Toxicology Risk Assessment

LHAMA

APPLICANT	:	Zhejiang Zibom Stationery Co., Ltd.
ADDRESS	:	Jiangwan industrial district, Yiwu City, Zhejiang Province
SAMPLE DESCRIPTION	:	24 color pencil
MANUFACTURER	:	Zhejiang Zibom Stationery Co., Ltd.
SAMPLE RECEIVED DATE	:	19-May-2016
FURTHER INFORMATIION DATE	:	27-May-2016
TURN AROUND TIME	:	27-May-2016 to 03-Jun-2016, 6 Working Days

********** FOR FURTHER DETAILS, PLEASE REFER TO THE FOLLOWING PAGE(S) **********

Signed for and on behalf of
Eurofins Product Testing Service (Shanghai) Co., Ltd

Terric Ji
Lab Manager

Introduction

LHAMA: The product, Color Pencil Lead, was evaluated for compliance with ASTM D4236: determination of whether the product is expected to pose any significant chronic adverse health effects to humans when used as intended or under circumstances involving reasonable foreseeable misuse. This evaluation was conducted in general accordance with the US Code of Federal Regulations (CFR) Title 16 (CPSC) Part 1500.14(b)(8) "Art Materials", and ASTM Standard D 4236 "Standard Practice for Labeling Art Materials for Chronic Health Hazards". Chronic toxicity was evaluated in accordance with the guidelines specified by the Consumer Product Safety Commission in 16 CFR 1500.135.

Disclaimer

This evaluation was conducted based solely on the product formulation and the information provided in the Consumer Product TRA Information Form. It was assumed that all product formulation details are accurate and that there are no additional ingredients that are not listed. Chemical testing was not conducted as part of this product evaluation and chemical analyses data were not provided in support of this evaluation. It was also assumed that any ingredients provided in the product formulation do not contain any impurities and/or contaminants (e.g., heavy metal(s) or lead) or infectious agents that would cause toxicity in a consumer who may be exposed to them. This product was not evaluated for toxicological considerations related to physical or chemical properties of the formulation (e.g., pH, viscosity, volatility) and potential for physical injury (e.g., choking hazard, aspiration risk, or mechanical irritation) was not considered.

This evaluation is relevant solely to the conditions described herein. Any substitution of ingredients, increase in ingredient concentrations, or change in use pattern will necessitate a new evaluation.

Exposure Considerations

Consideration was given to consumer exposure with intended product use and under circumstances involving reasonable foreseeable misuse. Intentional product misuse was not considered within the scope of the assessment. Chronic exposure is considered to occur via the dermal route and possibly the oral route through accidental ingestion. The inhalation route was not evaluated since none of the chemicals in the product formulation were considered sufficiently volatile for inhalation exposure.

Conclusions

LHAMA

Based on the available data, the submitted formulation would not be expected to pose any significant chronic adverse health effects to humans when used as intended or under circumstances involving reasonable foreseeable misuse. Chronic toxicity was evaluated in accordance with the guidelines specified by the Consumer Product Safety Commission in 16 CFR 1500.135.

<u>The product will not require any additional chronic health hazard labeling according to ASTM D4236.</u>

The product must bear the following statement:

“Conforms to ASTM D4236.”

Other requirements of 16 CFR 1500.14 pertaining to proper labeling of the product including format and placement of statements and additional precautionary statements must also be adhered to. Acute hazards (e.g., acute oral/dermal/inhalation toxicity) were not evaluated as part of the current assessment; labeling statements and signal word requirements may be necessary depending on acute hazards associated with the product.

TO BE CONTINUED

Additional Notes

- Available data indicate that C.I. basic violet 1 (CAS No. 8004-87-3) may pose an eye irritation/damage and carcinogenicity concern; however, potential for eye damage and carcinogenicity does not warrant product classification given the intended use and nature of the product.

Approval

(Signature)	Charles Lambert, Ph.D., DABT (Name, printed)
Certified Toxicologist (Title)	June 02, 2016 (Date)

TO BE CONTINUED

ATTACHMENT

Data issues or limitations that were identified during the assessment for each ingredient in the product are discussed below. Additional lines of evidence such as human experience that provide evidence for the safe use of the ingredient in the product are also described.

LHAMA

- Assessment of chronic toxicity potential of kaolin (CAS No. 1332-58-7), clay (CAS No. 1302-87-0), microcrystalline wax (CAS No. 63231-60-7), magnesium stearate (CAS No. 557-04-0), CMC carboxymethyl cellulose (CAS No. 9004-32-4), titanium dioxide (CAS No. 13463-67-7), iron oxide (CAS No. 1332-37-2), C.I. pigment green 7 (CAS No. 1328-53-6), C.I. pigment blue 15:0/pigment blue 15:3 (CAS No. 147-14-8), pigment red 57.1 (CAS No. 5281-04-9), and C.I. pigment yellow G (CAS No. 2512-29-0) was based on available animal data and/or human experience/use information.
- Assessment of chronic toxicity potential of C.I. pigment red 21 (CAS No. 6410-26-0) was assessed using limited toxicological data and human experience/use information for the related chemical, pigment red 2 (CAS No. 6041-94-7), as considered appropriate based on information provided by the U.S. National Library of Medicine (ChemIDplus database).
- Assessment of chronic toxicity potential of C.I. basic violet 1 (CAS No. 8004-87-3) was based on consideration of available animal data, and data for the structurally related chemical basic violet 3 (CAS No. 548-62-9).
- Pigment permanent orange (CAS No. 3520-72-7) is a benzidine-based dye; however, it is not classified as carcinogenic or mutagenic. Assessment of chronic toxicity potential of pigment permanent orange was based on consideration of limited available toxicity data and professional judgment.
- Assessment of carbon black (CAS No. 1333-86-4) was based on the assumption that carbon black used in this product was not prepared by the ‘‘impingement’’ or ‘‘channel’’ process, as suggested by the U.S. FDA (21 CFR 81.10). Assessment of chronic toxicity potential of carbon black was based on available animal data and human experience/use information.

Table 1: Product Formulation - Color Pencil Lead

Chemical Name	CAS No.	% By Weight
Kaolin	1332-58-7	45.0%
Clay	1302-87-0	10.0%
Paraffin wax	63231-60-7	10.0%
Magnesium salt	557-04-0	12.0%
CMC Carboxyl methyl cellulose	9004-32-4	12.0%
Titanium dioxide[a]	13463-67-7	up to 11.0%
Iron oxide	1332-37-2	up to 8.0%
C.I. Pigment red 21	6410-26-0	up to 9.0%
C.I. Pigment green 7	1328-53-6	up to 6.5%
C.I. Pigment blue 15:0/ Pigment blue 15:3	147-14-8	up to 9.0%
C.I. Basic violet 1	8004-87-3	up to 3.0%
Pigment red 57.1	5281-04-9	up to 8.0%
C.I. Pigment yellow G	2512-29-0	up to 9.0%
Pigment permanent orange	3520-72-7	up to 6.0%
Carbon black	1333-86-4	up to 11.0%

a Toxicological data for primary particles of titanium dioxide (i.e., >100 nm in size) were used in the current product evaluation; toxicity associated with exposure to ultrafine grades (i.e., nanoparticles) of titanium dioxide (i.e., <100 nm) was not considered.

*** END OF THE REPORT ***