli Lilly was no longer producing the methenamine tablets specified in the two carpet standards.¹

Consequently, the carpet industry asked for guidance in identifying an alternate source of methenamine tablets that could be used for testing for compliance with the standards. Commission staff met with members of the Carpet and Rug Institute to discuss the issue and to

¹ Telephone conversation between Margaret Neily, ES, CPSC and Cathy Sanzo, Morgan Lewis, counsel to the Carpet and Rug Institute, April 19, 2002.

review the carpet industry's test data.² The industry compared methenamine tablets manufactured by Eli Lilly and two other brands of methenamine tablets (Tablet B and Tablet C) and reported that there was no significant difference in weight among the tablets. In addition, the industry reported that the burning time of Tablet B was more consistent than the Lilly tablets. The industry's data also showed that Tablet C burned at higher temperatures, as measured by an infrared camera, than either the Lilly tablets or Tablet B. Even with these differences, tests on actual carpet showed consistency in passing and failing results among tablets from the three sources.

In 1976, at the request of Commission staff, the National Bureau of Standards (NBS) (now the National Institute for Standards and Technology (NIST)) conducted a limited comparison of thermal characteristics of Lilly tablets with three different expiration dates.^{3,4} In that study, NBS staff compared tablet weight, burn time, burn temperature, and heat of combustion of Lilly tablets used in the development of the carpet standards (circa 1969) with Lilly tablets having expiration dates of 1977 and 1981. NBS staff concluded that there were no significant differences in the thermal characteristics among the tablets tested. Further details about the NBS measurements including results and variability are discussed below in the corresponding sections under Test Program.

Commission staff developed a plan to more thoroughly evaluate the combustion characteristics of currently available methenamine tablets, since the industry data was limited to burn time and temperature measurements using instruments and methodology different from that used by NBS in 1976. In addition, the industry did not have early Eli Lilly tablets to use in comparison tests. The Commission staff evaluated presently available brands of methenamine tablets relative to each other and to samples of "old" Lilly tablets with 1977 and 1981 expiration dates. This evaluation used the same methodology employed by NBS in its 1976 evaluation except that modern, automated calorimetry was used to determine the heat of combustion for a large number of sample tablets. In addition, samples were also analyzed to determine their chemical components.

TEST PROGRAM

Methenamine Tablets

Methenamine tablets from six sources were included in the test program. Tablets from each of the six sources were not included in every evaluation due to the limited number of tablets available for some of the sources. In addition, Tablet A tablets were actually relabeled Eli Lilly

² Meeting between CPSC staff and members of the Carpet and Rug Institute and Shaw Industries Group, Inc., December 18, 2002, at CPSC Headquarters in Bethesda, Maryland.

³ Report of Tests on Methenamine Tablets Used in Carpet Testing, Joseph J. Loftus, National Bureau of Standards, February 1976.

⁴ Report of Tests on Methenamine Tablets Used in Carpet Testing, Supplemental Data, Joseph J. Loftus, National Bureau of Standards, March 1976.

tablets. Table 1 contains information about the different methenamine tablets studied in this evaluation including label identification and information about the tablet's expiration date. It has been the Commission staff's practice to not use expired Eli Lilly tablets when performing compliance tests of carpets and rugs.

TABLE 1
Methenamine Tablets

Label Identification	Expiration Date	Control Number
Eli Lilly NDC 0002-2535-02	8-1-2002	3ML08M
Eli Lilly NDC 0002-2535-02	1-1-1981	9UH25A
Eli Lilly NDC 2-Y35-40	3-1-1977	6LK34A
Tablet A*/Eli Lilly	none/8-1-2002	788-141/3ML08M
Tablet B NDC 0603-4475-21	None	002-043
Tablet C (no NDC number)	10-2005	4768

*Laboratory staff determined that Tablet A tablets were actually relabeled Eli Lilly 2002 tablets; a new label had been applied over the original Eli Lilly label.⁵

The 2002 Lilly tablets were from the current supply at the Commission's Laboratory. The 1981 Lilly tablets were obtained from CPSC's Directorate for Engineering Sciences and the 1977 Lilly tablets were obtained from NIST. Tablet B and Tablet C were purchased from their manufacturers. The Carpet and Rug Institute supplied Tablet A. The Carpet and Rug Institute also supplied additional bottles of the 2002 Lilly tablets and Tablet B. With the exception of the 1981 and 1977 Lilly tablets, all bottles were foil sealed when received for testing.

Chemical Analysis

Five tablet samples were analyzed by the CPSC Laboratory's Division of Chemistry (LSC) staff to determine the chemical composition of the tablets.⁶ The samples included the 1977, 1981, and 2002 Lilly tablets, Tablet B, and Tablet C.

The inorganic chemical composition of the tablets was determined using a Thermo Elemental Inductively Coupled Spectrometer (ICP). The results of the ICP analysis indicated that the tablets contained less than 0.1 ppm of ten inorganic elements screened.

The organic chemical composition of the tablets was determined using a Nicolet Fourier Transform Infrared Spectrometer (FTIR). Results of the FTIR analysis identified the tablet chemical as methenamine for the five tablets analyzed.

⁵ In a March 25, 2003 telephone conversation between Linda Fansler, LS, CPSC, and Tim Zigenfous, Advanced Testing Instrument Corporation, the North American representative of Tablet A, Mr. Zigenfous reported that Eli Lilly sold the remaining stock of the Lilly manufactured methenamine tablets, about 500 bottles, to the source for Tablet A.

⁶ Memorandum to Linda Fansler, LSE, from S. Chen, LSC and B. Jain, LSC, "Chemical Composition of the Methenamine Tablets," May 22, 2006, CPSC.

LSC staff concluded that the results from these analyses indicated that the five tablets have similar chemical composition, that they are essentially pure methenamine, and that they do not contain filler materials.

Statistical Input

In order to gain familiarity with the NBS methodology described in the 1976 NBS reports, a number of trial tests were conducted using tablets from several sources. The data from those tests were then analyzed to determine how to proceed with a formal evaluation.

CPSC's Directorate for Epidemiology staff provided guidance⁷ on the minimum sample size that would detect a statistical difference among the tablets in this test program. An estimate of an acceptable standard deviation of the pill characteristics was calculated by pooling the relevant standard deviations from the trial test measurements. Because the margin of error was unknown, a range of possible values was considered. For each comparison (NBS tests vs. CPSC staff tests), the relevant sample means were pooled to obtain an overall grand mean. Values of 1%, 2.5%, 5% and 10% of the overall grand mean were assumed to be the possible margins of error. Using the assumed margins of error, the sample sizes for a given level of confidence were determined. Tables 2 and 3 summarize the results.

TABLE 2
NBS Lilly Tests versus CPSC Staff Lilly and Tablet A Tests

K*	Weight (grams)		Burn Time (seconds)		Temperature (°C)	
	Margin of Error (in grams)	n	Margin of Error (in seconds)	n	Margin of Error (in °C)	n
0.01	0.001	>100	1.2	>100	10.0	>100
0.025	0.004	35	3.0	> 80	24.9	41
0.05	0.007	8	6.0	32	49.9	10
0.10	0.015	< 5	12.0	8	99.7	< 5

*K= % error

Note: Power = 0.90, α = 0.05

⁷ Email from R. Chowdhury, EPHA, to E. Krawiec, LSE, concerning statistical guidance, April 3, 2003, CPSC.

TABLE 3
NBS Lilly Tests versus CPSC Staff Tablet B Tests

K*	Weight (grams)		Burn Time (seconds)		Temperature (°C)	
	Margin of Error (in grams)	n	Margin of Error (in seconds)	n	Margin of Error (in °C)	n
0.01	0.001	>100	1.2	>100	9.9	>100
0.025	0.004	39	3.0	> 80	24.7	45
0.05	0.007	8	6.0	34	49.4	12
0.10	0.015	< 5	12.1	8	98.8	< 5

*K = % error

Note: *Power = 0.90, α = 0.05*

A minimum of 45 runs was chosen as the sample size. This sample size was selected to permit detecting small differences in critical parameters, in this case, less than a 5% difference in maximum temperature. The Epidemiology staff analysis indicated that, in order to detect a margin of error as small as 24.7°C in the difference of the mean temperatures (between the NBS Lilly tablets and Tablet B) with a confidence level at 95% and power at 90%, a minimum of 45 tablets from each manufacturer would have to be tested.

A sample size of 45 runs was not possible with the 1977 Lilly tablets because there were a limited number of those tablets available. In addition, because of the testing cost, the heat of combustion measurements were made on only 12 of each brand/expiration date of available tablets.

The following tests were included in the comparison evaluation of methenamine tablets:

- Tablet Weight,
- Burn Time,
- Burn Temperature, and
- Heat of Combustion.

Tablet Weight

The carpet and rug standards (16 C.F.R. Parts 1630 and 1631) specify that the weight of the methenamine tablet be “*approximately 0.149 grams.*” A tolerance is not specified.

The average weights of the 1977 (0.1459 grams) and 1981 (0.1453 grams) methenamine tablets measured in 1976 by NBS were below the weight (0.149 grams) specified in the standards. The NBS report indicates that the Commission’s Laboratory was at that time using the 1977 Lilly tablets for compliance testing.

Methenamine tablets from each of the six different sources were placed in a desiccator for a minimum of 24 hours then weighed using an analytical balance. This information was compared to data obtained by NBS in 1976. Table 4 presents the average weight and standard deviation for the tablets.

TABLE 4
Average Weight of Methenamine Tablets

Tablet Identification and Laboratory	Average Weight (grams)	Standard Deviation (+ or -)	Number of Tablets Weighed
2002 Lilly CPSC	0.1486	0.002	45
1981 Lilly CPSC	0.1481	0.004	45
1981 Lilly NBS	0.1452	0.004	25
1977 Lilly CPSC	0.1464	0.004	10*
1977 Lilly NBS	0.1459	0.006	20
Tablet A CPSC	0.1491	0.002	45
Tablet B CPSC	0.1493	0.004	45
Tablet C CPSC	0.1463	0.003	45

*Only 10 tablets were weighed due to the limited number of tablets available.

The average weight of the tablets in the current test program is heavier than the average weight of the tablets weighed by NBS in 1976. The weight range for the methenamine tablets reported in 1976 by NBS is 0.1345 to 0.1596 grams. The weight range for the tablets weighed during this evaluation is 0.1359 to 0.1576 grams.

Tablet Burn Time

The carpet and rug standards do not specify how long the methenamine tablets should burn while a carpet is being tested. However, NBS reported burn time measurements in its 1976 reports. In 1976, the average burn time for the 1977 Lilly tablets was 118 seconds, and the average burn time for the 1981 Lilly tablets was 124 seconds. The 1977 Lilly tablets had a range of burn times from approximately 97 seconds to 112 seconds. The range of burn times recorded for the 1981 Lilly tablets was 104 seconds to 120 seconds.

CPSC Laboratory staff measured the burn time for six different methenamine tablets following the NBS methodology. The burn time was measured using a stopwatch; as the tablets were lit using a match, the stopwatch was manually started. Laboratory staff observed the tablet burning and recorded the time when the flaming ceased. Table 5 presents the burn time test results for all the methenamine tablets.

**TABLE 5
Burn Time**

Tablet Identification and Laboratory	Average Burn Time (seconds)	Standard Deviation (+ or -)	Number of Tablets Burned
2002 Lilly CPSC	120.73	5	45
1981 Lilly CPSC	112.33	4	45
1981 Lilly NBS	123.64	4	25
1977 Lilly CPSC	106.90	5	10*
1977 Lilly NBS	117.60	8	20
Tablet A CPSC	120.07	6	45
Tablet B CPSC	130.24	3	45
Tablet C CPSC	116.07	3	45

*Only 10 tablets were burned due to the limited number of tablets available.

Tablet B had the longest average burn time at approximately 130 seconds. Statistical tests⁸ indicate the mean burn time for Tablet B was significantly different from the burn time for the other methenamine tablets.

The mean burn time for the 1977 Lilly (CPSC) tablets was also significantly different from the mean burn times of the other tablets with the exception of 1981 Lilly (CPSC). The average burn time of the 1977 Lilly (CPSC) tablets was less than all others, followed by the 1981 tablets.

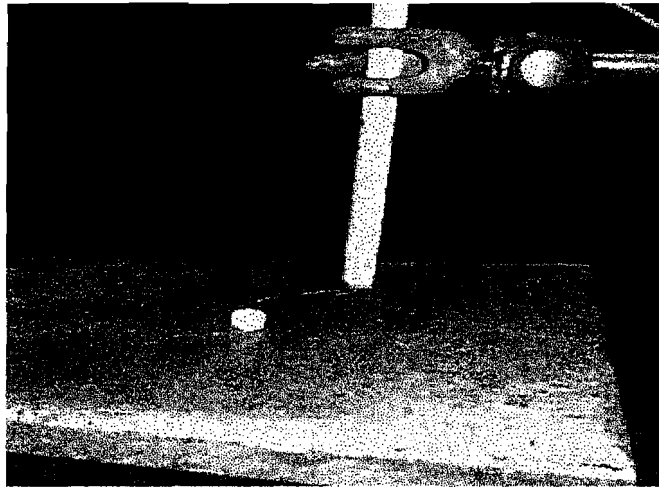
Maximum Temperature

Commission staff originally requested the 1976 study by NBS because members of the carpet industry claimed that the production of Lilly tablets at that time was burning hotter than those Lilly tablets manufactured around 1969 when the carpet standards became effective. As part of their test program, NBS recorded the temperatures from burning methenamine tablets. Maximum temperatures were measured by positioning a 30-gauge chromel alumel thermocouple approximately 1/16 inch above the top surface of the test tablet. The tablets were supported on a piece of cement asbestos board ¼-inch thick, and the entire assembly was enclosed in a test cabinet fitted with a door. The door of the cabinet was closed after igniting each tablet to avoid any draft disturbances to the flame.

The February 1976 NBS report cautions that a number of parameters can influence the temperature values obtained. The report listed influencing parameters as size (gauge and bead size) of the thermocouple wire used, the location of the thermocouple bead relative to the burning tablet, the recording device used, and the presence of a draft-free test environment. Laboratory staff considered these parameters when making temperature-recording measurements.

⁸ Email message from R. Chowdhury, EPA, to E. Krawiec, LSE, concerning weight, burn time and maximum temperature, June 13, 2003, CPSC.

In an effort to replicate the NBS procedure to measure burn temperatures, Laboratory staff recorded maximum burn temperatures using a 30-gauge chromel alumel thermocouple. A ceramic collar supported the thermocouple with the bead placed approximately 1/16 inch above the tablets being tested. The tablets were placed on a piece of 3/8-inch thick cement asbestos board, and the entire assembly was enclosed in a sealed hood. The door of the hood was closed after igniting each tablet to avoid disturbances to the flame. Photograph 1 shows the laboratory test set-up. Table 6 presents the average maximum temperatures for the methenamine tablets tested.



Photograph 1. Test set-up used to make maximum temperature measurements.

TABLE 6
Maximum Temperature

Tablet Identification and Laboratory	Average Max. Temperature (°C)	Standard Deviation (+ or -)	Number of Tablets Burned
2002 Lilly CPSC	926.07	25	45
1981 Lilly CPSC	891.22	42	45
1981 Lilly NBS	970.60	25	25
1977 Lilly CPSC	914.80	23	10*
1977 Lilly NBS	992.75	33	20
Tablet A CPSC	914.38	34	45
Tablet B CPSC	938.95	33	45
Tablet C CPSC	941.87	16	45

*Only 10 tablets were burned due to the limited number of tablets available.

The average maximum temperatures recorded in this current study are lower than the temperatures recorded by NBS in 1976. The average maximum temperature for the 1977 Lilly tablets was 993°C in 1976 and the average maximum temperature for the 1981 Lilly tablets was 971°C in 1976. Laboratory staff recorded between 891°C and 942°C for the average maximum temperatures for the methenamine tablets in the current study.

Figure 1 shows the average burn temperatures during their burning time for the methenamine tablets. The plot represents an average temperature of the total number of tablets tested for each of the six tablet types. The average burn temperatures achieved by Lilly 02, Tablet B and Tablet C are similar until approximately 100 seconds when the maximum temperatures are reached.

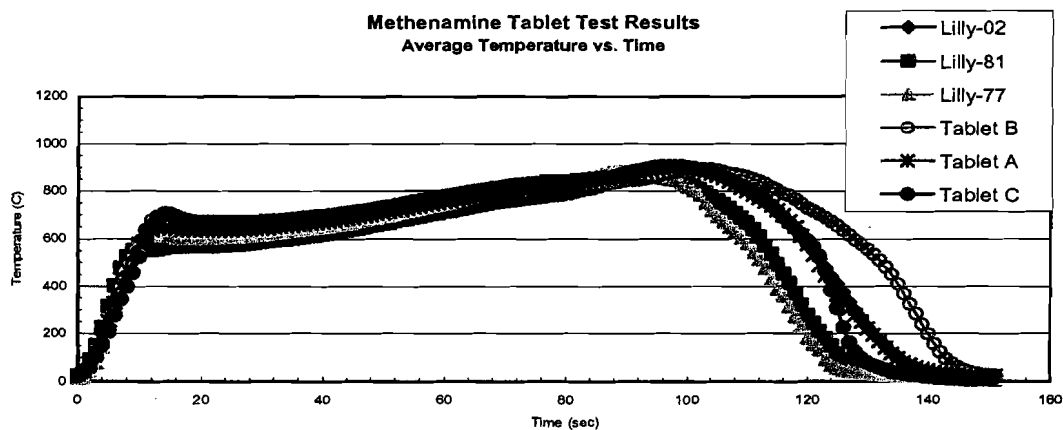


Figure 1. Average Burn Temperatures

Heat of Combustion

The carpet and rug standards do not specify how much energy should be liberated while a methenamine tablet is burning. However, in the 1976 NBS evaluation of 1977 and 1981 Lilly tablets, heat of combustion measurements were made using an oxygen bomb calorimeter. NBS conducted the test according to ASTM D3286-73, *Standard Test Method for Gross Calorific Value of Coal and Coke by the Isoperibol Bomb Calorimeter*.⁹

NBS reported values of 6905 calories/gram for 1981 Lilly tablets and 6898 calories/gram for 1977 Lilly tablets. The apparatus used by NBS required a sample larger than a single tablet. The standard method was to grind tablets into powder and then to form the powder into a cylinder using a precision press.

⁹ ASTM D3286-96 *Standard Test Method for Gross Calorific Value of Coal and Coke by the Isoperibol Bomb Calorimeter* was discontinued in 2000 and replaced by *D5865 Standard Test Method for Gross Calorific Value of Coal and Coke*.

Laboratory staff contracted with Hazen Research, Inc., an independent laboratory, to perform calorific value determinations on methenamine tablets with modern automated test equipment using ASTM D5865-00, *Standard Test Method for Gross Calorific Value of Coal and Coke*. Coded vials containing twelve tablets each of the five different kinds of methenamine tablets were sent to Hazen for analysis. To ensure a statistically valid test, the order of testing the tablets was randomized. In addition, to ensure the reproducibility of the calorimeter, benzoic acid (used for calorimeter certification and calibration per ASTM D5865) was tested after every sixth test of methenamine tablets. Table 7 presents the results of this testing along with the values obtained by NBS.

TABLE 7
Heat of Combustion

Tablet Identification and Laboratory	Heat of Combustion (calories/gram)	Standard Deviation (+ or -)	Number of Tests
2002 Lilly CPSC	7113	154	12
1981 Lilly CPSC	7054	112	12
1981 Lilly NBS	6905	not reported	1
1977 Lilly CPSC	6906	147	12
1977 Lilly NBS	6898	not reported	1
Tablet B CPSC	7146	48	12
Tablet C CPSC	7137	101	12
Benzoic Acid	6326	8	13

The heat of combustion values of the 1977 (6898 calories/gram) and 1981 (6905 calories/gram) Lilly tablets measured by NBS are lower than the average heat of combustion values measured in this study. The heat of combustion values measured for benzoic acid were consistent among themselves.

Statistical tests¹⁰ show that the mean heat of combustion value for the 1977 Lilly (CPSC) tablets is significantly lower than the average values of the other tablets measured by Hazen. There was no evidence of any difference in the mean values among the other methenamine tablets measured.

DISCUSSION

Methenamine tablets manufactured by the Eli Lilly Company have been used as an ignition source since 1970 when the carpet standards became effective. Aside from a limited study in 1976 by NBS, Commission staff has not evaluated the tablets to determine whether their physical or thermal properties have changed over the past 33 years. Subtle differences in manufacturing practices over the years could have introduced changes to these properties that went undetected.

¹⁰ Email message from R. Chowdhury, EPHA, to E. Krawiec, LSE, concerning heat of combustion analysis, June 4, 2003, CPSC.

Although limited information is available about the performance of the Lilly tablets in 1976, the performance of the 2002 Lilly tablets should also be considered when determining whether methenamine tablets manufactured by companies other than Eli Lilly meet the intent of the “or an equal” provision in the carpet standards.

The carpet standards provide no guidance on how to determine if methenamine tablets from different sources are “equal” to the specified tablet manufactured by Eli Lilly. However, two parameters are found in the definition section of the carpet standards.

The first parameter is chemical composition; the tablet is identified as a *methenamine* tablet. Chemical analysis determined no differences in chemical composition among the currently manufactured tablets; they are all pure methenamine. The second parameter is weight; the weight of the tablet is stated as *approximately 0.149 grams*. The 2002 Lilly Tablet, Tablet A and Tablet B weighed approximately 0.149 grams. Tablet C weighed approximately the same amount (0.146 grams) as the Lilly tablets with a 1977 expiration date did when they were measured by NBS in 1976.

Comparisons of burn time, average burn temperature, and heat of combustion were also made to evaluate the combustion properties of the different brands of methenamine tablets. Small differences were observed in the recorded combustion characteristics among the currently manufactured methenamine tablets and those measured in 1976 by NBS. Some of the observed differences may be due in part to the manufacturing process and test procedure. The pressing and curing processes determine the hardness of the tablets, which was not measured by CPSC Laboratory staff. The hardness may influence the initial burning of the surface of the tablets. In addition, the burn time measurements by CPSC staff, while conducted consistent with the NBS 1976 protocol, were made by observation and manually controlling a stopwatch. Slight differences in operator reaction times could introduce some variability as data is collected.

The 2002 Lilly Tablet and Tablet A were the only tablets with burn times that fell into the range of the average burn times recorded in 1976 (118 to 124 seconds). Tablet B tended to consistently burn longer with an average burn time of 130 seconds, while Tablet C consistently burned shorter with an average burn time of 116 seconds. However looking at the full range of burn time data, the average burn times for the 2002 Lilly Tablet, Tablet A and Tablet C fell into the range of burn times recorded in 1976 (104 to 132 seconds). Burn times for Tablet B extended slightly beyond that range at 114 to 134 seconds.

Although the differences in average burn times are viewed statistically as “significant differences,” the burn times for Tablet B and Tablet C were not that far outside the range of average burn times, considering the variability introduced by production and test methodologies. In addition, the full range of burn times indicates how similar the burn times are among these tablets. The average burn times of the methenamine tablets are plotted in Figure 2 below.

Methenamine Tablet Test Results

Average Burn Time (seconds)

	Lilly '02 CPSC	Lilly '81 CPSC	Lilly '81 NBS	Lilly '77 CPSC	Lilly '77 NBS	Tablet A CPSC	Tablet B CPSC	Tablet C CPSC
Avg	121	112	124	107	118	120	130	116
Std. Dev.	5	4	4	5	8	6	3	3
Range	108-129	104-120	113-132	97-113	104-130	110-131	114-134	107-122
No. of Tests	45	45	25	10	20	45	45	45

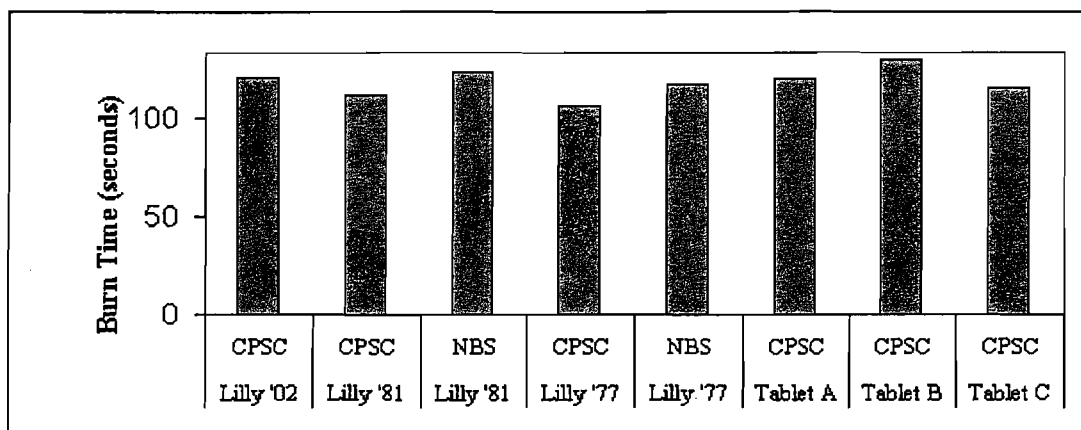


Figure 2. Average Burn Time

Differences in recorded maximum temperatures are influenced by measurement techniques. In the February 1976 report, NBS observed that the location of the thermocouple bead relative to the burning pill surface would influence the data collected. NBS suggested and used an arbitrary spacing of 1/16 inch between the surface of the tablet and the thermocouple bead. The maximum temperature occurs when the flame recedes and the thermocouple bead is in the tip of the cone of combustion. The flame typically recedes approximately 100 seconds into the burn. Laboratory staff took great care to maintain a 1/16-inch spacing between the thermocouple bead and the top of the tablet being tested (including measuring the spacing before every test). However, development of the cone of combustion over the relatively large surface area of the tablet relative to the size of the thermocouple bead can introduce uncontrollable variations in the temperature measured at a fixed location.

Differences in maximum temperatures were observed between the Lilly tablets in the 1976 NBS tests and Lilly 02 Tablets, Tablet B and Tablet C. However, there were no significant differences in maximum temperatures among the Lilly 02 Tablets, Tablet B and Tablet C. This is illustrated in Figure 3 below.

Methenamine Tablet Test Results

Average Maximum Temperature (°C)

	Lilly '02	Lilly '81	Lilly '81	Lilly '77	Lilly '77	Tablet A	Tablet B	Tablet C
	CPSC	CPSC	NBS	CPSC	NBS	CPSC	CPSC	CPSC
Avg	926	891	971	915	993	914	939	942
Std. Dev.	25	42	25	23	33	34	33	16
Range	874-999	802-975	917-1008	873-950	945-1066	848-1007	879-1038	909-976
No. of Tests	45	45	25	10	20	45	45	45

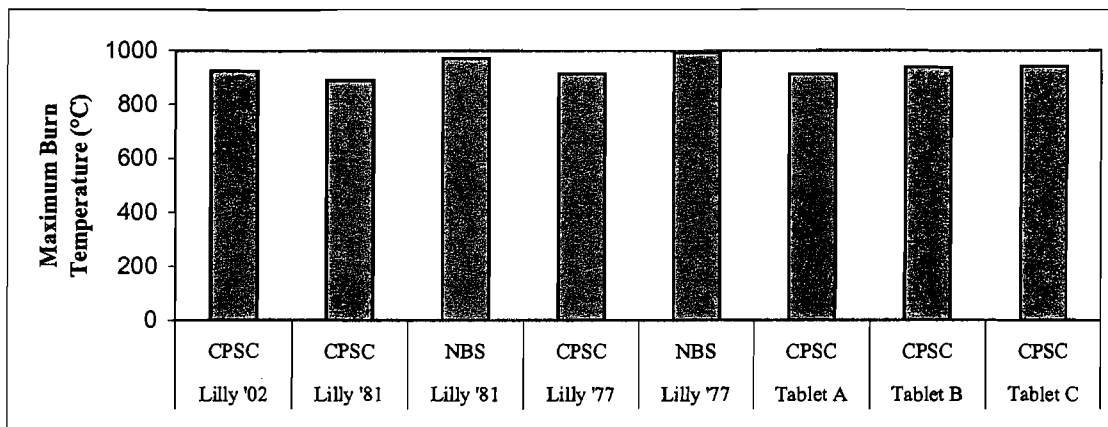


Figure 3. Average Burn Temperature

The differences in heat of combustion values between the tablets evaluated by NBS and the recently (2003) evaluated tablets could be due to the modern calorimetry equipment and procedures used by the CPSC staff's contractor. In the current evaluation, a larger number of test specimens were used. A calibration standard (benzoic acid) was included to ensure the reproducibility of the calorimeter. The standard deviation for the benzoic acid samples was very small, thus confirming that the microprocessor controlled calorimeter maintained accuracy during the series of tests conducted for CPSC.

NBS reported that the Handbook of Chemistry and Physics lists methenamine as hexamethylene-tetramine ($(CH_2)_6N_4$) having a heat of combustion value of 7180 calories/gram. The range of average heat of combustion values for the 2002 Lilly Tablet, Tablet B and Tablet C tablets is 7113 to 7146 calories/gram. These heat of combustion values deviate less than 1.0% from the handbook value.

Figure 4 is a plot of the heat of combustion data for the methenamine tablets used in this study and the 1976 NBS study.

Methenamine Tablet Test Results

Average Heat of Combustion (calories/gram)

	Lilly '02	Lilly '81	Lilly '81	Lilly '77	Lilly '77	Tablet B	Tablet C
	CPSC	CPSC	NBS	CPSC	NBS	CPSC	CPSC
Avg	7113	7054	6905	6906	6898	7146	7137
Std Dev	154	112		147		48	101
Range	6708-7333	6783-7147	6905	6697-7118	6898	7070-7206	6982-7269
No. of Tests	12	12	1	12	1	12	12

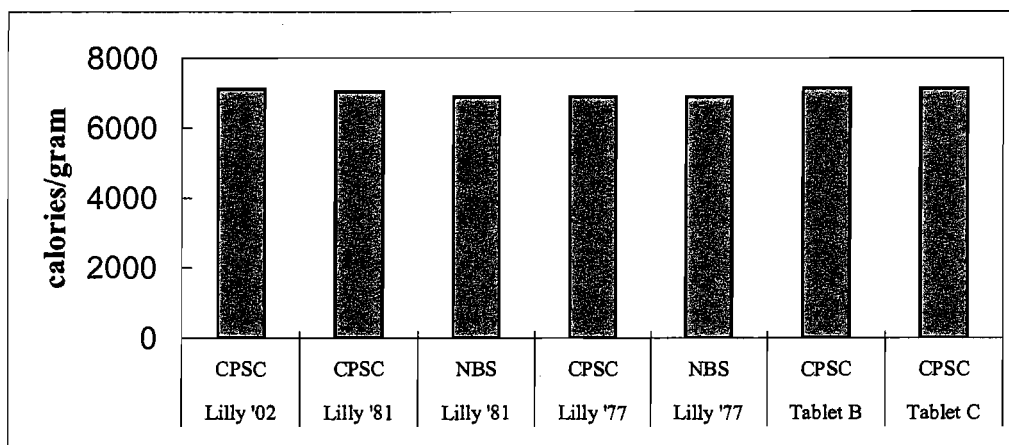


Figure 4. Average Heat of Combustion

Summary:

- The 2002 Lilly Tablet, Tablet B and Tablet C meet the two parameters specified in the carpet standards. They are all essentially pure methenamine and weigh approximately 0.149 grams.
- The 2002 Lilly Tablet, Tablet B and Tablet C all have heat of combustion values approximately equal to the standard value of methenamine.
- The 2002 Lilly Tablet, Tablet B and Tablet C all have similar maximum burn temperatures.
- Differences in data from the 1976 NBS study and the 2003 CPSC staff study may be due to differences in tablet manufacturing processes, test methodology and/or the number of samples tested in the 1976 study versus the 2003 study. Although some of these differences are viewed as “significant” as defined by statistical analysis of the data, the differences are small compared to the magnitudes of the values of the parameters and are small compared to the variations inherent in combustion tests.

CONCLUSIONS

The CPSC staff's evaluation of 2002 Lilly Tablets, Tablet B and Tablet C in comparison with each other and with tablets having expiration dates of 1977 and 1981 indicate that, for the purposes of determining conformance with the carpet standards:

1. Any of the pure methenamine tablets weighing approximately 0.149 grams may be used as the ignition source, and
2. The "pharmaceutical expiration date" of the tablets is not a suitable indicator of possible changes in the combustion characteristics of the tablets. Tablets at any age that have been properly stored and are physically intact may be used as the ignition source.

In addition, the parameters defining "or an equal tablet" in the carpet standards should be updated. Parameters to consider include chemical analysis, heat of combustion and weight. Standardized methods of analysis for each parameter should also be specified.



UNITED STATES
 CONSUMER PRODUCT SAFETY COMMISSION
 WASHINGTON, DC 20207

Memorandum

Date: May 22, 2006

TO : Patricia Adair, Project Manager, Carpets and Rugs *(PAC)*
 Directorate for Engineering Sciences

THROUGH: Edward W. Krawiec, Director, Division of Electrical Engineering *(EKW)*

FROM : Linda Fansler, Division of Electrical Engineering *(LF)*

SUBJECT : Methenamine Tablet Thickness

As requested, Laboratory Sciences staff measured the thickness of methenamine tablets from five sources. Ten methenamine tablets from each source were measured using a digital micrometer. The table below reports the individual measurements along with their averages (in bold font).

Tablet Identification and Thickness (mm)				
Lilly 2004	Lilly 1981	Tablet A	Tablet B	Tablet C
6.36	6.39	6.37	6.36	6.37
6.37	6.40	6.36	6.37	6.36
6.37	6.40	6.36	6.36	6.36
6.37	6.39	6.37	6.35	6.37
6.37	6.40	6.36	6.35	6.36
6.38	6.42	6.37	6.36	6.37
6.37	6.39	6.37	6.36	6.37
6.34	6.41	6.37	6.39	6.37
6.35	6.41	6.37	6.35	6.37
6.35	6.39	6.37	6.36	6.36
6.36	6.40	6.37	6.36	6.37



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: May 22, 2006

TO : Linda Fansler, LSE

THROUGH: Joel R. Recht, Ph.D., Director, LSC *JRR*

FROM : Shing-Bong Chen, Ph.D., LSC *SBC*
Bhawanji K. Jain, Chemist, LSC *BKJ*

SUBJECT : Chemical Composition of Methenamine Tablets

Five tablet samples in individual vials were received at the Division of Chemistry from the Division of Electrical Engineering (LSE). LSE requested determination of chemical composition of the tablets.

The inorganic chemical composition of the tablets was determined by dissolving a small portion of each tablet in 100 ml of water and subsequently doing an analysis with a Thermo Elemental Inductively Coupled Spectrometer (ICP). Screening for the presence of the following elements was conducted using the ICP's qualitative multi-quant method: Aluminum (Al), Barium (Ba), Calcium (Ca), Iron (Fe), Potassium (K), Magnesium (Mg), Sodium (Na), Phosphorus (P), Silicon (Si), and Zinc (Zn). The weight of tablets dissolved in water ranged from 10.7 milligrams to 22.3 milligrams. The results indicate solutions contained less than 0.1 ppm of these elements. The data are shown in Table I.

A Nicolet Fourier transform infrared spectrometer (FTIR) and an Aligent Technology gas chromatograph mass spectrometer (GC/MS) were used for the analysis of the organic chemicals in the tablets. Figure 1 shows the single peak gas-chromatogram of one of the tablet samples in methanol solution. The gas chromatograms of the other 4 tablets were similar. The computer library search of the peak indicates the sample tablet contains methenamine as shown in Figure 2. The FTIR spectra of all five tablets were similar. A computer library search again identified the tablet chemical as methenamine as shown in Figure 3.

The results from these instrumental analyses show that all five tablets have similar chemical composition. Thus the analyses indicate the tablets contain essentially no filler materials and are pure methenamine.

TABLE I**Intensity Response of metals for standards and tablets dissolved in 100 ml of water**

Standard		Al	Ba	Ca	Fe	K	Mg	Na	P	Si	Zn
0.1 PPM		10700	114000	163000	213	38	203000	53600	72	428	1320
1.0 PPM		33200	133000	143000	4850	119	142000	63800	530	1550	13000
10.0 PPM		241000	931000	1600000	54100	838	926000	167000	5240	12900	132000
BLANK (water)		9240	785	15000	29	54	1400	61900	58	271	38
	Tablet wt. (mgs) in 100 ml of water										
Tablet-A	22.3	9990	651	12200	32	51	1260	59200	48	156	31
Tablet-B	10.7	9720	645	6130	22	38	1380	59900	66	145	29
Tablet-C	14.4	10100	577	8100	25	51	1430	63800	69	123	41
Tablet-D	13.1	9080	900	7250	31	50	1320	62600	58	201	24
Tablet-E	17.4	9500	894	6050	28	54	1610	63000	56	0	34

Figure 1.

**Chromatogram of a Tablet Sample in Methanol
(temperature programming 80°C(1 min)/ 20°C/min /280°C)**

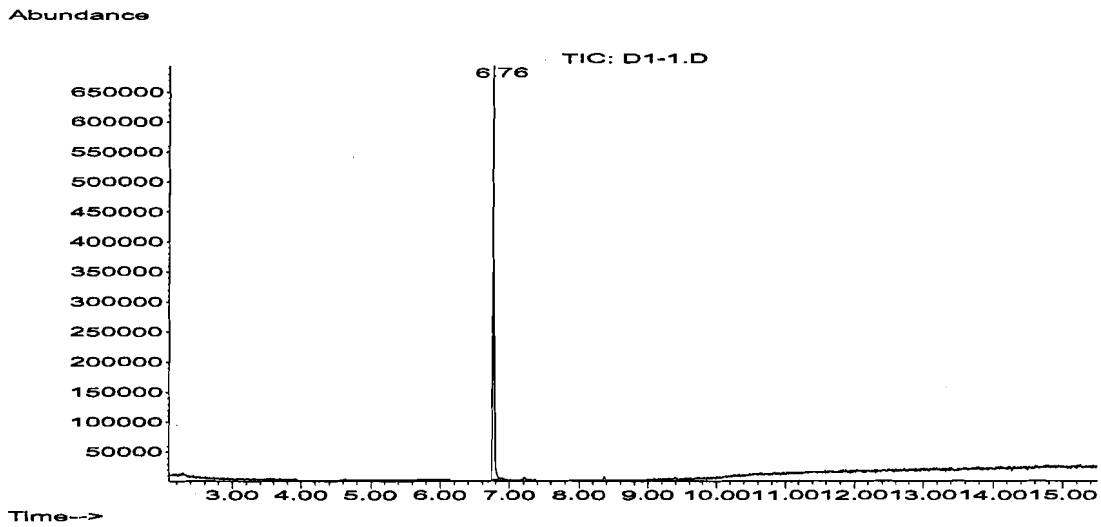


Figure 2.

Mass spectra of peak 6.76 min

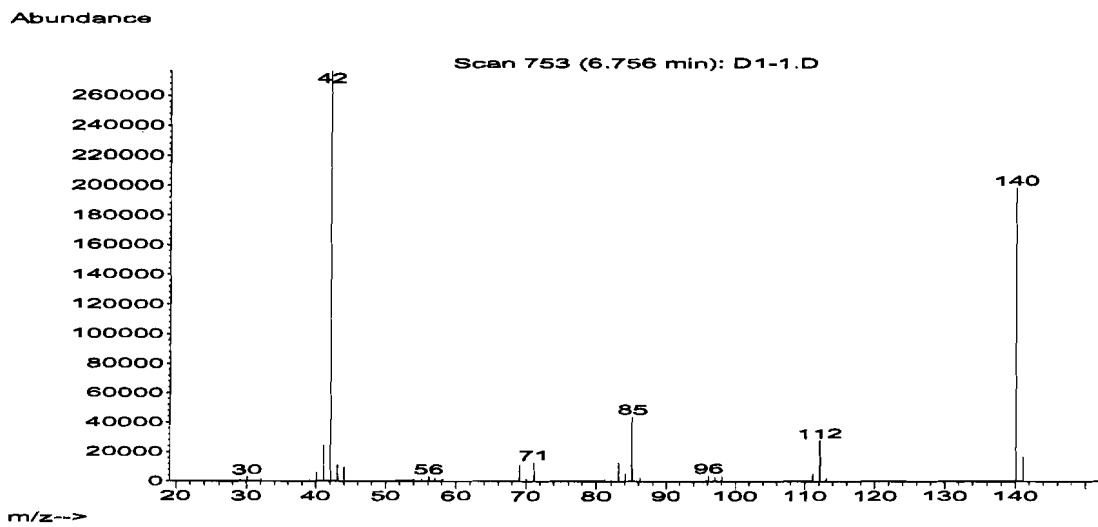
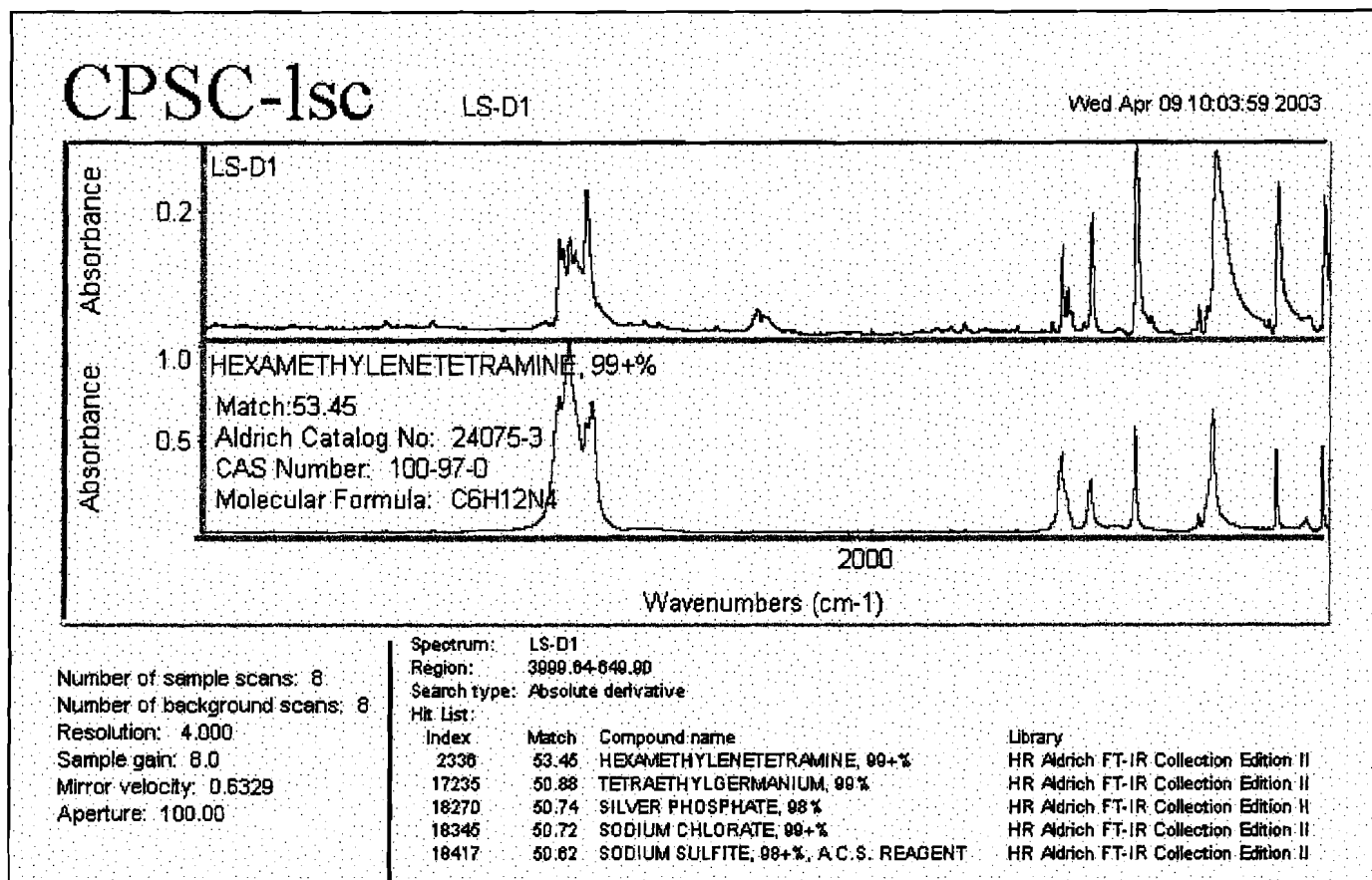


Figure 3.

IR spectra of search results



TAB B



U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Alan H. Schoem
Director
Office of Compliance

Tel: 301-504-7519
Fax: 301-504-0008
email: aschoem@cpsc.gov

July 29, 2004

Re: Equivalency of Methenamine Tablets
Standard for the Flammability of Carpets and Rugs
16 C.F.R. Parts 1630 and 1631

To Whom It May Concern:

This letter responds to inquiries recently received by the U.S. Consumer Product Safety Commission (CPSC) concerning the equivalency of methenamine tablets formerly manufactured by the Eli Lilly Company and similar tablets currently produced by other manufacturers.

As you know, the CPSC administers two flammability standards for carpets and rugs: 16 Code of Federal Regulations (C.F.R.) Part 1630 – Standard for the Surface Flammability of Carpets and Rugs and 16 C.F.R. Part 1631 -- Standard for the Surface Flammability of Small Carpets and Rugs. Both standards require a methenamine tablet as the standard ignition source for flammability performance testing. The standards define the ignition source as a methenamine tablet, weighing approximately 0.149 grams (2.30 grains), sold as Product No. 1588 in Catalog No. 79, December 1, 1969 by the Eli Lilly Company, or an equal tablet.

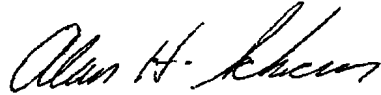
In April 2002, Commission staff learned that the Eli Lilly Company was no longer producing the methenamine tablets specified in the carpet and rug standards. Although the standards allow for the use of an "equal" methenamine tablet and give parameters for chemical composition and weight of the tablet, they do not provide any guidance on determining whether tablets from alternative sources are "equal" to those manufactured by the Eli Lilly Company. Therefore, in an effort to make such a determination, the Commission's Laboratory Sciences staff conducted testing designed to evaluate the weight, chemical composition, and combustion characteristics of presently available brands of methenamine tablets relative to each other and those produced by the Eli Lilly Company. The outcome of this testing indicates that tablets consisting of pure methenamine and weighing approximately 0.149 grams may be considered equivalent to the tablets formerly produced by the Eli Lilly Company. Therefore, tablets meeting these criteria may be used for purposes of determining conformance with the carpet and rug standards.

Page 2

The Commission staff is considering recommending to the Commission that it update the carpet and rug standards to reflect the above mentioned findings. Please contact Jason Hartman at (301) 504-7591, if you have any questions.

This interpretation is based on the information currently available to the staff and has not been reviewed or approved by the Commission.

Sincerely,

A handwritten signature in cursive script that reads "Alan H. Schoem".

Alan H. Schoem

TAB C



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: September 11, 2006

TO : Patricia K. Adair, ESFS
Project Manager, Carpets and Rugs

THROUGH: Gregory B. Rodgers, Ph.D. Associate Executive Director, Economic Analysis *GBR*
Deborah V. Aiken, P Aiken, Ph.D., Senior Staff Coordinator *DVA*

FROM : Terrance R. Karels, Directorate for Economic Analysis *TRK*

SUBJECT : Preliminary Regulatory Analysis --- Standards for Carpets and Rugs

The Commission is considering a technical amendment to the carpet and rug standards issued under the Flammable Fabrics Act (FFA). The staff's draft proposed amendment would revise the definition of the methenamine tablet, which is used as the ignition source for flammability performance testing.

Under 16 C.F.R., Parts 1630 and 1631, the standards specify the timed burning tablet as a "methenamine tablet, weighing approximately 0.149 grams (2.30 grains) sold.... by the **Eli Lilly Company**.... or an equal tablet." Since the standards were issued in 1970, manufacturers have used methenamine tablets produced by that single manufacturer (Lilly) to ensure compliance with Parts 1630 and 1631 of the FFA. However, Lilly ceased production of the test tablets in 2002, and other manufacturers are now producing methenamine tablets. The staff's draft proposed amendment would specify the size, weight, heat of combustion, and composition of a methenamine tablet that would be considered equivalent to the original Lilly tablet.

REQUIREMENTS OF THE ACT

The FFA requires that the Commission provide a preliminary analysis of the draft proposed rule during development of the Notice of Proposed Rulemaking. This preliminary analysis must contain:

- a description of the potential benefits and costs of the proposal;
- a discussion of the reasons any existing or potential voluntary standard should not be the basis for the proposal; and
- a description of any reasonable alternatives to the proposal.

Additionally, under the Regulatory Flexibility Act of 1980 (RFA), the Commission is required to address the potential economic effects of the draft proposed rule on small businesses and other small entities. Also, under the National Environmental Policy Act (NEPA), the Commission is required to consider the potential environmental effects of the draft proposed rule.

Potential Benefits and Costs

Since the alternative tablets described under this staff's draft proposed rule would share the same burn characteristics as those originally specified by the carpet and rug standards, the replacement tablets are not likely to result in any change in effectiveness compared to the original (Lilly) tablets; thus, they would not result in direct decreases or increases in rates of fire death, injury, or property damage associated with carpet or rug fires. The staff's draft proposed amendment would therefore not result in any changes in the expected benefits associated with the standards.

The staff's draft proposed amendment to the standards is not expected to increase costs to manufacturers of currently-complying carpets and rugs. The cost of the alternative tablet itself is not expected to be greater than the cost of a currently-allowed tablet (Lilly). The cost of the test tablets is considered to be minimal compared to other testing costs. If the amendment resulted in

increased testing (and increased testing costs), costs to manufacturers could increase. However, no additional testing or recordkeeping requirements are expected as a result of the staff proposal.

Standards

The Commission staff is aware of one existing U.S. voluntary standard regarding the type of ignition source to be used in testing the flammability of carpets and rugs. This standard, ASTM D2859-04, "Standard Test Method for Ignition Characteristics of Finished Textile Floor Covering Materials," describes the use of the Lilly tablet as satisfactory. It also states that "normal variation in the weight of the different tablets will not affect the test results."

There is an existing international voluntary standard developed by the International Organization for Standardization in 1982 (ISO 6925), that describes a tablet test for the flammability of textile floor coverings. The prescribed tablets are of "hexamethylenetetramine, flat, having a mass of 150mg (plus or minus 5mg) and a diameter of 6mm." The allowable variance is about 3.3%. The mass expressed in ISO 6925 is essentially equivalent to that specified in the U.S. standards under the FFA. While the ISO standard did not identify the Lilly tablet, it noted that the tablets were commercially available. Thus, the ISO-specified tablet is equivalent to the Lilly tablet in its specifications.

Canada's 1973 mandatory standard for carpets and textile floor coverings under the Hazardous Products Act, CGSB 4-GP-2, also specifies in its appendix the Lilly tablet as the ignition source. It notes that "normal variation in weight.... will not affect the test results."

Alternatives

The Commission may choose to use the definition of the test tablet as specified in ISO Standard 6925, which specifies that the burn test tablet have an approximate "mass of 150 mg," which may result in equivalent burn characteristics of alternative methenamine tablets that will

continue to be available. This could be accomplished through technical amendments to the carpet and rug standards.

Also, the Commission may choose to direct the staff to develop alternative *test methods or other substitute substances* that would result in heat-of-combustion values equivalent to that of the Lilly methenamine tablets. However, the staff is not aware of any such substitute product other than methenamine tablets. Any substitute testing process may result in short term disruptions in product development and testing, and in a potential for confusion by manufacturers as to the change in the testing process. Staff will solicit public comment on the availability and feasibility of alternative ignition sources.

Regulatory Flexibility Act

The RFA requires that the Commission consider whether a proposed rule would have a significant effect on a substantial number of small entities, including small businesses and small government entities. The staff's proposed amendment keeps current industry practices and procedures in place, and no additional actions would be required of small entities.

Based on available information, there would be little or no effect on small producers of carpets and rugs, since the standards already require that all carpets and rugs meet the criteria of the tests and, given the equivalence of the test tablets, the results of the tests should be the same. Consequently, the Commission could conclude that there are no expected economic consequences on a substantial number of small entities.

Environmental Impact

Under NEPA, there are requirements that the Commission consider the potential environmental impact as the result of a proposed rule. Since the staff's proposal continues current industry practices, with equivalent ignition tablets, and without any additional

requirements, staff expects no environmental impact as a result of the proposal. The amendment is not expected to have an impact on the production processes developed by manufacturers. Also, there is no expected impact on the amounts of materials used in manufacture, packaging or labeling. It would not render existing finished goods inventories, or works in progress, unsellable, or require destruction of these products.