

FACE PAINT

Service Requested: TRA(US)
Physical Form: Liquid
Date: June 27, 2016
Prepared for: UL Verification Services

67158-XXXX

1.0 Introduction

The product, *Face Paint*, was evaluated for its potential to be toxic (acute/chronic), corrosive, a skin/eye irritant, or strong sensitizer as defined in 16 CFR 1500.3(b)(5), (7)-(9) (Federal Hazardous Substances Act regulations). Chronic toxicity was evaluated in accordance with the guidelines specified by the Consumer Product Safety Commission in 16 CFR 1500.135.

2.0 Disclaimer

This evaluation was conducted based solely on the product formulation and the information provided in the Sample Submission Form (submitted June 21, 2016). It was assumed that all product formulation details are accurate and that there are no additional ingredients that are not listed. Chemical testing was not conducted as part of this product evaluation and chemical analyses data were not provided in support of this evaluation. It was also assumed that any ingredients provided in the product formulation do not contain any impurities and/or contaminants (e.g., heavy metal(s) or lead) or infectious agents that would cause toxicity in a consumer who may be exposed to them. This product was not evaluated for toxicological considerations related to physical or chemical properties of the formulation (e.g., pH, viscosity, volatility) and potential for physical injury (e.g., choking hazard, aspiration risk, or mechanical irritation) was not considered.

This evaluation is relevant solely to the conditions described herein. Any substitution of ingredients, increase in ingredient concentrations, or change in use pattern will necessitate a new evaluation.

3.0 Exposure Considerations

Consideration was given to consumer exposure with intended product use and under circumstances involving reasonable foreseeable misuse. Intentional product misuse was not considered within the scope of the assessment. This evaluation was conducted under the assumption that potential exposure to product ingredients is through the dermal route and possibly the oral route through accidental ingestion. The inhalation route was not evaluated since none of the chemicals in the product formulation were considered sufficiently volatile for inhalation exposure.

4.0 Conclusions

Based on available data, *Face Paint* MEETS the requirements for classification as not toxic (acute/chronic), corrosive, a skin/eye irritant, or strong sensitizer as defined in 16 CFR 1500.3, when used as intended or under circumstances involving reasonable foreseeable misuse.

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June 27, 2016

1

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Additional Notes

- C.I. Red 22 (CAS No. 6448-95-9) is listed as an azo pigment by the Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers and has been identified as a pigment that may have potential to release carcinogenic amines; however, based on the available data from the European Chemicals Agency's Classification and Labelling Inventory database and professional judgement C.I. red 22 is not expected to pose a safety concern at the concentration present in the product.

PRODUCT EVALUATION APPROVAL

(Signature)**Certified Toxicologist**

(Title)**Charles Lambert, Ph.D., DABT**

(Name, printed)**June 27, 2016**

(Date)

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June 27, 2016

2

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Table 1: Product Formulation – Face Paint

Chemical Name	CAS No.	% By Weight
Sodium myristate	822-12-8	50%
Sodium stearate	822-16-2	10%
Polyethylene glycol	25322-68-3	15%
Ion changed water	7732-18-5	20%
The product formulation contains one of the following colorants:		
C.I. Yellow 14	5468-75-7	up to 5%
C.I. Black 7	1333-86-4	up to 5%
C.I. Blue 15	147-14-8	up to 5%
C.I. Red 22	6448-95-9	up to 5%
C.I. Green 7	1328-53-6	up to 5%
C.I. Yellow 3	6486-23-3	up to 5%

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June 27, 2016

3

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Attachment

Upon consideration of toxicological data available for each ingredient in the product, various data issues/limitations were identified at the time of this assessment (provided below). Consideration was given to other lines of evidence (*e.g.*, human experience/use data) that provide evidence for the safety of use of the ingredients in the current product in the absence of adequate toxicological data.

- Assessment of acute toxicity, corrosivity, irritation, sensitization, and chronic toxicity potential sodium myristate (CAS No. 822-12-8) was based on consideration of human experience/use data and toxicological data for the structurally related fatty acid myristic acid (CAS No. 544-63-8) as considered appropriate by the Cosmetic Ingredient Review. According to the Cosmetic Ingredient Review, myristic acid is considered safe as used in cosmetics at concentration of up to 50%. Sodium myristate is also listed in the the EU Cosmetic Ingredients and Substances database with no use restrictions. Sodium myristate (listed as salts of fatty acids) is listed as a direct food additive by the U.S. FDA (21 CFR 172.863). Sodium myristate is listed in the Health Canada Natural Health Products Database as a non-medicinal anticaking agent, and emulsifying agent with no use restrictions. Based on the available information, sodium myristate is not considered to pose a safety concern at the concentration present in the product.
- Assessment of mucous membrane irritation and chronic toxicity potential of sodium stearate (CAS No. 822-16-2) was based on available animal data and human experience/use information. According to the U.S. FDA, sodium stearate is used as a food additive as a component of chewing gum base and in the manufacture of food packaging material (21 CFR 172.615, 181.29). Sodium stearate is listed in the EU Cosmetic Ingredients and Substances database with no use restrictions. Sodium stearate is listed in the Health Canada Natural Health Products Database as a non-medicinal anticaking agent, emulsifying agent, and solubilizing agent with no use restrictions. Based on the available information, sodium stearate is not considered to pose a safety concern at the concentration present in the product.
- Assessment of acute dermal and inhalation toxicity, mucous membrane irritation, and chronic toxicity potential of polyethylene glycol (CAS No. 25322-68-3) was based on consideration of toxicity data for the group of polyethylene glycol compounds identified with this CAS number, and human experience/use information. Polyethylene glycol (listed as polyethylene glycol (MW 200-9,500)) is listed as a multipurpose additive for direct addition to food for human consumption by the U.S. FDA (21 CFR 172.820). Polyethylene glycol (listed under several substance names) is listed in the EU Cosmetic Ingredients and Substances database with no use restrictions. Polyethylene glycol is also listed in the Health Canada Natural Health Products Ingredient Database as a non-medicinal ingredient with an acceptable daily intake of up to 10 mg/kg/day. Based on the available information, polyethylene glycol is not considered to pose a safety concern at the concentration present in the product.
- Assessment of acute dermal toxicity, corrosivity, irritation, sensitization, and chronic toxicity potential of C.I. yellow 14 (CAS No. 5468-75-7) was based on consideration of data for related diarylide yellow pigments, including C.I. pigment yellow 12 (CAS No. 6358-85-6), C.I. pigment yellow 13 (CAS No. 5102-83-0), and C.I. pigment yellow 83 (CAS No. 5567-15-7), as considered appropriate by the U.S. Environmental Protection Agency. Based on eye irritation data for related chemicals, C.I. yellow 14 may be slightly irritating to the eye; however, potential for irritation is not considered severe enough to warrant product classification given consideration of the concentration in the final product. Available data for related yellow pigments do not indicate that concern is warranted for chronic toxicity potential. Based on the available information, C.I. yellow 14 is not considered to pose a safety concern at the concentration present in the product.

TRA (US): Face Paint

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June 27, 2016

4

Initials: 

- Assessment of C.I. black 7 (CAS No. 1333-86-4) was based on the assumption that the pigment in this product was not prepared by the "impingement" or "channel" process, as suggested by the U.S. FDA (21 CFR 81.10). Assessment of sensitization and chronic toxicity potential of C.I. black 7 was based on consideration of limited available toxicity data and human experience/use information. Available data indicate that C.I. black 7 may be carcinogenic, based on inhalation and intratracheal rodent studies; however, potential for carcinogenicity does not warrant product classification given the nature of the product. C.I. Black 7 (listed as carbon black and CI 77266) is a colorant allowed in cosmetic products according to the EU Cosmetics Regulation (Regulation (EC) No 1223/2009), subject to purity criteria. C.I. Black 7 (listed as D&C black No. 2) is listed as a coloring agent allowed for use in cosmetic products by the U.S. FDA (21 CFR 74.2052), subject to Good Manufacturing Practices. Based on the available information, C.I. black 7 is not considered to pose a safety concern at the concentration present in the product.
- Assessment of acute dermal toxicity and chronic toxicity potential of C.I. blue 15 (CAS No. 147-14-8) was based on consideration of available animal data and human experience/use information. C.I. Blue 15 (listed as CI 71460 and 29H,31H-phthalocyaninato(2-)-N29,N30,N31,N32 copper) is a colorant allowed in cosmetic products with no use conditions according to the EU Cosmetics Regulation (Regulation (EC) No. 1223/2009). C.I. Blue 15 (listed as copper phthalocyanine) is listed in the Health Canada Health Product Ingredients Database as colour additive for topical application. Based on the available information, C.I. blue 15 is not considered to pose a safety concern at the concentration present in the product.
- Assessment of acute dermal toxicity, irritation, sensitization, and chronic toxicity potential of C.I. red 22 (CAS No. 6448-95-9) was based on available animal data and professional judgement. C.I. Red 22 has not been classified by the majority of notifiers according to the European Chemicals Agency's Classification and Labelling Inventory database. C.I. Red 22 is listed as an azo pigment by the Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers that may have potential to release carcinogenic amines; however, based on the available data from the European Chemicals Agency's Classification and Labelling Inventory database and professional judgement C.I. red 22 is not expected to pose a safety concern at the concentration present in the product. Based on the available data and professional judgment, C.I. red 22 is not considered to pose a safety concern at the concentration present in the product.
- Assessment of acute dermal toxicity, mucous membrane irritation, and chronic toxicity potential of C.I. green 7 (CAS No. 1328-53-6) was based on consideration of available animal data and human experience/use information. According to the EU Cosmetics Regulation (Regulation (EC) No. 1223/2009), C.I. green 7 (listed as CI 74260 and polychloro copper phthalocyanine) is a colorant allowed in cosmetic products, except in eye products. Based on the available information, C.I. green 7 is not considered to pose a safety concern at the concentration present in the product.
- Assessment of acute toxicity, corrosivity, irritation, sensitization, and chronic toxicity potential of C.I. yellow 3 (CAS No. 6486-23-3) was based on consideration of human experience/use information. C.I. Yellow 3 (listed as 2-[(4-chloro-2-nitrophenyl)azo]-N-(2-chlorophenyl)-3-oxobutamide and CI 11710) is a coloring agent allowed for use in cosmetic products not applied to mucous membranes, according to the EU Cosmetics Regulation (Regulation (EC) No. 1223/2009). Based on the available information, C.I. yellow 3 is not considered to pose a safety concern at the concentration present in the product.

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June 27, 2016

5

Initials: 



Test Report

No. SHAHG1700069201

Date: 06 Jan 2017

Page 1 of 4

The following sample(s) was/were submitted and identified on behalf of the clients as : FACE PAINT

SGS Job No. : SHHL1612076683ST - SH
 Item No. : MD800
 Manufacturer :
 Supplier :
 Country of Origin : CHINA
 Style No. : MD800
 Age Labelling : 3+
 Date of Sample Received : 03 Jan 2017
 Testing Period : 03 Jan 2017 - 06 Jan 2017
 Test Requested : Selected test(s) as requested by client.
 Test Method : Please refer to next page(s).
 Test Results : Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
EN71-9:2005+A1:2007 - Primary Aromatic Amines(As specified by client)	PASS
EN71-9:2005+A1:2007 - Colorants(As specified by client)	PASS

Signed for and on behalf of
 SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.

Serena Wang
 Approved Signatory



SGS-CSTC
 Inspection & Testing Services
 (Shanghai) Co., Ltd.

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Item Numbers: 67158-1003, 67158-1006

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Page 6 of 10

**Test Report**

No. SHAHG1700069201

Date: 06 Jan 2017

Page 2 of 4

Test Results :**Test Part Description :**

Specimen No.	SGS Sample ID	Description
SN1	SHA17-000692.001	Yellow paint+Blue paint+Green paint
SN2	SHA17-000692.002	Red paint+Black paint+White paint
SN3	SHA17-000692.003	Dark green paint(camouflage)+Brown paint(camouflage)+Black paint(camouflage)

Remarks :

- (1) 1 mg/kg = 0.0001%
 (2) MDL = Method Detection Limit
 (3) ND = Not Detected (< MDL)
 (4) "-" = Not Regulated

EN71-9:2005+A1:2007 - Primary Aromatic Amines(As specified by client)

Test Method : Sample preparation with reference to EN71-10:2005 followed by analysis with reference to EN71-11:2005.

Test Item(s)	CAS NO.	Limit	Unit	MDL	001	002	003
Aniline	62-53-3	5	mg/kg	2	ND	ND	ND
o-Toluidine	95-53-4	5	mg/kg	2	ND	ND	ND
2-Methoxyaniline	90-04-0	5	mg/kg	2	ND	ND	ND
4-Chloroaniline	106-47-8	5	mg/kg	2	ND	ND	ND
2-Naphthylamine	91-59-8	5	mg/kg	2	ND	ND	ND
Benzidine	92-87-5	5	mg/kg	2	ND	ND	ND
3,3'-Dimethylbenzidine	119-93-7	5	mg/kg	2	ND	ND	ND
3,3'-Dichlorobenzidine	91-94-1	5	mg/kg	2	ND	ND	ND
3,3'-Dimethoxybenzidine	119-90-4	5	mg/kg	2	ND	ND	ND

EN71-9:2005+A1:2007 - Colorants(As specified by client)

Test Method : Sample preparation with reference to EN71-10:2005 followed by analysis with reference to EN71-11:2005.

Test Item(s)	CAS NO.	Limit	Unit	MDL	001
Basic Red 9	569-61-9	10	mg/kg	2	ND
Acid Violet 49	1694-09-3	10	mg/kg	2	ND
Disperse Blue 1	2475-45-8	10	mg/kg	2	ND



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Item Numbers: 67158-1003, 67158-1006

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Test Report

No. SHAHG1700069201

Date: 06 Jan 2017

Page 3 of 4

Test Item(s)	CAS NO.	Limit	Unit	MDL	001
Disperse Blue 3	2475-46-9	10	mg/kg	2	ND
Basic Violet 1	8004-87-3	10	mg/kg	2	ND
Disperse Blue 106	68516-81-4/12223-01-7	10	mg/kg	2	ND
Solvent Yellow 1	60-09-3	10	mg/kg	2	ND
Basic Violet 3	548-62-9	10	mg/kg	2	ND
Disperse Orange 3	730-40-5	10	mg/kg	2	ND
Disperse Yellow 3	2832-40-8	10	mg/kg	2	ND
Disperse Red 1	2872-52-8	10	mg/kg	2	ND
Solvent Yellow 3	97-56-3	10	mg/kg	2	ND
Disperse Blue 124	61951-51-7	10	mg/kg	2	ND
Disperse Orange 37/76	12223-33-5	10	mg/kg	2	ND
Solvent Yellow 2	60-11-7	10	mg/kg	2	ND
Acid Red 26	3761-53-3	10	mg/kg	2	ND
Test Item(s)	CAS NO.	Limit	Unit	MDL	002
Basic Red 9	569-61-9	10	mg/kg	2	ND
Acid Violet 49	1694-09-3	10	mg/kg	2	ND
Disperse Blue 1	2475-45-8	10	mg/kg	2	ND
Disperse Blue 3	2475-46-9	10	mg/kg	2	ND
Basic Violet 1	8004-87-3	10	mg/kg	2	ND
Disperse Blue 106	68516-81-4/12223-01-7	10	mg/kg	2	ND
Solvent Yellow 1	60-09-3	10	mg/kg	2	ND
Basic Violet 3	548-62-9	10	mg/kg	2	ND
Disperse Orange 3	730-40-5	10	mg/kg	2	ND
Disperse Yellow 3	2832-40-8	10	mg/kg	2	ND
Disperse Red 1	2872-52-8	10	mg/kg	2	ND
Solvent Yellow 3	97-56-3	10	mg/kg	2	ND
Disperse Blue 124	61951-51-7	10	mg/kg	2	ND
Disperse Orange 37/76	12223-33-5	10	mg/kg	2	ND
Solvent Yellow 2	60-11-7	10	mg/kg	2	ND
Acid Red 26	3761-53-3	10	mg/kg	2	ND
Test Item(s)	CAS NO.	Limit	Unit	MDL	003
Basic Red 9	569-61-9	10	mg/kg	2	ND
Acid Violet 49	1694-09-3	10	mg/kg	2	ND
Disperse Blue 1	2475-45-8	10	mg/kg	2	ND
Disperse Blue 3	2475-46-9	10	mg/kg	2	ND
Basic Violet 1	8004-87-3	10	mg/kg	2	ND



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Page 8 of 10



Test Report

No. SHAHG1700069201

Date: 06 Jan 2017

Page 4 of 4

Test Item(s)	CAS NO.	Limit	Unit	MDL	003
Disperse Blue 106	68516-81-4/ 12223-01-7	10	mg/kg	2	ND
Solvent Yellow 1	60-09-3	10	mg/kg	2	ND
Basic Violet 3	548-62-9	10	mg/kg	2	ND
Disperse Orange 3	730-40-5	10	mg/kg	2	ND
Disperse Yellow 3	2832-40-8	10	mg/kg	2	ND
Disperse Red 1	2872-52-8	10	mg/kg	2	ND
Solvent Yellow 3	97-56-3	10	mg/kg	2	ND
Disperse Blue 124	61951-51-7	10	mg/kg	2	ND
Disperse Orange 37/76	12223-33-5	10	mg/kg	2	ND
Solvent Yellow 2	60-11-7	10	mg/kg	2	ND
Acid Red 26	3761-53-3	10	mg/kg	2	ND

Remark:

(1) Results shown are of the total weight of wet samples.

(2) Test was conducted on composite of random parts of the item as per client's request and the test result is the overall result.

Sample photo:



SGS authenticate the photo on original report only

*** End of Report ***



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Page 9 of 10

**Toxicology Risk Assessment**

Folder #: 1612978
Order #: 11341223
Report Date: June 27, 2016

Product Description:	Face Paint
Product SKU:	HY-800
Weight/Volume:	2.7g
Age Grading:	3 years +
Intended Use:	Painting on face
Test Requested:	US TRA
Test Performed By:	Intrinsic Health Sciences

Executive Summary: Based on the information provided by the client and when used under intended use or reasonable foreseeable misuse, this product meets the requirements in the following regulations:

US: Not toxic (acute/chronic), corrosive, skin/eye irritant or strong sensitizer according to 16 CFR 1500.3.

Submitted by:

Digitally signed by
lindsey.ciraulo@ul.com
DN: cn=lindsey.ciraulo@ul.com
Date: 2016.06.27 21:36:11 -04'00'

Lindsey Ciraulo
Consumer Client Services Specialist

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