



TECHNICAL REPORT

Report # 28827

**Thames & Kosmos, LLC
207 High Point Avenue
Portsmouth, RI 02871**

October 18, 2005

Requested by:	Ted McGuire
Authorization Received:	October 10, 2005
Sample Name #:	Creative Cosmetics Kit (Make –It-Yourself Cosmetic): Body Lotion, Shower Gel, Lip Gloss, and Make-up
Model/Style #:	642914
Sample Received:	October 10, 2005
Number of Samples:	1 Set
Condition Received:	Good
Testing Completed:	October 14, 2005

SUMMARY:

RESULTS

Toxicological Risk Assessment & FDA Labeling Requirements Review: See pages 2 – 4 for detailed findings.

Reviewed by:

John Luzzi
Senior Account Manager
lg

Toxicological Risk Assessment & FDA Labeling Requirements Review:

Sample ID: **Creative Cosmetics Kit (Make -It-Yourself Cosmetic) # 642914**
Body Lotion, Shower Gel, Lip Gloss, and Make-up

Background

A single consumer product contains a cream base (50 milliliters), a lotion base (90 mls.), a shower gel base (90 mls.), a deep blue color gel (6.5 mls.), a makeup base (15 mls.), two makeup colors (6.5 mls. each), a lip gloss base (18 mls.), three lip-gloss colors (6.5 mls each), a package of glitter (6.5 mls.), two perfume oils (10 mls. each), a nail polish (4.2 mls.), a lipstick (2.4 grams), an eye shadow (2.1 grams) and a variety of other items (applicators, bottles, jars, a measuring cup, a stirrer and a sheet of labels). Quantitative lists of ingredients in each of these components and Material Safety Data Sheets (MSDS) for the nail polish, eye shadow and the lipstick were submitted for review. It is assumed that these ingredients contain no contaminants at levels that would be toxic or irritating to a consumer who may be exposed to them. Intertek has requested that this product be evaluated for potential acute and chronic oral and dermal toxicity, corrosive/irritation potential and sensitization (allergic reactions) potential as defined in the U.S. Federal Hazardous Substances Act Regulations (16 CFR 1500.3(b)(5-9) and 16 CFR 1500.3(c)(I-5)). Since the Food and Drug Administration (FDA) considers lip gloss to be a cosmetic, it has been requested that the pigments in this material be checked for compliance with the FDA regulations for cosmetic products (21 CFR Parts 73, 74, 81,82,700,701 and 740).

Exposure Assessment

An exposure assessment scenario for a given chemical of concern to a potential human receptor consists of creating a series of logical pathways and events whereby that chemical could reasonably be expected to come into contact with that receptor. For purposes of this assessment, it is assumed that under worst case exposure scenarios, all the components of this product (approximately 337 grams; the maximum amount in a single consumer product) may make frequent direct contacts with the skin as multiple exposure events or smaller amounts of one or more of these components may occasionally be ingested or contact the eye as single exposure events. Any volatile ingredients released from the various components of this product are assumed to be diluted at least 10-fold by ambient air before being inhaled when this product is used as intended or under circumstances involving reasonable foreseeable misuse.

Toxicity Assessment

Computerized searches of the National Library of Medicine's toxicological databases provided no information to indicate that as much as 100 grams of the chemical listed above would be expected to be toxic via the oral or dermal routes of exposure, be corrosive or irritating to the skin. However, ingestion of or direct eye contact with several (but not all) of the chemicals in this product could cause irritation (which may cause nausea and vomiting for ingested material). In addition, indirect exposures via ingestion (via hand-to-mouth activities) and to the eyes (via hand-to-eye contact) as described above would not be expected to be toxic or corrosive to the eyes or be a sensitizer to the majority of individuals in the general population. Indirect contact with several of the chemicals in this product may be expected to cause some eye irritation cause corneal clouding, dermatitis and congestion to the liver and kidneys. The MSDS for the nail polish

Toxicological Risk Assessment & FDA Labeling Requirements Review, Cont'd:

indicated that it may cause drowsiness, dizziness, loss of coordination, fatigue, and may aggravate pre-existing certain health conditions (asthma-like conditions and skin disorders). Searches of the National Library of Medicine's toxicological databases and other sources provided information to suggest that, except for the shower gel base and the nail polish, all the ingredients at levels found in the other components of this product would not be expected to cause acute or chronic toxicity via the oral or dermal routes of exposure, be corrosive or irritating to the skin or eyes or be a sensitizer to the majority of individuals in the general population. None of the ingredients, in the various components of this product, has been identified as "strong sensitizers" by the Consumer Product Safety Commission (CPSC).

Risk Assessment

The potential risk from a chemical substance to an individual is a function of both the exposure to and toxicity of that particular chemical. Unless data are available to indicate otherwise, the shower base gel (containing sodium laureth sulfate) and the nail polish (containing butyl acetate, ethyl acetate, isopropyl alcohol and camphor) in this product would be expected to be irritating to mucous membranes lining the gastrointestinal tract (which may cause nausea, vomiting and diarrhea in some individuals) and the eyes. In addition to irritation, the nail polish may be expected to cause narcosis (the acetates) if directly inhaled from the bottle (not an intended use of the product) and corneal clouding if the ethyl acetate vapors or liquid in it were to contact the eyes.

No evidence has been found to indicate that any of the ingredients in the other components of this product would be expected to be toxic, be corrosive or irritating to the skin or eyes or be a sensitizer as defined in the regulations cited above. Consequently, provided the assumptions indicated above are correct, inhalation, oral or dermal exposures to the components of this product other than the shower base gel and the nail polish is not expected to cause any significant adverse health effects. However, a remote possibility exists that one or more of the ingredients in this material could cause an allergic reaction in those individuals who have become sensitized to those ingredients.

Conclusions

Based on a review of all the available information provided to date, it is the opinion of the reviewer that all the ingredients, at levels found in the lotion base, the deep blue color gel, the makeup base, the makeup colors, the lip gloss base, the lip-gloss colors, the package of glitter, the perfume oils, the lipstick, the eye shadow and the accessories (applicators, bottles, jars, a measuring cup, a stirrer and a sheet of labels) components of this "Make-It- Yourself Cosmetic Kit" product would not be expected to cause any significant acute or chronic toxicity, be corrosive or irritating to the skin or eyes in persons who may be exposed to them via the dermal (including the eyes) or oral route when this product is used as intended (or under circumstances involving reasonable foreseeable misuse). These ingredients would also not be expected to cause a sensitization (allergic) reaction in the vast majority of individuals in the general population. However, a very remote possibility exists that one or more of the ingredients in several components of this product could possibly cause an allergic reaction in those few individuals who are sensitized to them. Such an event, while expected to be extremely rare, cannot be absolutely ruled out.

Toxicological Risk Assessment & FDA Labeling Requirements Review, Cont'd:

Several ingredients, at levels found in the shower base gel (sodium laureth sulfate) and the nail polish (acetates, isopropyl alcohol and camphor) may be expected to be irritating to the eyes and mucous membranes lining the respiratory and gastrointestinal tracts. The acetates in the nail polish may also be expected to cause narcosis and possibly damage to the liver and kidneys if the contents of that material are directly inhaled from the bottle (an unintended use of the product but a reasonably expected misuse). The acetates in the nail polish are also quite flammable.

The FDA would consider most of the components of this product to be cosmetics. All the colorants in this product, except one, have been approved for use in cosmetics and none of the ingredients are prohibited or restricted for use in cosmetics by the FDA. The colorant identified as Bleu W 683, (CI 42051), also known as Acid Blue 3, calcium salt and Food Blue 5, is not listed as an approved colorant for cosmetics by the FDA (21 CFR 73, 74 or 82).

The FDA requires the principal display panel (the label) state the name of the product, the nature/use of the product (either name or illustration), the net quantity, the name and place of the US distributor, the country of origin (in English) and appropriate warning statements.

Because of the potential risks identified above, the following precautionary statements would be appropriate for two of the components of this product (Precautionary statements should be affixed to the appropriate component):

Shower Gel Base - CAUTION: May cause eye irritation on contact or nausea, vomiting or diarrhea if ingested.

Nail Polish - WARNING: Flammable Liquid. Do not use near fire or flame. May cause blindness or severe irritation on contact with eyes. May cause nausea, vomiting or diarrhea if ingested. Keep away from children. Do not inhale vapors directly from bottle (may cause narcosis or liver and kidney damage).

Reviewer: Michael J. Norvell, Ph. D., DABT

