



Test Report

No. HKHC1612008533HC-01

Date :Feb 13, 2017

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FAITH COSMETICS (GUANG ZHOU) TRADE CO.,LTD
6TH FLOOR,CHUANG JU BUSINESS BUILDING,NO.185 YUE XIU SOUTH ROAD,GUANG ZHOU CITY

This report supersedes testing report number HKHC1612008533HC

The following sample was submitted and identified by the client as LEGEND AGE HEALTHY CHERRY LIPSTICK (1 formulation).

Net Weight : 3.8 g per consumer product
SGS Report No. : HKHC1612008533HC
SGS Case No. : HKHC161200004102 (GZCPC161203911)
Sample Receiving Information : Formulation with chemical name, CAS no. and percentage
Region of Origin : China
Region of Destination : USA
Labelled Age Grading : 0+
Sample Receiving Date : Dec 16, 2016 – Feb 06, 2017
Test Period : Dec 16, 2016 – Feb 06, 2017

Test Requested

This Toxicological Risk Assessment (TRA) is carried out according to the US Food, Drug and Cosmetic Act (FD&C Act) 21 CFR Part 73, 74, 81, 82, 250.250, 700, and 740.

Test Results

Please refer to the following pages.

Conclusion

Please refer to *Section IV: CONCLUSIONS*.

Signed for and on behalf of
SGS Hong Kong Ltd.

Lee Chun Ngai, Gerald
MSc, MRSB, MBTS
Cosmetic Safety Assessor

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TOXICOLOGICAL RISK ASSESSMENT

INTRODUCTION

SGS is requested to review the safety of the product formula LEGEND AGE HEALTHY CHERRY LIPSTICK for consumer health and no other part of the product. The product is for US market and intended for application on lips for keeping it in good condition by babies of 0 year old or above. The net weight of the product (The formulation under assessment) is 3.8 g per consumer product. Detailed formulation is submitted by the client as in Section I. Ingredients are not presented in the report, whereas they are recorded in the SGS Archives.

LITERATURE SOURCES

This review was compiled by using information gathered from raw material suppliers and various online databases including the EU Scientific Committee on Consumer Safety (SCCS) opinions, Cosmetic Ingredients Review (CIR); detailed references are not reported here but are recorded in the SGS Scientific Archives.

Section I : FORMULATION

According to the client's needs and to protect business secrecy, detailed formulations are NOT presented in this report, whereas they are recorded in the SGS Archives. In case of medical events, it is the client's responsibility to provide the formulations to a patient's physician, or SGS upon request may furnish relevant medical units, on a confidential basis, information necessary to diagnose or treat cases of exposure without prior written authorization.

Fragrance

No fragrance components have been indicated to be present in the formulation.

Section II : COMPLIANCE WITH COSMETIC REGULATION

In accordance with US Food, Drug and Cosmetic Act, above-mentioned formulation contains restricted chemicals as below:

- (a) Yellow 5 is permitted for general cosmetics including eye area use, when it conforms to FDA specifications.
- (b) Red 22, Red 6, and Red 28 are permitted for general cosmetics, when it conforms to FDA specifications.

No information about manufacturing is available. It is highly recommended that the product is manufactured according to Good Manufacturing Practice (GMP). The ingredients used shall fulfill corresponding purity requirements. It is also assumed that the ingredients in this product contain no contaminants or residues at level that would be toxic, corrosive or irritating to the skin, eyes or mucous membranes, or cause a sensitization reaction in a consumer who may be exposed. If it is not the case, it will void this assessment.

None of the ingredients are prohibited to be used in cosmetic products as indicated in the US Food, Drug and Cosmetic Act (FD&C Act) 21 CFR Part 73, 74, 81, 82, 250.250, 700, and 740. It can be concluded that the formulation as supplied complies with US Food, Drug and Cosmetic Act.

Section III : CONSUMER HEALTH RISK ASSESSMENT

Afore-mentioned formulation has been reviewed for safety at the basis of the following assumptions.

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Consumer Exposure Scenario

The following assumptions have been made for assessment of exposure:

- Product category: Lipstick
- Physical form: Semi-solid
- Intended use: Application on lips for keeping it in good conditions
- Frequency of use: 1460 times per year
- Exposure route(s): Primarily via dermal contact and potential oral ingestion
- Product amount: 3.8 g
- Amount per application: 0.01 g
- Exposure area: 4.8 cm²
- Exposure duration: 360 minutes
- Body weight: 5 kg
- Target population: Babies of 0 year old or above

Risk Characterization for Consumer Health**Local Effects**

Irritation: Not expected to cause skin and eye irritation under normal and reasonably foreseeable conditions of use.

Sensitization: There are substances of allergenic potential but at low level that is not expected to induce an allergenic reaction in the majority of the users. However, sensitized people can react to allergen present at extremely low concentrations.

Phototoxicity: Exposure to this product is unlikely to result in phototoxic effects.

Systemic Effects

As there is a chance of ingestion of this lip product with customary use, the ingredients used should be of food grade or any appropriate grade. Provided the manufacturer's instructions are followed, this formulation is unlikely to cause damage to internal organs through skin and ingestion under normal and reasonably foreseeable conditions of use.

Joint Toxic Action

Based on current knowledge, joint toxic action is not anticipated.

Section IV : CONCLUSIONS:

The submitted formulation complies with the US Food, Drug and Cosmetic Act (FD&C Act) 21 CFR Part 73, 74, 81, 82, 250.250, 700, and 740. It is not expected to cause acute or chronic skin and eye irritation, acute or chronic oral, dermal or inhalation toxicity or be a strong sensitizer as defined in 16 CFR 1500.3(c)(4), 1500.3(c)(2), 1500.3(c)(3) and 1500.3(c)(5). The product is highly recommended to be manufactured according to Good Manufacturing Practice (GMP). Provided the manufacturer's instructions are followed and all the ingredients used are of cosmetic grade, it is considered that, in the present state of knowledge, the submitted formulation put on the market is unlikely to pose a significant risk to the health of intended consumer under normal and reasonably foreseeable conditions of use.

Recommended Safety Labelling

Use under adult supervision

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The validity of this review depends on accurate disclosure by both the manufacturer(s) of the components and of the finished products. Best professional capabilities are used in performing this review. If client wishes to use this opinion with any alterations to the submitted formula, SGS (HK) Ltd. or any of its employees will not be held liable for any injury or damage resulting from this product. A review of this assessment should be programmed at regular and frequent intervals (upon reformulation of the components or the finished products or upon any change to health and safety regulations).

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***** End of Report *****

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