



Labeling of Hazardous Art Materials Act (LHAMA)

Folder #: 1609205
Order #: 11270064
Report Date: May 4, 2016

Product Description:	Crayons
Product SKU:	AP2000; FP2000
Weight/Volume:	6g per crayon
Age Grading:	3 years +
Intended Use:	Drawing
Test Requested:	LHAMA
Test Performed By:	Intrinsic Health Sciences

Executive Summary: Based on the information provided by the client and when used under intended use or reasonable foreseeable misuse, this product meets the requirements in the following regulations:

LHAMA: Not expected to have significant chronic hazards or require additional chronic health hazard labeling as defined in 16 CFR 1500.135 and ASTM D-4236. The product may bear the statement "Conforms to ASTM D-4236."

Submitted by:

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CRAYONS (AP2000 & FP2000)

Service Requested: LHAMA
Physical Form: Solid
Date: May 03, 2016
Prepared for: UL Verification Services, Inc.

1.0 Introduction

The product, *Crayons (AP2000 & FP2000)*, was evaluated for compliance with ASTM D-4236: 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.

2.0 Disclaimer

This evaluation was conducted based solely on the product formulation and the information provided in the Sample Submission Form (submitted April 28, 2016). Refer to Table 1 for a product formulation summary outlining the maximum concentration of each ingredient present in the final product formulation and Table 2 for a complete list of color formulations evaluated. 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.

3.0 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. Any volatile compounds within the product were evaluated for the inhalation route of exposure.

4.0 Conclusions

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. The product will not require any additional chronic health hazard labeling according to ASTM D-4236.

The product must bear the following statement:

“Conforms to ASTM D-4236.”

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.

PRODUCT EVALUATION APPROVAL



(Signature)

Certified Toxicologist

(Title)

Charles Lambert, Ph.D., DABT

(Name, printed)

May 03, 2016

(Date)

Table 1: Product Formulation Summary – Crayons (AP2000 & FP2000)

Chemical Name	CAS No.	% By Weight
Paraffin wax	8002-74-2	73.50%
Stearic acid	57-11-4	8.5%
Calcium carbonate	471-34-1	14%
The product formulation contains up to 2 of the following colorants:		
Pigment green 7	1328-53-6	up to 3.44%
Pigment yellow 3	6486-23-3	up to 4%
Pigment red 48 calcium salt	7023-61-2	up to 3%
Pigment sky blue phthalocyanine 2ZU	12239-87-1	up to 4%

Table 2: Color Formulations Evaluated – Crayons (AP2000 & FP2000)

Chemical Name	CAS No.	% By Weight
16# Green		
Paraffin wax	8002-74-2	73.50%
Stearic acid	57-11-4	8.5%
Calcium carbonate	471-34-1	14%
Pigment green 7	1328-53-6	3.44%
Pigment yellow 3	6486-23-3	0.56%
#9 Red		
Paraffin wax	8002-74-2	73.50%
Stearic acid	57-11-4	8.5%
Calcium carbonate	471-34-1	14%
Pigment red 48 calcium salt	7023-61-2	3%
Pigment yellow 3	6486-23-3	1%
10# Blue		
Paraffin wax	8002-74-2	73.50%
Stearic acid	57-11-4	8.5%
Calcium carbonate	471-34-1	14%
Pigment sky blue phthalocyanine 2ZU	12239-87-1	4%
11# Yellow		
Paraffin wax	8002-74-2	73.50%
Stearic acid	57-11-4	8.5%
Calcium carbonate	471-34-1	14%
Pigment yellow 3	6486-23-3	4%

Attachment

Upon consideration of toxicological data available for each ingredient in the product, various data issues/limitations were identified at the time of this assessment (provided below). Consideration was given to other lines of evidence (*e.g.*, human experience/use data) that provide evidence for the safety of use of the ingredients in the current product in the absence of adequate toxicological data.

- Assessment of chronic toxicity potential of paraffin wax (CAS No. 8002-74-2), stearic acid (CAS No. 57-11-4), calcium carbonate (CAS No. 471-34-1), pigment green 7 (CAS No. 1328-53-6), pigment yellow 3 (CAS No. 6486-23-3), and pigment sky blue phthalocyanine 2ZU (CAS No. 12239-87-1) was based on available animal data and/or human experience/use information.
- Assessment of chronic toxicity potential of pigment red 48 calcium salt (CAS No. 7023-61-2) was based on consideration of human experience/use information for CI 15865 (CAS No. 3564-21-4) and related salts.