

BIO RISK

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STATEMENT OF CONFORMANCE FOR ART MATERIALS

(LHAMA, CALIFORNIA PROPOSITION 65, US TOXICITY RISK ASSESSMENT, CANADIAN HAZARDOUS (TOYS) REGULATIONS and EU TOY STANDARD EN71-3: 2013

January 7, 2015

TO : Barbara Lee
7053 Vernon Rd
Hestand, KY 42151

FROM: JOHN J. CLARY, PH.D, FELLOW A.T.S.

ART MATERIAL: Crayon Rocks from Barbara Lee, its Franchisees, Distributors
and Dealers

Remarks

This review is based on current chemical composition of the above named material, and specific information on acute and chronic toxicity, physical form, bioavailability, and concentrations used, standard practices and related information. The confidential risk assessment on the material itself is attached. This material must be re-evaluated at least every five years (January 7, 2020).

Conclusion:

In my professional judgment, based on this evaluation, your art material listed above conforms to ASTM D 4236 (LHAMA - 16 CFR 1500.14). It is my opinion that this material under reasonable handling or use (includes reasonable foreseeable accidental handling or use) should not cause personal injury or substantial illness nor would it be expected to be toxic, corrosive, flammable or combustible, an irritant or a strong sensitizer by the oral, dermal or inhalation routes of exposure as defined in the FHSA Regulations (16 CFR 1500.3 (b) (5), (8), (9) and the Canadian Hazardous (toys) Regulation (Toxicological Hazards - Schedule I and II).

The statement "**conforms to ASTM D 4236**" is required for chronic toxicity on the label

No labeling listed below is also required under FHSA, US TOXICITY RISK ASSESSMENT and CANADIAN HAZARDOUS (TOYS) REGULATION (Toxicological Hazards) or under the provisions of The California Safe Drinking Water and Toxic Enforcement Act of 1986.

In compliance with EN 71-3: 2013

This material is determined to be non-toxic under proposed use conditions

John J. Clary, Ph.D.
Certified in General Toxicology
Fellow, A.T.S.

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RISK ASSESSMENT FOR ART MATERIALS

(LHAMA, CALIFORNIA PROPOSITION 65, US TOXICITY RISK ASSESSMENT, CANADIAN HAZARDOUS (TOYS) REGULATIONS and EU TOY STANDARD EN71-3: 2013

NON-CONFIDENTIAL

January 7, 2015

ART MATERIAL: Crayon Rocks from Barbara Lee, its Franchisees, Distributors and Dealers

INGREDIENTS: MAJOR

Wax
Calcium Carbonate
Pigments – Confidential

MINOR

OVERALL EVALUATION

TOXICITY

The wax is semi solid food grade wax. It should not be of acute or chronic concern from a toxicity point of view. It is used in making candles and soap. It has no TLV.

Calcium carbonate is not considered acutely toxic. No long-term toxicity is expected from this material. It has no TLV.

EXPOSURE

Crayon Rocks are classified as crayon and therefore are exempt from the size requirement for children under 3 years of age. Crayon Rocks weigh approximately 4.5-5.0 grams and are approximately 1.2 inches long by 3/4 inches wide by 5/8 inches tall. They are solid, made primarily from hydrogenated soybean oil and calcium carbonate and pigments. Inhalation exposure would not be expected from using these crayon rocks. Oral exposure would be possible if crayon rocks are placed in the mouth. A child could mistake Crayon Rocks as a candy. Skin contact is expected during use. The exposure to these metal and metal salts pigments or inclusion pigments will be essentially zero. The pigments and inclusion pigments will be dispersed in the wax crayon and skin contact with any significant amount of pigments is very unlikely.

RISK CHARACTERIZATION

Chronic Toxicity

No concerns under proposed use conditions.

Acute Toxicity

Non-irritating to skin and eye. No concerns under proposed use conditions.

European Standard for Toy Safety - EN 71

- Part 1. Mechanical and Physical Properties of toy - In Compliance
- Part 2. Flammability of toys - In Compliance
- Part 3. Migration of certain elements (2013) - In Compliance with EN71-3:2013 Standard. Based on composite sample results (all Crayons)
Category 111 (scrapped off toy material)

Element	2013 Standard Category 111 Migration limits (mg/kg)	Crayon Rock Crayons Range of migration levels (mg/kg)
Aluminum	70,000	1-79.5
Antimony	560	<0.20
Arsenic	47	<0.20
Barium	56,000	<0.20-110
Boron	15,000	<0.25
Cadmium	23	<0.20
Chromium	460	<0.20-0.30
Cobalt	130	<0.20 - 0.20
Copper	7,700	<0.20
Lead	180	<0.20
Manganese	15,000	0.20-0.90
Mercury	94	<0.20
Nickel	930	<0.20
Selenium	460	<0.20
Strontium	56,000	<2.50- 3.0
Tin	180,000	<0.50-0.50
Zinc	46,000	0.30-0.55

The levels of most soluble elements are at or below level of detection by standard methods. All migration level of elements in crayon are in compliance with EN71-3:2013. Report from Kirby Memorial Health Center Dec 23, 2013

CONCLUSION


Crayon Rocks are made primarily from waxes. The use of this art material under normal conditions should not produce any acute or chronic health effect. Some pigments may be considered hazardous (chronic toxicity, skin and eye irritants), but the solid crayon rock should be non-toxic as the pigments are encapsulated in the wax crayon.

Because children could mistake the Crayon Rocks as candy, it is recommended that they be used under adult supervision to prevent accidental ingestion.

No labeling other than the statement "conforms to ASTM D 4236" is required. No labeling is required under the FHSA or under California Proposition 65.

Crayon Rocks are not classified, under the Canadian Hazardous (toys) Regulation (Toxicological Hazards - Schedule I and II), as toxic, corrosive, flammable, quick skin bonding agent or are they sold in pressured containers.

Crayon Rocks are in compliance with EU Toy Standard EN71-3:2013


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