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March 25, 2013

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Mr. Todd A. Stevenson
The Secretariat, Office of the Secretary
Division of Information Management
Office of General Counsel
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814

Re: BIC USA Functional Purpose Test Exception Request

Dear Todd:

I am attaching for filing with the Office of the Secretary, a Functional Purpose Test Exception Request on behalf of BIC USA ("Request").

Attached to the Request are six attachments. Attachments 2 and 5, the Bureau Veritas test reports, each contain a confidential photo of a prototype BIC Children's Pen, at page 3 of the reports. Attachment 6, the Statement of Greg Gorder, contains a confidential photo of several prototype BIC Children's Pens at page 2 of the Bureau Veritas test report included with his Statement. We request Section 6(a) confidential treatment for these three pages containing photos of the BIC Children's Pen. This product has never before been seen in the U.S. market, is a highly proprietary design and would be of great commercial value to BIC's competitors. We ask that these photos not be included in the public file at this time.

BIC USA is planning on launching the BIC Children's Pen in January 2014.

Please let me know if you have any questions regarding this filing.

Very truly yours,



David H. Baker
Attorney for BIC USA

Enclosures (Request and six attachments)

BEFORE THE
U.S. CONSUMER PRODUCT SAFETY COMMISSION

REQUEST FOR FUNCTIONAL PURPOSE TEST EXCEPTION
PURSUANT TO SECTION 101(b)(1)
OF THE CONSUMER PRODUCT SAFETY IMPROVEMENT ACT
15 U.S.C. SECTION 1278a(b)(1)

ON BEHALF OF
BIC USA INC.

Summary

BIC USA Inc. ("BIC USA") is a leading manufacturer and distributor of stationery products such as writing instruments including ball point pens, gel ink pens, roller ball pens, mechanical pencils, highlighters, permanent and dry erase markers as well as correction fluid and other correcting products.

BIC has developed a new line of writing instrument products aimed at helping children learn to write. One of the products is a pen product, sized and shaped for children age 5 and up. To the best of BIC's knowledge of the market place, this is a totally new product and would be the first, widely distributed, pen product designed primarily for use by children in the U.S.

Like most ball point pens manufactured throughout the world, the pen point on this new children's pen contains total lead in excess of 100 ppm. As the Commission will recall from the Request for Exclusion for Pen Tips submitted by the Writing Instrument Manufacturers Association ("WIMA") in 2009, most pen points, whether composed of brass or nickel silver, have total lead content in excess of 2,500 ppm. See WIMA Submission dated February 9, 2009. As a result, virtually all pens sold in the U.S. would have violated Section 101(b) of the Consumer Product Safety Improvement Act of 2008.

Although the WIMA Petition for an Exclusion was ultimately denied by the Commission, by a 1-1 tie vote, with Commissioner Nord voting to grant the Petition to exclude pens from the Section 101(b) prohibition on products containing any lead, the Commission also ruled at the same time that most pens are not children's products, and therefore are not subject to the total lead limits. This ruling, announced by then General Counsel Cheryl Falvey, in a letter dated June 4, 2009, was referenced in both the Yea vote by Commissioner Nord and the Nay vote by Commissioner Moore.

Unfortunately, for BIC USA, their new children's pen *is* subject to the Section 101(a) total lead standard because it falls under the subset of pen products clearly designed and intended primarily for use by children aged 12 or younger. See Section 3(a)(2) of CPSA; 15 U.S.C. Section 2051(a)(2). While the sale of the new pen will be legally permissible throughout the rest of the world, the pen would likely violate Section 101 (a) of the CPSIA in the United States. For this reason, BIC USA files this Request for Exception under amended Section 101(b)(1) of the Consumer Product Safety Improvement Act of 2008, as amended by P.L. No. 112-28; H.R. 2517, August 12, 2011.

As is detailed below, it is not practicable or technologically feasible to utilize a pen point assembly that contains less than 100 ppm total lead. As is further noted below, the BIC Children's Pen is not likely to be ingested or mouthed. See attached Statement of Christine Wood. Finally, the potential exposure to lead through hand to mouth transfer by a user of the pen would be 0.31 µg/day of lead, well below the CPSC staff threshold of 2.2 µg/day of lead. See attached Statement of Greg Gorder. Accordingly, the request meets the statutory criteria for a functional purpose exception.

Background of BIC USA Inc.

BIC USA is part of the BIC Group, which manufactures and distributes BIC branded products in more than 160 countries around the world. Every day, consumers around the world purchase more than 25 million BIC stationery products. BIC USA's headquarters are located in Shelton, Connecticut. In addition, BIC USA has operations in Milford, Connecticut; Gaffney, South Carolina; Charlotte, North Carolina; Middleton, Wisconsin; Sleepy Eye, Minnesota; Red Wing, Minnesota; Clearwater, Florida and St. Petersburg, Florida. BIC USA employs 2,800 people in the United States in the manufacture, distribution, marketing and sale of its products.

In 1945, Marcel Bich, the founder of the company, started working with his partner, Edouard Buffard, manufacturing parts for fountain pens in a factory in Clichy, France, just outside of Paris. During this time, Marcel Bich realized the enormous potential for the ballpoint pen. He adapted and improved a process for making ballpoints invented by the Hungarian Laszlo Biro and in December 1950, launched his own ballpoint pen - the BIC Cristal ballpoint pen. The high quality and affordable price of the BIC Cristal ballpoint pen meant that it was quickly adopted by an increasing number of consumers. In 1958, Marcel Bich brought his BIC Cristal ballpoint pen to the United States.

BIC made the ballpoint pen a success. Today, BIC offers a large range of ballpoint pens designed and developed from this heritage of quality and expertise in ballpoint technology. Since its beginnings in 1950, BIC has refined the machines and manufacturing processes needed to manufacture pens in mass production while assuring high quality. Every ballpoint pen delivers the same quality writing from start to finish. The BIC Cristal Pen draws a line 2 km long, which is as good at the end as at the beginning. These processes are highly technical and continuously modified to meet the requirements of an increasingly diversified product line. Well-trained employees, a rigorous quality control system and a focus on continuous improvement by BIC's Research & Development team, ensure a high level of product quality.

Request for Exception

The Commission issued procedural regulations for filing for requests for exclusion under former Section 101(b). See 16 CFR Part 1500.89 published on March 11, 2009 at 74 Fed. Reg. 10475 (2009). It is my

understanding that these regulations are in the process of being updated to cover functional purpose test exceptions. However, in the absence of updated regulations reflecting the amendments to the CPSIA, BIC USA is following Part 1500.89 in its request for exception.

Part 1500.89(d)(4)(i): Description of the Product or material and how it is used by a child.

The product for which this exception is being requested is a ballpoint pen which has been designed and is intended primarily for children age 5 and up (the "BIC Children's Pen"). More specifically, the functional purpose exception is being requested for the point component of the BIC Children's Pen. All other accessible components of the BIC Children's Pen contain total lead below 100 ppm.

The parts of a ballpoint pen - a traditional ballpoint pen used by consumers of all ages for their writing needs, are shown in the diagram in Attachment 1.

The writing cartridge or ink system is comprised of a tungsten carbide ball encased in a nickel silver or brass housing (point and point support) and finished on a machine using specific tools. The consistently regular performance of the manufacturing tools guarantees the quality of the finished product. The cartridge is made up of the point and point support subassembly (which is the subject of this request for exception), and a tube filled with ink. BIC manufactures its ballpoint pen ink systems in its own factories to ensure the highest levels of quality.

BIC has more than 60 years of experience in the manufacture of nickel silver and brass points for writing cartridges. Significant time and resources are devoted to understanding the compatibility of point materials with inks. Writing performance is impacted by the relative compatibility of the point and ink. In this new Children's Pen, BIC will use one of its standard ballpoint pen cartridges that contains a nickel silver point and a nickel silver point support.

The BIC Children's Pen has been designed with experts in hand writing and ergonomics to address the specific needs of young children who are in the early stage process of learning to write. Today, children are learning to write with ballpoint pens that are designed for the needs of all consumers - not the specific needs of young hands.

Part 1500.89(d)(4)(ii): Representative data on the lead content of parts of the product or material used in the product of a product.

The accessible portion of the nickel silver point assembly that BIC proposes to use in its BIC Children's Pen contains total lead of approximately 8,720 ppm (point and point support subassembly). See Attachment 2, Bureau Veritas Technical Report No. (5113) 030-0017 Revision dated March 8, 2013.

Part 1500.89(d)(4)(iii): All relevant data or information on manufacturing processes through which lead may be introduced into the material or product.

Lead is contained in the nickel silver alloy purchased by BIC for use in the manufacture of its nickel silver point and nickel silver point support. Lead is commonly used in this metal alloy to impart strength and durability and make the metal easily processed during the production process for the point and point support components. These metal alloys contain lead that is physically bound in the metal. The lead is not a coating on the point that can be scraped off and ingested.

Part 1500.89(d)(4)(iv): An assessment of the likelihood or lack thereof that the manufacturing processes will result in the lead contamination of a material or product that does not ordinarily contain lead.

Again, the lead is contained in the metal alloy BIC purchases for its nickel silver points. These metal alloys contain lead that is physically bound in the metal. The lead is not a coating on the point that can be scraped or contaminate a component or material that it comes into contact with. BIC routinely conducts total lead testing on the plastic components of its ballpoint pens and has no data to suggest any lead contamination of other materials or components.

Part 1500.89(d)(4)(v): All relevant data or information on the facilities used to manufacture the material or product and any other materials used in the product.

The nickel silver point and nickel silver point support are both manufactured in BIC owned factories around the world. The metal alloy used in the production is sourced globally for all BIC factories producing the nickel silver point according to a global material and supplier specification.

Part 1500.89(d)(vi): An assessment of the likelihood or lack thereof that the use of leaded material in a facility will result in lead contamination of a material or product that does not contain lead.

Lead is not introduced into the nickel silver component at BIC's production facility where it makes the points and point supports. The lead is introduced into the metal alloy that BIC purchases from a third party supplier during the alloy manufacturing process. There is no lead introduced into the manufacturing process by BIC. See above responses regarding contamination.

Part 1500.89(d)(4)(vii): Any other information relevant to the potential for lead content of the products or material to exceed the statutory lead limit specified in the request.

None

Part 1500.89(d)(4)(viii): Detailed information on the relied upon test methods for measuring lead content of products or materials including the type of equipment used or any other techniques employed and a statement as to why the data is representative of the lead content of the such product or materials generally.

CPSC-CH-E1001-08.1, Standard Operating Procedure for Determining Total Lead (Pb) in Metal Children's Products, Revision June 21, 2010.

16 CFR Part 1500.53, Test Method for Simulating Use and Abuse of Toys and Other Articles Intended for Use by Children Over 36, but Not Over 96 Months of Age, subsections (b),(d),(e), (f) and (g).

Technology Sciences Group, Inc. Wipe Protocol: Pen-Tip-to-Hand Simulated Transfer Using Modified Method NIOSH 9100. See Attachment 3.

Part 1500.89(d)(4)(ix): Any data or information that is unfavorable to the request that is reasonably available to the requestor.

None.

In addition to providing the information requested in the Commission's earlier regulations, BIC USA will also briefly review the statutory criteria under revised Section 101(b).

It is not practicable or technologically feasible to manufacture the product by removing the excess lead or making the lead inaccessible – 15 U.S.C. 1278a(b)(1)(A)(i)

BIC has more than 60 years of expertise and experience in the production of points for ballpoint pens. The materials used in the production of these points have been carefully selected, tested and qualified for compatibility with our inks and with BIC's high speed production equipment. BIC has invested millions of dollars in high speed manufacturing equipment for its point and cartridge production. BIC would experience much lower point manufacturing productivity if the metal alloy used to produce the nickel silver points did not contain lead at a level described herein. (See specific values above). If BIC were able to change the metal alloy to reduce the lead content to below 100 ppm, it would experience reduced machine speeds and only be able to cycle its machines once instead of twice as it does now. It would also likely require changes to the tooling and cutting oil used in the production of the points. All of these potential impacts would have to be thoroughly studied at significant cost and delay. Such changes would take up significant resources and capital to validate and implement.

As noted above, the only metal alloy available for pen points that contains lead below 100 ppm is stainless steel. Today, BIC does not produce stainless steel points in any of its factories. Stainless steel points are more commonly used with water based inks typically found in roller ball pens and gel ink pens. The BIC Children's Pen will not contain a water based ink. It will contain a solvent based ink as is typically found in BIC's ballpoint pens, and in almost all ballpoint pens sold throughout the world.

The stainless steel points that are commercially available and contain less than 100 ppm of total lead are much more expensive than the nickel silver points BIC makes in its own factories. Even if BIC were able to overcome the technical and feasibility challenges described above, by using a stainless steel point with a solvent based ink, there would be a 78% increase in the cost of this component part that would effectively eliminate the Children's Pen from the product line in the US.

The product or part is not likely to be placed in the mouth or ingested – 15 U.S.C. Section 1278a(b)(1)(A)(ii)

The point, which is the subject of this functional purpose exception request, is not likely to be ingested. See Attachment 4, Statement of Christine Wood, Exponent. The point is securely adhered to the ink cartridge and is therefore not easily detachable. Recently, BIC conducted mechanical hazards testing of the BIC Children's Pen pursuant to 16 CFR Part 1500.53(b),(d),(e),(f) and (g). See Attachment 5, Bureau

Veritas Technical Report No. (5113) 030-0019 dated February 6, 2013. The results of that testing confirmed that no small parts were released. In addition, the BIC Children's Pen is designed without a cap, clip or pen body that can be opened, further minimizing the likelihood of ingestion.

Moreover, the point, which is the subject of this functional purpose exception request, is not likely to be placed in the mouth. As noted in Dr. Wood's Statement, the frequency of mouthing of objects in this age range is relatively low. And because the pen point is sharp, BIC's experience has been that children do not mouth the pen point end of the product. As noted in Dr. Wood's statement, the design of the BIC's Children's Pen makes it even more unlikely that the product would be mouthed. The orientation of the pen, when held in a child's hand, clearly has the point away from the user. Also the point is retractable, and when retracted, the point is not even available for contact with the mouth.

The exception will have no measurable adverse effect on public health or safety taking into account normal and foreseeable use and abuse - 15 U.S.C. Section 1278a(b)(1)(iii)

The BIC Children's Pen has been specifically designed for children who are early stage writers just learning the proper techniques for holding and gripping a pen for writing. With this objective, the BIC Children's Pen is marked to prompt children to hold the pen in the correct location. The gripping area has been specifically designed and includes a guiding line to aid in correct placement of the fingers. This helps the child to position his or her fingers correctly on the pen. In addition, the nose cone section of the pen barrel has been specifically designed so that it is not comfortable to grip as placement of the fingers too far forward is a common bad habit that early stage writers develop. The nose cone area is just behind the writing tip and nickel silver point. If the nose cone is not comfortable for gripping, then it is not likely that a child's fingers would be in contact with the pen point during normal use conditions.

Additionally, the exposed surface area of the nickel silver pen point is so small that it would itself be difficult to grip even by the smallest of fingers. The pen point represents less than 1% of the total surface area of the BIC Children's Pen. BIC commissioned lead testing of the BIC Children's Pen by Technology Sciences Group, Inc. ("TSG") in Davis, California. Greg Gorder, a Senior Managing Scientist at TSG, conducted a wipe test of the pen point using the methodology set forth in Attachment 3, based on the CPSC's vinyl wipe test. Squeezing the pen point between thumb and index finger and wiping it for 30 full 360 degree rotations resulted in an average lead release of 0.62 µg/wipe. Mr. Gorder assumed that this was a worst case analysis, assuming purposeful dermal contact. Using a hand to mouth analysis with the 50% factor used by CPSC staff, the potential exposure to lead would be 0.31 µg/day. See Attachment 6, Statement of Greg Gorder. In the CPSC staff document, the staff established 2.2 µg/day of lead as the exposure threshold for "no measurable increase in blood lead levels of a child" CPSC Staff Report, November 2012, *CPSC Section 101(b): Functional Purpose Exception from the Lead Content Limit for Children's Products for a Specific Product, Class of Product, Material or Component Part*. So even under a worst case analysis, the potential hand to mouth exposure to lead from the BIC Children's Pen is seven times lower than the threshold established by the staff.

Accordingly, based upon the CPSC Staff Report, and extensive testing by TSG, the BIC Children's Pen will have no measurable adverse effect on public health or safety.

Conclusion

In conclusion, BIC USA respectfully requests that the Commission grant an exception from the total lead limit of 100 ppm under Section 101(a) for the point component of the BIC Children's Pen (point and point support). It is neither technologically possible, nor commercially viable for BIC to manufacture this new Children's Pen with a pen point component that would comply with the total lead limit of 100 PPM. As discussed above, the product is not likely to be mouthed or ingested. Finally, as outlined in Greg Gorder's Statement, an exception will have no measurable adverse effect on public health or safety. Accordingly, the request meets the statutory standard for a functional purpose exception.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "David H. Baker", with a stylized flourish at the end.

David H. Baker

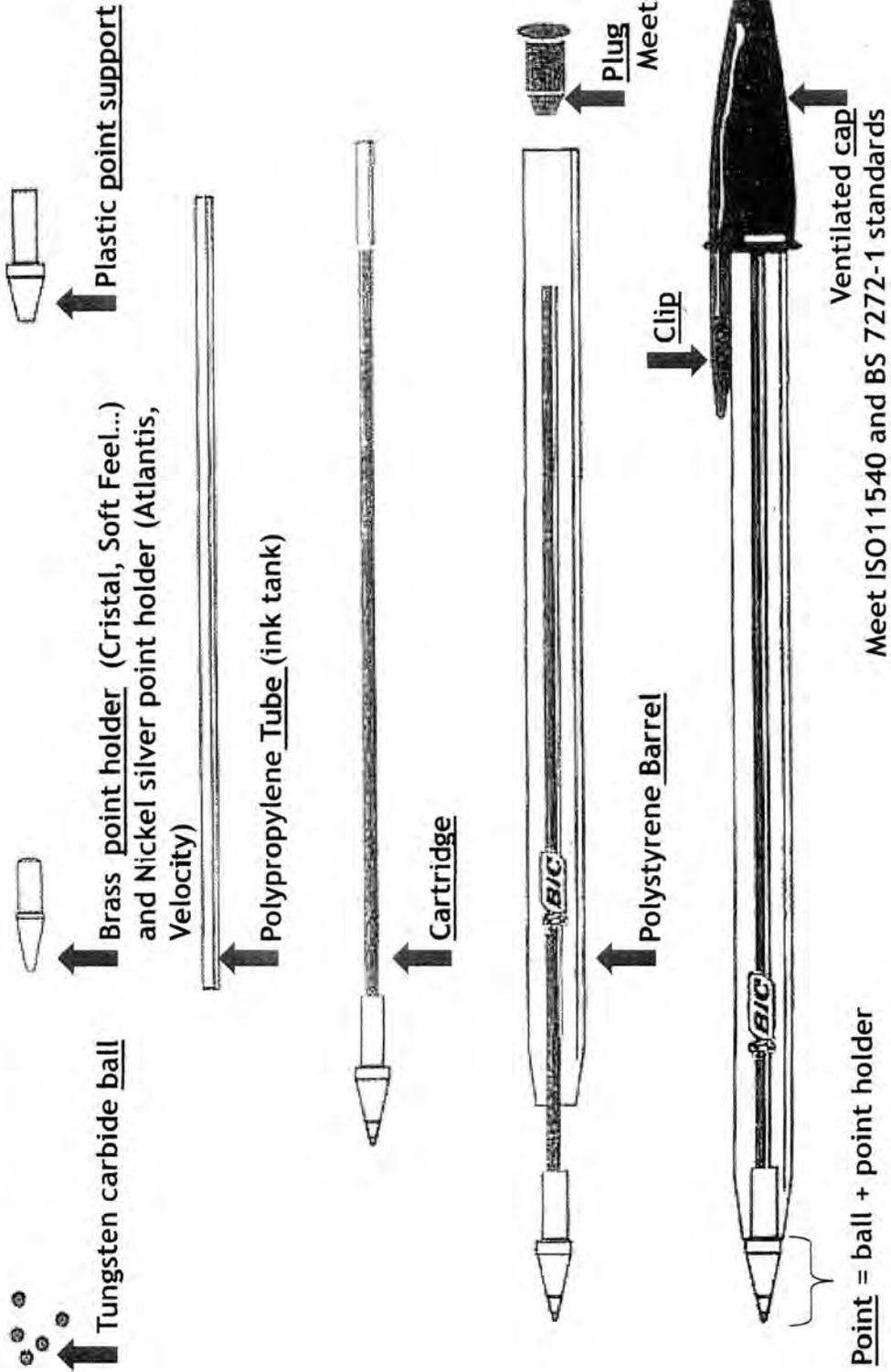
Attorney for BIC USA

March 25, 2013



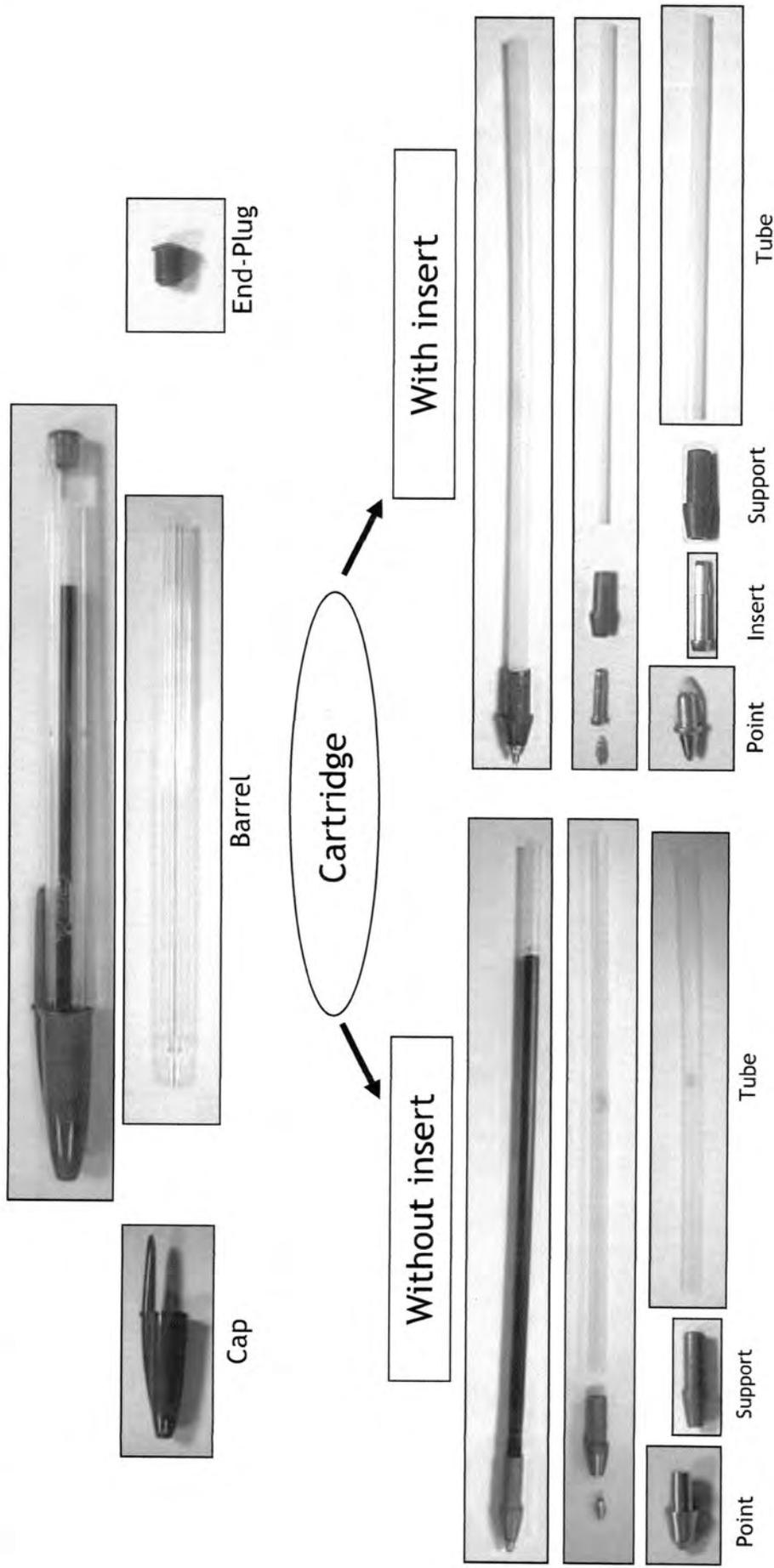
Components of a ball pen

COMPONENTS





We have 2 different Cristal



Cristal 1006

Cristal 725





**BUREAU
VERITAS**

CONSUMER PRODUCTS SERVICES DIVISION

BIC USA, INC. (CT)

Technical Report: (5113)030-0017 Revision

March 8, 2013

Date Received: January 30, 2013

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JOANNE CARSON
BIC USA, INC. (CT)
ONE BIC WAY, SUITE 1
SHELTON, CT 06484
UNITED STATES

Sample Description:	BIC BEGINNER PEN, ISR #3828	Sample Size:	7
Vendor:	N/A	Style No(s):	N/A
Manufacturer:	N/A	SKN/SKU No.:	N/A
Buyer:	N/A	PO No.:	N/A
Labeled Age Grade:	N/A	Ref #:	N/A
Appropriate Age Grade:	N/A	Country of Origin:	NO INFORMATION
Client Specified Age Grade:	N/A	Assortment No.:	N/A
Tested Age Grade:	N/A		
UPC Code:	N/A		

EXECUTIVE SUMMARY:

The sample(s) was tested to the following requirement(s) and the data provided is for informational purposes only:

- The total lead content of 100ppm requirements in substrate materials (Consumer Products Safety Improvement Act (CPSIA) of 2008).

Note: At the request of the client, this report has been revised to add sample preparation statement.

BVCPS Buffalo Contact Information for this Report:

Administrative Questions: Kathy Kubiak Phone: 716-505-3465 kathy.kubiak@us.bureauveritas.com

Technical Questions: Alison Tuzzolino Phone: 716-505-3434 alison.tuzzolino@us.bureauveritas.com

Bureau Veritas
Consumer Products Services, Inc.

Alison Tuzzolino, Product Chemist
Analytical Services

/sw

cc: GILLIAN ROSENBLOOM, BIC USA, INC. (CT)



**BUREAU
VERITAS**

BIC USA, INC. (CT)
Technical Report: **(5113)030-0017R**
March 8, 2013
Page 2 of 3

RESULTS:

TOTAL LEAD CONTENT IN SUBSTRATE (100PPM) (Consumer Product Safety Improvement Act (CPSIA) of 2008)

Test Method: U.S. CPSC-CH-E1001-08.1 (June 21, 2010) or U.S. CPSC-CH-E1002-08.1 (June 21, 2010).

Sample Preparation: Sample was prepared by cutting the accessible exposed metal tip of the pen.

Analyte			Lead	Conclusion
Requirement: Maximum allowable limit:			100 mg/kg	
Sample Description			Result	Conclusion
Color / Component	Location	Style	(mg/kg)	
(A) Metal	Pen tip	-	8720	Data

LT = Less Than

* = Average of duplicate analyses

mg/kg = milligrams per kilogram (ppm = parts per million)

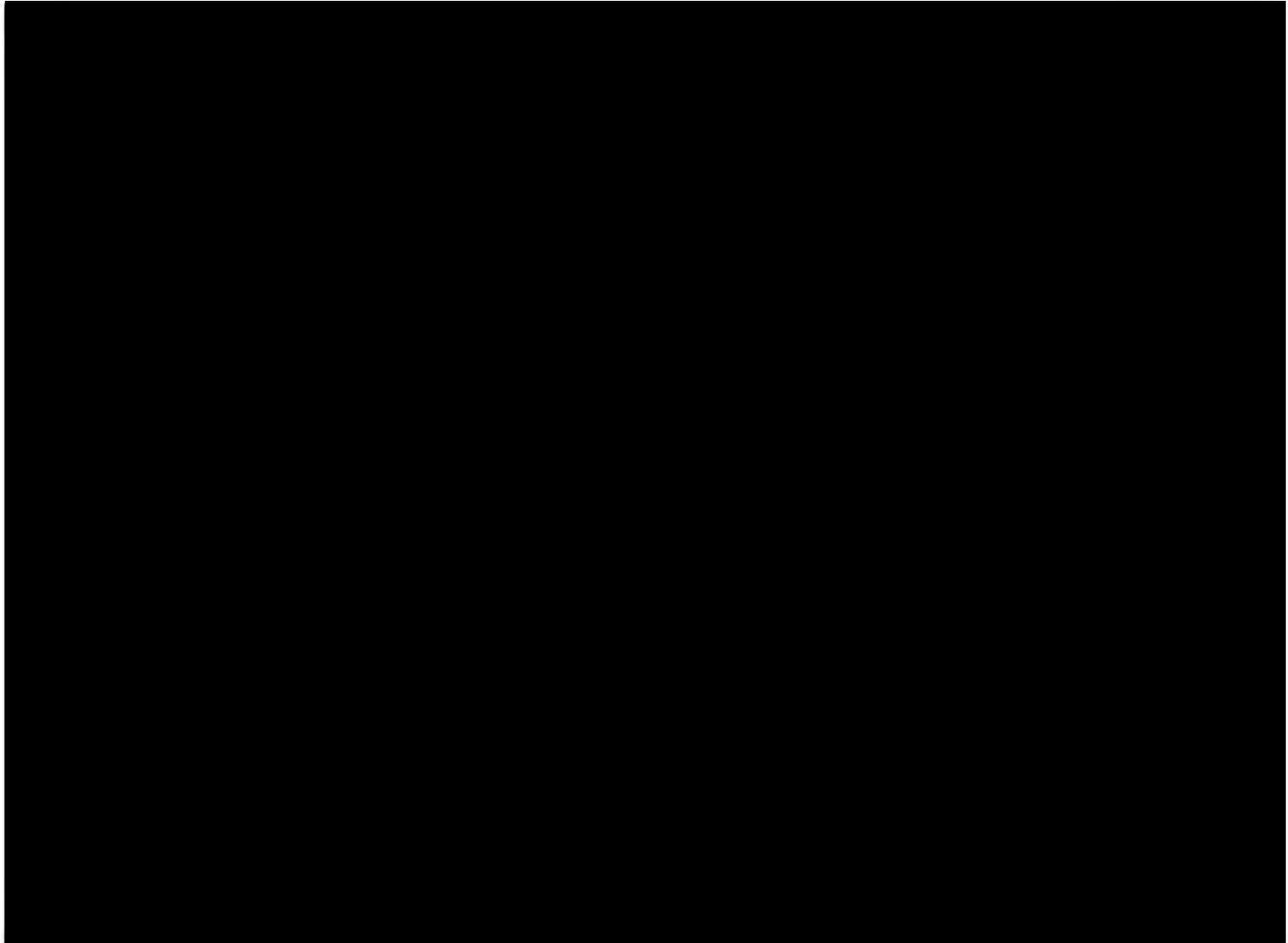


**BUREAU
VERITAS**

BIC USA, INC. (CT)
Technical Report: **(5113)030-0017R**
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CONFIDENTIAL

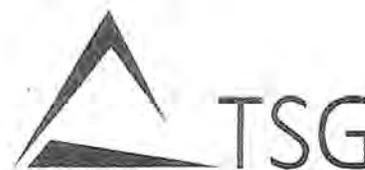
EXHIBIT #1



SAMPLE PRODUCT

CONFIDENTIAL

Technology Sciences Group Inc.
 Greg W Gorder, Ph.D.
 Senior Managing Scientist



WIPE PROTOCOL: Pen Tip-to-Hand Simulated Transfer Using Modified Method NIOSH 9100:

Method NIOSH 9100 is modified as follows to measure accessible lead that could potentially transfer from pen tip to hand. Cross out text represents deletions from NIOSH Method 8100 and underline text represents additions:

- PURPOSE:** Determination of surface contamination by lead and its compounds.
- LIMIT OF DETECTION:** Analysis will be conducted 2 µg Pb per sample (0.02 µg/cm² for 100 cm² area) by flame AAS or ICP; 0.1 µg Pb per sample (0.001 µg/cm² for 100 cm² area) by or graphite furnace AAS, as needed to obtain a detection limit no higher than 0.5 µg/wipe.
- FIELD EQUIPMENT:**
- ~~1. Bags, plastic, sealable (e.g., with attached wire, tape or "zip" type seal).~~
 - Sample pads, 2" x 2", sterile cotton gauze (Curity™, Johnson & Johnson™, or equivalent), ~~or ashless quantitative filter paper.~~
- NOTE: Wash'n Dri™ wipes may also be used. Other wipes may not ash properly, or may have a significant lead blank value.
- Gloves, latex, disposable.
 - ~~4. Template, plastic, 10 cm x 10 cm, or other standard size.~~ Two BIC Beginner's Pens
 - Water, distilled, in plastic squeeze bottle.
- SAMPLING:**
- Using a new pair of gloves, remove a ~~gauze~~ pad from its ~~protective~~ package. Moisten the ~~gauze~~ pad with approximately 1 to 2 mL of distilled water.
 NOTE 1: Apply no more distilled water than that necessary to moisten approximately the central 80% of the area of the gauze pad. Excess distilled water may cause sample loss due to dripping from the gauze pad.
 NOTE 2: If using the premoistened Wash'n Dri™, omit the distilled water.
 - ~~Place the template over the area to be sampled.~~ Wipe First BIC Beginner's Pen as Follows: Fold pad into quarters and grasp with left hand (reverse if left handed) holding between thumb and index finger. Extend pen tip to writing position. Grasp pen with right hand (reverse if left handed) and place pen tip between pad (i.e., pen tip surrounded on all sides by pad) with pen tip squeezed firmly between thumb and index finger. Rotate pen back and forth making quarter to half turns with right hand while firmly grasping pen tip within pad in left hand (hands reversed if left handed) wiping. Wipe the pen-tip surface to be sampled with firm pressure for 15 seconds making at least 30 partial rotations of the pen (if necessary to make at least 30 rotations, extend the time), using 3 to 4 vertical S-strokes. Fold the exposed side of the pad in and wipe the area with 3 to 4 horizontal S-strokes. Fold the pad once more and wipe the area with 3 to 4 vertical S-strokes.

Pen Tip-to-Hand Simulated Transfer Using Modified Method NIOSH 9100

January 31, 2013

Page 2 of 2

3. ~~Place the folded pad, exposed side in, and place it in a new plastic bag. Seal and label the bag clearly. Discard the gloves.~~

4. Wipe Second BIC Beginner's Pen as Follows: Repeat step 1 to moisten pad. Fold pad, extend pen tip, and grasp pen and pad as described in step 2. Rotate pen tip back and forth as described in step 2 but for at least 1 minute or 120 partial rotations. Repeat step 3 to label sample.

~~4. Clean the template in preparation for the next wipe sample.~~

5. Include two blank pads (moistened and placed in bags) with each sample set.

SAMPLE

Use the procedure of NIOSH Method 7105, including final sample dilution to 10 mL

PREP:

NOTE: Additional portions of nitric acid may be needed for complete digestion of the sample, including the pad. Include appropriate media and reagent blanks.

MEASUREMENT:

~~Analyze~~ Screening of all samples by flame AAS or ICP, followed by use of graphite furnace AAS for those samples giving "Not Detected" is an efficient scheme to obtain a detection limit of 0.5 µg/per sample or less. Use the procedures of NIOSH Methods 7082 (Lead by flame AAS), 7300 (Elements by ICP), 7105 (Lead by graphite furnace AAS), or other appropriate methods such as ASTM E1613-12.



March 20, 2013

Statement of Christine T. Wood, Ph. D.

I have been asked by BIC to evaluate the likelihood of young children ingesting or mouthing the point of BIC Children's Pens.

I received a Bachelor's Degree in psychology with Distinction and Honors from Stanford University and hold a Ph.D. in experimental psychology also from Stanford University.

I am a Principal Scientist and the Director of the Human Factors Practice at Exponent. My work with Exponent includes the analysis and evaluation of human factors issues for many different products. As part of that work, I analyze the developmental abilities and limitations of children at different ages and the ways these impact how they engage in activities and use products in different environments. I investigate the accident patterns that are unique to children and the effectiveness of strategies used to reduce child injury. I have conducted tests of young children to investigate their patterns of interactions with various products, including toys, play yards, high chairs, child restraint systems, controls inside motor vehicles, and trunks of motor vehicles.

Based on my review of the materials cited in this statement, examination of an exemplar BIC Children's Pen, my experience, education, and training, I offer the following opinions to a reasonable degree of scientific certainty:

Ingestion of the point is unlikely.

The point, which is the subject of this functional purpose exception request, is not likely to be ingested. BIC conducted use and abuse testing of the BIC Children's Pen pursuant to ASTM F926-11 for products intended for use by children who are at least three years of age but less than six years of age.¹ The results of that testing confirmed that the point and point support do not detach from the writing instrument after use and abuse testing. Further, unlike other pen designs, the BIC Children's Pen is designed without a cap, clip, or pen body that can be opened, preventing access to the spring, other interior components, and potentially the tip.

¹ BIC Beginner Pen, Technical Evaluation (5113) 030-0019, Bureau Veritas, February 06, 2013

Mouthing of the point is unlikely.

The point is not likely to be placed in the mouth. The frequency of object-to-mouth contacts has been observed for children of different age groups. Children within the approximate age range of users of BIC Children's Pens (i.e. 5 to 12 years old) have the lowest frequency of object-to-mouth contacts compared with children in younger age groups.² For example, in a summary of the published scientific literature on mouthing prepared by the U.S. Environmental Protection Agency, for the age group 6 years through 10 years, on average, there was a frequency of approximately one object-to-mouth contact observed per hour indoors.³ In contrast, the frequency of object-to-mouth contacts per hour for younger children was at least ten times higher. Studies of mouthing behavior of children in the relevant age group report a wide variety of objects being mouthed including fingers/hands, clothing, blankets, toys, and paper/wrappers.⁴ Pencils have sometimes been identified. In the literature reviewed by the EPA,⁵ I am unaware of any published study of mouthing for the relevant age group in which it was reported that pens were mouthed. Further, the point of a pen is unlikely to be mouthed because the orientation of a pen when held in the hand to write does not present the point toward the user. The design features of the BIC Children's Pen that make ingestion of the point unlikely also contribute to making mouthing the point unlikely. The point is retractable, and when retracted the point is not available for contact with the mouth.

The points of many traditional ballpoint pens generally available in the market today are composed of the same metal alloys as the point of the BIC Children's Pen, as more fully described in BIC's submission to the CPSC to which this statement is attached. Mouthing and ingestion of the points of pens, in general, is unlikely. The introduction of BIC Children's Pens into the marketplace will not increase the likelihood of mouthing and ingestion of points compared to children's use of traditional ballpoint pens. Unlike other styles of pens that have a

² Xue, J; Zartarian, V; Tulve, N; Moya, J; Freeman, N; Auyeung, W; Beamer, P. (2010). A metaanalysis of children's object-to-mouth frequency data for estimating non-dietary ingestion exposure. *J Expo Sci Environ Epidemiol* 20: 536-545. <http://dx.doi.org/10.1038/jes.2009.42>.

³ U.S. Environmental Protection Agency (EPA). (2011) Exposure Factors Handbook: 2011 Edition. National Center for Environmental Assessment, Washington, DC; EPA/600/R-09/052F. Available from the National Technical Information Service, Springfield, VA, and online at <http://www.epa.gov/ncea/efh>., Chapter 4, Table 4-1.

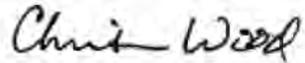
⁴ Beamer, P; Key, ME; Ferguson, AC; Canales, RA; Auyeung, W; Leckie, JO. (2008). Quantified activity pattern data from 6 to 27-month-old farmworker children for use in exposure assessment. *Environ Res* 108: 239-246. <http://dx.doi.org/10.1016/j.envres.2008.07.007>; Stanek, EJ, III; Calabrese, EJ; Mundt, K; Pekow, P; Yeatts, KB. (1998). Prevalence of soil mouthing/ingestion among healthy children aged 1 to 6. *Journal of Soil Contamination* 7: 227-242.

⁵ U.S. Environmental Protection Agency (EPA). (2011) Exposure Factors Handbook: 2011 Edition. National Center for Environmental Assessment, Washington, DC; EPA/600/R-09/052F. Available from the National Technical Information Service, Springfield, VA, and online at <http://www.epa.gov/ncea/efh>.

Page 3

fixed, extended point, the point of the BIC Children's Pen completely retracts by twisting one half of the pen body. In addition, the BIC Children's Pen is designed to meet the needs of children who are learning proper gripping techniques and control of a pen while writing.

Sincerely,

A handwritten signature in cursive script that reads "Christine T. Wood".

Christine T. Wood, Ph.D.
Principal Scientist
Director, Human Factors
(650) 688-7134 direct
(650) 328-2981 fax
cwood@exponent.com



**BUREAU
VERITAS**

CONSUMER PRODUCTS SERVICES DIVISION

BIC CORPORATION

Technical Report: (5113)030-0019
Date Received: February 01, 2013

February 06, 2013
Page 1 of 3

JOANNE CARSON
BIC CORPORATION
ONE BIC WAY, SUITE 1
SHELTON, CT 06484
UNITED STATES

Sample Description:	BIC BEGINNER PEN, ISR #3828	Sample Size:	7
Vendor:	N/A	Style No(s):	N/A
Manufacturer:	N/A	SKN/SKU No.:	N/A
Buyer:	N/A	PO No.:	N/A
Labeled Age Grade:	NOT PRESENT	Ref #:	N/A
Appropriate Age Grade:	NOT REQUESTED	Country of Origin:	NO INFORMATION
Client Specified Age Grade:	4+	Assortment No.:	N/A
Tested Age Grade:	CHILDREN PRODUCTS, OVER 4 YEARS OF AGE		
UPC Code:	N/A		

EXECUTIVE SUMMARY:

The sample(s) MEETS the following requirement(s):

- The mechanical hazards requirements of the tested sections of Canada Consumer Product Safety Act, Toys Regulations, SOR/2011-17 and Schedule 2.

The sample(s) was tested to the following requirement(s) and the data provided is for informational purposes only:

- The mechanical hazards requirements of 16 CFR 1500, "Federal Hazardous Substances Act Regulations".
 - No sharp points or sharp edges were present when tested according to the specified regulations and age grade.
 - No small parts were released when tested according to the specified regulations and age grade.



**BUREAU
VERITAS**

BIC CORPORATION
Technical Report: **(5113)030-0019**
February 06, 2013
Page 2 of 3

BVCPS Buffalo Contact Information for this Report:

Administrative Questions: Kathy Kubiak Phone: 716-505-3465 kathy.kubiak@us.bureauveritas.com
Technical Questions: Philip Carlisle Phone: 716-505-3399 philip.carlisle@us.bureauveritas.com

Bureau Veritas
Consumer Products Services, Inc.

Philip Carlisle
Product Test Engineer,
Toy and Juvenile Products Department

/gf

cc: GILLIAN ROSENBLOOM, BIC CORPORATION

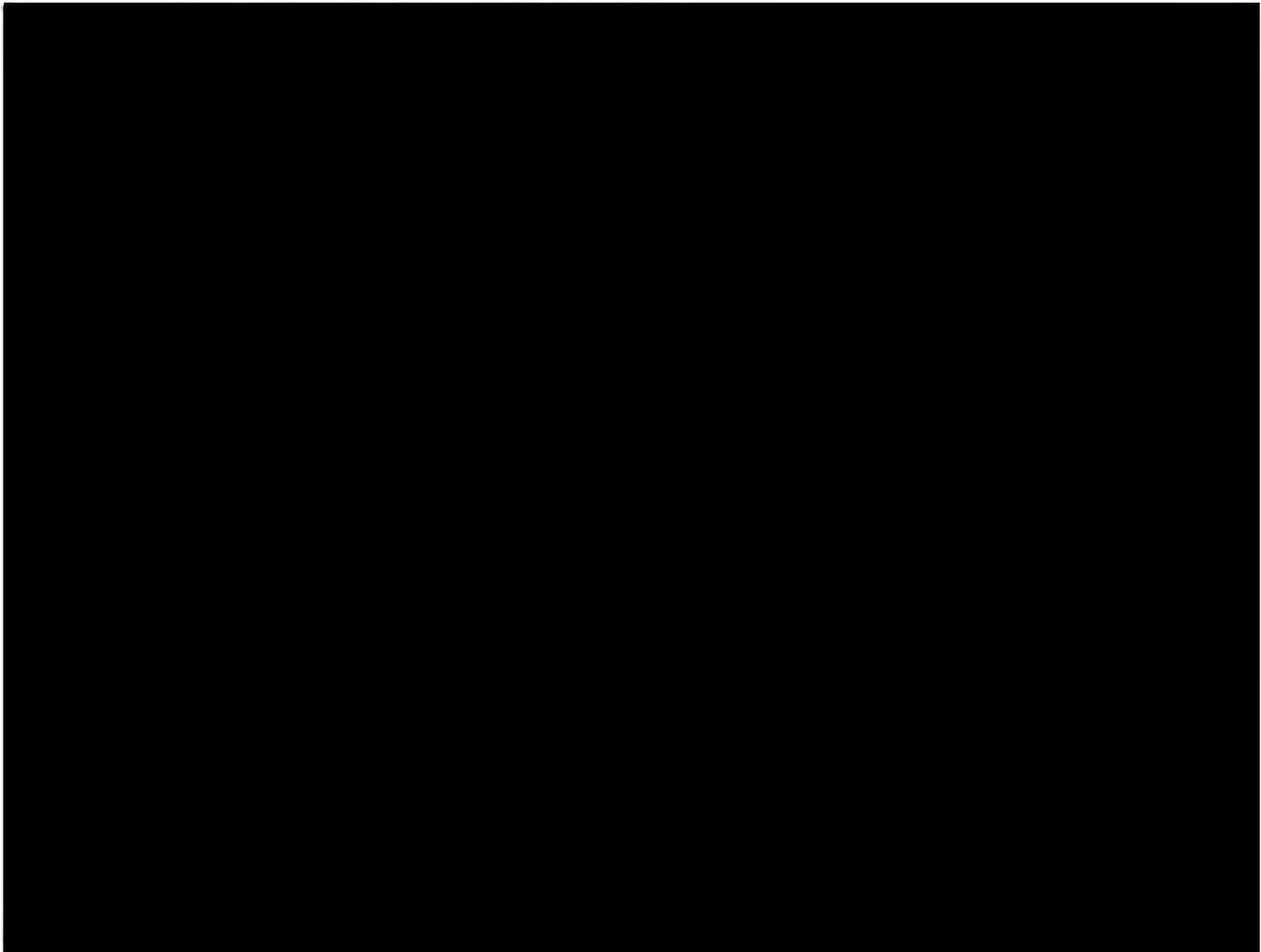


**BUREAU
VERITAS**

BIC CORPORATION
Technical Report: **(5113)030-0019**
February 06, 2013
Page 3 of 3

CONFIDENTIAL

EXHIBIT # 1



SAMPLE PRODUCT

CONFIDENTIAL



Technology Sciences Group Inc.

712 Fifth St., Suite A
 Davis, CA 95616
 Direct: (530) 757-1281
 Fax: (530) 757-1299
 E-Mail: GGorder@TSGUSA.com

Greg W Gorder, Ph.D.
 Senior Managing Scientist

STATEMENT OF GREG W. GORDER Ph.D.
 March 21, 2013

My name is Greg W. Gorder and I am a Senior Managing Scientist at Technology Sciences Group Inc. (TSG). I am an experienced exposure/risk assessor and obtained a Ph.D. in Entomology/Environmental Toxicology at Iowa State University. I joined TSG in 2000. My C.V. is attached to this Statement.

On behalf of BIC USA Inc. (BIC), I was asked to assess potential exposures to lead from the BIC Children's Pen to determine if it meets the standard of "no measureable increase in blood lead levels of a child" as required for an exception under the Consumer Product Safety Improvement Act (CPSIA). The Children's Pen requires an exception because it has a nickel-silver point that is partially accessible and exceeds the 100 ppm total lead standard for children's products under the CPSIA. TSG developed a test protocol to assess lead exposures that could potentially occur as a result of extensive, purposeful dermal contact with the pen point followed by hand-to-mouth contact, even though contact of this type is very unlikely to occur. The attached protocol (**Exhibit 1**) used a wipe test for lead based on the NIOSH 9100 wipe test and increased the contact per wipe to 30 strokes to match the approach the Consumer Product Safety Commission (CPSC) used in their vinyl wipe test. The BIC test evaluated lead released from both the accessible portion of the conical-shaped nickel-silver point (i.e., the wipe samples) and the ball at the tip of the point that contacts the writing surface (i.e., the ink controls). The test represented worst-case, infrequent exposures because dermal contact with the nickel-silver point is unlikely during normal use or abuse (e.g., abuse does not increase accessibility of the point).

Summary: Use of the BIC Children's Pen to apply ink marks to a wipe did not result in measurable lead release (lead reporting limit of 0.1 µg/wipe) as shown by the ink blank results (**Exhibit 2¹**). Squeezing the accessible nickel-silver pen point between the thumb and index finger and wiping for 30 full 360 degree rotations resulted in an average lead release of 0.62 µg/wipe. Squeezing the accessible nickel-silver pen point between the thumb and index finger and wiping for 120 full 360 degree rotations resulted in an average lead release of 1.05 µg/wipe, showing that the rate of lead release decreases dramatically with increased contact (i.e., the 4-fold increase in wiping resulted in just a 1.7-fold increase in lead released). Lead release rates may be exaggerated in the first wipes of a new pen.

Conclusion: The 0.62 µg of lead average for 30-rotation wipes represents a worst-case estimate for transfer to a user's fingers that might occur on an infrequent basis due to extensive, purposeful dermal

¹ Bureau Veritas, March 6, 2013. BIC Children's Ball Pen Point Wipe Tested for Lead.

contact. This could lead to potential ingestion of 0.31 µg of lead based on a presumption of 50% hand to mouth transfer often used by CPSC staff. CPSC identified 2.2 µg/day of ingested lead as the exposure threshold for "no measurable increase in blood lead levels of a child"² based on average daily exposures. Potential daily ingestion of 0.31 µg of lead is below the CPSC threshold; however, extensive, purposeful lead exposures of the type measured for the pen point would occur infrequently, if at all because the test was designed to determine how much lead could be released rather than mimic potential exposures from product use. Even if we presume that average daily exposures to lead from the pen point are 0.31 µg/day, those exposures would be 7-fold below the CPSC threshold for no measurable increased in blood lead levels of a child.

Considerations and Assessment

Dermal Exposure to Lead from the BIC Children's Pen is Unlikely to Occur: Numerous factors make it unlikely that use of the pen will result in dermal exposure to lead at the level measured including the following:

- **Impossible to Grasp Nickel-Silver Point and Write:** When used for writing, there will be no dermal contact with the pen point because it is impossible to grasp the pen by the accessible nickel-silver point and still write with the pen.
- **Difficult to Contact Point While Writing:** As shown in the photo in Exhibit 2, the BIC Children's Pen has a ridge above the point to assist with the writing grasp. The ridge makes it unlikely that there will be dermal contact of any type with the point during normal use.
- **Lead Not Transferred with Ink Released from the Point:** The ink controls in Exhibit 2 show that when marking with the pen, lead is not released. If a child were to write on their skin, measurable levels of lead would not be transferred to the skin.

Test Method is a Very Conservative Estimate of Exposures on Days Exposures Occur: The 30 rotation test was based on the existing CPSC wipe test for lead in vinyl (i.e., 3 x 10 wipe strokes = 30 wipe strokes) rather than anticipated exposure from the BIC Children's Pen. 30 rotations of the pen is nearly a minute of squeezing and rotating so it far exceeds typical contact with the pen point.

- **Potential Dermal Exposures = 0.62 µg [Dermal]:** This is the average result for 30-rotation wipes in Exhibit 2. The 30-rotation test result shows that it is possible to transfer lead by squeezing the pen point and rotating; however, the test results represent a worst-case exposure scenario that would occur infrequently if at all.

² CPSC Staff Report, November 2012. CPSIA Section 101(b): Functional Purpose Exception from Lead Content Limit for Children's Products for a Specific Product, Class of Product, Material, or Component Part.

Exposure Assessment and Potential Adjustments: Exposure presumptions that should be considered for adjustment in the assessment include the frequency for exposures and the ongoing lead release levels.

- **Hand-To-Mouth Transfer Fraction = 0.5 [Ingestion Fraction]:** Lead transferred from the BIC Children's Pen to the user's skin would need to be ingested to affect blood lead level. Ingestion primarily applies to lead on a child's finger tips. Transfer occurs due to hand-to-mouth transfer and can be direct (e.g., placing fingers into their mouth) or indirect (e.g., handling food or an object and then placing the food or object into their mouth). CPSC often presumes that 50% of the lead on a child's fingertips can be ingested and that was the level identified in the November 2012 staff report cited in footnote 2.

- **Potential Adjustment, Exposure Frequency:** CPSC staff based the threshold level of 2.2 µg/day lead ingested on calculations using the US Environmental Protection Agency's Integrated Exposure Uptake Biokinetic (IEUBK) Model. The IEUBK model presumes that exposures occur daily so the 2.2 µg/day threshold is an average daily exposure. Exposures to lead at the level measured by 30 rotations would occur infrequently, if at all, because the 30 surface wipes (i.e., 30 rotations) followed the general approach used in the CPSC vinyl wipe test and did not mimic minimal contact with the pen point that could occur during product use.

- **Potential Adjustment, Lead Release is Lower After Initial Rotations:** The 120-rotation wipes (i.e., over 3 minutes of squeezing and rotating) contained just 1.7-fold more lead than the 30 rotation wipes showing that removable lead levels decrease with increased contact and may only apply to newly manufactured points. Lead release over the final 90 rotations may be a better estimate of ongoing lead release than the initial 30 rotations. If so, the estimate would change to 0.14 µg per 30 rotations (i.e., 1.05 µg - 0.62 µg = 0.43 µg/90 rotations or 0.14 µg/30 rotations), over a 4-fold adjustment relative to the 30-rotation result.

Although the potential adjustments described above may be appropriate, they have not been applied. Exposures were calculated for the purpose of the CPSIA exception as shown below using Eq 1:

$$\begin{aligned} \text{Exposure} &= \text{Dermal} \times \text{Ingestion Fraction} && \text{(Eq. 1)} \\ &= 0.62 \mu\text{g/day} \times 0.5 = 0.31 \mu\text{g/day} \end{aligned}$$

The assessed exposure of 0.31 µg/day is over 7-fold below the 2.2 µg/day threshold for "no measurable increase in blood lead levels of a child in the November 2012 CPSC staff report.

Respectfully submitted,

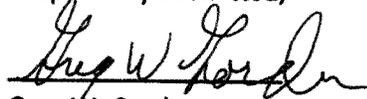

Greg W. Gorder

Exhibit 1

Pen Point Wipe Test Protocol



WIPE PROTOCOL: Pen Tip-to-Hand Simulated Transfer Using Modified Method NIOSH 9100:

Method NIOSH 9100 is modified as follows to measure accessible lead that could potentially transfer from pen tip to hand. Cross out text represents deletions from NIOSH Method 8100 and underline text represents additions:

- PURPOSE:** Determination of surface contamination by lead and its compounds.
- LIMIT OF DETECTION:** Analysis will be conducted 2 µg Pb per sample (0.02 µg/cm² for 100 cm² area) by flame AAS or ICP; 0.1 µg Pb per sample (0.001 µg/cm² for 100 cm² area) by or graphite furnace AAS, as needed to obtain a detection limit no higher than 0.5 µg/wipe.
- FIELD EQUIPMENT:**
- ~~1. Bags, plastic, sealable (e.g., with attached wire, tape or "zip" type seal).~~
 2. Sample pads, 2" x 2", sterile cotton gauze (Curity™, Johnson & Johnson™, or equivalent), or ashless quantitative filter paper.
NOTE: Wash'n Dri™ wipes may also be used. Other wipes may not ash properly, or may have a significant lead blank value.
 3. Gloves, latex, disposable.
 4. ~~Template, plastic, 10 cm x 10 cm, or other standard size.~~ Two BIC Beginner's Pens
 5. Water, distilled, in plastic squeeze bottle.
- SAMPLING:**
1. Using a new pair of gloves, remove a ~~gauze pad~~ from its ~~protective package~~. Moisten the ~~gauze pad~~ with approximately 1 to 2 mL of distilled water.
NOTE 1: Apply no more distilled water than that necessary to moisten approximately the central 80% of the area of the gauze pad. Excess distilled water may cause sample loss due to dripping from the gauze pad.
NOTE 2: If using the premoistened Wash'n Dri™, omit the distilled water.
 2. Place the template over the area to be sampled. Wipe First BIC Beginner's Pen as Follows: Fold pad into quarters and grasp with left hand (reverse if left handed) holding between thumb and index finger. Extend pen tip to writing position. Grasp pen with right hand (reverse if left handed) and place pen tip between pad (i.e., pen tip surrounded on all sides by pad) with pen tip squeezed firmly between thumb and index finger. Rotate pen back and forth making quarter to half turns with right hand while firmly grasping pen tip within pad in left hand (hands reversed if left handed) wiping. Wipe the pen tip surface to be sampled with firm pressure for 15 seconds making at least 30 partial rotations of the pen (if necessary to make at least 30 rotations, extend the time), using 3 to 4 vertical S-strokes. Fold the exposed side of the pad in and wipe the area with 3 to 4 horizontal S-strokes. Fold the pad once more and wipe the area with 3 to 4 vertical S-strokes.

Pen Tip-to-Hand Simulated Transfer Using Modified Method NIOSH 9100

January 31, 2013

Page 2 of 2

3. ~~Fold~~ Place the folded pad, exposed side in, and place it in a new plastic bag. Seal and label the bag clearly. Discard the gloves.

4. Wipe Second BIC Beginner's Pen as Follows: Repeat step 1 to moisten pad. Fold pad, extend pen tip, and grasp pen and pad as described in step 2. Rotate pen tip back and forth as described in step 2 but for at least 1 minute or 120 partial rotations. Repeat step 3 to label sample.

4. ~~Clean the template in preparation for the next wipe sample.~~

5. Include two blank pads (moistened and placed in bags) with each sample set.

SAMPLE

Use the procedure of NIOSH Method 7105, including final sample dilution to 10 mL

PREP:

NOTE: Additional portions of nitric acid may be needed for complete digestion of the sample, including the pad. Include appropriate media and reagent blanks.

MEASUREMENT:

Analyze ~~Screening of~~ all samples by flame AAS or ICP, ~~followed by use of~~ graphite furnace AAS ~~for those samples giving "Not Detected" is an efficient scheme~~ to obtain a detection limit of 0.5 μg /per sample or less. Use the procedures of NIOSH Methods 7082 (Lead by flame AAS), 7300 (Elements by ICP), 7105 (Lead by graphite furnace AAS), or other appropriate methods such as ASTM E1613-12.

Exhibit 2

Bureau Veritas Report: Wipe Test Data



Product Solution

Engineering Services Group

Product Description:

BIC Beginner Ball Pen Tip wipe tested for Lead

Report Number:
(5113)036-0119 Revision 1

Received Date:
February 5, 2013

Report Date:
February 14, 2013

Revision Date:
March 6, 2013

Prepared for:

**Ms. Gillian Rosenbloom
BIC Corporation
One BIC Way, Suite 1
Shelton, CT 06484**

Contents:
Report: Pages 1-4



**BUREAU
VERITAS**

Bureau Veritas Consumer Product Services, Inc.
100 Northpointe Parkway, Buffalo, NY 14228 USA
Tel: (716) 505-3300 • Fax: (716) 505-3301
Website: www.bureauveritas.com

Prepared by: Mike Monaco
Bureau Veritas
Consumer Product Services -
Engineering Services Group

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BUREAU
VERITAS

Product Solution

Report Number: (5113)036-0119 Revision 1

Project Scope

At the request of the client, (4) four samples of BIC Beginner Ball Pens were submitted for a Product Solution to analyze the amount of lead in the pen tips. The method for wiping the pen tips both 30 times and 120 times as well as the unit of measure, reporting limit required were all supplied by the client's toxicology firm. In addition, BVCPS was asked to perform and supply information on laboratory control sample wipes.

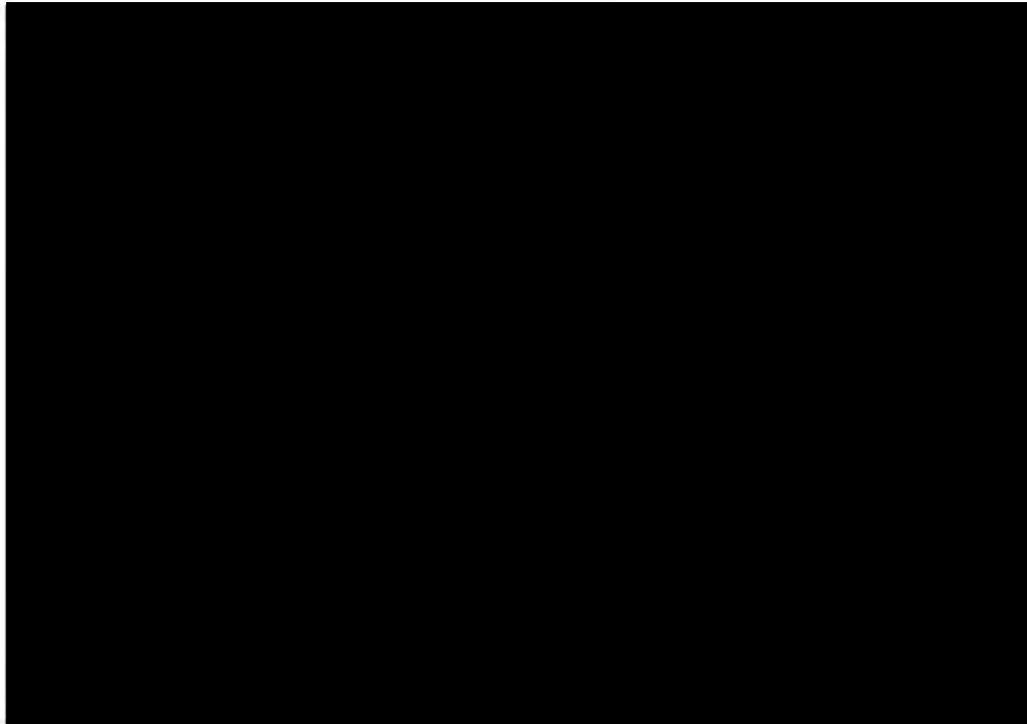
An e-mail quotation, #ESQ130122, was supplied by Bureau Veritas Consumer Products Services, Inc. (BVCPS) to the client outlining the price and scope of work to be performed to meet the client's request.

Executive Summary

Please refer to the results section of the report for the chart illustrating the data obtained from the testing conducted on the pen tips. Also please refer to the write-up and chart in the Methods/Evaluation section of the report for the laboratory control sample wipes.

Samples/Products Tested

CONFIDENTIAL



CONFIDENTIAL



Methods / Evaluation

This Product Solution utilized the following method which was directed by the client's toxicology firm:

Wipes were taken using Palintest wipe media in accordance with NIOSH Method 9100. The tips of two pens were wiped 30 times each and the tips of the other two pens were wiped 120 times each.

Wipe samples were collected by folding the Palintest wipe material into a triangular configuration. The tip of the pen was held inside the wipe, squeezed between the thumb and index finger, and rotated a full 360° a total of 15 times. The tip of the pen was then removed and placed into a clean area on the same wipe and rotated another 15 times. Therefore, the pens with 30 rotations were sampled on two areas of the wipe material. The pens with 120 rotations were sampled on eight clean areas of the wipe material. The 30 rotation wipes represented nearly one minute of wiping and 120 rotations represented at least three minutes of wiping. Ink was released from the pen tips during wiping.

The individual wipe samples were digested using nitric acid, sulfuric acid, and hydrogen peroxide according to OSHA method ID-125 (Metal and Metalloid Particulates in Workplace Atmospheres). The resulting extract was analyzed for lead using inductively coupled argon plasma with mass spectrometry (ICP-MS).

Quality control samples (two blank wipes, four laboratory control spikes, and ink controls) were prepared and analyzed along with the samples. The quality control spikes were created by adding a known amount of lead to a wipe, in duplicate, at levels 3X the reporting limit (0.3 µg) and 5X the reporting limit (0.5 µg).

As shown in the table below, the average recovery of the laboratory control spikes was 109%.

Laboratory Control Spike Level (µg/wipe)	Recovery (%)	
	Trial 1	Trial 2
0.3	107	109
0.5	109	111

In blank wipes there was no lead detected above the reporting limit of 0.1 microgram/wipe.

The presence of lead in the ink was evaluated by placing an ink mark on a Palintest wipe to mimic the collected samples, without rotating the pen tip against the wipe. The four ink-marked wipes were prepared and analyzed the same way as the pen tip rotation wipes. Ink controls did not have any lead detected above the reporting limit of 0.1 micrograms/wipe.



Results

The evaluation and analysis conducted on the pen tips of the four BIC Beginner Ball Pens products exhibited the following data:

Sample ID	Lead Concentration (µg/wipe)	
	Trial 1	Trial 2
30 rotations	0.59	0.65
120 rotations	1.0	1.1

The results are reported in the table above as mass of lead per wipe

The information in this report is reported as **DATA ONLY**.

BVCPS Buffalo Contact Information for this Report:

Administrative Questions: Kathy Kubiak Phone: 716-505-3465 kathy.kubiak@us.bureauveritas.com
Technical Questions: Michael Monaco Phone: 716-505-3420 mike.monaco@us.bureauveritas.com

Bureau Veritas
Consumer Products Services, Inc.

Michael A. Monaco
Senior Project Engineer
Engineering Services Group

/jy

Note 1: This evaluation/analysis was performed at a Bureau Veritas Consumer Products Services, Inc. approved subcontract lab.

Note 2: At the request of the client, the report was revised to clarify the testing method used in this analysis.

Assessor's C.V.

Greg W. Gorder, PhD

Technology Sciences Group, Inc: 712 Fifth Street, Suite A; Davis, CA 95616
(530) 757-1281

Professional Experience:

Technology Sciences Group, Inc; Davis, CA

2000 – Present

Senior Managing Scientist

- **Proposition 65 Exposure Assessments:** Has been assisting companies on all types of Proposition 65 matters since 2000. TSG's primary exposure assessor. In the past twelve months, has assessed oral, dermal, and inhalation exposures for multiple products covering at least 18 different chemicals.
- **Consumer Product Volatile Organic Chemical (VOC) Requirements:** Has been assisting companies with guidance on product VOC issues since 2000. States such as California limit consumer product VOC levels in response to Federal Clean Air standards.
- **Safer Consumer Product (SCP) Requirements:** Has been tracking the development of states legislation targeting "green chemistry" principles for ingredient standards in consumer products for TSG and provides companies with SCP guidance.

Zeneca Ag Products; Richmond, CA

1989 – 1999

Principle Research Scientist, Environmental Sciences Department

- **Management:** Managed a team of four scientist conducting environmental fate studies under Good Laboratory Practice (GLP) for US Environmental Protection Agency (EPA) registration of new active ingredients.
- **Study Expert:** Selected Zeneca lead (Study Expert) for Plant Metabolism Studies. Dr. Gorder managed and directed numerous in-house and contracted studies and introduced methods to enhance report-writing efficiency including the development of report templates.
- **Product Manager:** Selected Environmental Sciences Product Manager for Roneet Herbicide. Dr. Gorder identified gaps in the EPA re-registration submission package, secured funds for three new studies and conducted Dietary Exposure Evaluation Modeling (DEEM) under the federal Food Quality Protection Act.

Dow Chemical; Walnut Creek, CA

1986 – 1989

Senior Research Biochemist, Insecticide Discovery Biochemistry Section

- **Insecticidal Bio-rational Leads:** Contributed to identification and development of screening leads such as natural oils, spider venoms, and structural derivative synthesis. Dr. Gorder hosted seminars of experts to discuss areas of potential new insecticide chemistry and supported lead development by isolating the most insecticidal fractions of the oils and venoms for identification of active ingredients. His efforts on *Holena curta* venom were important in identifying Curtatoxin and co-authored a publication in the *Journal of Biological Chemistry*.

Postdoctoral Experience:

UC Berkeley; Berkeley, CA; Professor J. E. Casida **1983 – 1986**

Cornell University; Ithaca, NY; Professor C. F. Wilkinson **1980 – 1982**

- **Novel Insecticidal Mechanism:** Discovered that the organophosphorous insecticides phospholan and mephospholan are pro-insecticides that require metabolic activation. Dr. Gorder used model systems coupled with two dimensional Nuclear Magnetic Resonance (NMR) to identify the metabolic activation steps and novel alkylation (i.e., not phosphorylation) reaction with biological targets.
- **Cytochrome P450 Structure-Activity Relationships:** Identified hydroxylation rates and sites on toluene compounds (substituted in *ortho*, *meta*, or *para* positions with electron-donating or electron-withdrawing substituents) catalyzed by Phenobarbital-induced Cytochromes P450 under conditions of optimized Michaelis-Menten kinetics.

Education:

PhD Entomology/Environmental Toxicology **1980**

- Iowa State University, Ames IA under Professor P. A. Dahm
- Dissertation: Carbofuran Persistence in Soil and Efficacy for Corn Rootworm Larval Control

MS Entomology **1976**

- University of Wisconsin, Madison, WI under E. P. Lichtenstein
- Thesis: Degradation of Parathion by Cranberry Soil Microorganism

BS Microbiology **1974**

- University of Wisconsin, Madison, WI senior thesis under J. Gregory Zeikus
- Senior Thesis: Effects of Pesticides on Methanogenesis in Mendota Lake Sediments

Publications:

Eight publications from 1980 – 1990 (seven as senior author) in journals that include Journal of Biological Chemistry, Bio-Organic Chemistry, Journal of Agricultural and Food Chemistry and Canadian Journal of Microbiology. Details are available on request.