

TEST REPORT

Test Report # 19H-006616(A3) Date of Report Issue: November 12, 2019
Date of Sample Received: September 3, 2019 Pages: Page 1 of 4

CLIENT INFORMATION:

Company: Imagen Brands
Recipient: Carissa Roepke
Recipient Email: CarissaR@imagenbrands.com



SAMPLE INFORMATION:

Description: JS-02028C_Metallic Ball Lip Balm, JS-02042A_Metallic Star Lip Balm, JS-02002A_Metallic Classic Lip Balm, JS-02036A_Metallic Box Lip Balm, JS-02028B_Candy Colored Sphere Lip Balm, JS-02045_Animal Lip Balm
Assortment: Met Silver, Met Rose Gold, Purchase Order Number: -
Met Pink, Met Turquoise,
Met Gold, Met Blue, Met Red, Met Green, Met Purple, Red, Green, Blue, Purple, Pink, Yellow, Lime, White Panda, Tan Dog, Brown Monkey, Fox
SKU/style No.: Refer to Page 2 Toy Co./Agency: -
Factory/Supplier/Vendor: Jessie Commodity Co Ltd Country of Origin: China
Country of Distribution: United States, Canada Labeled Age Grade: -
Quantity Submitted: Refer to Page 2 Recommended Age Grade: -
Testing Period: 09/10/2019 – 09/27/2019 Tested Age Grade: -
10/08/2019 – 10/28/2019
11/05/2019 – 11/07/2019
11/12/2019 – 11/12/2019

OVERALL RESULT:

PASS with information

Refer to page 3 for test result summary and appropriate notes.
QIMA Testing (HK) Limited

Kevin Huang Fei Ho
Technical Manager

SKU/STYLE NO./ QUANTITY SUBMITTED DETAILED:

Style description	SKU No.	Qty.
JS-02028C_Metallic Ball Lip Balm - Silver	JS-02028C Met Silver	4 pcs
JS-02028C_Metallic Ball Lip Balm - Pink	JS-02028C Met Pink	5 pcs
JS-02042A_Metallic Star Lip Balm - Gold	JS-02042A Met Gold	5 pcs
JS-02042A_Metallic Star Lip Balm - Silver	JS-02042A Met Silver	5 pcs
JS-02002A_Metallic Classic Lip Balm - Gold	JS-02002A Met Gold	5 pcs
JS-02002A_Metallic Classic Lip Balm - Silver	JS-02002A Met Silver	5 pcs
JS-02036A_Metallic Box Lip Balm - Red	JS-02036A Met Red	5 pcs
JS-02036A_Metallic Box Lip Balm - Blue	JS-02036A Met Blue	5 pcs
JS-02036A_Metallic Box Lip Balm - Silver	JS-02036A Met Silver	5 pcs
JS-02036A_Metallic Box Lip Balm - Green	JS-02036A Met Green	4 pcs
JS-02036A_Metallic Box Lip Balm - Lime	JS-02036A Met Green	5 pcs
JS-02036A_Metallic Box Lip Balm - Purple	JS-02036A Met Purple	5 pcs
JS-02036A_Metallic Box Lip Balm - Gold	JS-02036A Met Gold	5 pcs
JS-02036A_Metallic Box Lip Balm - Pink	JS-02036A Met Pink	5 pcs
Parts	-	4 lots
JS-02045_Animal Lip Balm - Fox	JS-02045 Fox	5 pcs
JS-02045_Animal Lip Balm - Panda	JS-02045 White Panda	5 pcs
JS-02045_Animal Lip Balm - Dog	JS-02045 Tan Dog	5 pcs
JS-02045_Animal Lip Balm - Monkey	JS-02045 Brown Monkey	3 pcs
JS-02028B_Candy Colored Sphere Lip Balm - Red	JS-02028B Pink	5 pcs
JS-02028B_Candy Colored Sphere Lip Balm - Yellow	JS-02036A Yellow	6 pcs
JS-02028B_Candy Colored Sphere Lip Balm - Green	JS-02028B Lime	5 pcs
JS-02028B_Candy Colored Sphere Lip Balm - Blue	JS-02028B Blue	6 pcs
JS-02028B_Candy Colored Sphere Lip Balm - Purple	JS-02036A Purple	5 pcs

TEST RESULTS SUMMARY:

At the request of the client, the following tests were conducted:

CONCLUSION	TEST(S) CONDUCTED
PASS with information	Toxicological Risk Assessment (TRA) for the Federal Food, Drug, and Cosmetic Act (FD&C Act - CFR21) and its amendments ¹
PASS with information	Toxicological Risk Assessment (TRA) for the Food and Drugs Act, R.S.C. 1985, c.F-27, Cosmetic Regulations (C.R.C., c. 869) as amended, and the Consumer Packaging and Labelling Act. ¹

Note 1: It is required to place the following Safety Labeling in the product:

Use of this product by children should be supervised by an adult.
This product is intended for external use only and should not be ingested.
Stop using this product if you develop redness or itching.

Appendix I attached.

-End Report-

Appendix I: Toxicological Risk Assessment (Report 17-6353-RA62543) from Delphic HSE Solutions Ltd.

Toxicological Risk Assessment



Lip Balm

PRODUCT DETAILS

Type of Product: Lip balm | Leave on
Physical Form: Solid, Waxy
Client: Imagen Brands
 4680 Parkway Dr Suite 200
 Mason, OH 45040

Product Reference
 19H-006616

PHYSICAL / CHEMICAL CHARACTERISTICS

Appearance: Colourless Opaque Waxy
Odour: Characteristic - Perfume
Melting Point: 130 - 150°F
pH: Not Provided
Specific Gravity: Not Provided

Viscosity: Not Provided
Water Solubility: Not Provided
Log Kow: Not Provided
Particle Size: Not Provided

Limited physical-chemical data were supplied for review. The manufacturer/organisation responsible for placing the product on the market must ensure the physical-chemical properties of the product do not significantly impact on the toxicological profile of the product under normal conditions of use.

FORMULATION OVERVIEW

The formulation of this product has not been disclosed, and is held in confidence by Delphic HSE Solutions Ltd. For information concerning the formulation of this product, please refer any enquiries to the manufacturer.

SAFETY WARNINGS / INSTRUCTIONS

Use of this product by children should be supervised by an adult.
 This product is intended for external use only and should not be ingested.
 Stop using this product if you develop redness or itching.

The formulation of this product has not been disclosed, and is held in confidence by Delphic HSE Solutions Ltd.
For information concerning the formulation of this product, please refer any enquiries to the manufacturer.

EXPOSURE SCENARIO

Intended Consumer:	Children 3+	Minimum Expected Body Weight	14kg
Single Exposure:	10 mg 4 x Day	Diluted in use:	No
Retention Factor:	1	Retained Exposure:	2.857 mg/kg/day
Exposure to Neat Product:		Exposure to Diluted Product:	Product Not Diluted in Use
Body Site(s):	Lips		
Surface Area:	3.9 cm ²		
Exposure Level:	10.256 mg/cm ²		
Exposure Time:	Left on		

Manufacturers Instructions for Use

No specific instructions for use were provided for review.

Information on Previous Sales / Complaints

Details of previous sales and complaints data has not been supplied for review. This assessment is, therefore, completed on the assumption that no previous health-related complaints have been reported by consumers. If this is incorrect the manufacturer/responsible person must notify Delphic HSE of all such reported complaints so that the assessment can be updated.

Going forward the manufacturer/responsible person must ensure that details of any concerns or complaints relating to consumer safety and adverse health effects are provided to Delphic HSE so that the safety assessment can be updated accordingly.

Information on User Trials / Product Testing

Details of user trials/additional product safety testing have not been supplied for review, and this assessment is conducted on the basis that no such testing has been undertaken. Should this be inaccurate, or additional testing be conducted in the future, Delphic HSE should be notified of the details of such testing so this safety assessment can be updated accordingly.

Product Review

A Lip Balm intended for use by children (>3 yr) for the US and the Canadian markets. The following is a summary of review of the toxicological data on ingredients in the formulation.

For some of the ingredients in the formulation, the No Observed Adverse Effect Levels (NOAELs) were not available; however, these ingredients are still considered low risk based on their long history of safe use or lack of biological activity or a reason as explained in the the individual ingredient toxicological summary in annex I. For other ingredients, where NOAELs were available, the MoS calculated by standard toxicological practices as recommended by established scientific bodies (SCCS or Cosmetic Ingredient Review panel or other legal bodies) resulted in low risk outcome.

The product contains a number of different petroleum based ingredients in it. In order for the product to comply with regulations the full refining history of this ingredient must be known and should not contain any carcinogenic impurities.

The formulations contains a proprietary fragrance in it. The full composition of this fragrance is not known and hence it is recommended that manufacturer ensure that there are no substances in the fragrance that do not comply with EU Cosmetic Regulation 1223/2009. However, based on the IFRA certificate, it can be concluded that, this fragrance can be present in Class 1 products including lip balms at a maximum concentration of 5.33%, therefore, the current level can be considered as low risk for skin sensitization.

The manufacturer must also ensure that all raw materials used in the formulation are of suitable safe cosmetic grade and/or manufactured under GMP conditions as required by the regions to be sold.

Overall, based on the above information, the formulation for use in a Lip Balm for use by children (>3 yr) is unlikely to be a significant concern for health in the majority of individuals.

Skin Toxicity - Neat Product

The product as supplied may cause slight skin irritation especially if exposure is prolonged and/or repeated.

Exposure to this product is unlikely to result in photo-toxic effects.

There are low levels of substances present in this product which are known to cause an allergic reaction. The concentrations are sufficiently low not to present a risk of inducing allergy. However people already sensitised may show an adverse reaction when using this product. The identity of these ingredients will be shown on the label, enabling those potentially affected to avoid contact.

Unlikely to produce systemic toxicity following skin contact.

Eye Toxicity - Neat Product

May irritate the eye.

Oral Toxicity - Neat Product

All materials if swallowed in large amounts have the potential to cause injury. If incidentally swallowed in small amounts, the formulation as supplied may cause slight, transient irritation to the mouth and upper digestive tract.

Not expected to produce systemic toxicity following ingestion. All materials if swallowed in large amounts have the potential to cause injury.

Inhalation Toxicity

It is unlikely that inhalation will be a route of exposure.

Required Safety Labelling

Use of this product by children should be supervised by an adult.
This product is intended for external use only and should not be ingested.
Stop using this product if you develop redness or itching.

Overall Safety & Compliance

Under normal or reasonably foreseeable conditions of use, a product made to this formulation is unlikely to produce an abnormally high number of adverse reactions. The product will give consumers the level of safety they can reasonably expect.

The ingredients are legally permitted as per the Federal Food, Drug, and Cosmetic Act (FD&C Act - CFR21) and its amendments. They must comply with the relevant purity standards. The product must be manufactured in accordance with FD&C guidance on Good Manufacturing Practice.

The ingredients are legally permitted according to the Health Canada's List of Prohibited and Restricted Cosmetic Ingredients (The Cosmetic Ingredient "Hotlist") 2005 as amended, and must comply with the regulatory requirements of the Food and Drugs Act, R.S.C. 1985, c.F-27, Cosmetic Regulations (C.R.C., c. 869) as amended, and the Consumer Packaging and Labelling Act. The product must be made in accordance with Canadian Good Manufacturing Practices.



Toxicological & Regulatory Assessor

N. Ramesh N. Reddy

Dr. Ramesh N. Reddy, DVM, PhD, DABT

23 Sep 2019

This report consists of 4 pages plus a Regulatory and Ingredient Data Annex. It is only valid as the original, complete document.