Health Sciences

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A Toxicological Risk Assessment (TRA) for Gelli Baff

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Executive Summary

Exponent evaluated a new formulation of the Gelli Baff product, relative to North American and European toy safety regulations and standards. The product is sometimes called Squishy Baff, depending on the market. Gelli Baff is a water-absorbing powder consisting of sodium polyacrylate and pigments. It is mixed with bath water to gelatinize the water. Sodium chloride is added to dissociate the gel and restore it to a liquid form that can be easily disposed down the drain.

Three concerns were raised in a TRA performed in 2010 for Spin Master (Rauckman, 2010), including: (1) dermal irritation potential, (2) inhalation toxicity potential, and (3) use of two pigments with documented concerns. The offending pigments were replaced with pigments that are of no concern. To address the potential for skin irritation and sensitization, *in vitro* tests were conducted for skin irritation, skin sensitization, and vaginal irritation and no concerns were found (Institute for In Vitro Sciences, 2011, 2012a, 2012b). Inhalation toxicity was addressed by the manufacturer by measuring the particle size distribution of the product. No particles were found in the inhalable range; thus, inhalation exposure is not an issue.

Additionally, chemical testing was performed on the product using a simulated perspiration method. A small amount of aluminum was found in the sodium chloride packet, which is not of concern. No other metals were detected and the screens did not identify any organic material.

The Gelli Baff product does not raise any concerns for health risk for children using the product and is compliant with all safety standards discussed in the report.

There is some potential for acrylates to cause skin irritation and/or skin sensitization, though only free monomer in polyacrylate would be able to penetrate the skin. Out of precaution, we agree with the manufacturer's offer to add the following warning statement:

> "Wash off thoroughly after use. Should there be any signs of skin irritation or redness during or after use, rinse with plenty of cold water. If symptoms persist seek medical advice."

Introduction

Spin Master has requested that Exponent evaluate the toxicity and potential health risk associated with the Gelli Baff bath product relative to toy safety regulations in North America and Europe. The product is also sold under the name Squishy Baff, depending on the market. Spin Master has provided a characterization and leachability analysis of the product components prepared by Chemir Analytical Services (Chemir Analytical Services, 2011), and a particle size analysis prepared by Malvern Laboratories (Malvern Laboratories, 2011). Further, Exponent arranged for tests of skin irritation, skin sensitization, and vaginal irritation at the Institute for In Vitro Sciences, Inc (Institute for In Vitro Sciences, Inc, 2011, 2012a, 2012b). In this report, Exponent provides a review of the reports, a summary of the results, and a toxicological and health risk assessment (TRA) of the components that were identified.

Gelli Baff is a water-absorbing, pigmented powder comprised primarily of sodium polyacrylate. The Gelli Baff is mixed with bath water, which results in a gelatinizing of the water into a semisolid gel. Sodium chloride (i.e., table salt) is added to dissociate the gel and restore it to its liquid form and allowing it to be disposed down residential drains. Gelli Baff is marketed to children and comes in a variety of colors.

When used children may be exposed to the chemical compounds through a variety of pathways:

- Dermal: Skin contact with the bath product results in dermal exposure where the chemical penetrates the skin and gets into the body. Also, the chemicals can dissolve into perspiration and remain on the skin surface for a period of time, allowing more time for the chemical to diffuse through the skin.

- Mouthing: Children frequently mouth objects, particularly children under two years of age. The chemical can dissolve into saliva and be ingested into the body.

- Inhalation: Children can be easily exposed to chemicals while breathing, especially in powdered form.

To evaluate these exposure pathways, it is important to consider the potential skin penetration, the solubility of the chemical in perspiration or saliva, and the particle size of the chemical.

A previous version of the Gelli Baff product was evaluated for Spin Master (Rauckman, 2010). Several concerns were raised:

- The potential for dermal irritation or sensitization based on anecdotal information on sodium polyacrylate, the key constituent in Gelli Baff.

- The potential of inhalation toxicity based on a reported inhalation toxicity test showing significant toxicity to very small particles of sodium polyacrylate.

- The use of two pigments with potential concerns, including one that is a sensitizer and another that is banned in hair dyes.

This report addresses these issues. Specifically, the two pigments of concern have been removed. The skin irritation potential is addressed by use of an *in vitro* test. Inhalation toxicity is addressed through analysis of particle size data provided by the manufacturer.

The remainder of this report is organized as follows:

- Review of Testing Reports

- Toxicological and Health Risk Assessment

- Summary and Conclusions

Review of Testing Reports

Analyses from multiple laboratories were conducted to assess the chemical components and potential health risk of Gelli Baff:

- Chemir Analytical Services performed a chemical characterization of components (Chemir Analytical Services, 2011).
- The Institute for In Vitro Sciences, Inc. reported the results of skin irritation, skin sensitization, and vaginal irritation tests (Institute for In Vitro Sciences, Inc., 2011, 2012a, 2012b).
- Malvern Lab reported results of an analysis on the particle size. This report was commissioned by the Gelli Baff manufacturer and provided to Spin Master.
- Testing by Intertek on metal and phthalates.

This section provides a review of these findings from the laboratories.

Chemical Analysis for Leaching into Simulated Perspiration

Chemir Analytical conducted simulated perspiration testing on samples of Gelli Baff. The test extracts leachable fractions of metals and organic compounds and identifies them using inductively coupled plasma (ICP) or Liquid Chromatography/Mass Spectrometry (LC/MS) or Gas Chromatography/Mass Spectrometry (GC/MS) analysis.

A test was performed on a composite of four Gelli Baff colors, including lava blast, princess pink, blue lagoon, and magic swamp. This sample is labeled "Step 1 composite." A separate sample of the sodium chloride material was labeled as "Step 2."

Metal analysis results

The results for leachable metals detected by ICP in the simulated perspiration extracts are summarized in Table 1. No metals were detected above detection limits in the Gelli Baff composite, which includes sodium polyacrylate and pigments. Leachable aluminum was measured above detection limits in one of the duplicate preparations of the sodium chloride material indicating leachable aluminum is detectable around the detection limit, i.e 20 ppm for this material. Dermal uptake of aluminum at those levels is expected to be minimal. Sodium chloride, known as common table salt, is included in the packaging to help with the disposal of the Gelli Baff and is not a component of the bath.

Table 1. Results for simulated perspiration extract analyzed by ICP analysis

Element	Step 1 Composite Concentration (ppm)	Step 2 Concentration (ppm)
Aluminum (Al)	< 20 ppm	28.1*
Chromium (Cr)	< 2.50 ppm	< 2.50 ppm
Antimony (Sb)	< 2.50 ppm	< 2.50 ppm
Mercury (Hg)	< 0.05 ppm	< 0.05 ppm
Arsenic (As)	< 2.50 ppm	< 2.50 ppm
Cadmium (Cd)	< 2.50 ppm	< 2.50 ppm
Lead (Pb)	< 2.50 ppm	< 2.50 ppm
Selenium (Se)	< 2.50 ppm	< 2.50 ppm

*Duplicate preparation was below detection limit of 20 ppm

Additional testing by Intertek (Sept 26, 2011 report) confirms the Chemir metals analysis.

Organic chemical analysis results

The simulated perspiration samples were analyzed by LC/MS and GC/MS for identification of non-polar and semi-polar compounds. No significant peaks were observed in the extract of either sample by GC/MS or LC/MS. Therefore, the analysis indicates no significant organic material is available for leaching in simulated perspiration suggesting risk for dermal uptake is not expected.

Additional testing by Intertek (July 20, 2011) show no detection of regulated phthalates (DBP, BBP, DEHP, DnOP, DINP, DIDP, and DnHP).

In Vitro Irritation and Sensitization Tests

The Institute for In Vitro Sciences conducted tests for skin irritation (Institute for In Vitro Sciences, 2011), skin sensitization (Institute for In Vitro Sciences, 2012a), and vaginal irrigation (Institute for In Vitro Sciences, 2012b). All of these tests were negative, indicating no potential for irritation or sensitization.

It is noted that the manufacturer has indicated that the product has been used for over 6 years with sales of 5 million units and there have been no complaints of allergic or irritation reactions. They also note that eczema and psoriasis sufferers like using the product.

Out of precaution, we agree with the manufacturer's offer to add the following warning statement:

> "Wash off thoroughly after use. Should there be any signs of skin irritation or redness during or after use, rinse with plenty of cold water. If symptoms persist seek medical advice."

Particle Size Analysis

Particle sizes below 10 µm may raise concerns for acute inhalation exposure since particles below 10 µm can penetrate into the deepest part of the lungs. The manufacturer provided a particle size analysis conducted by Malvern Laboratories. The analysis found no particles less than 40 µm; thus, there is no concern for acute inhalation exposure.

Toxicological and Health Risk Assessment

We evaluated the regulatory status from statutes and regulations affecting toy and cosmetic manufacturers in the U.S., Canada and Europe for each of the chemicals disclosed by the manufacturers. The regulatory agencies and programs include:

- California Proposition 65 (Prop 65): The presence of the chemical on the Office of Environmental Health Hazard Assessment, California, Prop 65 list of reproductive toxicants or carcinogens, thus requiring labeling in California unless the risk is below a threshold.

- Washington State Department of Ecology (WDOE) Children's Safe Products Act (CSPA): If the chemical is included on the chemical of high concern to children (CHCC) list, manufacturers are required to notify WDOE.

- Maine Chemicals of High Concern List. If a chemical is identified on this list, notification is required.

- Environment Canada, Canadian Environmental Protection Act (CEPA): The presence of the chemical on the CEPA Priority Substance List.

- European Database Export Import of Dangerous Chemicals (EDEXIM): The presence of the chemical on the Institute for Health and Consumer Protection of the Joint Research Centre of the European Commission's Regulation 689/2008 list of chemicals subject to the export notification procedure.

- European Directive 2009/48/EC on toy safety: The directive includes a number of banned fragrances in toys, limits for metals and restrictions on substances classified as carcinogenic, mutagenic, or toxic for reproduction (CMR), as well as several general requirements for toy safety.

- British Standard (EN 71-9:2005): The presence of the chemical in *Safety of toys – Part 9: Organic chemical compounds – Requirements.* There are thresholds levels for a number of the constituents that depend on the product's intended usage.

- European Committee Directive 2002/61/EC restrictions on the marketing and use of azo colourants (2002/61/EC): The presence of the chemical on the list of colorants restricted for marketing and use of certain dangerous substances and preparations.

- European Chemicals Agency (ECHA) Substances of Very High Concern (SVHC): The presence of the chemical on the SVHC list of chemicals in the ECHA authorization for the REACH regulation program.

  None of the constituents of the product are on any of the lists.

Table 4. Summary of the Regulatory Determinations for Chemical Compounds

Chemical	CAS No.	United States			Canada	Europe				
		Prop 65	Maine	WA State	CEPA	EU EDEXIM	EU Toy Safety	EN 71-9:2005	2002/61/EC	REACH SVHC
Sodium polyacrylate (9003-04-7)	110-30-5	No	No	No	No	No	No	No	No	No
Grape seed oil (8024-22-4)	147-14-8	No	No	No	No	No	No	No	No	No
CI 17200 (D&C Red 33) (3567-66-6)	989-38-8	No	No	No	No	No	No	No	No	No
Sodium Chloride (7647-14-5)	5242-49-9	No	No	No	No	No	No	No	No	No
CI 47005 (D&C Yellow 10) (8004-92-0/94891-332-4)	7429-90-5	No	No	No	No	No	No	No	No	No
CI 42090 (FD&Blue 1) (3844-45-9)	13463-67-7	No	No	No	No	No	No	No	No	No

Chemical Review of Gelli Baff Compounds

Sodium polyacrylate

Sodium polyacrylate is listed under the Everything Added to Food in the United States (EAFUS) database. This list represents food additive ingredients that the FDA has either approved for direct or indirect food additives or listed or affirmed as Generally Recognized as Safe (GRAS). Current 21 CFR regulations lists sodium polyacrylate as an indirect food additive permitted in food for human consumption.

It is well known that acrylate-based molecules can cause skin sensitization under certain circumstances[1]. However, polyacrylate is unlikely to penetrate the skin due to its large molecular size. Nonetheless, free monomer within polyacrylate could result in some exposure. There is some literature that shows possible skin sensitization with polyacrylate[2]. However, polyacrylates (and other acrylates) are commonly used in cosmetics and considered safe[3]. They are also used in baby diapers. A skin sensitization test conducted by the Institute of In Vitro Sciences indicated no potential for skin irritation for this product.

Issues have been raised about potential inhalation toxicity for sodium polyacrylate. One MSDS states the following (http://www.hmsmedical.com/images/44-OC%20MSDS.pdf):

> "Chronic inhalation exposure to rates for a lifetime (two years) using sodium polyacrylate that had been micronized to a respirable particle size (less than 10 microns) produced non-specific inflammation and chronic lung injury at 0.2 mg/m³ and 0.8 mg/m³. Also, at 0.8 mg/m³, tumors were seen in some test animals. In the absence of chronic inflammation, tumors are not expected. There were no adverse effects detected at 0.05 mg/m³."

The key point regarding this test is that the material was "micronized" mechanically (i.e., artificially) to be less than 10 microns (i.e., the cutoff for the respirable range). The testing done by Malvern Laboratories shows that there are no particles below 10 microns in the Gelli Baff. Therefore, inhalation exposure is not expected to be a concern.

[1] http://www.skintherapyletter.com/derm_news/2007.5/8.html

[2] http://www.ncbi.nlm.nih.gov/pubmed/15235538

[3] http://www.cosmeticsinfo.org/ingredient_details.php?ingredient_id=721

Grape seed oil

Grape seed oil is derived from grape seed and is commonly used as a cooking oil, and cosmetic ingredient as a skin occlusive for control of skin moisture (Baumann, 2009).

CI 17200 (D&C Red 33)

CI 17200 (D&C Red 33) is a colorant listed under the Database of Common Household Products as a common ingredient in a variety of personal care products including soap, shampoo, insect repellent, and cosmetics. The pigment can be safely used in food and in cosmetics[4].

Sodium chloride

Sodium chloride, commonly known as table salt, is listed under a number of 21 CFR regulatory titles.

CI 47005 (D&C Yellow 10)

CI 47005 (D&C Yellow 10) is a yellow colorant, listed under the Database of Common Household Products as an ingredient for a number of personal care products including perfume, cologne, toothpaste, hand lotion and shampoo.

The U.S. FDA lists CI 47005 as acceptable for use in cosmetics[5] and coloring drugs provided that it does not contain certain impurities[6]. The Chemir analysis shows that the listed impurities are not present. The cosmetics industry also considers the pigment to be safe[7].

CI 42090 (FD&Blue 1)

CI 42090 (FD& Blue 1) is a blue colorant added in many cosmetic products and house cleaning supplies and is listed under the Database of Common Household Products and EAFUS. It is acceptable for use in cosmetics[8].

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[4] http://www.cosmeticsinfo.org/ingredient_details.php?ingredient_id=596

[5] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=74.2710&SearchTerm=yellow

[6] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=74.1710&SearchTerm=d%26c%20yellow%20no%2E%2010

[7] http://www.cosmeticsinfo.org/ingredient_details.php?ingredient_id=1015

[8] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=74.2101&SearchTerm=blue

Summary and Conclusions

Exponent evaluated the previous TRA for the Gelli Baff product and assessed the toxicity and potential health risk associated with the ingredients. The product was evaluated relative to toy safety regulations and standards in North America and Europe. The constituents are of low toxicity and some are considered acceptable as indirect or direct food additives, or generally recognized as safe (GRAS) by the FDA. The product was also tested for skin irritation, skin sensitization, and vaginal irritation and was negative.

Exponent concludes that none of the constituents in the Gelli Baff product pose a significant health risk to children using the product. Furthermore, the Gelli Baff constituents meet the following criteria:

- No chemicals are present on the Institute for Health and Consumer Protection of the Joint Research Centre of the European Commission's Regulation 689/2008 list of chemicals subject to export notification procedure (EDEXIM).

- The chemicals are not included on the list of organic chemical compounds in the British Standard (EN 71-9:2005) recommendation for toy safety.

- The chemicals are not included in the Washington State or Maine lists of chemicals of concern in toys.

- The toy constituents are in compliance with Directive 2009/48/EC of the European Parliament in regards to toy safety.

- The toy is compliant with the Toy Regulations of the Canada Consumer Product Safety Act on the basis of the high LD_{50} values and the lack of sensitization, among other factors.

Skin irritation, skin sensitization, and vaginal irritation *in vitro* tests were conducted and the conclusion was that the product is non-irritating and non-sensitizing. It is important to note that there is always uncertainty associated with skin irritation and skin sensitization due to its sometimes rare nature and the difficulty of accurately testing for rare occurrences.

Exponent's evaluation is based on the chemical constituents disclosed by the manufacturer and/or detected in the chemical testing. Our conclusions assume that this information is complete and accurate. Our evaluation is based on publicly available information regarding the toxicity of the chemical constituents in the product. This report addresses only safety issues related to chemical exposure and the relevant portions of the regulations and laws related to chemical safety.

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