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February 9, 2009

VIA HAND DELIVERY and EMAIL

John Gibson Mullan, Esquire
Director of Compliance
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, Maryland 20814

Cheryl A. Falvey, Esquire
General Counsel
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, Maryland 20814

Re: Section 101 Request for Lead Content Exclusion for Pen Point Components

Dear Mr. Mullan and Ms. Falvey:

The Writing Instrument Manufacturers Association ("WIMA") is the U.S. trade association of the pen, pencil and eraser industry. Our members account for approximately 75% of the manufacture and distribution of writing instruments in this country. A list of our members is attached as Exhibit 1. WIMA has regularly participated in rulemakings before the CPSC since the agency's formation in 1973.

We are writing to you about a very serious compliance problem involving lead in ball point pens and roller ball pens. Based upon our analysis, all pen points used in these products, when marketed as children's products as defined by Section 235(a) of the CPSIA, will be violative of Section 101(a)(2) of the CPSIA when the total lead provision goes into effect on February 10, 2009. And there is no alternative metal that can be used for pen points that does not contain some violative quantity of lead. Accordingly, WIMA, on behalf of its members, and any other importers, manufacturers or distributors similarly impacted, files this Section 101 Request for Lead Content Exclusion for Pen Point Components. The Request is supported by a toxicological study and report from

Woodhall Stopford, MD, MSPH and Danielle Capellini, B.Sc., MHA, which is attached as Exhibit 2.

For your convenience, we are following the outline set forth in proposed 16 CFR Part 1500.89 (c)(4) for requests for lead content exclusions. To the extent that additional information is required by the final rule, we would be pleased to supplement this request with such information.

Part 1500.89(c)(4)(i) Detailed Description of the Product:

Pen point components are the portion of the pen that holds the ball, which in turn delivers ink to the paper. A depiction of the typical parts of a pen is attached as Exhibit 3.

Part 1500.89(c)(4)(ii) Data on the Lead Content of the Pen Point Component:

Pen point components contain lead in quantities far in excess of the 600 PPM total lead standard prescribed by Section 101(a)(2) of the CPSIA. Most pen point components are made from brass, and lead is a necessary ingredient, because it permits the pen point component to be easily machined during production of the pen point, and because it makes the pen point component much more durable. Lead levels for brass pen point components range from 2.5% total lead to 5% total lead. Some pen point components in more expensive pens are made from stainless steel or nickel silver and have lower total lead levels (ranging from .10% to 2%), but will still be violative of the total lead standard after February 10, 2009. However, the vast majority of pen point components (our estimate is more than 85%) are made from brass and have much higher lead levels.

In a previously considered FAQ, CPSC staff stated that unless the ball point pen is considered a children's product (Section 235(a) of the CPSIA), the pen would not be considered violative of the Section 101(a)(2) standard. See http://www.cpsc.gov/ABOUT/Cpsia/faq/faqs.html. While it is certainly true that many ball point pens and roller ball pens are sold primarily for business or office product purposes, or for use by older students and adults, and others are sold primarily for advertising specialty purposes, and would not be subject to the lead standards, there remains a substantial quantity of these products which are expressly sold to school systems, or are sold to retailers, who primarily market these products to children 12 and younger.

According to our members, after consultation with the manufacturers of pen point components, there is no ready substitute for these brass, stainless steel or silver nickel components. WIMA first became aware of this problem in October and was hopeful, initially, that some substitute material could be utilized. However, according to our supplier members, there is no known substitute for the brass, stainless steel or silver nickel pen point components and it will likely take two or more years to develop a substitute (if one is available). In the interim, all ball point pens sold in the U.S., which meet the definition of children's product under the CPSIA, will be in violation of the total lead standard on February 10, 2009. Retractable and stick ball point pens account for approximately 85% of all pens sold in this country, and for approximately 95% of pens

sold for use in schools, or by children under the age of 12. Our rough estimate is that this problem impacts four to five billion ball point pens. Roller ball pens are also often sold to children 12 and younger. Our rough estimate is that this problem impacts another one billion roller ball pens.

Part 1500.89(c)(4)(iii) Data or Information on Manufacturing Processes through which Lead may be Introduced into the Pen Point Component:

Lead is introduced into the pen point component by mixing brass, which is a metal alloy containing lead, with pure metals, in an induction heating oven. The lead physically attaches to the metals while in the melting chamber. The resulting product used for the pen point component therefore contains lead levels ranging from 1 to 5%.

Part 1500.89(c)(4)(iv) Any Other Information Relevant to the Potential for Lead Content of the Pen Point Component to Exceed the CPSIA Lead Limits.

None at this time.

Part 1500.89(c)(4)(v) Detailed Information on the Relied Upon Test Methods for Measuring Lead Content of Pen Point Component (including equipment used and technique employed) and Why Data is Representative of the Lead Content of Pen Point Generally:

We apologize for the last minute nature of this request for exclusion, however, the reason for the delay in filing is arguably a good one. During December 2008 and January 2009, WIMA had actual testing conducted on a wide sampling of pen point components by Danielle Cappellini, B.Sc., MHA of the Kirby Memorial Health Center laboratory in Wilkes-Barre, Pennsylvania. This testing was then analyzed by Dr. Woodhall Stopford, MD, MSPH of Duke University Medical Center. (Dr. Stopford may be familiar to some CPSC staff as he is the nationally recognized toxicologist for the ACMI, PMA and WIMA certification programs.) The Stopford/Cappellini report dated February 8, 2009 and entitled "Bioaccessibility of Lead in Metal Pen Tips" is attached as Exhibit 2. We would note that, in accordance with Section 101(b)(1)(A), this report has been peer reviewed by members of WIMA's Toxicology Advisory Board, comprised of the following toxicologists:

Tom Starr, PhD
TBS Associates
7500 Rainwater Road
Raleigh, NC 27615

John H. Mennear, PhD
Consulting Toxicologist
103 Eagle Court
Cary, NC 27511
James Lamb, PhD

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Elaina Kenyon, PhD
US EPA
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Research Triangle, NC 27711

In order to reduce the length of this filing, we have not included copies of the CVs of the members of the WIMA Toxicology Advisory Board. However, we would be happy to provide them to you upon request.

The statutory standard for exclusion of certain materials or products under the CPSIA is as follows:

The Commission, may, by regulation exclude a specific product or material from the prohibition in subsection (a) if the Commission, after notice and a hearing, determines on the basis of the best-available, objective, peer-reviewed, scientific evidence that lead in such product or material will neither-

- *(A) result in the absorption of any lead into the human body, taking into account normal and reasonably foreseeable use and abuse of the such product by a child, including swallowing, mouthing, breaking or other children's activities, and the aging of the product; nor*
- *(B) have any other adverse impact on public health or safety.*

Section 101(b)(2)(A) and (B) of CPSIA.

The conclusions of this peer-reviewed report are first, that skin and mouth exposure to lead do not occur with normal and reasonably foreseeable use of pens, and that if incidental exposure occurs, it will not result in absorption of lead in a detectable range. Report at page 6, "*Does lead absorption occur from use of pens*?

Thus, the Stopford/Cappellini report clearly establishes by the best-available, peer-reviewed, scientific evidence that lead in the pen point component will not "…result in the absorption of any lead into the human body…" Section 101(b)(1)(A) of the CPSIA.

Second, the report establishes that even the remote possibility of exposure to lead would be well below the lowest, most stringent, standard in the country for lead, the Proposition 65 standard for reproductive harm, which is 0.5 micrograms per day. Report at page 6, "*Does lead absorption from use of metal pens present a public health risk?"* As Table 4 of the report shows, the possibility of absorbed lead from a pen point component is less than 0.012 micrograms a day. Such exposure is virtually impossible to measure, it is so low. As the authors of the report state, it is "..a non-detectable amount." Report at page 7, *Conclusions*. Clearly, the report establishes that lead in the pen point component

would not "…have any other adverse impact on public health or safety. Section 101(b)(1)(B) of the CPSIA.

Conclusion:

As a result of this unique situation, in accordance with Section 101(b)(1) of the CPSIA, WIMA is requesting that pen point components be excluded from the new total lead standard because as demonstrated by the Stopford/Cappellini peer-reviewed report: (A) the lead in the pen point component will not result in the absorption of any lead into the human body and (B) there is no adverse impact on public health or safety. In further support of this request, WIMA notes that hundreds of billions of pens with this type of pen component containing lead have been sold for over the past fifty years with no known adverse health or safety impact.

In conclusion, WIMA, on behalf of its members, and for the benefit of the entire pen industry in the United States, respectfully requests that the Commission exclude pen point components from the Section 102(a) total lead requirement. WIMA notes that without such an exclusion, the annual manufacture, distribution and sale of five to seven billion pen products will come to a halt in this country.

Respectfully submitted,

David H. Baker
General Counsel and Executive Director
Writing Instrument Manufacturers Association

cc: Ms. Mary Toro, Deputy Director of Regulatory Enforcement

Enclosures Listed Below:

Exhibit 1 – List of WIMA Members
Exhibit 2 - Stopford/Cappellini Report
Exhibit 3 - Photo of Pen Parts and Line Drawing of Pen Point Component

Exhibit 1

List of WIMA Members

Apex Machine Company
Avins Industrial Products Corp
BIC Corporation
California Cedar Products
Chad Labs Corporation
Cly-Del Manufacturing Company
Crayola LLC
Crown Roll Leaf
Dixon Ticonderoga Co.
Egyptian Lacquer Mfg. Co.
Filtrona Fibertec, Inc.
General Pencil Company
Ideal Metal Manufacturing, LLC
J. Rousek Co.
Jensen's
JSB, Inc. (UpWrite Pens)
Listo Pencil Corp.
Mitsubishi Pencil Corp. of America
Moon Products/MegaBrands America
Musgrave Pencil Company, Inc.
Myron Manufacturing Corp.
National Pen Corp.
Navajo Manufacturing Company
Orient Corporation of America
Pentel of America
Pilot Pen Corp. of America
Pointe International
Porex Porous Products Group
Products & Ventures International
Rosinco AB
Sanford
Shachihata USA
Simmons Rennolds Associates LLC
Specialty Adhesives & Coatings
Staedtler, Inc.
Tennessee Technical Coatings Corp.
Tombow
U&J International, Inc.
United Color Manufacturing, Inc.
Webtech

Exhibit 2

Duke University Medical Center
Department of Community & Family Medicine
Division of Occupational & Environmental Medicine
Box 3934
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February 8, 2009

Bioaccessibility of Lead in Metal Pen Tips

Woodhall Stopford, MD, MSPH and Danielle Cappellini, B. Sc, MHA

Introduction

Metal point pens are made with milled tip components made of stainless steel, nickel silver or brass alloys that may contain in excess of 0.06% lead. Such tip components, however, can only be removed from pens or cartridges with tools and, therefore, do not pose an ingestion concern. Metal pen tips are not designed to be grasped during drawing and would only be expected to come into contact with skin or saliva by incidental contact. The following study addresses issues of whether absorption could occur in an age category of children (ages 6-12) who might use metal pens in a school setting. Ten types of metal pen tips were obtained from manufacturers in bulk. Nineteen pens were obtained at retail to determine exposed tip length. Tips were analyzed for total lead and for bioaccessible lead using synthetic sweat and synthetic saliva.

Methods

Total Lead: EPA SW-846 Method 6200 was used to test for lead content in bulk samples of pen tips by x-ray fluorescence (XRF). This is a nondestructive procedure and was originally developed for testing packaging to address issues of conformance with landfill ordinances (USEPA, 2007). For these analyses a Niton XL3t XFR (Thermo Fischer Scientific) laboratory unit was used. This method is sensitive to 2.5 ppm (microgram/g) lead and correlates well with destructive digestive methods and analysis by atomic absorption spectroscopy (Cappellini and Stopford, 2008)

Synthetic Sweat: A sweat equivalent salt mixture was prepared with technical grade reagents to conform with EN1811 (a synthetic sweat method used to test nickel containing materials that come into prolonged contact with skin) using the following salt proportions:

	g/L of DI Water
Urea	1
Sodium Chloride	5
Lactic Acid	940 microliters

pH was adjusted to 7.6 with a solution of ammonium hydroxide.

Synthetic Saliva: A saliva equivalent salt mixture was prepared with technical grade reagents to conform with DIN 53160 (a synthetic saliva method developed to determine extraction of dyes from articles) using the following salt proportions:

	g/L of DI Water
Sodium Bicarbonate	4.2
Sodium Chloride	0.5
Potassium Chloride	0.2

pH was adjusted to 7.3 with 2N HCl.

Lead extraction: Four to 8 pen tips from each batch were submersed in synthetic sweat and synthetic saliva (to make up approximately 1 gm of pen tips/per 50 ml of extractant) and extracted for 15 minutes. Pen tips were extracted at 37º C in the sweat solution without shaking. Pen tips were extracted in the saliva solution in a reciprocal shaker water bath at 37^{o} C. Whether or not a shaker was used was based on the specifications in the synthetic sweat or saliva test methods. The extractants were then analyzed for lead by graphite furnace atomic absorption spectroscopy (EPA SW-846 Method 7421). This analytical method has a method detection of 1 ppm (1 microgram/g). Duplicate testing was done when detectable lead levels were found.

Tip length: The exposed length of each metal pen tip was measured to the nearest millimeter. Tips were then removed from the pens or cartridges and the total pen tip length was measured to the nearest millimeter. In each instance tools (pliers, hacksaw or knife) had to be used to remove the tips from the pens or cartridges.

Results

Results for total lead found in the pen tip samples and the results of extractions are summarized in the following table:

Table 1: Total and Bioaccessible Lead levels in Pen Tips

Metal Pen Tip Batch	Single Tip Weight (g)	XRF Lead Value (microgram/g)	Soluble Lead released per tip (micrograms)	Soluble Lead released per tip (micrograms)
			Synthetic sweat	Synthetic saliva
1	0.3001	25630	0.7-1.0	1.2/1.2
2	0.1439	27714	0.5-0.6	0.8-0.9
3	0.2270	1070	<0.3	<0.3
4	0.2250	1335	<0.3	<0.3
5	0.2166	1111	<0.3	<0.3
6	0.2721	13825	<0.3	<0.3
7	0.2197	21571	<0.3	<0.3
8	0.2836	15937	<0.3	<0.3
9	0.2193	22756	<0.3	<0.3
10	0.2725	18912	<0.3	<0.3

In the 19 pens, the exposed portion of the pen tip was 3-4 mm. The ratio of exposed length to total length of the pen tips was 0.34 ± 0.05 (1 sd). Release rates were adjusted to reflect the length of the tip that could come into contact with sweat or saliva by multiplying this ratio times the measured release rate for the entire tip.

When expressed in terms of microgram of lead release in one minute of contact, after adjusting for average length of the pen tip that is available for touching or mouthing, the results are as follows:

Table 2: Release rate (micrograms lead released in one minute of contact)

Metal Pen Tip Batch	Release rate to sweat (micrograms)	Release rate to saliva (micrograms)
1	0.016-0.021	0.027/0.027
2	0.011-0.013	0.019-0.021
3	<0.005	<0.005
4	<0.005	<0.005
5	<0.005	<0.005
6	<0.006	<0.006
7	<0.005	<0.005
8	<0.006	<0.006
9	<0.005	<0.005
10	<0.006	<0.006

Discussion

Choice of pH of extractant fluids

pH in axillary sweat has been found to approach that of serum (Burry et al., 2001). In adults blood pH averages 7.4 with children being found to have that blood pH by age 7-12 (Dong et al, 1985) with slightly lower pHs in younger children. Ecrine sweat glands in the palms are, however, shorter and palmar sweat can be slightly alkaline with an average pH of 7.6 with CO_2 equilibration in experimental animals (Goldsmith, 1983). This pH range is similar to that found in the palmar sweat of man where pH's can range to 7.5-7.8 (Kuno, 1956). A pH of 7.6 was chosen for this study.

The pH of saliva has been investigated in a study conducted by the National Institute of Public Health and the Environment of the Netherlands (RIVM, 1998), a study designed to investigate phthalate release from plastics when mouthed. The saliva pH of 3 groups of participants was measured with mean pH values ranging from 7.3-7.4. A pH of 7.3 was chosen for this study.

Lead release and exposure from contact with sweat and saliva

Although all pen tips tested contained >600 ppm total lead, less than 0.1% of the total lead was released in 15 minutes with exposure of the pen tips to synthetic saliva or sweat (Table 1) with no detectable release from 8 of 10 batches of pen tips. There was no correlation between total lead content and potential for lead release when pen tips came into contact with synthetic sweat or saliva.

When exposures were corrected to represent exposures to the exposed portion of the tip, exposures from skin contact or mouthing would be expected to be less than 0.03 micrograms in one minute of contact (Table 2), a non-detectable level.

Absorption from skin contact

Skin contact to metal pen tips does not occur during their use because the pens are always held well above the tip so that any contact would be incidental. Soluble lead salts can be absorbed with skin contact with absorption rates ranging from 0.00003-00025% per minute of the applied solution (Moore, et al. (1980). When absorption rates for soluble lead salts are taken into account, skin absorption from incidental contact to these metal pen tips would be as follows:

Table 3: Amount of lead absorbed in one minute of sweat contact

Metal Pen Tip Batch	Absorbed lead (micrograms)
1	<0.00000004
2	<0.00000003
3	<0.00000002
4	<0.00000002
5	<0.00000002
6	<0.00000002
7	<0.00000002
8x	<0.00000002
9	<0.00000002
10	<0.00000002

Since exposure would, at best, be incidental, exposure and absorption would be expected to be well less than the amounts found in this study after one minute of contact to synthetic sweat (Tables 2 and 3).

Absorption from mouthing

Mouthing of non-toy items is uncommon in 3 year old children and is not found in older children. RIVM (1998) found that such behavior occurred for 2 minutes of the waking day in 3 year old children. Freeman, et al. (2001) found, however, that from the age of 5-12 no mouthing of objects could be detected in any hour, a significant difference from children ages 3-4 where an average of 3 such incidents occurred each hour. Absorption efficiency of soluble lead from the gastrointestinal track is usually considered to be 40% for most models (Oomen, et al., 2003). The amount of lead absorbed from saliva contact to metal pen tips for one minute would be expected to be as follows:

Table 4: Amount of lead absorbed in one minute of saliva contact

Metal Pen Tip Batch	Absorbed lead (micrograms)
1	<0.012
2	<0.009
3	<0.002
4	<0.002
5	<0.002
6	<0.003
7	<0.002
8	<0.003
9	<0.002
10	<0.003

Since exposure would be incidental, exposure and absorption would be expected to be well less than the amounts found released after one minute of contact with synthetic saliva in this study (Tables 2 and 4).

Does lead absorption occur from use of pens?

Skin exposure to metal pen tips does not occur with normal use. If skin contact did occur, lead exposure would be in the non-detectable range, i.e., in the sub-microgram range as noted in Table 2 and absorption associated with such exposures would also be non-detectable, i.e., in the subpicogram range, well less than the amounts determined for one minute of sweat contact noted in Table 3.

Mouthing of non-toy objects is uncommon in 3 year old children and is not found in older children. Lead exposure would not be expected in older children from mouthing of metal pen tips. If mouthing occurred, lead exposure and absorption would be incidental and in the non-detectable range, i.e., in the submicrogram range, well less than the amounts determined for one minute of saliva contact noted in Tables 2 and 4.

Does lead absorption from use of metal pens present a public health risk?
California's Office of Environmental Health Hazard Assessment has completed a risk assessment for acceptable daily exposures to lead and has determined a maximum allowable dose level (absorbed lead) of 0.5 micrograms/day for the most sensitive endpoint (reproductive toxicity). Any possible exposures to lead from metal pen tips would be well below this level and, consequently, absorption of lead from incidental exposures to metal pen tips would not present a risk to public health.

Conclusions

Metal pen tips investigated in this study contained greater than 0.06% total lead but the amount that could be extracted with synthetic sweat or saliva was <0.1% of the total amount of lead present, being non-detectable in 80% of the batches tested. When corrected for the length of the pen tip that could come into contact with the skin or mouth, <0.03 micrograms of lead were found to be released in one minute of contact, an amount that is non-detectable. Since exposure would be incidental and only to the exposed portion of the pen tip, exposures would be expected to be well less than 0.03 micrograms a day, a non-detectable amount. The skin acts as an excellent barrier to absorption of soluble lead salts. Incidental skin exposure to metal pen tips would be expected to be associated with an absorbed dose of well less than 0.00000004 micrograms a day, a non-detectable amount. Exposures from incidental mouthing would be expected to be well less than 0.012 micrograms a day, a non-detectable amount. Absorption of lead from these incidental exposures would not present a public health risk.

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Exhibit 3

Photo of Pen Parts and Line Drawing of Pen Point Component supplied in paper filing with Office of the Secretary.