SECTION 1:

DESCRIPTION OF THE COSMETIC PRODUCT

Product name:	Face paint 00
Responsible Person Name（EU）:	Mid Ocean BV.
Responsible Person Address（EU）:	Wellensiekstraat 2, 6718 XZ Ede, The Netherlands.
Responsible Person Name（UK）:	Midocean Brands UK, Ltd.
Responsible Person Address（UK）:	1st Floor 5 Century Court, Tolpits Lane, Watford, Hertfordshire, England, WD18 9PX
Applicant/Company name:	Mid Ocean Brands B.V.
Address:	Unit 711-716, 7/F, Tower A, 83 King Lam Street, Cheung Sha Wan, Kowloon, Hong Kong.
Item number:	MO2807, MO8274
Vendor code:	111041
Internal product name:	**NA**
Formula number:	**NA**
Code number:	**NA**
Product family:	Make-up products
Product sub-family:	Body or face paint, including carnival make up
Product type:	Leave-on
Physical form:	Solid/pressed powder
Net Weight:	4g, 9g
Target:	Adult and children over 3 years
Country of Origin:	China
Country first placed on the market (EU):	The Netherlands
CPNP Reference	MO8274-00: 2533083, MO2807-00: 5483525
SCPN Reference	MO8274-00: UKCP-44604430, MO2807-00: UKCP-78613669

SECTION 2:

COSMETIC PRODUCT SAFETY REPORT

PART A - COSMETIC PRODUCT SAFETY INFORMATION

1 Qualitative and quantitative composition of the cosmetic product

The original formulation of the product can be found in Appendix I.

Table 1 - qualitative and quantitative composition

Red paintstick

No.	INCI Name	Wt (%)	Mixture ratio (%)	Actual Wt (%)	CAS.	Function
1	PARAFFINUM LIQUIDUM	27.90	100	27.90	232-455-8	Antistatic /mollient / Skin Protecting/solvent
2	CERA MICROCRISTALLINA	26	100	26	264-038-1	Binding/emulsion Stabilising /Opacifying/Viscosity Controlling
3	BEESWAX	15	100	15	616-889-9	Emollient/emulsifying
4	MICA	12	100	12	310-127-6	Opacifying
5	CERESIN	10	100	10	232-290-1	Antistatic/Binding/Emulsion Stabilising /Opacifying/Viscosity Controlling
6	METHYLHEPTYL PALMITATE	5	98	5	1341-38-4	Skin Conditioning / Emollient
7	CI 15850	4	100	4	227-497-9	Cosmetic colorant
8	PHENOXYETHANOL	0.1	100	0.1	204-589-7	Preservative

Green paintstick

No.	INCI Name	Wt (%)	Mixture ratio (%)	Actual Wt (%)	CAS.	Function
1	PARAFFINUM LIQUIDUM	27.90	100	27.90	232-455-8	Antistatic /mollient / Skin Protecting/solvent
2	CERA MICROCRISTALLINA	26	100	26	264-038-1	Binding/emulsion Stabilising /Opacifying/Viscosity Controlling
3	BEESWAX	15	100	15	616-889-9	Emollient/emulsifying
4	MICA	12	100	12	310-127-6	Opacifying
5	CERESIN	10	100	10.	232-290-1	Antistatic/Binding/Emulsion Stabilising /Opacifying/Viscosity Controlling
6	METHYLHEPTYL PALMITATE	5	98	5	1341-38-4	Skin Conditioning / Emollient
7	CI 74260	4	100	4	215-524-7	Cosmetic colorant
8	PHENOXYETHANOL	0.1	100	0.1	204-589-7	Preservative

2 Physical/chemical characteristics and stability of the cosmetic product

2.1 Physical/chemical characteristics of substances or mixtures

Physical/chemical properties of the substance or mixture can be found in the MSDS or COA document in Appendix II.

Table 2 - specifications of each raw material

No.	Raw material name	Supplier	INCI Name	Composition (%)	Assay or Active Ingredient (%)
1	PARAFFINUM LIQUIDUM		PARAFFINUM LIQUIDUM	100	97.0~103.0
2	Microcrystalline paraffin wax		CERA MICROCRISTALLINA	100	n.a.
3	Beeswax		BEESWAX	100	n.a.

		Ltd.			
4	Mica Powder		MICA	100	n.a.
5	White ozocerite		CERESIN	100	n.a.
6	CRODAMOL™ OP-LQ-(SG)		METHYLHEPTYL PALMITATE	100	≥ 98
7	Phenoxyethanol		PHENOXYETHANOL	100	⩾ 99.80
8	Red		CI 15850	100	97.0~103.0
9	Green		CI 74260	100	n.a.

The product is free of nanomaterials and CMR substances, which can be found in the declaration in Appendix III.

2.2 Physical/chemical characteristics of the finished cosmetic product

This description is to contain the specifications of the finished product. Please refer to Appendix IV for the original product specification document.
- Physical form: Solid:Cream/ paste
- Color: Refer to standard sample
- Odor: Weak aromatic

2.3 Stability of the cosmetic product

The product has undergone stability testing and preservative challenge testing. The product's PAO (Period After Opening) is 18 months, which is labelled on the product packaging. Please refer to Appendix V for detailed information.

2.3.1 Stability testing

Stability test is an destruction test on the packaged product. The formulations of the Face paint series are similar, and the primary packaging materials are identical. Therefore, destruction testing was performed only on the red paintstick. The original report is given in Appendix VI.

The products were stored for 3 month at -5±1°C, room condition, and 40±2°C, 60±5% humidity. The appearance, odor, colour and pH of the products no significant changes have occurred at 3 months.

2.3.2 Preservative efficacy study

The preservative challenge test was performed on red paintstick in accordance with European Pharmacopoeia 10.0 5.1.3, as the formulations are similar and share the same preservative system of face paint series. The original report is presented in Appendix VII.

For escherichia coli, staphylococcus aureus and pseudomonas aeruginosa, the logarithmic difference of the test results on day 14 was greater than 3; the logarithmic difference of the test results from day 14 to 28 did not decrease.

For candida albicans and aspergillus brasiliensis, the logarithmic difference of the results was greater than 1 at day 14; there was no decrease in the logarithmic difference of the results from day 14 to day 28.

3 Microbiological quality

According to the SCCS's 'Notes of guidance for the testing of cosmetic ingredients and the safety evaluation' (12th Revision, 2023), total aerobic mesophilic microorganisms (bacteria plus yeast and

mould) should not exceed 10^3 cfu/g or 10^3 cfu/mL in Category 2 products (i.e. all but cosmetics intended for children under 3 years of age, to be used in the eye area and on mucous membranes). *Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Candida albicans* are considered to be the main potential pathogens in cosmetic products. These should not to be detectable in 1 g or mL in Category 2 products.

The product was microbiologically tested and all indicators met the requirements. The original report is attached in Appendix VIII for further reference.

4 Impurities, traces, information about the packaging material

4.1 Impurities and traces

The product was tested for traces of lead, mercury, arsenic, antimony, cadmium and soluble nickel, and the results met the requirements of EU cosmetic limit(s) (Germany BVL 2016), which can be found in Appendix IX.

4.2 The relevant characteristics of packaging material

The relevant characteristics of packaging materials in direct contact with the finished product are important for the safety of the cosmetic product.

According to Appendix X, the packaging is compliant with EU REACH Regulation and does not contain any substances mentioned in the candidate list of SVHC.

The product is offered in two packaging formats, the material compositions of the two container (or primary packaging) types are as follows.

Table 3 - Packaging composition

MO2807

Raw material name	Description	CAS	Supplier
Polystyrene (PS)	Plastic lid, colorless transparent hard plastic	9003-53-6	
Polypropylene (PP)	Plastic holder, white hard plastic	9003-07-0	
Polypropylene (PP)	Plastic case, white hard plastic	9003-07-0	

MO8274

Raw material name	Description	CAS	Supplier
Polystyrene (PS)	Plastic case, colorless transparent hard plastic	9003-53-6	
Acrylonitrile utadiene Styrene (ABS)	Plastic lid and case, beige hard plastic with silvery coating	97048-04-9	
Acrylonitrile utadiene Styrene (ABS)	Plastic knob, black hard plastic	97048-04-9	
Polypropylene (PP)	Plastic holder, translucent hard plastic	9003-07-0	

4.2.1 Chemical purity of the packaging materials

The analytical testing result of container indicated Cadmium, Lead, Mercury, Hexavalent Chromium complies with the limit of European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste and its amended directives. The original report is given in Appendix XI.

4.2.2 Compatibility of package

The formulations of the Face paint series are similar, and the primary packaging materials are identical. Therefore, Packaging compatibility tests was performed only on the red paintstick. The original report is given in Appendix VI.

The products were stored for 3 month at -5±1°C, room condition, and 40±2°C, 60±5% humidity. The appearance, odor, colour, pH and appearance of the package of the products no significant changes have occurred at 3 months.

5 Normal and reasonably foreseeable use

This product is a face paint used for makeup.

The normal use of this product is intended to be applied as face paint by 3 years old and above. Other usage is not foreseeable.

As the printed instructions of use and warning is clear to describe the product usage and appropriate enough to avoid misuse, no special warnings or instructions of use are further required.

Please refer to the product label attached in Appendix XII for further reference.

6 Exposure to the cosmetic product

Area of application	Face
Surface area of application (cm^2)	565
Amount applied (g) per day	0.51
Duration	Leave-on
Retention factor	1
Frequency	1/day[2]
Possible exposure routes	Dermal
Target group for use	Adult and children over 3 years

No nanomaterials are used in the product, so the effect of particle size on exposure is not considered.

7 Exposure to the substances

The assessment of the exposure to each of the substances contained in the cosmetic product is necessary in order to assess the risk associated with each individual substance.

Exposure levels to the substances are generally calculated based on the following equation, as outlined in the SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation (12th Revision, 2023).

$$SED = E_{product} \times \frac{C(\%)}{100} \times \frac{DAp(\%)}{100} \times Rf$$

Where,
SED (mg/kg bw/day): Systemic exposure dose
Eproduct (mg/kg bw/day): Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application.
C(%): Concentration of the substance under study in the finished cosmetic product on the application site
DAp (%): Dermal absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions. Calculated as 100 %.
Rf: Retention factor

Default values for body weights of children is 23.1kg.

Table 4 - systemic exposure dose of each ingredient

Red paintstick

INGREDIENT (INCI)	% (W/W)	Retention factor	Amount applied (g) per day	Eproduct (mg/kg bw/day)	SED （mg/kg/day）
PARAFFINUM LIQUIDUM	27.90	1	0.51	510	6.15974026
CERA MICROCRISTALLINA	26	1	0.51	510	5.74025974
BEESWAX	15	1	0.51	510	3.311688312
MICA	12	1	0.51	510	2.649350649
CERESIN	10	1	0.51	510	2.207792208
METHYLHEPTYL PALMITATE	5	1	0.51	510	1.103896104
CI 15850	4	1	0.51	510	0.883116883
PHENOXYETHANOL	0.1	1	0.51	510	0.022077922

Green paintstick

INGREDIENT (INCI)	% (W/W)	Retention factor	Amount applied (g) per day	Eproduct (mg/kg bw/day)	SED （mg/kg/day）
PARAFFINUM LIQUIDUM	27.90	1	0.51	510	6.15974026
CERA MICROCRISTALLINA	26	1	0.51	510	5.74025974
BEESWAX	15	1	0.51	510	3.311688312
MICA	12	1	0.51	510	2.649350649
CERESIN	10	1	0.51	510	2.207792208
METHYLHEPTYL PALMITATE	5	1	0.51	510	1.103896104
CI 74260	4	1	0.51	510	0.883116883
PHENOXYETHANOL	0.1	1	0.51	510	0.022077922

8 Toxicological profile of the substances

Table 5 - safety assessment conclusion of all ingredients

Red paintstick

No.	INGREDIENT (INCI)	%(w/w)	Max. allowed conc. in reference	Margin of Safety	Assessment Conclusion	Reference
1	PARAFFINUM LIQUIDUM	27.90	87.95	n.a.	Conforms to accepted external review in a cosmetic product.	China NIFDC: Raw Material Usage Information for Marketed Products
2	CERA MICROCRISTALLINA	26	50	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
3	BEESWAX	15	56	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel.Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 2005,24(Suppl. 1) : 1–102

4	MICA	12	Mica, a silicate mineral with generally negligible transdermal absorption and potential systemic toxicity. And it can be used as coloring agent for cosmetics in EU, USA, China and other regions without restriction requirements.			
5	CERESIN	10	25	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
6	METHYLHEPTYL PALMITATE	5	n.a.	855.15	MOS > 100, the raw material is considered acceptable for safety evaluation.	QSAR Toolbox. Detailed information can be found in the description below and Appendix XVII
7	CI 15850	4	n.a.	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex IV
8	PHENOXYETHANOL	0.1	1.0	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex V

Green paintstick

No.	INGREDIENT (INCI)	%(w/w)	Max. allowed conc. in reference	Margin of Safety	Assessment Conclusion	Reference
1	PARAFFINUM LIQUIDUM	27.90	87.95	n.a.	Conforms to accepted external review in a cosmetic product.	China NIFDC: Raw Material Usage Information for Marketed Products
2	CERA MICROCRISTALLINA	26	50	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
3	BEESWAX	15	56	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel.Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 2005,24(Suppl. 1) : 1–102
4	MICA	12	Mica, a silicate mineral with generally negligible transdermal absorption and potential systemic toxicity. And it can be used as coloring agent for cosmetics in EU, USA, China and other regions without restriction requirements.			
5	CERESIN	10	25	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
6	METHYLHEPTYL PALMITATE	5	n.a.	855.15	MOS > 100, the raw material is considered acceptable for safety evaluation.	QSAR Toolbox. Detailed information can be found in the description below and Appendix XVII
7	CI 74260	4	n.a.	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex IV
8	PHENOXYETHANOL	0.1	1.0	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex V

Toxicological profile of METHYLHEPTYL PALMITATE (CAS# 1341-38-4, Isooctyl palmitate)

Toxicological endpoints[1]:

Acute toxicity: The acute oral LD_{50} value of the test item methylheptyl palmitate was estimated > 5000 $mg/kg^{-1}$of body weight for female rats.

Skin irritation: The test item 1341-38-4 Isooctyl palmitate is considered non-irritant to skin in the Reconstructed human Epidermis (RhE) Test Method.

Eye irritation: The test item 1341-38-4 Isooctyl palmitate showed no effects on the cornea of the bovine eye.

Skin sensitization: The skin sensitizing potential of Isooctyl palmitate was assessed using the murine local lymph node assay. Based on the results of the study, Isooctyl palmitate is not considered a skin sensitizer under the conditions of the LLNA study.

Genetic toxicity: Based on the results of the study it is concluded that 1341-38-4 Isooctyl palmitate is not mutagenic in the Salmonella typhimurium strains TA97a, TA98, TA100, TA102 and TA1535 in the absence and presence of metabolic activation under the experi-mental conditions in this study.

Repeated dose toxicity: No available data. Using the QSAR Toolbox for read-across analysis, the predicted NOAEL value is 944 mg/kg bw/d[2].

Conclusion:

A calculated Margin of Safety (MoS) value more than 100 is deemed acceptable for safety evaluation.

9 Undesirable effects and serious undesirable effects

None reported.

10 Information on the cosmetic product

No other relevant information.

PART B - Cosmetic Product Safety Assessment

1 Assessment conclusion

This cosmetic product can be considered as safe to human health and compliant with the EU Cosmetics Regulation (EC) 1223/2009 when used under normal and reasonably foreseeable use.

This assessment is conditional on the Responsible Person complying with the conditions in the notes and any other purity restrictions listed.

2 Labelled warnings and instructions of use

Detailed warnings and instructions of use are labelled on the product packaging.

Warning: Not suitable for children under 3 years. Small parts.
Achtung: Nicht für Kinder unter dreiJahren geeignet. Kleine Teile.
Attention. Ne convient pasaux enfants de moins de 3 ans. Petites pièces.
Advertencia. No conveniente para niños menores de 3 años. Piezas pequeñas.
Avvertenza. Non adatto a bambini di età inferiore a 3 anni. Contiene parti piccole.
Waarschuwing: Niet geschikt voor kinderen jonger dan 3 jaar. Kleine onderdelen.
Ostrzeżenie. Nieodpowiednie dla dzieci w wieku poniżej 3 lat. Male części.

[1] ECHA. REACH registered subatances factsheets of Isooctyl palmitate (CAS no.: 1341-38-4) https://echa.europa.eu/registration-dossier/-/registered-dossier/29334/11

[2] Prediction of NOAEL of Read-across prediction report from QSAR TOOLBOX.

3 Reasoning

This study evaluated the Face paint.

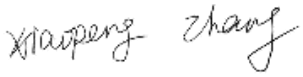
None of the ingredients used in the formulation are classified as hazardous substances. Based on the assessment in Part A, Section 8 "Toxicological Profile of the Substances", the use of all substances in the product is safe.

Provided the manufacturer's instructions are followed and all the ingredients used are of cosmetic grade or other appropriate, 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.

4 Assessor's credential and approval of Part B

Assessor: Xiaopeng Zhang, PhD, DABT, DCST

Name: Xiaopeng Zhang
Address: 288 Qiuyi Road, Binjiang District, Hangzhou, Zhejiang Province, China

Signature: 

Date: 31/10/2025

The curriculum vitae of the assessor can be found in Appendix XIII.

SECTION 3:

Method of manufacture, statement of compliance with GMP

The manufacturing process for the product can be found in Appendix XIV.

The product is manufactured in accordance with ISO 22716, standards developed for and by the cosmetic industry. Please refer to the ISO certificate in Appendix XV.

SECTION 4:

Proof of effect claimed

This product is a face paint used for makeup.

The intended use of the product can be identified through sensory evaluation. As the product label does not include any efficacy claims beyond those stated above, no substantiation documents for efficacy are required.

SECTION 5:

Data on animal testing

According to the manufacturer's declaration, neither the product nor the substances contained have been tested on animals. The declaration can be found in Appendix XVI.

The manufacturer does not conduct animal testing on finished products unless required by regulatory authorities in a few countries.

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SECTION 1:

DESCRIPTION OF THE COSMETIC PRODUCT

Product name:	Face paint 03
Responsible Person Name（EU）:	Mid Ocean BV.
Responsible Person Address（EU）:	Wellensiekstraat 2, 6718 XZ Ede, The Netherlands.
Responsible Person Name（UK）:	Midocean Brands UK, Ltd.
Responsible Person Address（UK）:	1st Floor 5 Century Court, Tolpits Lane, Watford, Hertfordshire, England, WD18 9PX
Applicant/Company name:	Mid Ocean Brands B.V.
Address:	Unit 711-716, 7/F, Tower A, 83 King Lam Street, Cheung Sha Wan, Kowloon, Hong Kong.
Item number:	MO2807, MO8274
Vendor code:	111041
Internal product name:	**NA**
Formula number:	**NA**
Code number:	**NA**
Product family:	Make-up products
Product sub-family:	Body or face paint, including carnival make up
Product type:	Leave-on
Physical form:	Solid/pressed powder
Net Weight:	4g, 9g
Target:	Adult and children over 3 years
Country of Origin:	China
Country first placed on the market (EU):	The Netherlands
CPNP Reference	MO8274-03: 2533108, MO2807-03: 5483572
SCPN Reference	MO8274-03: UKCP-13537600, MO2807-03: UKCP-36954959

SECTION 2:

COSMETIC PRODUCT SAFETY REPORT

PART A - COSMETIC PRODUCT SAFETY INFORMATION

1 Qualitative and quantitative composition of the cosmetic product

The original formulation of the product can be found in Appendix I.

Table 1 - qualitative and quantitative composition

Red paintstick

No.	INCI Name	Wt (%)	Mixture ratio (%)	Actual Wt (%)	CAS.	Function
1	PARAFFINUM LIQUIDUM	27.90	100	27.90	232-455-8	Antistatic /mollient / Skin Protecting/solvent
2	CERA MICROCRISTALLINA	26	100	26	264-038-1	Binding/emulsion Stabilising /Opacifying/Viscosity Controlling
3	BEESWAX	15	100	15	616-889-9	Emollient/emulsifying
4	MICA	12	100	12	310-127-6	Opacifying
5	CERESIN	10	100	10	232-290-1	Antistatic/Binding/Emulsion Stabilising /Opacifying/Viscosity Controlling
6	METHYLHEPTYL PALMITATE	5	98	5	215-675-9	Skin Conditioning / Emollient
7	CI 15850	4	100	4	227-497-9	Cosmetic colorant
8	PHENOXYETHANOL	0.1	100	0.1	204-589-7	Preservative

Yellow paintstick

No.	INCI Name	Wt (%)	Mixture ratio (%)	Actual Wt (%)	CAS.	Function
1	PARAFFINUM LIQUIDUM	27.90	100	27.90	232-455-8	Antistatic /mollient / Skin Protecting/solvent
2	CERA MICROCRISTALLINA	26	100	26	264-038-1	Binding/emulsion Stabilising /Opacifying/Viscosity Controlling
3	BEESWAX	15	100	15	616-889-9	Emollient/emulsifying
4	MICA	12	100	12	310-127-6	Opacifying
5	CERESIN	10	100	10	232-290-1	Antistatic/Binding/Emulsion Stabilising /Opacifying/Viscosity Controlling
6	METHYLHEPTYL PALMITATE	5	98	5	1341-38-4	Skin Conditioning / Emollient
7	CI 19140	4	100	4	12225-21-7	Cosmetic colorant
8	PHENOXYETHANOL	0.1	100	0.1	204-589-7	Preservative

Black paintstick

No.	INCI Name	Wt (%)	Mixture ratio (%)	Actual Wt (%)	CAS.	Function
1	PARAFFINUM LIQUIDUM	27.90	100	27.90	232-455-8	Antistatic /mollient / Skin Protecting/solvent
2	CERA MICROCRISTALLINA	26	100	26	264-038-1	Binding/emulsion Stabilising /Opacifying/Viscosity Controlling
3	BEESWAX	15	100	15	616-889-9	Emollient/emulsifying
4	MICA	12	100	12	310-127-6	Opacifying
5	CERESIN	10	100	10	232-290-1	Antistatic/Binding/Emulsion Stabilising /Opacifying/Viscosity Controlling
6	METHYLHEPTYL PALMITATE	5	98	5	1341-38-4	Skin Conditioning / Emollient
7	CI 77266	4	100	4	1333-86-4	Cosmetic colorant
8	PHENOXYETHANOL	0.1	100	0.1	204-589-7	Preservative

2 Physical/chemical characteristics and stability of the cosmetic product

2.1 Physical/chemical characteristics of substances or mixtures

Physical/chemical properties of the substance or mixture can be found in the MSDS or COA document in Appendix II.

Table 2 - specifications of each raw material

No.	Raw material name	Supplier	INCI Name	Composition (%)	Assay or Active Ingredient (%)
1	PARAFFINUM LIQUIDUM		PARAFFINUM LIQUIDUM	100	97.0~103.0
2	Microcrystalline paraffin wax		CERA MICROCRISTALLINA	100	n.a.
3	Beeswax		BEESWAX	100	n.a.
4	Mica Powder		MICA	100	n.a.
5	White ozocerite		CERESIN	100	n.a.
6	CRODAMOL™ OP-LQ-(SG)		METHYLHEPTYL PALMITATE	100	≥ 98
7	Phenoxyethanol		PHENOXYETHANOL	100	⩾ 99.80
8	Red		CI 15850	100	97.0~103.0
9	Yellow		C 19140	100	n.a.
10	Black		CI 77266	100	n.a.

According the wording of conditions of use and warnings for CI 77266 of Regulation EC) No 1223/2009 of the European parliament and of the council: purity > 97 %, with the following impurity profile: ash content ⩽ 0,15 %, total sulphur ⩽ 0,65 %, total PAH ⩽ 500 ppb and benzo(a)pyrene ⩽ 5 ppb, ibenz (a,h) anthracene ⩽ 5 ppb, total As ⩽ 3 ppm, total Pb ⩽ 10 ppm, total Hg ⩽ 1 ppm. The CI 77266 in the product comply with the above requirements, please refer to Appendix II.

The product is free of nanomaterials and CMR substances, which can be found in the declaration in Appendix III.

2.2 Physical/chemical characteristics of the finished cosmetic product

This description is to contain the specifications of the finished product. Please refer to Appendix IV for the original product specification document.
- Physical form: Solid:Cream/ paste
- Color: Refer to standard sample
- Odor: Weak aromatic

2.3 Stability of the cosmetic product

The product has undergone stability testing and preservative challenge testing. The product's PAO (Period After Opening) is 18 months, which is labelled on the product packaging. Please refer to Appendix V for detailed information.

2.3.1 Stability testing

Stability test is an destruction test on the packaged product. The formulations of the Face paint series are similar, and the primary packaging materials are identical. Therefore, destruction testing was performed only on the red paintstick. The original report is given in Appendix VI.

The products were stored for 3 month at -5±1°C, room condition, and 40±2°C, 60±5% humidity. The appearance, odor, colour and pH of the products no significant changes have occurred at 3 months.

2.3.2 Preservative efficacy study

The preservative challenge test was performed on red paintstick in accordance with European Pharmacopoeia 10.0 5.1.3, as the formulations are similar and share the same preservative system of face paint series. The original report is presented in Appendix VII.

For escherichia coli, staphylococcus aureus and pseudomonas aeruginosa, the logarithmic difference of the test results on day 14 was greater than 3; the logarithmic difference of the test results from day 14 to 28 did not decrease.

For candida albicans and aspergillus brasiliensis, the logarithmic difference of the results was greater than 1 at day 14; there was no decrease in the logarithmic difference of the results from day 14 to day 28.

3 Microbiological quality

According to the SCCS's 'Notes of guidance for the testing of cosmetic ingredients and the safety evaluation' (12th Revision, 2023), total aerobic mesophilic microorganisms (bacteria plus yeast and mould) should not exceed 10^3 cfu/g or 10^3 cfu/mL in Category 2 products (i.e. all but cosmetics intended for children under 3 years of age, to be used in the eye area and on mucous membranes). *Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Candida albicans* are considered to be the main potential pathogens in cosmetic products. These should not to be detectable in 1 g or mL in Category 2 products.

The product was microbiologically tested and all indicators met the requirements. The original report is attached in Appendix VIII for further reference.

4 Impurities, traces, information about the packaging material

4.1 Impurities and traces

The product was tested for traces of lead, mercury, arsenic, antimony, cadmium and soluble nickel, and the results met the requirements of EU cosmetic limit(s) (Germany BVL 2016), which can be found in Appendix IX.

4.2 The relevant characteristics of packaging material

The relevant characteristics of packaging materials in direct contact with the finished product are important for the safety of the cosmetic product.

According to Appendix X, the packaging is compliant with EU REACH Regulation and does not contain any substances mentioned in the candidate list of SVHC.

The product is offered in two packaging formats, the material compositions of the two container (or primary packaging) types are as follows.

Table 3 - Packaging composition

MO2807

Raw material name	Description	CAS	Supplier

Polystyrene (PS)	Plastic lid, colorless transparent hard plastic	9003-53-6	
Polypropylene (PP)	Plastic holder, white hard plastic	9003-07-0	
Polypropylene (PP)	Plastic case, white hard plastic	9003-07-0	

MO28274

Raw material name	Description	CAS	Supplier
Polystyrene (PS)	Plastic case, colorless transparent hard plastic	9003-53-6	
Acrylonitrile utadiene Styrene (ABS)	Plastic lid and case, beige hard plastic with silvery coating	97048-04-9	
Acrylonitrile utadiene Styrene (ABS)	Plastic knob, black hard plastic	97048-04-9	
Polypropylene (PP)	Plastic holder, translucent hard plastic	9003-07-0	

4.2.1 Chemical purity of the packaging materials

The analytical testing result of container indicated Cadmium, Lead, Mercury, Hexavalent Chromium complies with the limit of European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste and its amended directives. The original report is given in Appendix XI.

4.2.2 Compatibility of package

The formulations of the Face paint series are similar, and the primary packaging materials are identical. Therefore, Packaging compatibility tests was performed only on the red paintstick. The original report is given in Appendix VI.

The products were stored for 3 month at -5±1°C, room condition, and 40±2°C, 60±5% humidity. The appearance, odor, colour, pH and appearance of the package of the products no significant changes have occurred at 3 months.

5 Normal and reasonably foreseeable use

This product is a face paint used for makeup.

The normal use of this product is intended to be applied as face paint by 3 years old and above. Other usage is not foreseeable.

As the printed instructions of use and warning is clear to describe the product usage and appropriate enough to avoid misuse, no special warnings or instructions of use are further required.

Please refer to the product label attached in Appendix XII for further reference.

6 Exposure to the cosmetic product

Area of application	Face
Surface area of application (cm^2)	565
Amount applied (g) per day	0.51
Duration	Leave-on
Retention factor	1
Frequency	$1/day^2$
Possible exposure routes	Dermal
Target group for use	Adult and children over 3 years

No nanomaterials are used in the product, so the effect of particle size on exposure is not considered.

7 Exposure to the substances

The assessment of the exposure to each of the substances contained in the cosmetic product is necessary in order to assess the risk associated with each individual substance.

Exposure levels to the substances are generally calculated based on the following equation, as outlined in the SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation (12th Revision, 2023).

$$SED = E_{product} \times \frac{C(\%)}{100} \times \frac{DAp(\%)}{100} \times Rf$$

Where,
SED (mg/kg bw/day): Systemic exposure dose
Eproduct (mg/kg bw/day): Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application.
C(%): Concentration of the substance under study in the finished cosmetic product on the application site
DAp (%): Dermal absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions. Calculated as 100 %.
Rf: Retention factor

Default values for body weights of children is 23.1kg.

Table 4 - systemic exposure dose of each ingredient

Red paintstick

INGREDIENT (INCI)	% (W/W)	Retention factor	Amount applied (g) per day	Eproduct (mg/kg bw/day)	SED（mg/kg/day）
PARAFFINUM LIQUIDUM	27.90	1	0.51	510	6.15974026
CERA MICROCRISTALLINA	26	1	0.51	510	5.74025974
BEESWAX	15	1	0.51	510	3.311688312
MICA	12	1	0.51	510	2.649350649
CERESIN	10	1	0.51	510	2.207792208
METHYLHEPTYL PALMITATE	5	1	0.51	510	1.103896104
CI 15850	4	1	0.51	510	0.883116883
PHENOXYETHANOL	0.1	1	0.51	510	0.022077922

Yellow paintstick

INGREDIENT (INCI)	% (W/W)	Retention factor	Amount applied (g) per day	Eproduct (mg/kg bw/day)	SED（mg/kg/day）
PARAFFINUM LIQUIDUM	27.90	1	0.51	510	6.15974026
CERA MICROCRISTALLINA	26	1	0.51	510	5.74025974
BEESWAX	15	1	0.51	510	3.311688312
MICA	12	1	0.51	510	2.649350649
CERESIN	10	1	0.51	510	2.207792208
METHYLHEPTYL PALMITATE	5	1	0.51	510	1.103896104
CI 19140	4	1	0.51	510	0.883116883
PHENOXYETHANOL	0.1	1	0.51	510	0.022077922

Black paintstick

INGREDIENT (INCI)	% (W/W)	Retention factor	Amount applied (g) per day	Eproduct (mg/kg bw/day)	SED （mg/kg/day）
PARAFFINUM LIQUIDUM	27.90	1	0.51	510	6.15974026
CERA MICROCRISTALLINA	26	1	0.51	510	5.74025974
BEESWAX	15	1	0.51	510	3.311688312
MICA	12	1	0.51	510	2.649350649
CERESIN	10	1	0.51	510	2.207792208
METHYLHEPTYL PALMITATE	5	1	0.51	510	1.103896104
CI 77266	4	1	0.51	510	0.883116883
PHENOXYETHANOL	0.1	1	0.51	510	0.022077922

8 Toxicological profile of the substances

Table 5 - safety assessment conclusion of all ingredients

Red paintstick

No.	INGREDIENT (INCI)	%(w/w)	Max. allowed conc. in reference	Margin of Safety	Assessment Conclusion	Reference
1	PARAFFINUM LIQUIDUM	27.90	87.95	n.a.	Conforms to accepted external review in a cosmetic product.	China NIFDC: Raw Material Usage Information for Marketed Products
2	CERA MICROCRISTALLINA	26	50	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
3	BEESWAX	15	56	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel.Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 2005,24(Suppl. 1) : 1–102
4	MICA	12	Mica, a silicate mineral with generally negligible transdermal absorption and potential systemic toxicity. And it can be used as coloring agent for cosmetics in EU, USA, China and other regions without restriction requirements.			
5	CERESIN	10	25	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
6	METHYLHEPTYL PALMITATE	5	n.a.	855.15	MOS > 100, the raw material is considered acceptable for safety evaluation.	QSAR Toolbox. Detailed information can be found in the description below and Appendix XVII
7	CI 15850	4	n.a.	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex IV
8	PHENOXYETHANOL	0.1	1.0	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex V

Yellow paintstick

No.	INGREDIENT (INCI)	%(w/w)	Max. allowed	Margin of	Assessment Conclusion	Reference

			conc. in reference	Safety		
1	PARAFFINUM LIQUIDUM	27.90	87.95	n.a.	Conforms to accepted external review in a cosmetic product.	China NIFDC: Raw Material Usage Information for Marketed Products
2	CERA MICROCRISTALLINA	26	50	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
3	BEESWAX	15	56	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel.Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 2005,24(Suppl. 1) : 1–102
4	MICA	12	Mica, a silicate mineral with generally negligible transdermal absorption and potential systemic toxicity. And it can be used as coloring agent for cosmetics in EU, USA, China and other regions without restriction requirements.			
5	CERESIN	10	25	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
6	METHYLHEPTYL PALMITATE	5	n.a.	855.15	MOS > 100, the raw material is considered acceptable for safety evaluation.	QSAR Toolbox. Detailed information can be found in the description below and Appendix XVII
7	CI 19140	4	n.a.	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex IV
8	PHENOXYETHANOL	0.1	1.0	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex V

Black paintstick

No.	INGREDIENT (INCI)	%(w/w)	Max. allowed conc. in reference	Margin of Safety	Assessment Conclusion	Reference
1	PARAFFINUM LIQUIDUM	27.90	87.95	n.a.	Conforms to accepted external review in a cosmetic product.	China NIFDC: Raw Material Usage Information for Marketed Products
2	CERA MICROCRISTALLINA	26	50	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
3	BEESWAX	15	56	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel.Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 2005,24(Suppl. 1) : 1–102
4	MICA	12	Mica, a silicate mineral with generally negligible transdermal absorption and potential systemic toxicity. And it can be used as coloring agent for cosmetics in EU, USA, China and other regions without restriction requirements.			

5	CERESIN	10	25	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
6	METHYLHEPTYL PALMITATE	5	n.a.	855.15	MOS > 100, the raw material is considered acceptable for safety evaluation.	QSAR Toolbox. Detailed information can be found in the description below and Appendix XVII
7	CI 77266	4	n.a.	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex IV
8	PHENOXYETHANOL	0.1	1.0	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex V

Toxicological profile of METHYLHEPTYL PALMITATE (CAS# 1341-38-4, Isooctyl palmitate)

Toxicological endpoints[1]:

Acute toxicity: The acute oral LD_{50} value of the test item methylheptyl palmitate was estimated > 5000 $mg/kg^{-1}$of body weight for female rats.

Skin irritation: The test item 1341-38-4 Isooctyl palmitate is considered non-irritant to skin in the Reconstructed human Epidermis (RhE) Test Method.

Eye irritation: The test item 1341-38-4 Isooctyl palmitate showed no effects on the cornea of the bovine eye.

Skin sensitization: The skin sensitizing potential of Isooctyl palmitate was assessed using the murine local lymph node assay. Based on the results of the study, Isooctyl palmitate is not considered a skin sensitizer under the conditions of the LLNA study.

Genetic toxicity: Based on the results of the study it is concluded that 1341-38-4 Isooctyl palmitate is not mutagenic in the Salmonella typhimurium strains TA97a, TA98, TA100, TA102 and TA1535 in the absence and presence of metabolic activation under the experi-mental conditions in this study.

Repeated dose toxicity: No available data. Using the QSAR Toolbox for read-across analysis, the predicted NOAEL value is 944 mg/kg bw/d[2].

Conclusion:

A calculated Margin of Safety (MoS) value more than 100 is deemed acceptable for safety evaluation.

9 Undesirable effects and serious undesirable effects

None reported.

10 Information on the cosmetic product

No other relevant information.

PART B - Cosmetic Product Safety Assessment

1 Assessment conclusion

This cosmetic product can be considered as safe to human health and compliant with the EU Cosmetics Regulation (EC) 1223/2009 when used under normal and reasonably foreseeable use.

This assessment is conditional on the Responsible Person complying with the conditions in the notes and any other purity restrictions listed.

[1] ECHA. REACH registered subatances factsheets of Isooctyl palmitate (CAS no.: 1341-38-4) https://echa.europa.eu/registration-dossier/-/registered-dossier/29334/11

[2] Prediction of NOAEL of Read-across prediction report from QSAR TOOLBOX.

2 Labelled warnings and instructions of use

Detailed warnings and instructions of use are labelled on the product packaging.

Warning: Not suitable for children under 3 years. Small parts.
Achtung: Nicht für Kinder unter drei Jahren geeignet. Kleine Teile.
Attention. Ne convient pas aux enfants de moins de 3 ans. Petites pièces.
Advertencia. No conveniente para niños menores de 3 años. Piezas pequeñas.
Avvertenza. Non adatto a bambini di età inferiore a 3 anni. Contiene parti piccole.
Waarschuwing: Niet geschikt voor kinderen jonger dan 3 jaar. Kleine onderdelen.
Ostrzeżenie. Nieodpowiednie dla dzieci w wieku poniżej 3 lat. Małe części.

3 Reasoning

This study evaluated the Face paint.

None of the ingredients used in the formulation are classified as hazardous substances. Based on the assessment in Part A, Section 8 "Toxicological Profile of the Substances", the use of all substances in the product is safe.

Provided the manufacturer's instructions are followed and all the ingredients used are of cosmetic grade or other appropriate, 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.

4 Assessor's credential and approval of Part B

Assessor: Xiaopeng Zhang, PhD, DABT, DCST

Name: Xiaopeng Zhang
Address: 288 Qiuyi Road, Binjiang District, Hangzhou, Zhejiang Province, China

Signature: Xiaopeng Zhang

Date: 31/10/2025

The curriculum vitae of the assessor can be found in Appendix XIII.

SECTION 3:

Method of manufacture, statement of compliance with GMP

The manufacturing process for the product can be found in Appendix XIV.

The product is manufactured in accordance with ISO 22716, standards developed for and by the cosmetic industry. Please refer to the ISO certificate in Appendix XV.

SECTION 4:

Proof of effect claimed

This product is a face paint used for makeup.

The intended use of the product can be identified through sensory evaluation. As the product label does not include any efficacy claims beyond those stated above, no substantiation documents for efficacy are required.

SECTION 5:

Data on animal testing

According to the manufacturer's declaration, neither the product nor the substances contained have been tested on animals. The declaration can be found in Appendix XVI.

The manufacturer does not conduct animal testing on finished products unless required by regulatory authorities in a few countries.

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SECTION 1:

DESCRIPTION OF THE COSMETIC PRODUCT

Product name:	Face paint 04
Responsible Person Name（EU）:	Mid Ocean BV.
Responsible Person Address（EU）:	Wellensiekstraat 2, 6718 XZ Ede, The Netherlands.
Responsible Person Name（UK）:	Midocean Brands UK, Ltd.
Responsible Person Address（UK）:	1st Floor 5 Century Court, Tolpits Lane, Watford, Hertfordshire, England, WD18 9PX
Applicant/Company name:	Mid Ocean Brands B.V.
Address:	Unit 711-716, 7/F, Tower A, 83 King Lam Street, Cheung Sha Wan, Kowloon, Hong Kong.
Item number:	MO2807, MO8274
Vendor code:	111041
Internal product name:	**NA**
Formula number:	**NA**
Code number:	**NA**
Product family:	Make-up products
Product sub-family:	Body or face paint, including carnival make up
Product type:	Leave-on
Physical form:	Solid/pressed powder
Net Weight:	4g, 9g
Target:	Adult and children over 3 years
Country of Origin:	China
Country first placed on the market (EU):	The Netherlands
CPNP Reference	MO8274-04: 2533135, MO2807-04: 5483601
SCPN Reference	MO8274-04: UKCP-47020006, MO2807-04: UKCP-63292668

SECTION 2:

COSMETIC PRODUCT SAFETY REPORT

PART A - COSMETIC PRODUCT SAFETY INFORMATION

1 Qualitative and quantitative composition of the cosmetic product

The original formulation of the product can be found in Appendix I.

Table 1 - qualitative and quantitative composition

Blue paintstick

No.	INCI Name	Wt (%)	Mixture ratio (%)	Actual Wt (%)	CAS.	Function
1	PARAFFINUM LIQUIDUM	27.90	100	27.90	232-455-8	Antistatic /mollient / Skin Protecting/solvent
2	CERA MICROCRISTALLINA	26	100	26	264-038-1	Binding/emulsion Stabilising /Opacifying/Viscosity Controlling
3	BEESWAX	15	100	15	616-889-9	Emollient/emulsifying
4	MICA	12	100	12	310-127-6	Opacifying
5	CERESIN	10	100	10	232-290-1	Antistatic/Binding/Emulsion Stabilising /Opacifying/Viscosity Controlling
6	METHYLHEPTYL PALMITATE	5	98	5	215-675-9	Skin Conditioning / Emollient
7	CI 42090	4	100	4	227-497-9	Cosmetic colorant
8	PHENOXYETHANOL	0.1	100	0.1	204-589-7	Preservative

Yellow paintstick

No.	INCI Name	Wt (%)	Mixture ratio (%)	Actual Wt (%)	CAS.	Function
1	PARAFFINUM LIQUIDUM	27.90	100	27.90	232-455-8	Antistatic /mollient / Skin Protecting/solvent
2	CERA MICROCRISTALLINA	26	100	26	264-038-1	Binding/emulsion Stabilising /Opacifying/Viscosity Controlling
3	BEESWAX	15	100	15	616-889-9	Emollient/emulsifying
4	MICA	12	100	12	310-127-6	Opacifying
5	CERESIN	10	100	10	232-290-1	Antistatic/Binding/Emulsion Stabilising /Opacifying/Viscosity Controlling
6	METHYLHEPTYL PALMITATE	5	98	5	1341-38-4	Skin Conditioning / Emollient
7	CI 19140	4	100	4	12225-21-7	Cosmetic colorant
8	PHENOXYETHANOL	0.1	100	0.1	204-589-7	Preservative

2 Physical/chemical characteristics and stability of the cosmetic product

2.1 Physical/chemical characteristics of substances or mixtures

Physical/chemical properties of the substance or mixture can be found in the MSDS or COA document in Appendix II.

Table 2 - specifications of each raw material

No.	Raw material name	Supplier	INCI Name	Composition (%)	Assay or Active Ingredient (%)
1	PARAFFINUM LIQUIDUM		PARAFFINUM LIQUIDUM	100	97.0~103.0
2	Microcrystalline paraffin wax		CERA MICROCRISTALLINA	100	n.a.
3	Beeswax		BEESWAX	100	n.a.

		Ltd.			
4	Mica Powder		MICA	100	n.a.
5	White ozocerite		CERESIN	100	n.a.
6	CRODAMOL™ OP-LQ-(SG)		METHYLHEPTYL PALMITATE	100	≥ 98
7	Phenoxyethanol		PHENOXYETHANOL	100	⩾ 99.80
8	Blue		CI 42090	100	n.a.
9	Yellow		C 19140	100	n.a.

The product is free of nanomaterials and CMR substances, which can be found in the declaration in Appendix III.

2.2 Physical/chemical characteristics of the finished cosmetic product

This description is to contain the specifications of the finished product. Please refer to Appendix IV for the original product specification document.
- Physical form: Solid:Cream/ paste
- Color: Refer to standard sample
- Odor: Weak aromatic

2.3 Stability of the cosmetic product

The product has undergone stability testing and preservative challenge testing. The product's PAO (Period After Opening) is 18 months, which is labelled on the product packaging. Please refer to Appendix V for detailed information.

2.3.1 Stability testing

Stability test is an destruction test on the packaged product. The formulations of the Face paint series are similar, and the primary packaging materials are identical. Therefore, destruction testing was performed only on the red paintstick. The original report is given in Appendix VI.

The products were stored for 3 month at -5±1°C, room condition, and 40±2°C, 60±5% humidity. The appearance, odor, colour and pH of the products no significant changes have occurred at 3 months.

2.3.2 Preservative efficacy study

The preservative challenge test was performed on red paintstick in accordance with European Pharmacopoeia 10.0 5.1.3, as the formulations are similar and share the same preservative system of face paint series. The original report is presented in Appendix VII.

For escherichia coli, staphylococcus aureus and pseudomonas aeruginosa, the logarithmic difference of the test results on day 14 was greater than 3; the logarithmic difference of the test results from day 14 to 28 did not decrease.

For candida albicans and aspergillus brasiliensis, the logarithmic difference of the results was greater than 1 at day 14; there was no decrease in the logarithmic difference of the results from day 14 to day 28.

3 Microbiological quality

According to the SCCS's 'Notes of guidance for the testing of cosmetic ingredients and the safety evaluation' (12th Revision, 2023), total aerobic mesophilic microorganisms (bacteria plus yeast and

mould) should not exceed 10^3 cfu/g or 10^3 cfu/mL in Category 2 products (i.e. all but cosmetics intended for children under 3 years of age, to be used in the eye area and on mucous membranes). *Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Candida albicans* are considered to be the main potential pathogens in cosmetic products. These should not to be detectable in 1 g or mL in Category 2 products.

The product was microbiologically tested and all indicators met the requirements. The original report is attached in Appendix VIII for further reference.

4 Impurities, traces, information about the packaging material

4.1 Impurities and traces

The product was tested for traces of lead, mercury, arsenic, antimony, cadmium and soluble nickel, and the results met the requirements of EU cosmetic limit(s) (Germany BVL 2016), which can be found in Appendix IX.

4.2 The relevant characteristics of packaging material

The relevant characteristics of packaging materials in direct contact with the finished product are important for the safety of the cosmetic product.

According to Appendix X, the packaging is compliant with EU REACH Regulation and does not contain any substances mentioned in the candidate list of SVHC.

The product is offered in two packaging formats, the material compositions of the two container (or primary packaging) types are as follows.

Table 3 - Packaging composition

MO2807

Raw material name	Description	CAS	Supplier
Polystyrene (PS)	Plastic lid, colorless transparent hard plastic	9003-53-6	
Polypropylene (PP)	Plastic holder, white hard plastic	9003-07-0	
Polypropylene (PP)	Plastic case, white hard plastic	9003-07-0	

MO28274

Raw material name	Description	CAS	Supplier
Polystyrene (PS)	Plastic case, colorless transparent hard plastic	9003-53-6	
Acrylonitrile utadiene Styrene (ABS)	Plastic lid and case, beige hard plastic with silvery coating	97048-04-9	
Acrylonitrile utadiene Styrene (ABS)	Plastic knob, black hard plastic	97048-04-9	
Polypropylene (PP)	Plastic holder, translucent hard plastic	9003-07-0	

4.2.1 Chemical purity of the packaging materials

The analytical testing result of container indicated Cadmium, Lead, Mercury, Hexavalent Chromium complies with the limit of European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste and its amended directives. The original report is given in Appendix XI.

4.2.2 Compatibility of package

The formulations of the Face paint series are similar, and the primary packaging materials are identical. Therefore, Packaging compatibility tests was performed only on the red paintstick. The original report is given in Appendix VI.

The products were stored for 3 month at -5±1°C, room condition, and 40±2°C, 60±5% humidity. The appearance, odor, colour, pH and appearance of the package of the products no significant changes have occurred at 3 months.

5 Normal and reasonably foreseeable use

This product is a face paint used for makeup.

The normal use of this product is intended to be applied as face paint by 3 years old and above. Other usage is not foreseeable.

As the printed instructions of use and warning is clear to describe the product usage and apporiate enough to avoid misuse, no special warnings or instructions of use are further required.

Please refer to the product label attached in Appendix XII for further reference.

6 Exposure to the cosmetic product

Area of application	Face
Surface area of application (cm^2)	565
Amount applied (g) per day	0.51
Duration	Leave-on
Retention factor	1
Frequency	1/day[2]
Possible exposure routes	Dermal
Target group for use	Adult and children over 3 years

No nanomaterials are used in the product, so the effect of particle size on exposure is not considered.

7 Exposure to the substances

The assessment of the exposure to each of the substances contained in the cosmetic product is necessary in order to assess the risk associated with each individual substance.

Exposure levels to the substances are generally calculated based on the following equation, as outlined in the SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation (12th Revision, 2023).

$$SED = E_{product} \times \frac{C(\%)}{100} \times \frac{DAp(\%)}{100} \times Rf$$

Where,
SED (mg/kg bw/day): Systemic exposure dose
Eproduct (mg/kg bw/day): Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application.
C(%): Concentration of the substance under study in the finished cosmetic product on the application site
DAp (%): Dermal absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions. Calculated as 100 %.
Rf: Retention factor

Default values for body weights of children is 23.1kg.

Table 4 - systemic exposure dose of each ingredient

Blue paintstick

INGREDIENT (INCI)	% (W/W)	Retention factor	Amount applied (g) per day	Eproduct (mg/kg bw/day)	SED （mg/kg/day）
PARAFFINUM LIQUIDUM	27.90	1	0.51	510	6.15974026
CERA MICROCRISTALLINA	26	1	0.51	510	5.74025974
BEESWAX	15	1	0.51	510	3.311688312
MICA	12	1	0.51	510	2.649350649
CERESIN	10	1	0.51	510	2.207792208
METHYLHEPTYL PALMITATE	5	1	0.51	510	1.103896104
CI 42090	4	1	0.51	510	0.883116883
PHENOXYETHANOL	0.1	1	0.51	510	0.022077922

Yellow paintstick

INGREDIENT (INCI)	% (W/W)	Retention factor	Amount applied (g) per day	Eproduct (mg/kg bw/day)	SED （mg/kg/day）
PARAFFINUM LIQUIDUM	27.90	1	0.51	510	6.15974026
CERA MICROCRISTALLINA	26	1	0.51	510	5.74025974
BEESWAX	15	1	0.51	510	3.311688312
MICA	12	1	0.51	510	2.649350649
CERESIN	10	1	0.51	510	2.207792208
METHYLHEPTYL PALMITATE	5	1	0.51	510	1.103896104
CI 19140	4	1	0.51	510	0.883116883
PHENOXYETHANOL	0.1	1	0.51	510	0.022077922

8 Toxicological profile of the substances

Table 5 - safety assessment conclusion of all ingredients

Blue paintstick

No.	INGREDIENT (INCI)	%(w/w)	Max. allowed conc. in reference	Margin of Safety	Assessment Conclusion	Reference
1	PARAFFINUM LIQUIDUM	27.90	87.95	n.a.	Conforms to accepted external review in a cosmetic product.	China NIFDC: Raw Material Usage Information for Marketed Products
2	CERA MICROCRISTALLINA	26	50	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
3	BEESWAX	15	56	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel.Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 2005,24(Suppl. 1) : 1–102

4	MICA	12	Mica, a silicate mineral with generally negligible transdermal absorption and potential systemic toxicity. And it can be used as coloring agent for cosmetics in EU, USA, China and other regions without restriction requirements.			
5	CERESIN	10	25	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
6	METHYLHEPTYL PALMITATE	5	n.a.	855.15	MOS > 100, the raw material is considered acceptable for safety evaluation.	QSAR Toolbox. Detailed information can be found in the description below and Appendix XVII
7	CI 42090	4	n.a.	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex IV
8	PHENOXYETHANOL	0.1	1.0	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex V

Yellow paintstick

No.	INGREDIENT (INCI)	%(w/w)	Max. allowed conc. in reference	Margin of Safety	Assessment Conclusion	Reference
1	PARAFFINUM LIQUIDUM	27.90	87.95	n.a.	Conforms to accepted external review in a cosmetic product.	China NIFDC: Raw Material Usage Information for Marketed Products
2	CERA MICROCRISTALLINA	26	50	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
3	BEESWAX	15	56	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel.Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 2005,24(Suppl. 1) : 1–102
4	MICA	12	Mica, a silicate mineral with generally negligible transdermal absorption and potential systemic toxicity. And it can be used as coloring agent for cosmetics in EU, USA, China and other regions without restriction requirements.			
5	CERESIN	10	25	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
6	METHYLHEPTYL PALMITATE	5	n.a.	855.15	MOS > 100, the raw material is considered acceptable for safety evaluation.	QSAR Toolbox. Detailed information can be found in the description below and Appendix XVII
7	CI 19140	4	n.a.	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex IV
8	PHENOXYETHANOL	0.1	1.0	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex V

Toxicological profile of METHYLHEPTYL PALMITATE (CAS# 1341-38-4, Isooctyl palmitate)

Toxicological endpoints[1]:

Acute toxicity: The acute oral LD_{50} value of the test item methylheptyl palmitate was estimated > 5000 $mg/kg^{-1}$of body weight for female rats.

Skin irritation: The test item 1341-38-4 Isooctyl palmitate is considered non-irritant to skin in the Reconstructed human Epidermis (RhE) Test Method.

Eye irritation: The test item 1341-38-4 Isooctyl palmitate showed no effects on the cornea of the bovine eye.

Skin sensitization: The skin sensitizing potential of Isooctyl palmitate was assessed using the murine local lymph node assay. Based on the results of the study, Isooctyl palmitate is not considered a skin sensitizer under the conditions of the LLNA study.

Genetic toxicity: Based on the results of the study it is concluded that 1341-38-4 Isooctyl palmitate is not mutagenic in the Salmonella typhimurium strains TA97a, TA98, TA100, TA102 and TA1535 in the absence and presence of metabolic activation under the experi-mental conditions in this study.

Repeated dose toxicity: No available data. Using the QSAR Toolbox for read-across analysis, the predicted NOAEL value is 944 mg/kg bw/d[2].

Conclusion:

A calculated Margin of Safety (MoS) value more than 100 is deemed acceptable for safety evaluation.

9 Undesirable effects and serious undesirable effects

None reported.

10 Information on the cosmetic product

No other relevant information.

PART B - Cosmetic Product Safety Assessment

1 Assessment conclusion

This cosmetic product can be considered as safe to human health and compliant with the EU Cosmetics Regulation (EC) 1223/2009 when used under normal and reasonably foreseeable use.

This assessment is conditional on the Responsible Person complying with the conditions in the notes and any other purity restrictions listed.

2 Labelled warnings and instructions of use

Detailed warnings and instructions of use are labelled on the product packaging.

Warning: Not suitable for children under 3 years. Small parts.
Achtung: Nicht für Kinder unter dreiJahren geeignet. Kleine Teile.
Attention. Ne convient pasaux enfants de moins de 3 ans. Petites pièces.
Advertencia. No conveniente para niños menores de 3 años. Piezas pequeñas.
Avvertenza. Non adatto a bambini di età inferiore a 3 anni. Contiene parti piccole.
Waarschuwing: Niet geschikt voor kinderen jonger dan 3 jaar. Kleine onderdelen.
Ostrzeżenie. Nieodpowiednie dla dzieci w wieku poniżej 3 lat. Male części.

[1] ECHA. REACH registered subatances factsheets of Isooctyl palmitate (CAS no.: 1341-38-4) https://echa.europa.eu/registration-dossier/-/registered-dossier/29334/11

[2] Prediction of NOAEL of Read-across prediction report from QSAR TOOLBOX.

3 Reasoning

This study evaluated the Face paint.

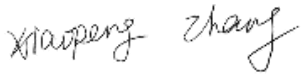
None of the ingredients used in the formulation are classified as hazardous substances. Based on the assessment in Part A, Section 8 "Toxicological Profile of the Substances", the use of all substances in the product is safe.

Provided the manufacturer's instructions are followed and all the ingredients used are of cosmetic grade or other appropriate, 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.

4 Assessor's credential and approval of Part B

Assessor: Xiaopeng Zhang, PhD, DABT, DCST

Name: Xiaopeng Zhang
Address: 288 Qiuyi Road, Binjiang District, Hangzhou, Zhejiang Province, China

Signature: 

Date: 31/10/2025

The curriculum vitae of the assessor can be found in Appendix XIII.

SECTION 3:

Method of manufacture, statement of compliance with GMP

The manufacturing process for the product can be found in Appendix XIV.

The product is manufactured in accordance with ISO 22716, standards developed for and by the cosmetic industry. Please refer to the ISO certificate in Appendix XV.

SECTION 4:

Proof of effect claimed

This product is a face paint used for makeup.

The intended use of the product can be identified through sensory evaluation. As the product label does not include any efficacy claims beyond those stated above, no substantiation documents for efficacy are required.

SECTION 5:

Data on animal testing

According to the manufacturer's declaration, neither the product nor the substances contained have been tested on animals. The declaration can be found in Appendix XVI.

The manufacturer does not conduct animal testing on finished products unless required by regulatory authorities in a few countries.

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SECTION 1:

DESCRIPTION OF THE COSMETIC PRODUCT

Product name:	Face paint 05
Responsible Person Name（EU）:	Mid Ocean BV.
Responsible Person Address（EU）:	Wellensiekstraat 2, 6718 XZ Ede, The Netherlands.
Responsible Person Name（UK）:	Midocean Brands UK, Ltd.
Responsible Person Address（UK）:	1st Floor 5 Century Court, Tolpits Lane, Watford, Hertfordshire, England, WD18 9PX
Applicant/Company name:	Mid Ocean Brands B.V.
Address:	Unit 711-716, 7/F, Tower A, 83 King Lam Street, Cheung Sha Wan, Kowloon, Hong Kong.
Item number:	MO2807, MO8274
Vendor code:	111041
Internal product name:	**NA**
Formula number:	**NA**
Code number:	**NA**
Product family:	Make-up products
Product sub-family:	Body or face paint, including carnival make up
Product type:	Leave-on
Physical form:	Solid/pressed powder
Net Weight:	4g, 9g
Target:	Adult and children over 3 years
Country of Origin:	China
Country first placed on the market (EU):	The Netherlands
CPNP Reference	MO8274-05: 2533173, MO2807-05: 5483641
SCPN Reference	MO8274-05: UKCP-12381864, MO2807-05: UKCP-52288844

SECTION 2:

COSMETIC PRODUCT SAFETY REPORT

PART A - COSMETIC PRODUCT SAFETY INFORMATION

1 Qualitative and quantitative composition of the cosmetic product

The original formulation of the product can be found in Appendix I.

Table 1 - qualitative and quantitative composition

Red paintstick

No.	INCI Name	Wt (%)	Mixture ratio (%)	Actual Wt (%)	CAS.	Function
1	PARAFFINUM LIQUIDUM	27.90	100	27.90	232-455-8	Antistatic /mollient / Skin Protecting/solvent
2	CERA MICROCRISTALLINA	26	100	26	264-038-1	Binding/emulsion Stabilising /Opacifying/Viscosity Controlling
3	BEESWAX	15	100	15	616-889-9	Emollient/emulsifying
4	MICA	12	100	12	310-127-6	Opacifying
5	CERESIN	10	100	10	232-290-1	Antistatic/Binding/Emulsion Stabilising /Opacifying/Viscosity Controlling
6	METHYLHEPTYL PALMITATE	5	98	5	215-675-9	Skin Conditioning / Emollient
7	CI 15850	4	100	4	227-497-9	Cosmetic colorant
8	PHENOXYETHANOL	0.1	100	0.1	204-589-7	Preservative

Yellow paintstick

No.	INCI Name	Wt (%)	Mixture ratio (%)	Actual Wt (%)	CAS.	Function
1	PARAFFINUM LIQUIDUM	27.90	100	27.90	232-455-8	Antistatic /mollient / Skin Protecting/solvent
2	CERA MICROCRISTALLINA	26	100	26	264-038-1	Binding/emulsion Stabilising /Opacifying/Viscosity Controlling
3	BEESWAX	15	100	15	616-889-9	Emollient/emulsifying
4	MICA	12	100	12	310-127-6	Opacifying
5	CERESIN	10	100	10	232-290-1	Antistatic/Binding/Emulsion Stabilising /Opacifying/Viscosity Controlling
6	METHYLHEPTYL PALMITATE	5	98	5	1341-38-4	Skin Conditioning / Emollient
7	CI 19140	4	100	4	12225-21-7	Cosmetic colorant
8	PHENOXYETHANOL	0.1	100	0.1	204-589-7	Preservative

2 Physical/chemical characteristics and stability of the cosmetic product

2.1 Physical/chemical characteristics of substances or mixtures

Physical/chemical properties of the substance or mixture can be found in the MSDS or COA document in Appendix II.

Table 2 - specifications of each raw material

No.	Raw material name	Supplier	INCI Name	Composition (%)	Assay or Active Ingredient (%)
1	PARAFFINUM LIQUIDUM		PARAFFINUM LIQUIDUM	100	97.0~103.0
2	Microcrystalline paraffin wax		CERA MICROCRISTALLINA	100	n.a.
3	Beeswax		BEESWAX	100	n.a.

		Ltd.			
4	Mica Powder		MICA	100	n.a.
5	White ozocerite		CERESIN	100	n.a.
6	CRODAMOL™ OP-LQ-(SG)		METHYLHEPTYL PALMITATE	100	≥ 98
7	Phenoxyethanol		PHENOXYETHANOL	100	⩾ 99.80
8	Red		CI 15850	100	97.0~103.0
9	Yellow		C 19140	100	n.a.

The product is free of nanomaterials and CMR substances, which can be found in the declaration in Appendix III.

2.2 Physical/chemical characteristics of the finished cosmetic product

This description is to contain the specifications of the finished product. Please refer to Appendix IV for the original product specification document.
- Physical form: Solid:Cream/ paste
- Color: Refer to standard sample
- Odor: Weak aromatic

2.3 Stability of the cosmetic product

The product has undergone stability testing and preservative challenge testing. The product's PAO (Period After Opening) is 18 months, which is labelled on the product packaging. Please refer to Appendix V for detailed information.

2.3.1 Stability testing

Stability test is an destruction test on the packaged product. The formulations of the Face paint series are similar, and the primary packaging materials are identical. Therefore, destruction testing was performed only on the red paintstick. The original report is given in Appendix VI.

The products were stored for 3 month at -5±1°C, room condition, and 40±2°C, 60±5% humidity. The appearance, odor, colour and pH of the products no significant changes have occurred at 3 months.

2.3.2 Preservative efficacy study

The preservative challenge test was performed on red paintstick in accordance with European Pharmacopoeia 10.0 5.1.3, as the formulations are similar and share the same preservative system of face paint series. The original report is presented in Appendix VII.

For escherichia coli, staphylococcus aureus and pseudomonas aeruginosa, the logarithmic difference of the test results on day 14 was greater than 3; the logarithmic difference of the test results from day 14 to 28 did not decrease.

For candida albicans and aspergillus brasiliensis, the logarithmic difference of the results was greater than 1 at day 14; there was no decrease in the logarithmic difference of the results from day 14 to day 28.

3 Microbiological quality

According to the SCCS's 'Notes of guidance for the testing of cosmetic ingredients and the safety evaluation' (12th Revision, 2023), total aerobic mesophilic microorganisms (bacteria plus yeast and

mould) should not exceed 10^3 cfu/g or 10^3 cfu/mL in Category 2 products (i.e. all but cosmetics intended for children under 3 years of age, to be used in the eye area and on mucous membranes). *Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Candida albicans* are considered to be the main potential pathogens in cosmetic products. These should not to be detectable in 1 g or mL in Category 2 products.

The product was microbiologically tested and all indicators met the requirements. The original report is attached in Appendix VIII for further reference.

4 Impurities, traces, information about the packaging material

4.1 Impurities and traces

The product was tested for traces of lead, mercury, arsenic, antimony, cadmium and soluble nickel, and the results met the requirements of EU cosmetic limit(s) (Germany BVL 2016), which can be found in Appendix IX.

4.2 The relevant characteristics of packaging material

The relevant characteristics of packaging materials in direct contact with the finished product are important for the safety of the cosmetic product.

According to Appendix X, the packaging is compliant with EU REACH Regulation and does not contain any substances mentioned in the candidate list of SVHC.

The product is offered in two packaging formats, the material compositions of the two container (or primary packaging) types are as follows.

Table 3 - Packaging composition

MO2807

Raw material name	Description	CAS	Supplier
Polystyrene (PS)	Plastic lid, colorless transparent hard plastic	9003-53-6	
Polypropylene (PP)	Plastic holder, white hard plastic	9003-07-0	
Polypropylene (PP)	Plastic case, white hard plastic	9003-07-0	

MO28274

Raw material name	Description	CAS	Supplier
Polystyrene (PS)	Plastic case, colorless transparent hard plastic	9003-53-6	
Acrylonitrile utadiene Styrene (ABS)	Plastic lid and case, beige hard plastic with silvery coating	97048-04-9	
Acrylonitrile utadiene Styrene (ABS)	Plastic knob, black hard plastic	97048-04-9	
Polypropylene (PP)	Plastic holder, translucent hard plastic	9003-07-0	

4.2.1 Chemical purity of the packaging materials

The analytical testing result of container indicated Cadmium, Lead, Mercury, Hexavalent Chromium complies with the limit of European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste and its amended directives. The original report is given in Appendix XI.

4.2.2 Compatibility of package

The formulations of the Face paint series are similar, and the primary packaging materials are identical. Therefore, Packaging compatibility tests was performed only on the red paintstick. The original report is given in Appendix VI.

The products were stored for 3 month at -5±1°C, room condition, and 40±2°C, 60±5% humidity. The appearance, odor, colour, pH and appearance of the package of the products no significant changes have occurred at 3 months.

5 Normal and reasonably foreseeable use

This product is a face paint used for makeup.

The normal use of this product is intended to be applied as face paint by 3 years old and above. Other usage is not foreseeable.

As the printed instructions of use and warning is clear to describe the product usage and apporiate enough to avoid misuse, no special warnings or instructions of use are further required.

Please refer to the product label attached in Appendix XII for further reference.

6 Exposure to the cosmetic product

Area of application	Face
Surface area of application (cm^2)	565
Amount applied (g) per day	0.51
Duration	Leave-on
Retention factor	1
Frequency	1/day[2]
Possible exposure routes	Dermal
Target group for use	Adult and children over 3 years

No nanomaterials are used in the product, so the effect of particle size on exposure is not considered.

7 Exposure to the substances

The assessment of the exposure to each of the substances contained in the cosmetic product is necessary in order to assess the risk associated with each individual substance.

Exposure levels to the substances are generally calculated based on the following equation, as outlined in the SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation (12th Revision, 2023).

$$SED = E_{product} \times \frac{C(\%)}{100} \times \frac{DAp(\%)}{100} \times Rf$$

Where,
SED (mg/kg bw/day): Systemic exposure dose
Eproduct (mg/kg bw/day): Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application.
C(%): Concentration of the substance under study in the finished cosmetic product on the application site
DAp (%): Dermal absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions. Calculated as 100 %.
Rf: Retention factor

Default values for body weights of children is 23.1kg.

Table 4 - systemic exposure dose of each ingredient

Red paintstick

INGREDIENT (INCI)	% (W/W)	Retention factor	Amount applied (g) per day	Eproduct (mg/kg bw/day)	SED （mg/kg/day）
PARAFFINUM LIQUIDUM	27.90	1	0.51	510	6.15974026
CERA MICROCRISTALLINA	26	1	0.51	510	5.74025974
BEESWAX	15	1	0.51	510	3.311688312
MICA	12	1	0.51	510	2.649350649
CERESIN	10	1	0.51	510	2.207792208
METHYLHEPTYL PALMITATE	5	1	0.51	510	1.103896104
CI 15850	4	1	0.51	510	0.883116883
PHENOXYETHANOL	0.1	1	0.51	510	0.022077922

Yellow paintstick

INGREDIENT (INCI)	% (W/W)	Retention factor	Amount applied (g) per day	Eproduct (mg/kg bw/day)	SED （mg/kg/day）
PARAFFINUM LIQUIDUM	27.90	1	0.51	510	6.15974026
CERA MICROCRISTALLINA	26	1	0.51	510	5.74025974
BEESWAX	15	1	0.51	510	3.311688312
MICA	12	1	0.51	510	2.649350649
CERESIN	10	1	0.51	510	2.207792208
METHYLHEPTYL PALMITATE	5	1	0.51	510	1.103896104
CI 19140	4	1	0.51	510	0.883116883
PHENOXYETHANOL	0.1	1	0.51	510	0.022077922

8 Toxicological profile of the substances

Table 5 - safety assessment conclusion of all ingredients

Red paintstick

No.	INGREDIENT (INCI)	%(w/w)	Max. allowed conc. in reference	Margin of Safety	Assessment Conclusion	Reference
1	PARAFFINUM LIQUIDUM	27.90	87.95	n.a.	Conforms to accepted external review in a cosmetic product.	China NIFDC: Raw Material Usage Information for Marketed Products
2	CERA MICROCRISTALLINA	26	50	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
3	BEESWAX	15	56	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel.Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 2005,24(Suppl. 1) : 1–102

4	MICA	12	Mica, a silicate mineral with generally negligible transdermal absorption and potential systemic toxicity. And it can be used as coloring agent for cosmetics in EU, USA, China and other regions without restriction requirements.			
5	CERESIN	10	25	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
6	METHYLHEPTYL PALMITATE	5	n.a.	855.15	MOS > 100, the raw material is considered acceptable for safety evaluation.	QSAR Toolbox. Detailed information can be found in the description below and Appendix XVII
7	CI 15850	4	n.a.	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex IV
8	PHENOXYETHANOL	0.1	1.0	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex V

Yellow paintstick

No.	INGREDIENT (INCI)	%(w/w)	Max. allowed conc. in reference	Margin of Safety	Assessment Conclusion	Reference
1	PARAFFINUM LIQUIDUM	27.90	87.95	n.a.	Conforms to accepted external review in a cosmetic product.	China NIFDC: Raw Material Usage Information for Marketed Products
2	CERA MICROCRISTALLINA	26	50	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
3	BEESWAX	15	56	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel.Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 2005,24(Suppl. 1) : 1–102
4	MICA	12	Mica, a silicate mineral with generally negligible transdermal absorption and potential systemic toxicity. And it can be used as coloring agent for cosmetics in EU, USA, China and other regions without restriction requirements.			
5	CERESIN	10	25	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
6	METHYLHEPTYL PALMITATE	5	n.a.	855.15	MOS > 100, the raw material is considered acceptable for safety evaluation.	QSAR Toolbox. Detailed information can be found in the description below and Appendix XVII
7	CI 19140	4	n.a.	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex IV
8	PHENOXYETHANOL	0.1	1.0	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex V

Toxicological profile of METHYLHEPTYL PALMITATE (CAS# 1341-38-4, Isooctyl palmitate)

Toxicological endpoints[1]:

Acute toxicity: The acute oral LD_{50} value of the test item methylheptyl palmitate was estimated > 5000 $mg/kg^{-1}$of body weight for female rats.

Skin irritation: The test item 1341-38-4 Isooctyl palmitate is considered non-irritant to skin in the Reconstructed human Epidermis (RhE) Test Method.

Eye irritation: The test item 1341-38-4 Isooctyl palmitate showed no effects on the cornea of the bovine eye.

Skin sensitization: The skin sensitizing potential of Isooctyl palmitate was assessed using the murine local lymph node assay. Based on the results of the study, Isooctyl palmitate is not considered a skin sensitizer under the conditions of the LLNA study.

Genetic toxicity: Based on the results of the study it is concluded that 1341-38-4 Isooctyl palmitate is not mutagenic in the Salmonella typhimurium strains TA97a, TA98, TA100, TA102 and TA1535 in the absence and presence of metabolic activation under the experi-mental conditions in this study.

Repeated dose toxicity: No available data. Using the QSAR Toolbox for read-across analysis, the predicted NOAEL value is 944 mg/kg bw/d[2].

Conclusion:

A calculated Margin of Safety (MoS) value more than 100 is deemed acceptable for safety evaluation.

9 Undesirable effects and serious undesirable effects

None reported.

10 Information on the cosmetic product

No other relevant information.

PART B - Cosmetic Product Safety Assessment

1 Assessment conclusion

This cosmetic product can be considered as safe to human health and compliant with the EU Cosmetics Regulation (EC) 1223/2009 when used under normal and reasonably foreseeable use.

This assessment is conditional on the Responsible Person complying with the conditions in the notes and any other purity restrictions listed.

2 Labelled warnings and instructions of use

Detailed warnings and instructions of use are labelled on the product packaging.

Warning: Not suitable for children under 3 years. Small parts.
Achtung: Nicht für Kinder unter dreiJahren geeignet. Kleine Teile.
Attention. Ne convient pasaux enfants de moins de 3 ans. Petites pièces.
Advertencia. No conveniente para niños menores de 3 años. Piezas pequeñas.
Avvertenza. Non adatto a bambini di età inferiore a 3 anni. Contiene parti piccole.
Waarschuwing: Niet geschikt voor kinderen jonger dan 3 jaar. Kleine onderdelen.
Ostrzeżenie. Nieodpowiednie dla dzieci w wieku poniżej 3 lat. Male części.

[1]ECHA. REACH registered subatances factsheets of Isooctyl palmitate (CAS no. 1341-38-4)
https://echa.europa.eu/registration-dossier/-/registered-dossier/29334/11

[2] Prediction of NOAEL of Read-across prediction report from QSAR TOOLBOX.

3 Reasoning

This study evaluated the Face paint.

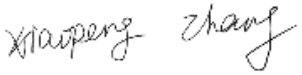
None of the ingredients used in the formulation are classified as hazardous substances. Based on the assessment in Part A, Section 8 "Toxicological Profile of the Substances", the use of all substances in the product is safe.

Provided the manufacturer's instructions are followed and all the ingredients used are of cosmetic grade or other appropriate, 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.

4 Assessor's credential and approval of Part B

Assessor: Xiaopeng Zhang, PhD, DABT, DCST

Name: Xiaopeng Zhang
Address: 288 Qiuyi Road, Binjiang District, Hangzhou, Zhejiang Province, China

Signature: 

Date: 31/10/2025

The curriculum vitae of the assessor can be found in Appendix XIII.

SECTION 3:

Method of manufacture, statement of compliance with GMP

The manufacturing process for the product can be found in Appendix XIV.

The product is manufactured in accordance with ISO 22716, standards developed for and by the cosmetic industry. Please refer to the ISO certificate in Appendix XV.

SECTION 4:

Proof of effect claimed

This product is a face paint used for makeup.

The intended use of the product can be identified through sensory evaluation. As the product label does not include any efficacy claims beyond those stated above, no substantiation documents for efficacy are required.

SECTION 5:

Data on animal testing

According to the manufacturer's declaration, neither the product nor the substances contained have been tested on animals. The declaration can be found in Appendix XVI.

The manufacturer does not conduct animal testing on finished products unless required by regulatory authorities in a few countries.

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SECTION 1:

DESCRIPTION OF THE COSMETIC PRODUCT

Product name:	Face paint 06
Responsible Person Name（EU）:	Mid Ocean BV.
Responsible Person Address（EU）:	Wellensiekstraat 2, 6718 XZ Ede, The Netherlands.
Responsible Person Name（UK）:	Midocean Brands UK, Ltd.
Responsible Person Address（UK）:	1st Floor 5 Century Court, Tolpits Lane, Watford, Hertfordshire, England, WD18 9PX
Applicant/Company name:	Mid Ocean Brands B.V.
Address:	Unit 711-716, 7/F, Tower A, 83 King Lam Street, Cheung Sha Wan, Kowloon, Hong Kong.
Item number:	MO2807, MO8274
Vendor code:	111041
Internal product name:	**NA**
Formula number:	**NA**
Code number:	**NA**
Product family:	Make-up products
Product sub-family:	Body or face paint, including carnival make up
Product type:	Leave-on
Physical form:	Solid/pressed powder
Net Weight:	4g, 9g
Target:	Adult and children over 3 years
Country of Origin:	China
Country first placed on the market (EU):	The Netherlands
CPNP Reference	MO8274-06: 2533122, MO2807-06: 5483656
SCPN Reference	MO8274-06: UKCP-37483224, MO2807-06: UKCP-33436556

SECTION 2:

COSMETIC PRODUCT SAFETY REPORT

PART A - COSMETIC PRODUCT SAFETY INFORMATION

1 Qualitative and quantitative composition of the cosmetic product

The original formulation of the product can be found in Appendix I.

Table 1 - qualitative and quantitative composition

Red paintstick

No.	INCI Name	Wt (%)	Mixture ratio (%)	Actual Wt (%)	CAS.	Function
1	PARAFFINUM LIQUIDUM	27.90	100	27.90	232-455-8	Antistatic /mollient / Skin Protecting/solvent
2	CERA MICROCRISTALLINA	26	100	26	264-038-1	Binding/emulsion Stabilising /Opacifying/Viscosity Controlling
3	BEESWAX	15	100	15	616-889-9	Emollient/emulsifying
4	MICA	12	100	12	310-127-6	Opacifying
5	CERESIN	10	100	10	232-290-1	Antistatic/Binding/Emulsion Stabilising /Opacifying/Viscosity Controlling
6	METHYLHEPTYL PALMITATE	5	98	5	215-675-9	Skin Conditioning / Emollient
7	CI 15850	4	100	4	227-497-9	Cosmetic colorant
8	PHENOXYETHANOL	0.1	100	0.1	204-589-7	Preservative

White paintstick

No.	INCI Name	Wt (%)	Mixture ratio (%)	Actual Wt (%)	CAS.	Function
1	PARAFFINUM LIQUIDUM	27.90	100	27.90	232-455-8	Antistatic /mollient / Skin Protecting/solvent
2	CERA MICROCRISTALLINA	26	100	26	264-038-1	Binding/emulsion Stabilising /Opacifying/Viscosity Controlling
3	BEESWAX	15	100	15	616-889-9	Emollient/emulsifying
4	MICA	12	100	12	310-127-6	Opacifying
5	CERESIN	10	100	10	232-290-1	Antistatic/Binding/Emulsion Stabilising /Opacifying/Viscosity Controlling
6	METHYLHEPTYL PALMITATE	5	98	5	1341-38-4	Skin Conditioning / Emollient
7	CI 77891	4	100	4	12225-21-7	Cosmetic colorant
8	PHENOXYETHANOL	0.1	100	0.1	204-589-7	Preservative

2 Physical/chemical characteristics and stability of the cosmetic product

2.1 Physical/chemical characteristics of substances or mixtures

Physical/chemical properties of the substance or mixture can be found in the MSDS or COA document in Appendix II.

Table 2 - specifications of each raw material

No.	Raw material name	Supplier	INCI Name	Composition (%)	Assay or Active Ingredient (%)
1	PARAFFINUM LIQUIDUM		PARAFFINUM LIQUIDUM	100	97.0~103.0
2	Microcrystalline paraffin wax		CERA MICROCRISTALLINA	100	n.a.
3	Beeswax		BEESWAX	100	n.a.

		Ltd.			
4	Mica Powder		MICA	100	n.a.
5	White ozocerite		CERESIN	100	n.a.
6	CRODAMOL™ OP-LQ-(SG)		METHYLHEPTYL PALMITATE	100	≥ 98
7	Phenoxyethanol		PHENOXYETHANOL	100	⩾ 99.80
8	Red		CI 15850	100	97.0~103.0
9	titanium dioxide		CI 77891	100	97.0~103.0

The product is free of nanomaterials and CMR substances, which can be found in the declaration in Appendix III.

2.2 Physical/chemical characteristics of the finished cosmetic product

This description is to contain the specifications of the finished product. Please refer to Appendix IV for the original product specification document.
- Physical form: Solid:Cream/ paste
- Color: Refer to standard sample
- Odor: Weak aromatic

2.3 Stability of the cosmetic product

The product has undergone stability testing and preservative challenge testing. The product's PAO (Period After Opening) is 18 months, which is labelled on the product packaging. Please refer to Appendix V for detailed information.

2.3.1 Stability testing

Stability test is an destruction test on the packaged product. The formulations of the Face paint series are similar, and the primary packaging materials are identical. Therefore, destruction testing was performed only on the red paintstick. The original report is given in Appendix VI.

The products were stored for 3 month at -5±1°C, room condition, and 40±2°C, 60±5% humidity. The appearance, odor, colour and pH of the products no significant changes have occurred at 3 months.

2.3.2 Preservative efficacy study

The preservative challenge test was performed on red paintstick in accordance with European Pharmacopoeia 10.0 5.1.3, as the formulations are similar and share the same preservative system of face paint series. The original report is presented in Appendix VII.

For escherichia coli, staphylococcus aureus and pseudomonas aeruginosa, the logarithmic difference of the test results on day 14 was greater than 3; the logarithmic difference of the test results from day 14 to 28 did not decrease.

For candida albicans and aspergillus brasiliensis, the logarithmic difference of the results was greater than 1 at day 14; there was no decrease in the logarithmic difference of the results from day 14 to day 28.

3 Microbiological quality

According to the SCCS's 'Notes of guidance for the testing of cosmetic ingredients and the safety evaluation' (12th Revision, 2023), total aerobic mesophilic microorganisms (bacteria plus yeast and

mould) should not exceed 10^3 cfu/g or 10^3 cfu/mL in Category 2 products (i.e. all but cosmetics intended for children under 3 years of age, to be used in the eye area and on mucous membranes). *Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Candida albicans* are considered to be the main potential pathogens in cosmetic products. These should not to be detectable in 1 g or mL in Category 2 products.

The product was microbiologically tested and all indicators met the requirements. The original report is attached in Appendix VIII for further reference.

4 Impurities, traces, information about the packaging material

4.1 Impurities and traces

The product was tested for traces of lead, mercury, arsenic, antimony, cadmium and soluble nickel, and the results met the requirements of EU cosmetic limit(s) (Germany BVL 2016), which can be found in Appendix IX.

4.2 The relevant characteristics of packaging material

The relevant characteristics of packaging materials in direct contact with the finished product are important for the safety of the cosmetic product.

According to Appendix X, the packaging is compliant with EU REACH Regulation and does not contain any substances mentioned in the candidate list of SVHC.

The product is offered in two packaging formats, the material compositions of the two container (or primary packaging) types are as follows.

Table 3 - Packaging composition

MO2807

Raw material name	Description	CAS	Supplier
Polystyrene (PS)	Plastic lid, colorless transparent hard plastic	9003-53-6	
Polypropylene (PP)	Plastic holder, white hard plastic	9003-07-0	
Polypropylene (PP)	Plastic case, white hard plastic	9003-07-0	

MO28274

Raw material name	Description	CAS	Supplier
Polystyrene (PS)	Plastic case, colorless transparent hard plastic	9003-53-6	
Acrylonitrile utadiene Styrene (ABS)	Plastic lid and case, beige hard plastic with silvery coating	97048-04-9	
Acrylonitrile utadiene Styrene (ABS)	Plastic knob, black hard plastic	97048-04-9	
Polypropylene (PP)	Plastic holder, translucent hard plastic	9003-07-0	

4.2.1 Chemical purity of the packaging materials

The analytical testing result of container indicated Cadmium, Lead, Mercury, Hexavalent Chromium complies with the limit of European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste and its amended directives. The original report is given in Appendix XI.

4.2.2 Compatibility of package

The formulations of the Face paint series are similar, and the primary packaging materials are identical. Therefore, Packaging compatibility tests was performed only on the red paintstick. The original report is given in Appendix VI.

The products were stored for 3 month at -5±1°C, room condition, and 40±2°C, 60±5% humidity. The appearance, odor, colour, pH and appearance of the package of the products no significant changes have occurred at 3 months.

5 Normal and reasonably foreseeable use

This product is a face paint used for makeup.

The normal use of this product is intended to be applied as face paint by 3 years old and above. Other usage is not foreseeable.

As the printed instructions of use and warning is clear to describe the product usage and apporiate enough to avoid misuse, no special warnings or instructions of use are further required.

Please refer to the product label attached in Appendix XII for further reference.

6 Exposure to the cosmetic product

Area of application	Face
Surface area of application (cm^2)	565
Amount applied (g) per day	0.51
Duration	Leave-on
Retention factor	1
Frequency	1/day[2]
Possible exposure routes	Dermal
Target group for use	Adult and children over 3 years

No nanomaterials are used in the product, so the effect of particle size on exposure is not considered.

7 Exposure to the substances

The assessment of the exposure to each of the substances contained in the cosmetic product is necessary in order to assess the risk associated with each individual substance.

Exposure levels to the substances are generally calculated based on the following equation, as outlined in the SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation (12th Revision, 2023).

$$SED = E_{product} \times \frac{C(\%)}{100} \times \frac{DAp(\%)}{100} \times Rf$$

Where,
SED (mg/kg bw/day): Systemic exposure dose
Eproduct (mg/kg bw/day): Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application.
C(%): Concentration of the substance under study in the finished cosmetic product on the application site
DAp (%): Dermal absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions. Calculated as 100 %.
Rf: Retention factor

Default values for body weights of children is 23.1kg.

Table 4 - systemic exposure dose of each ingredient

Red paintstick

INGREDIENT (INCI)	% (W/W)	Retention factor	Amount applied (g) per day	Eproduct (mg/kg bw/day)	SED （mg/kg/day）
PARAFFINUM LIQUIDUM	27.90	1	0.51	510	6.15974026
CERA MICROCRISTALLINA	26	1	0.51	510	5.74025974
BEESWAX	15	1	0.51	510	3.311688312
MICA	12	1	0.51	510	2.649350649
CERESIN	10	1	0.51	510	2.207792208
METHYLHEPTYL PALMITATE	5	1	0.51	510	1.103896104
CI 15850	4	1	0.51	510	0.883116883
PHENOXYETHANOL	0.1	1	0.51	510	0.022077922

White paintstick

INGREDIENT (INCI)	% (W/W)	Retention factor	Amount applied (g) per day	Eproduct (mg/kg bw/day)	SED （mg/kg/day）
PARAFFINUM LIQUIDUM	27.90	1	0.51	510	6.15974026
CERA MICROCRISTALLINA	26	1	0.51	510	5.74025974
BEESWAX	15	1	0.51	510	3.311688312
MICA	12	1	0.51	510	2.649350649
CERESIN	10	1	0.51	510	2.207792208
METHYLHEPTYL PALMITATE	5	1	0.51	510	1.103896104
CI 77891	4	1	0.51	510	0.883116883
PHENOXYETHANOL	0.1	1	0.51	510	0.022077922

8 Toxicological profile of the substances

Table 5 - safety assessment conclusion of all ingredients

Red paintstick

No.	INGREDIENT (INCI)	%(w/w)	Max. allowed conc. in reference	Margin of Safety	Assessment Conclusion	Reference
1	PARAFFINUM LIQUIDUM	27.90	87.95	n.a.	Conforms to accepted external review in a cosmetic product.	China NIFDC: Raw Material Usage Information for Marketed Products
2	CERA MICROCRISTALLINA	26	50	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
3	BEESWAX	15	56	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel.Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 2005,24(Suppl. 1) : 1–102

4	MICA	12	Mica, a silicate mineral with generally negligible transdermal absorption and potential systemic toxicity. And it can be used as coloring agent for cosmetics in EU, USA, China and other regions without restriction requirements.			
5	CERESIN	10	25	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
6	METHYLHEPTYL PALMITATE	5	n.a.	855.15	MOS > 100, the raw material is considered acceptable for safety evaluation.	QSAR Toolbox. Detailed information can be found in the description below and Appendix XVII
7	CI 15850	4	n.a.	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex IV
8	PHENOXYETHANOL	0.1	1.0	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex V

White paintstick

No.	INGREDIENT (INCI)	%(w/w)	Max. allowed conc. in reference	Margin of Safety	Assessment Conclusion	Reference
1	PARAFFINUM LIQUIDUM	27.90	87.95	n.a.	Conforms to accepted external review in a cosmetic product.	China NIFDC: Raw Material Usage Information for Marketed Products
2	CERA MICROCRISTALLINA	26	50	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
3	BEESWAX	15	56	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel.Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 2005,24(Suppl. 1) : 1–102
4	MICA	12	Mica, a silicate mineral with generally negligible transdermal absorption and potential systemic toxicity. And it can be used as coloring agent for cosmetics in EU, USA, China and other regions without restriction requirements.			
5	CERESIN	10	25	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
6	METHYLHEPTYL PALMITATE	5	n.a.	855.15	MOS > 100, the raw material is considered acceptable for safety evaluation.	QSAR Toolbox. Detailed information can be found in the description below and Appendix XVII
7	CI 77891	4	n.a.	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex IV
8	PHENOXYETHANOL	0.1	1.0	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex V

Toxicological profile of METHYLHEPTYL PALMITATE (CAS# 1341-38-4, Isooctyl palmitate)

Toxicological endpoints[1]:

Acute toxicity: The acute oral LD_{50} value of the test item methylheptyl palmitate was estimated > 5000 $mg/kg^{-1}$of body weight for female rats.

Skin irritation: The test item 1341-38-4 Isooctyl palmitate is considered non-irritant to skin in the Reconstructed human Epidermis (RhE) Test Method.

Eye irritation: The test item 1341-38-4 Isooctyl palmitate showed no effects on the cornea of the bovine eye.

Skin sensitization: The skin sensitizing potential of Isooctyl palmitate was assessed using the murine local lymph node assay. Based on the results of the study, Isooctyl palmitate is not considered a skin sensitizer under the conditions of the LLNA study.

Genetic toxicity: Based on the results of the study it is concluded that 1341-38-4 Isooctyl palmitate is not mutagenic in the Salmonella typhimurium strains TA97a, TA98, TA100, TA102 and TA1535 in the absence and presence of metabolic activation under the experi-mental conditions in this study.

Repeated dose toxicity: No available data. Using the QSAR Toolbox for read-across analysis, the predicted NOAEL value is 944 mg/kg bw/d[2].

Conclusion:

A calculated Margin of Safety (MoS) value more than 100 is deemed acceptable for safety evaluation.

9 Undesirable effects and serious undesirable effects

None reported.

10 Information on the cosmetic product

No other relevant information.

PART B - Cosmetic Product Safety Assessment

1 Assessment conclusion

This cosmetic product can be considered as safe to human health and compliant with the EU Cosmetics Regulation (EC) 1223/2009 when used under normal and reasonably foreseeable use.

This assessment is conditional on the Responsible Person complying with the conditions in the notes and any other purity restrictions listed.

2 Labelled warnings and instructions of use

Detailed warnings and instructions of use are labelled on the product packaging.

Warning: Not suitable for children under 3 years. Small parts.
Achtung: Nicht für Kinder unter dreiJahren geeignet. Kleine Teile.
Attention. Ne convient pasaux enfants de moins de 3 ans. Petites pièces.
Advertencia. No conveniente para niños menores de 3 años. Piezas pequeñas.
Avvertenza. Non adatto a bambini di età inferiore a 3 anni. Contiene parti piccole.
Waarschuwing: Niet geschikt voor kinderen jonger dan 3 jaar. Kleine onderdelen.
Ostrzeżenie. Nieodpowiednie dla dzieci w wieku poniżej 3 lat. Male części.

[1]ECHA. REACH registered subatances factsheets of Isooctyl palmitate (CAS no. 1341-38-4)
https://echa.europa.eu/registration-dossier/-/registered-dossier/29334/11

[2] Prediction of NOAEL of Read-across prediction report from QSAR TOOLBOX.

3 Reasoning

This study evaluated the Face paint.

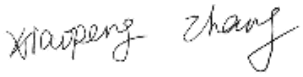
None of the ingredients used in the formulation are classified as hazardous substances. Based on the assessment in Part A, Section 8 "Toxicological Profile of the Substances", the use of all substances in the product is safe.

Provided the manufacturer's instructions are followed and all the ingredients used are of cosmetic grade or other appropriate, 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.

4 Assessor's credential and approval of Part B

Assessor: Xiaopeng Zhang, PhD, DABT, DCST

Name: Xiaopeng Zhang
Address: 288 Qiuyi Road, Binjiang District, Hangzhou, Zhejiang Province, China

Signature: 

Date: 31/10/2025

The curriculum vitae of the assessor can be found in Appendix XIII.

SECTION 3:

Method of manufacture, statement of compliance with GMP

The manufacturing process for the product can be found in Appendix XIV.

The product is manufactured in accordance with ISO 22716, standards developed for and by the cosmetic industry. Please refer to the ISO certificate in Appendix XV.

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Proof of effect claimed

This product is a face paint used for makeup.

The intended use of the product can be identified through sensory evaluation. As the product label does not include any efficacy claims beyond those stated above, no substantiation documents for efficacy are required.

SECTION 5:

Data on animal testing

According to the manufacturer's declaration, neither the product nor the substances contained have been tested on animals. The declaration can be found in Appendix XVI.

The manufacturer does not conduct animal testing on finished products unless required by regulatory authorities in a few countries.

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SECTION 1:

DESCRIPTION OF THE COSMETIC PRODUCT

Product name:	Face paint 08
Responsible Person Name（EU）:	Mid Ocean BV.
Responsible Person Address（EU）:	Wellensiekstraat 2, 6718 XZ Ede, The Netherlands.
Responsible Person Name（UK）:	Midocean Brands UK, Ltd.
Responsible Person Address（UK）:	1st Floor 5 Century Court, Tolpits Lane, Watford, Hertfordshire, England, WD18 9PX
Applicant/Company name:	Mid Ocean Brands B.V.
Address:	Unit 711-716, 7/F, Tower A, 83 King Lam Street, Cheung Sha Wan, Kowloon, Hong Kong.
Item number:	MO2807, MO8274
Vendor code:	111041
Internal product name:	**NA**
Formula number:	**NA**
Code number:	**NA**
Product family:	Make-up products
Product sub-family:	Body or face paint, including carnival make up
Product type:	Leave-on
Physical form:	Solid/pressed powder
Net Weight:	4g, 9g
Target:	Adult and children over 3 years
Country of Origin:	China
Country first placed on the market (EU):	The Netherlands
CPNP Reference	MO8274-08: 2533176, MO2807-08: 5483684
SCPN Reference	MO8274-08: UKCP-90738303, MO2807-08: UKCP-84052942

SECTION 2:

COSMETIC PRODUCT SAFETY REPORT

PART A - COSMETIC PRODUCT SAFETY INFORMATION

1 Qualitative and quantitative composition of the cosmetic product

The original formulation of the product can be found in Appendix I.

Table 1 - qualitative and quantitative composition

Yellow paintstick

No.	INCI Name	Wt (%)	Mixture ratio (%)	Actual Wt (%)	CAS.	Function
1	PARAFFINUM LIQUIDUM	27.90	100	27.90	232-455-8	Antistatic /mollient / Skin Protecting/solvent
2	CERA MICROCRISTALLINA	26	100	26	264-038-1	Binding/emulsion Stabilising /Opacifying/Viscosity Controlling
3	BEESWAX	15	100	15	616-889-9	Emollient/emulsifying
4	MICA	12	100	12	310-127-6	Opacifying
5	CERESIN	10	100	10	232-290-1	Antistatic/Binding/Emulsion Stabilising /Opacifying/Viscosity Controlling
6	METHYLHEPTYL PALMITATE	5	98	5	1341-38-4	Skin Conditioning / Emollient
7	CI 19140	4	100	4	12225-21-7	Cosmetic colorant
8	PHENOXYETHANOL	0.1	100	0.1	204-589-7	Preservative

Red paintstick

No.	INCI Name	Wt (%)	Mixture ratio (%)	Actual Wt (%)	CAS.	Function
1	PARAFFINUM LIQUIDUM	27.90	100	27.90	232-455-8	Antistatic /mollient / Skin Protecting/solvent
2	CERA MICROCRISTALLINA	26	100	26	264-038-1	Binding/emulsion Stabilising /Opacifying/Viscosity Controlling
3	BEESWAX	15	100	15	616-889-9	Emollient/emulsifying
4	MICA	12	100	12	310-127-6	Opacifying
5	CERESIN	10	100	10	232-290-1	Antistatic/Binding/Emulsion Stabilising /Opacifying/Viscosity Controlling
6	METHYLHEPTYL PALMITATE	5	98	5	215-675-9	Skin Conditioning / Emollient
7	CI 15850	4	100	4	227-497-9	Cosmetic colorant
8	PHENOXYETHANOL	0.1	100	0.1	204-589-7	Preservative

Black paintstick

No.	INCI Name	Wt (%)	Mixture ratio (%)	Actual Wt (%)	CAS.	Function
1	PARAFFINUM LIQUIDUM	27.90	100	27.90	232-455-8	Antistatic /mollient / Skin Protecting/solvent
2	CERA MICROCRISTALLINA	26	100	26	264-038-1	Binding/emulsion Stabilising /Opacifying/Viscosity Controlling
3	BEESWAX	15	100	15	616-889-9	Emollient/emulsifying
4	MICA	12	100	12	310-127-6	Opacifying
5	CERESIN	10	100	10	232-290-1	Antistatic/Binding/Emulsion Stabilising /Opacifying/Viscosity Controlling
6	METHYLHEPTYL PALMITATE	5	98	5	1341-38-4	Skin Conditioning / Emollient
7	CI 77266	4	100	4	1333-86-4	Cosmetic colorant
8	PHENOXYETHANOL	0.1	100	0.1	204-589-7	Preservative

2 Physical/chemical characteristics and stability of the cosmetic product

2.1 Physical/chemical characteristics of substances or mixtures

Physical/chemical properties of the substance or mixture can be found in the MSDS or COA document in Appendix II.

Table 2 - specifications of each raw material

No.	Raw material name	Supplier	INCI Name	Composition (%)	Assay or Active Ingredient (%)
1	PARAFFINUM LIQUIDUM		PARAFFINUM LIQUIDUM	100	97.0~103.0
2	Microcrystalline paraffin wax		CERA MICROCRISTALLINA	100	n.a.
3	Beeswax		BEESWAX	100	n.a.
4	Mica Powder		MICA	100	n.a.
5	White ozocerite		CERESIN	100	n.a.
6	CRODAMOL™ OP-LQ-(SG)		METHYLHEPTYL PALMITATE	100	≥ 98
7	Phenoxyethanol		PHENOXYETHANOL	100	⩾ 99.80
8	Yellow		C 19140	100	n.a.
9	Red		CI 15850	100	97.0~103.0
10	Black		CI 77266	100	n.a.

According the wording of conditions of use and warnings for CI 77266 of Regulation EC) No 1223/2009 of the European parliament and of the council: purity > 97 %, with the following impurity profile: ash content ⩽ 0,15 %, total sulphur ⩽ 0,65 %, total PAH ⩽ 500 ppb and benzo(a)pyrene ⩽ 5 ppb, ibenz (a,h) anthracene ⩽ 5 ppb, total As ⩽ 3 ppm, total Pb ⩽ 10 ppm, total Hg ⩽ 1 ppm. The CI 77266 in the product comply with the above requirements, please refer to Appendix II.

The product is free of nanomaterials and CMR substances, which can be found in the declaration in Appendix III.

2.2 Physical/chemical characteristics of the finished cosmetic product

This description is to contain the specifications of the finished product. Please refer to Appendix IV for the original product specification document.
- Physical form: Solid:Cream/ paste
- Color: Refer to standard sample
- Odor: Weak aromatic

2.3 Stability of the cosmetic product

The product has undergone stability testing and preservative challenge testing. The product's PAO (Period After Opening) is 18 months, which is labelled on the product packaging. Please refer to Appendix V for detailed information.

2.3.1 Stability testing

Stability test is an destruction test on the packaged product. The formulations of the Face paint series are similar, and the primary packaging materials are identical. Therefore, destruction testing was performed only on the red paintstick. The original report is given in Appendix VI.

The products were stored for 3 month at -5±1°C, room condition, and 40±2°C, 60±5% humidity. The appearance, odor, colour and pH of the products no significant changes have occurred at 3 months.

2.3.2 Preservative efficacy study

The preservative challenge test was performed on red paintstick in accordance with European Pharmacopoeia 10.0 5.1.3, as the formulations are similar and share the same preservative system of face paint series. The original report is presented in Appendix VII.

For escherichia coli, staphylococcus aureus and pseudomonas aeruginosa, the logarithmic difference of the test results on day 14 was greater than 3; the logarithmic difference of the test results from day 14 to 28 did not decrease.

For candida albicans and aspergillus brasiliensis, the logarithmic difference of the results was greater than 1 at day 14; there was no decrease in the logarithmic difference of the results from day 14 to day 28.

3 Microbiological quality

According to the SCCS's 'Notes of guidance for the testing of cosmetic ingredients and the safety evaluation' (12th Revision, 2023), total aerobic mesophilic microorganisms (bacteria plus yeast and mould) should not exceed 10^3 cfu/g or 10^3 cfu/mL in Category 2 products (i.e. all but cosmetics intended for children under 3 years of age, to be used in the eye area and on mucous membranes). *Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Candida albicans* are considered to be the main potential pathogens in cosmetic products. These should not to be detectable in 1 g or mL in Category 2 products.

The product was microbiologically tested and all indicators met the requirements. The original report is attached in Appendix VIII for further reference.

4 Impurities, traces, information about the packaging material

4.1 Impurities and traces

The product was tested for traces of lead, mercury, arsenic, antimony, cadmium and soluble nickel, and the results met the requirements of EU cosmetic limit(s) (Germany BVL 2016), which can be found in Appendix IX.

4.2 The relevant characteristics of packaging material

The relevant characteristics of packaging materials in direct contact with the finished product are important for the safety of the cosmetic product.

According to Appendix X, the packaging is compliant with EU REACH Regulation and does not contain any substances mentioned in the candidate list of SVHC.

The product is offered in two packaging formats, the material compositions of the two container (or primary packaging) types are as follows.

Table 3 - Packaging composition

MO2807

Raw material name	Description	CAS	Supplier

Polystyrene (PS)	Plastic lid, colorless transparent hard plastic	9003-53-6	
Polypropylene (PP)	Plastic holder, white hard plastic	9003-07-0	
Polypropylene (PP)	Plastic case, white hard plastic	9003-07-0	

MO28274

Raw material name	Description	CAS	Supplier
Polystyrene (PS)	Plastic case, colorless transparent hard plastic	9003-53-6	
Acrylonitrile utadiene Styrene (ABS)	Plastic lid and case, beige hard plastic with silvery coating	97048-04-9	
Acrylonitrile utadiene Styrene (ABS)	Plastic knob, black hard plastic	97048-04-9	
Polypropylene (PP)	Plastic holder, translucent hard plastic	9003-07-0	

4.2.1 Chemical purity of the packaging materials

The analytical testing result of container indicated Cadmium, Lead, Mercury, Hexavalent Chromium complies with the limit of European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste and its amended directives. The original report is given in Appendix XI.

4.2.2 Compatibility of package

The formulations of the Face paint series are similar, and the primary packaging materials are identical. Therefore, Packaging compatibility tests was performed only on the red paintstick. The original report is given in Appendix VI.

The products were stored for 3 month at -5±1°C, room condition, and 40±2°C, 60±5% humidity. The appearance, odor, colour, pH and appearance of the package of the products no significant changes have occurred at 3 months.

5 Normal and reasonably foreseeable use

This product is a face paint used for makeup.

The normal use of this product is intended to be applied as face paint by 3 years old and above. Other usage is not foreseeable.

As the printed instructions of use and warning is clear to describe the product usage and apporiate enough to avoid misuse, no special warnings or instructions of use are further required.

Please refer to the product label attached in Appendix XII for further reference.

6 Exposure to the cosmetic product

Area of application	Face
Surface area of application (cm^2)	565
Amount applied (g) per day	0.51
Duration	Leave-on
Retention factor	1
Frequency	$1/day^2$
Possible exposure routes	Dermal
Target group for use	Adult and children over 3 years

No nanomaterials are used in the product, so the effect of particle size on exposure is not considered.

7 Exposure to the substances

The assessment of the exposure to each of the substances contained in the cosmetic product is necessary in order to assess the risk associated with each individual substance.

Exposure levels to the substances are generally calculated based on the following equation, as outlined in the SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation (12th Revision, 2023).

$$SED = E_{product} \times \frac{C(\%)}{100} \times \frac{DAp(\%)}{100} \times Rf$$

Where,
SED (mg/kg bw/day): Systemic exposure dose
Eproduct (mg/kg bw/day): Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application.
C(%): Concentration of the substance under study in the finished cosmetic product on the application site
DAp (%): Dermal absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions. Calculated as 100 %.
Rf: Retention factor

Default values for body weights of children is 23.1kg.

Table 4 - systemic exposure dose of each ingredient

Yellow paintstick

INGREDIENT (INCI)	% (W/W)	Retention factor	Amount applied (g) per day	Eproduct (mg/kg bw/day)	SED （mg/kg/day）
PARAFFINUM LIQUIDUM	27.90	1	0.51	510	6.15974026
CERA MICROCRISTALLINA	26	1	0.51	510	5.74025974
BEESWAX	15	1	0.51	510	3.311688312
MICA	12	1	0.51	510	2.649350649
CERESIN	10	1	0.51	510	2.207792208
METHYLHEPTYL PALMITATE	5	1	0.51	510	1.103896104
CI 19140	4	1	0.51	510	0.883116883
PHENOXYETHANOL	0.1	1	0.51	510	0.022077922

Red paintstick

INGREDIENT (INCI)	% (W/W)	Retention factor	Amount applied (g) per day	Eproduct (mg/kg bw/day)	SED （mg/kg/day）
PARAFFINUM LIQUIDUM	27.90	1	0.51	510	6.15974026
CERA MICROCRISTALLINA	26	1	0.51	510	5.74025974
BEESWAX	15	1	0.51	510	3.311688312
MICA	12	1	0.51	510	2.649350649
CERESIN	10	1	0.51	510	2.207792208
METHYLHEPTYL PALMITATE	5	1	0.51	510	1.103896104
CI 15850	4	1	0.51	510	0.883116883
PHENOXYETHANOL	0.1	1	0.51	510	0.022077922

Black paintstick

INGREDIENT (INCI)	% (W/W)	Retention factor	Amount applied (g) per day	Eproduct (mg/kg bw/day)	SED （mg/kg/day）
PARAFFINUM LIQUIDUM	27.90	1	0.51	510	6.15974026
CERA MICROCRISTALLINA	26	1	0.51	510	5.74025974
BEESWAX	15	1	0.51	510	3.311688312
MICA	12	1	0.51	510	2.649350649
CERESIN	10	1	0.51	510	2.207792208
METHYLHEPTYL PALMITATE	5	1	0.51	510	1.103896104
CI 77266	4	1	0.51	510	0.883116883
PHENOXYETHANOL	0.1	1	0.51	510	0.022077922

8 Toxicological profile of the substances

Table 5 - safety assessment conclusion of all ingredients

Yellow paintstick

No.	INGREDIENT (INCI)	%(w/w)	Max. allowed conc. in reference	Margin of Safety	Assessment Conclusion	Reference
1	PARAFFINUM LIQUIDUM	27.90	87.95	n.a.	Conforms to accepted external review in a cosmetic product.	China NIFDC: Raw Material Usage Information for Marketed Products
2	CERA MICROCRISTALLINA	26	50	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
3	BEESWAX	15	56	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel.Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 2005,24(Suppl. 1) : 1–102
4	MICA	12	Mica, a silicate mineral with generally negligible transdermal absorption and potential systemic toxicity. And it can be used as coloring agent for cosmetics in EU, USA, China and other regions without restriction requirements.			
5	CERESIN	10	25	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
6	METHYLHEPTYL PALMITATE	5	n.a.	855.15	MOS > 100, the raw material is considered acceptable for safety evaluation.	QSAR Toolbox. Detailed information can be found in the description below and Appendix XVII
7	CI 19140	4	n.a.	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex IV
8	PHENOXYETHANOL	0.1	1.0	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex V

Red paintstick

No.	INGREDIENT (INCI)	%(w/w)	Max. allowed conc. in reference	Margin of Safety	Assessment Conclusion	Reference
1	PARAFFINUM LIQUIDUM	27.90	87.95	n.a.	Conforms to accepted external review in a cosmetic product.	China NIFDC: Raw Material Usage Information for Marketed Products
2	CERA MICROCRISTALLINA	26	50	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
3	BEESWAX	15	56	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel.Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 2005,24(Suppl. 1) : 1–102
4	MICA	12	Mica, a silicate mineral with generally negligible transdermal absorption and potential systemic toxicity. And it can be used as coloring agent for cosmetics in EU, USA, China and other regions without restriction requirements.			
5	CERESIN	10	25	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
6	METHYLHEPTYL PALMITATE	5	n.a.	855.15	MOS > 100, the raw material is considered acceptable for safety evaluation.	QSAR Toolbox. Detailed information can be found in the description below and Appendix XVII
7	CI 15850	4	n.a.	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex IV
8	PHENOXYETHANOL	0.1	1.0	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex V

Black paintstick

No.	INGREDIENT (INCI)	%(w/w)	Max. allowed conc. in reference	Margin of Safety	Assessment Conclusion	Reference
1	PARAFFINUM LIQUIDUM	27.90	87.95	n.a.	Conforms to accepted external review in a cosmetic product.	China NIFDC: Raw Material Usage Information for Marketed Products
2	CERA MICROCRISTALLINA	26	50	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
3	BEESWAX	15	56	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel.Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 2005,24(Suppl. 1) : 1–102

4	MICA	12	Mica, a silicate mineral with generally negligible transdermal absorption and potential systemic toxicity. And it can be used as coloring agent for cosmetics in EU, USA, China and other regions without restriction requirements.			
5	CERESIN	10	25	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
6	METHYLHEPTYL PALMITATE	5	n.a.	855.15	MOS > 100, the raw material is considered acceptable for safety evaluation.	QSAR Toolbox. Detailed information can be found in the description below and Appendix XVII
7	CI 77266	4	n.a.	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex IV
8	PHENOXYETHANOL	0.1	1.0	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex V

Toxicological profile of METHYLHEPTYL PALMITATE (CAS# 1341-38-4, Isooctyl palmitate)

Toxicological endpoints[1]:

Acute toxicity: The acute oral LD_{50} value of the test item methylheptyl palmitate was estimated > 5000 $mg/kg^{-1}$of body weight for female rats.

Skin irritation: The test item 1341-38-4 Isooctyl palmitate is considered non-irritant to skin in the Reconstructed human Epidermis (RhE) Test Method.

Eye irritation: The test item 1341-38-4 Isooctyl palmitate showed no effects on the cornea of the bovine eye.

Skin sensitization: The skin sensitizing potential of Isooctyl palmitate was assessed using the murine local lymph node assay. Based on the results of the study, Isooctyl palmitate is not considered a skin sensitizer under the conditions of the LLNA study.

Genetic toxicity: Based on the results of the study it is concluded that 1341-38-4 Isooctyl palmitate is not mutagenic in the Salmonella typhimurium strains TA97a, TA98, TA100, TA102 and TA1535 in the absence and presence of metabolic activation under the experi-mental conditions in this study.

Repeated dose toxicity: No available data. Using the QSAR Toolbox for read-across analysis, the predicted NOAEL value is 944 mg/kg bw/d[2].

Conclusion:

A calculated Margin of Safety (MoS) value more than 100 is deemed acceptable for safety evaluation.

9 Undesirable effects and serious undesirable effects

None reported.

10 Information on the cosmetic product

No other relevant information.

PART B - Cosmetic Product Safety Assessment

1 Assessment conclusion

This cosmetic product can be considered as safe to human health and compliant with the EU

[1]ECHA. REACH registered subatances factsheets of Isooctyl palmitate (CAS no. 1341-38-4) https://echa.europa.eu/registration-dossier/-/registered-dossier/29334/11

[2] Prediction of NOAEL of Read-across prediction report from QSAR TOOLBOX.

Cosmetics Regulation (EC) 1223/2009 when used under normal and reasonably foreseeable use.

This assessment is conditional on the Responsible Person complying with the conditions in the notes and any other purity restrictions listed.

2 Labelled warnings and instructions of use

Detailed warnings and instructions of use are labelled on the product packaging.

Warning: Not suitable for children under 3 years. Small parts.
Achtung: Nicht für Kinder unter dreiJahren geeignet. Kleine Teile.
Attention. Ne convient pasaux enfants de moins de 3 ans. Petites pièces.
Advertencia. No conveniente para niños menores de 3 años. Piezas pequeñas.
Avvertenza. Non adatto a bambini di età inferiore a 3 anni. Contiene parti piccole.
Waarschuwing: Niet geschikt voor kinderen jonger dan 3 jaar. Kleine onderdelen.
Ostrzeżenie. Nieodpowiednie dla dzieci w wieku poniżej 3 lat. Male części.

3 Reasoning

This study evaluated the Face paint.

None of the ingredients used in the formulation are classified as hazardous substances. Based on the assessment in Part A, Section 8 "Toxicological Profile of the Substances", the use of all substances in the product is safe.

Provided the manufacturer's instructions are followed and all the ingredients used are of cosmetic grade or other appropriate, 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.

4 Assessor's credential and approval of Part B

Assessor: Xiaopeng Zhang, PhD, DABT, DCST

Name: Xiaopeng Zhang
Address: 288 Qiuyi Road, Binjiang District, Hangzhou, Zhejiang Province, China

Signature: Xiaopeng Zhang

Date: 31/10/2025

The curriculum vitae of the assessor can be found in Appendix XIII.

SECTION 3:

Method of manufacture, statement of compliance with GMP

The manufacturing process for the product can be found in Appendix XIV.

The product is manufactured in accordance with ISO 22716, standards developed for and by the cosmetic industry. Please refer to the ISO certificate in Appendix XV.

SECTION 4:

Proof of effect claimed

This product is a face paint used for makeup.

The intended use of the product can be identified through sensory evaluation. As the product label does not include any efficacy claims beyond those stated above, no substantiation documents for efficacy are required.

SECTION 5:

Data on animal testing

According to the manufacturer's declaration, neither the product nor the substances contained have been tested on animals. The declaration can be found in Appendix XVI.

The manufacturer does not conduct animal testing on finished products unless required by regulatory authorities in a few countries.

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SECTION 1:

DESCRIPTION OF THE COSMETIC PRODUCT

Product name:	Face paint 09
Responsible Person Name（EU）:	Mid Ocean BV.
Responsible Person Address（EU）:	Wellensiekstraat 2, 6718 XZ Ede, The Netherlands.
Responsible Person Name（UK）:	Midocean Brands UK, Ltd.
Responsible Person Address（UK）:	1st Floor 5 Century Court, Tolpits Lane, Watford, Hertfordshire, England, WD18 9PX
Applicant/Company name:	Mid Ocean Brands B.V.
Address:	Unit 711-716, 7/F, Tower A, 83 King Lam Street, Cheung Sha Wan, Kowloon, Hong Kong.
Item number:	MO2807, MO8274
Vendor code:	111041
Internal product name:	**NA**
Formula number:	**NA**
Code number:	**NA**
Product family:	Make-up products
Product sub-family:	Body or face paint, including carnival make up
Product type:	Leave-on
Physical form:	Solid/pressed powder
Net Weight:	4g, 9g
Target:	Adult and children over 3 years
Country of Origin:	China
Country first placed on the market (EU):	The Netherlands
CPNP Reference	MO8274-09: 2533189, MO2807-09: 5483922
SCPN Reference	MO8274-09: UKCP-26079736, MO2807-09: UKCP-45421117

SECTION 2:

COSMETIC PRODUCT SAFETY REPORT

PART A - COSMETIC PRODUCT SAFETY INFORMATION

1 Qualitative and quantitative composition of the cosmetic product

The original formulation of the product can be found in Appendix I.

Table 1 - qualitative and quantitative composition

Red paintstick

No.	INCI Name	Wt (%)	Mixture ratio (%)	Actual Wt (%)	CAS.	Function
1	PARAFFINUM LIQUIDUM	27.90	100	27.90	232-455-8	Antistatic /mollient / Skin Protecting/solvent
2	CERA MICROCRISTALLINA	26	100	26	264-038-1	Binding/emulsion Stabilising /Opacifying/Viscosity Controlling
3	BEESWAX	15	100	15	616-889-9	Emollient/emulsifying
4	MICA	12	100	12	310-127-6	Opacifying
5	CERESIN	10	100	10	232-290-1	Antistatic/Binding/Emulsion Stabilising /Opacifying/Viscosity Controlling
6	METHYLHEPTYL PALMITATE	5	98	5	215-675-9	Skin Conditioning / Emollient
7	CI 15850	4	100	4	227-497-9	Cosmetic colorant
8	PHENOXYETHANOL	0.1	100	0.1	204-589-7	Preservative

White paintstick

No.	INCI Name	Wt (%)	Mixture ratio (%)	Actual Wt (%)	CAS.	Function
1	PARAFFINUM LIQUIDUM	27.90	100	27.90	232-455-8	Antistatic /mollient / Skin Protecting/solvent
2	CERA MICROCRISTALLINA	26	100	26	264-038-1	Binding/emulsion Stabilising /Opacifying/Viscosity Controlling
3	BEESWAX	15	100	15	616-889-9	Emollient/emulsifying
4	MICA	12	100	12	310-127-6	Opacifying
5	CERESIN	10	100	10	232-290-1	Antistatic/Binding/Emulsion Stabilising /Opacifying/Viscosity Controlling
6	METHYLHEPTYL PALMITATE	5	98	5	1341-38-4	Skin Conditioning / Emollient
7	CI 77891	4	100	4	12225-21-7	Cosmetic colorant
8	PHENOXYETHANOL	0.1	100	0.1	204-589-7	Preservative

Green paintstick

No.	INCI Name	Wt (%)	Mixture ratio (%)	Actual Wt (%)	CAS.	Function
1	PARAFFINUM LIQUIDUM	27.90	100	27.90	232-455-8	Antistatic /mollient / Skin Protecting/solvent
2	CERA MICROCRISTALLINA	26	100	26	264-038-1	Binding/emulsion Stabilising /Opacifying/Viscosity Controlling
3	BEESWAX	15	100	15	616-889-9	Emollient/emulsifying
4	MICA	12	100	12	310-127-6	Opacifying
5	CERESIN	10	100	10.	232-290-1	Antistatic/Binding/Emulsion Stabilising /Opacifying/Viscosity Controlling
6	METHYLHEPTYL PALMITATE	5	98	5	1341-38-4	Skin Conditioning / Emollient
7	CI 74260	4	100	4	215-524-7	Cosmetic colorant
8	PHENOXYETHANOL	0.1	100	0.1	204-589-7	Preservative

2 Physical/chemical characteristics and stability of the cosmetic product

2.1 Physical/chemical characteristics of substances or mixtures

Physical/chemical properties of the substance or mixture can be found in the MSDS or COA document in Appendix II.

Table 2 - specifications of each raw material

No.	Raw material name	Supplier	INCI Name	Composition (%)	Assay or Active Ingredient (%)
1	PARAFFINUM LIQUIDUM		PARAFFINUM LIQUIDUM	100	97.0~103.0
2	Microcrystalline paraffin wax		CERA MICROCRISTALLINA	100	n.a.
3	Beeswax		BEESWAX	100	n.a.
4	Mica Powder		MICA	100	n.a.
5	White ozocerite		CERESIN	100	n.a.
6	CRODAMOL™ OP-LQ-(SG)		METHYLHEPTYL PALMITATE	100	≥ 98
7	Phenoxyethanol		PHENOXYETHANOL	100	⩾ 99.80
8	Red		CI 15850	100	97.0~103.0
9	titanium dioxide		CI 77891	100	97.0~103.0
9	Green		CI 74260	100	n.a.

According the wording of conditions of use and warnings for CI 77266 of Regulation EC) No 1223/2009 of the European parliament and of the council: purity > 97 %, with the following impurity profile: ash content ⩽ 0,15 %, total sulphur ⩽ 0,65 %, total PAH ⩽ 500 ppb and benzo(a)pyrene ⩽ 5 ppb, ibenz (a,h) anthracene ⩽ 5 ppb, total As ⩽ 3 ppm, total Pb ⩽ 10 ppm, total Hg ⩽ 1 ppm. The CI 77266 in the product comply with the above requirements, please refer to Appendix II.

The product is free of nanomaterials and CMR substances, which can be found in the declaration in Appendix III.

2.2 Physical/chemical characteristics of the finished cosmetic product

This description is to contain the specifications of the finished product. Please refer to Appendix IV for the original product specification document.
- Physical form: Solid:Cream/ paste
- Color: Refer to standard sample
- Odor: Weak aromatic

2.3 Stability of the cosmetic product

The product has undergone stability testing and preservative challenge testing. The product's PAO (Period After Opening) is 18 months, which is labelled on the product packaging. Please refer to Appendix V for detailed information.

2.3.1 Stability testing

Stability test is an destruction test on the packaged product. The formulations of the Face paint series are similar, and the primary packaging materials are identical. Therefore, destruction testing was performed only on the red paintstick. The original report is given in Appendix VI.

The products were stored for 3 month at -5±1°C, room condition, and 40±2°C, 60±5% humidity. The appearance, odor, colour and pH of the products no significant changes have occurred at 3 months.

2.3.2 Preservative efficacy study

The preservative challenge test was performed on red paintstick in accordance with European Pharmacopoeia 10.0 5.1.3, as the formulations are similar and share the same preservative system of face paint series. The original report is presented in Appendix VII.

For escherichia coli, staphylococcus aureus and pseudomonas aeruginosa, the logarithmic difference of the test results on day 14 was greater than 3; the logarithmic difference of the test results from day 14 to 28 did not decrease.

For candida albicans and aspergillus brasiliensis, the logarithmic difference of the results was greater than 1 at day 14; there was no decrease in the logarithmic difference of the results from day 14 to day 28.

3 Microbiological quality

According to the SCCS's 'Notes of guidance for the testing of cosmetic ingredients and the safety evaluation' (12th Revision, 2023), total aerobic mesophilic microorganisms (bacteria plus yeast and mould) should not exceed 10^3 cfu/g or 10^3 cfu/mL in Category 2 products (i.e. all but cosmetics intended for children under 3 years of age, to be used in the eye area and on mucous membranes). *Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Candida albicans* are considered to be the main potential pathogens in cosmetic products. These should not to be detectable in 1 g or mL in Category 2 products.

The product was microbiologically tested and all indicators met the requirements. The original report is attached in Appendix VIII for further reference.

4 Impurities, traces, information about the packaging material

4.1 Impurities and traces

The product was tested for traces of lead, mercury, arsenic, antimony, cadmium and soluble nickel, and the results met the requirements of EU cosmetic limit(s) (Germany BVL 2016), which can be found in Appendix IX.

4.2 The relevant characteristics of packaging material

The relevant characteristics of packaging materials in direct contact with the finished product are important for the safety of the cosmetic product.

According to Appendix X, the packaging is compliant with EU REACH Regulation and does not contain any substances mentioned in the candidate list of SVHC.

The product is offered in two packaging formats, the material compositions of the two container (or primary packaging) types are as follows.

Table 3 - Packaging composition

MO2807

Raw material name	Description	CAS	Supplier

Polystyrene (PS)	Plastic lid, colorless transparent hard plastic	9003-53-6	
Polypropylene (PP)	Plastic holder, white hard plastic	9003-07-0	
Polypropylene (PP)	Plastic case, white hard plastic	9003-07-0	

MO28274

Raw material name	Description	CAS	Supplier
Polystyrene (PS)	Plastic case, colorless transparent hard plastic	9003-53-6	
Acrylonitrile utadiene Styrene (ABS)	Plastic lid and case, beige hard plastic with silvery coating	97048-04-9	
Acrylonitrile utadiene Styrene (ABS)	Plastic knob, black hard plastic	97048-04-9	
Polypropylene (PP)	Plastic holder, translucent hard plastic	9003-07-0	

4.2.1 Chemical purity of the packaging materials

The analytical testing result of container indicated Cadmium, Lead, Mercury, Hexavalent Chromium complies with the limit of European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste and its amended directives. The original report is given in Appendix XI.

4.2.2 Compatibility of package

The formulations of the Face paint series are similar, and the primary packaging materials are identical. Therefore, Packaging compatibility tests was performed only on the red paintstick. The original report is given in Appendix VI.

The products were stored for 3 month at -5±1°C, room condition, and 40±2°C, 60±5% humidity. The appearance, odor, colour, pH and appearance of the package of the products no significant changes have occurred at 3 months.

5 Normal and reasonably foreseeable use

This product is a face paint used for makeup.

The normal use of this product is intended to be applied as face paint by 3 years old and above. Other usage is not foreseeable.

As the printed instructions of use and warning is clear to describe the product usage and apporiate enough to avoid misuse, no special warnings or instructions of use are further required.

Please refer to the product label attached in Appendix XII for further reference.

6 Exposure to the cosmetic product

Area of application	Face
Surface area of application (cm^2)	565
Amount applied (g) per day	0.51
Duration	Leave-on
Retention factor	1
Frequency	$1/day^2$
Possible exposure routes	Dermal
Target group for use	Adult and children over 3 years

No nanomaterials are used in the product, so the effect of particle size on exposure is not considered.

7 Exposure to the substances

The assessment of the exposure to each of the substances contained in the cosmetic product is necessary in order to assess the risk associated with each individual substance.

Exposure levels to the substances are generally calculated based on the following equation, as outlined in the SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation (12th Revision, 2023).

$$SED = E_{product} \times \frac{C(\%)}{100} \times \frac{DAp(\%)}{100} \times Rf$$

Where,
SED (mg/kg bw/day): Systemic exposure dose
Eproduct (mg/kg bw/day): Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application.
C(%): Concentration of the substance under study in the finished cosmetic product on the application site
DAp (%): Dermal absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions. Calculated as 100 %.
Rf: Retention factor

Default values for body weights of children is 23.1kg.

Table 4 - systemic exposure dose of each ingredient

Red paintstick

INGREDIENT (INCI)	% (W/W)	Retention factor	Amount applied (g) per day	Eproduct (mg/kg bw/day)	SED （mg/kg/day）
PARAFFINUM LIQUIDUM	27.90	1	0.51	510	6.15974026
CERA MICROCRISTALLINA	26	1	0.51	510	5.74025974
BEESWAX	15	1	0.51	510	3.311688312
MICA	12	1	0.51	510	2.649350649
CERESIN	10	1	0.51	510	2.207792208
METHYLHEPTYL PALMITATE	5	1	0.51	510	1.103896104
CI 15850	4	1	0.51	510	0.883116883
PHENOXYETHANOL	0.1	1	0.51	510	0.022077922

White paintstick

INGREDIENT (INCI)	% (W/W)	Retention factor	Amount applied (g) per day	Eproduct (mg/kg bw/day)	SED （mg/kg/day）
PARAFFINUM LIQUIDUM	27.90	1	0.51	510	6.15974026
CERA MICROCRISTALLINA	26	1	0.51	510	5.74025974
BEESWAX	15	1	0.51	510	3.311688312
MICA	12	1	0.51	510	2.649350649
CERESIN	10	1	0.51	510	2.207792208
METHYLHEPTYL PALMITATE	5	1	0.51	510	1.103896104
CI 77891	4	1	0.51	510	0.883116883
PHENOXYETHANOL	0.1	1	0.51	510	0.022077922

Green paintstick

INGREDIENT (INCI)	% (W/W)	Retention factor	Amount applied (g) per day	Eproduct (mg/kg bw/day)	SED （mg/kg/day）
PARAFFINUM LIQUIDUM	27.90	1	0.51	510	6.15974026
CERA MICROCRISTALLINA	26	1	0.51	510	5.74025974
BEESWAX	15	1	0.51	510	3.311688312
MICA	12	1	0.51	510	2.649350649
CERESIN	10	1	0.51	510	2.207792208
METHYLHEPTYL PALMITATE	5	1	0.51	510	1.103896104
CI 74260	4	1	0.51	510	0.883116883
PHENOXYETHANOL	0.1	1	0.51	510	0.022077922

8 Toxicological profile of the substances

Table 5 - safety assessment conclusion of all ingredients

Red paintstick

No.	INGREDIENT (INCI)	%(w/w)	Max. allowed conc. in reference	Margin of Safety	Assessment Conclusion	Reference
1	PARAFFINUM LIQUIDUM	27.90	87.95	n.a.	Conforms to accepted external review in a cosmetic product.	China NIFDC: Raw Material Usage Information for Marketed Products
2	CERA MICROCRISTALLINA	26	50	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
3	BEESWAX	15	56	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel.Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 2005,24(Suppl. 1) : 1–102
4	MICA	12	Mica, a silicate mineral with generally negligible transdermal absorption and potential systemic toxicity. And it can be used as coloring agent for cosmetics in EU, USA, China and other regions without restriction requirements.			
5	CERESIN	10	25	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
6	METHYLHEPTYL PALMITATE	5	n.a.	855.15	MOS > 100, the raw material is considered acceptable for safety evaluation.	QSAR Toolbox. Detailed information can be found in the description below and Appendix XVII
7	CI 15850	4	n.a.	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex IV
8	PHENOXYETHANOL	0.1	1.0	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex V

White paintstick

No.	INGREDIENT (INCI)	%(w/w)	Max. allowed	Margin of	Assessment Conclusion	Reference

			conc. in reference	Safety		
1	PARAFFINUM LIQUIDUM	27.90	87.95	n.a.	Conforms to accepted external review in a cosmetic product.	China NIFDC: Raw Material Usage Information for Marketed Products
2	CERA MICROCRISTALLINA	26	50	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
3	BEESWAX	15	56	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel.Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 2005,24(Suppl. 1) : 1–102
4	MICA	12	Mica, a silicate mineral with generally negligible transdermal absorption and potential systemic toxicity. And it can be used as coloring agent for cosmetics in EU, USA, China and other regions without restriction requirements.			
5	CERESIN	10	25	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
6	METHYLHEPTYL PALMITATE	5	n.a.	855.15	MOS > 100, the raw material is considered acceptable for safety evaluation.	QSAR Toolbox. Detailed information can be found in the description below and Appendix XVII
7	CI 77891	4	n.a.	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex IV
8	PHENOXYETHANOL	0.1	1.0	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex V

Green paintstick

No.	INGREDIENT (INCI)	%(w/w)	Max. allowed conc. in reference	Margin of Safety	Assessment Conclusion	Reference
1	PARAFFINUM LIQUIDUM	27.90	87.95	n.a.	Conforms to accepted external review in a cosmetic product.	China NIFDC: Raw Material Usage Information for Marketed Products
2	CERA MICROCRISTALLINA	26	50	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
3	BEESWAX	15	56	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel.Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 2005,24(Suppl. 1) : 1–102
4	MICA	12	Mica, a silicate mineral with generally negligible transdermal absorption and potential systemic toxicity. And it can be used as coloring agent for cosmetics in EU, USA, China and other regions without restriction requirements.			

5	CERESIN	10	25	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
6	METHYLHEPTYL PALMITATE	5	n.a.	855.15	MOS > 100, the raw material is considered acceptable for safety evaluation.	QSAR Toolbox. Detailed information can be found in the description below and Appendix XVII
7	CI 74260	4	n.a.	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex IV
8	PHENOXYETHANOL	0.1	1.0	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex V

Toxicological profile of METHYLHEPTYL PALMITATE (CAS# 1341-38-4, Isooctyl palmitate)

Toxicological endpoints[1]:

Acute toxicity: The acute oral LD_{50} value of the test item methylheptyl palmitate was estimated > 5000 $mg/kg^{-1}$of body weight for female rats.

Skin irritation: The test item 1341-38-4 Isooctyl palmitate is considered non-irritant to skin in the Reconstructed human Epidermis (RhE) Test Method.

Eye irritation: The test item 1341-38-4 Isooctyl palmitate showed no effects on the cornea of the bovine eye.

Skin sensitization: The skin sensitizing potential of Isooctyl palmitate was assessed using the murine local lymph node assay. Based on the results of the study, Isooctyl palmitate is not considered a skin sensitizer under the conditions of the LLNA study.

Genetic toxicity: Based on the results of the study it is concluded that 1341-38-4 Isooctyl palmitate is not mutagenic in the Salmonella typhimurium strains TA97a, TA98, TA100, TA102 and TA1535 in the absence and presence of metabolic activation under the experi-mental conditions in this study.

Repeated dose toxicity: No available data. Using the QSAR Toolbox for read-across analysis, the predicted NOAEL value is 944 mg/kg bw/d[2].

Conclusion:

A calculated Margin of Safety (MoS) value more than 100 is deemed acceptable for safety evaluation.

9 Undesirable effects and serious undesirable effects

None reported.

10 Information on the cosmetic product

No other relevant information.

PART B - Cosmetic Product Safety Assessment

1 Assessment conclusion

This cosmetic product can be considered as safe to human health and compliant with the EU Cosmetics Regulation (EC) 1223/2009 when used under normal and reasonably foreseeable use.

This assessment is conditional on the Responsible Person complying with the conditions in the notes and any other purity restrictions listed.

[1]ECHA. REACH registered subatances factsheets of Isooctyl palmitate (CAS no. 1341-38-4)
https://echa.europa.eu/registration-dossier/-/registered-dossier/29334/11

[2] Prediction of NOAEL of Read-across prediction report from QSAR TOOLBOX.

2 Labelled warnings and instructions of use

Detailed warnings and instructions of use are labelled on the product packaging.

Warning: Not suitable for children under 3 years. Small parts.
Achtung: Nicht für Kinder unter dreiJahren geeignet. Kleine Teile.
Attention. Ne convient pasaux enfants de moins de 3 ans. Petites pièces.
Advertencia. No conveniente para niños menores de 3 años. Piezas pequeñas.
Avvertenza. Non adatto a bambini di età inferiore a 3 anni. Contiene parti piccole.
Waarschuwing: Niet geschikt voor kinderen jonger dan 3 jaar. Kleine onderdelen.
Ostrzeżenie. Nieodpowiednie dla dzieci w wieku poniżej 3 lat. Male części.

3 Reasoning

This study evaluated the Face paint.

None of the ingredients used in the formulation are classified as hazardous substances. Based on the assessment in Part A, Section 8 "Toxicological Profile of the Substances", the use of all substances in the product is safe.

Provided the manufacturer's instructions are followed and all the ingredients used are of cosmetic grade or other appropriate, 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.

4 Assessor's credential and approval of Part B

Assessor: Xiaopeng Zhang, PhD, DABT, DCST

Name: Xiaopeng Zhang
Address: 288 Qiuyi Road, Binjiang District, Hangzhou, Zhejiang Province, China

Signature: Xiaopeng Zhang

Date: 31/10/2025

The curriculum vitae of the assessor can be found in Appendix XIII.

SECTION 3:

Method of manufacture, statement of compliance with GMP

The manufacturing process for the product can be found in Appendix XIV.

The product is manufactured in accordance with ISO 22716, standards developed for and by the cosmetic industry. Please refer to the ISO certificate in Appendix XV.

SECTION 4:

Proof of effect claimed

This product is a face paint used for makeup.

The intended use of the product can be identified through sensory evaluation. As the product label does not include any efficacy claims beyond those stated above, no substantiation documents for efficacy are required.

SECTION 5:

Data on animal testing

According to the manufacturer's declaration, neither the product nor the substances contained have been tested on animals. The declaration can be found in Appendix XVI.

The manufacturer does not conduct animal testing on finished products unless required by regulatory authorities in a few countries.

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SECTION 1:

DESCRIPTION OF THE COSMETIC PRODUCT

Product name:	Face paint 37
Responsible Person Name（EU）:	Mid Ocean BV.
Responsible Person Address（EU）:	Wellensiekstraat 2, 6718 XZ Ede, The Netherlands.
Responsible Person Name（UK）:	Midocean Brands UK, Ltd.
Responsible Person Address（UK）:	1st Floor 5 Century Court, Tolpits Lane, Watford, Hertfordshire, England, WD18 9PX
Applicant/Company name:	Mid Ocean Brands B.V.
Address:	Unit 711-716, 7/F, Tower A, 83 King Lam Street, Cheung Sha Wan, Kowloon, Hong Kong.
Item number:	MO2807, MO8274
Vendor code:	111041
Internal product name:	**NA**
Formula number:	**NA**
Code number:	**NA**
Product family:	Make-up products
Product sub-family:	Body or face paint, including carnival make up
Product type:	Leave-on
Physical form:	Solid/pressed powder
Net Weight:	4g, 9g
Target:	Adult and children over 3 years
Country of Origin:	China
Country first placed on the market (EU):	The Netherlands
CPNP Reference	MO8274-37: 2533196, MO2807-37: 5483934
SCPN Reference	MO8274-37: UKCP-94358093, MO2807-37: UKCP-42482342

SECTION 2:

COSMETIC PRODUCT SAFETY REPORT

PART A - COSMETIC PRODUCT SAFETY INFORMATION

1 Qualitative and quantitative composition of the cosmetic product

The original formulation of the product can be found in Appendix I.

Table 1 - qualitative and quantitative composition

Red paintstick

No.	INCI Name	Wt (%)	Mixture ratio (%)	Actual Wt (%)	CAS.	Function
1	PARAFFINUM LIQUIDUM	27.90	100	27.90	232-455-8	Antistatic /mollient / Skin Protecting/solvent
2	CERA MICROCRISTALLINA	26	100	26	264-038-1	Binding/emulsion Stabilising /Opacifying/Viscosity Controlling
3	BEESWAX	15	100	15	616-889-9	Emollient/emulsifying
4	MICA	12	100	12	310-127-6	Opacifying
5	CERESIN	10	100	10	232-290-1	Antistatic/Binding/Emulsion Stabilising /Opacifying/Viscosity Controlling
6	METHYLHEPTYL PALMITATE	5	98	5	215-675-9	Skin Conditioning / Emollient
7	CI 15850	4	100	4	227-497-9	Cosmetic colorant
8	PHENOXYETHANOL	0.1	100	0.1	204-589-7	Preservative

White paintstick

No.	INCI Name	Wt (%)	Mixture ratio (%)	Actual Wt (%)	CAS.	Function
1	PARAFFINUM LIQUIDUM	27.90	100	27.90	232-455-8	Antistatic /mollient / Skin Protecting/solvent
2	CERA MICROCRISTALLINA	26	100	26	264-038-1	Binding/emulsion Stabilising /Opacifying/Viscosity Controlling
3	BEESWAX	15	100	15	616-889-9	Emollient/emulsifying
4	MICA	12	100	12	310-127-6	Opacifying
5	CERESIN	10	100	10	232-290-1	Antistatic/Binding/Emulsion Stabilising /Opacifying/Viscosity Controlling
6	METHYLHEPTYL PALMITATE	5	98	5	1341-38-4	Skin Conditioning / Emollient
7	CI 77891	4	100	4	12225-21-7	Cosmetic colorant
8	PHENOXYETHANOL	0.1	100	0.1	204-589-7	Preservative

Blue paintstick

No.	INCI Name	Wt (%)	Mixture ratio (%)	Actual Wt (%)	CAS.	Function
1	PARAFFINUM LIQUIDUM	27.90	100	27.90	232-455-8	Antistatic /mollient / Skin Protecting/solvent
2	CERA MICROCRISTALLINA	26	100	26	264-038-1	Binding/emulsion Stabilising /Opacifying/Viscosity Controlling
3	BEESWAX	15	100	15	616-889-9	Emollient/emulsifying
4	MICA	12	100	12	310-127-6	Opacifying
5	CERESIN	10	100	10	232-290-1	Antistatic/Binding/Emulsion Stabilising /Opacifying/Viscosity Controlling
6	METHYLHEPTYL PALMITATE	5	98	5	215-675-9	Skin Conditioning / Emollient
7	CI 42090	4	100	4	227-497-9	Cosmetic colorant
8	PHENOXYETHANOL	0.1	100	0.1	204-589-7	Preservative

2 Physical/chemical characteristics and stability of the cosmetic product

2.1 Physical/chemical characteristics of substances or mixtures

Physical/chemical properties of the substance or mixture can be found in the MSDS or COA document in Appendix II.

Table 2 - specifications of each raw material

No.	Raw material name	Supplier	INCI Name	Composition (%)	Assay or Active Ingredient (%)
1	PARAFFINUM LIQUIDUM		PARAFFINUM LIQUIDUM	100	97.0~103.0
2	Microcrystalline paraffin wax		CERA MICROCRISTALLINA	100	n.a.
3	Beeswax		BEESWAX	100	n.a.
4	Mica Powder		MICA	100	n.a.
5	White ozocerite		CERESIN	100	n.a.
6	CRODAMOL™ OP-LQ-(SG)		METHYLHEPTYL PALMITATE	100	≥ 98
7	Phenoxyethanol		PHENOXYETHANOL	100	⩾ 99.80
8	Red		CI 15850	100	97.0~103.0
9	titanium dioxide		CI 77891	100	97.0~103.0
9	Blue		CI 42090	100	n.a.

The product is free of nanomaterials and CMR substances, which can be found in the declaration in Appendix III.

2.2 Physical/chemical characteristics of the finished cosmetic product

This description is to contain the specifications of the finished product. Please refer to Appendix IV for the original product specification document.
- Physical form: Solid:Cream/ paste
- Color: Refer to standard sample
- Odor: Weak aromatic

2.3 Stability of the cosmetic product

The product has undergone stability testing and preservative challenge testing. The product's PAO (Period After Opening) is 18 months, which is labelled on the product packaging. Please refer to Appendix V for detailed information.

2.3.1 Stability testing

Stability test is an destruction test on the packaged product. The formulations of the Face paint series are similar, and the primary packaging materials are identical. Therefore, destruction testing was performed only on the red paintstick. The original report is given in Appendix VI.

The products were stored for 3 month at -5±1°C, room condition, and 40±2°C, 60±5% humidity. The appearance, odor, colour and pH of the products no significant changes have occurred at 3 months.

2.3.2 Preservative efficacy study

The preservative challenge test was performed on red paintstick in accordance with European Pharmacopoeia 10.0 5.1.3, as the formulations are similar and share the same preservative system of face paint series. The original report is presented in Appendix VII.

For escherichia coli, staphylococcus aureus and pseudomonas aeruginosa, the logarithmic difference of the test results on day 14 was greater than 3; the logarithmic difference of the test results from day 14 to 28 did not decrease.

For candida albicans and aspergillus brasiliensis, the logarithmic difference of the results was greater than 1 at day 14; there was no decrease in the logarithmic difference of the results from day 14 to day 28.

3 Microbiological quality

According to the SCCS's 'Notes of guidance for the testing of cosmetic ingredients and the safety evaluation' (12th Revision, 2023), total aerobic mesophilic microorganisms (bacteria plus yeast and mould) should not exceed 10^3 cfu/g or 10^3 cfu/mL in Category 2 products (i.e. all but cosmetics intended for children under 3 years of age, to be used in the eye area and on mucous membranes). *Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Candida albicans* are considered to be the main potential pathogens in cosmetic products. These should not to be detectable in 1 g or mL in Category 2 products.

The product was microbiologically tested and all indicators met the requirements. The original report is attached in Appendix VIII for further reference.

4 Impurities, traces, information about the packaging material

4.1 Impurities and traces

The product was tested for traces of lead, mercury, arsenic, antimony, cadmium and soluble nickel, and the results met the requirements of EU cosmetic limit(s) (Germany BVL 2016), which can be found in Appendix IX.

4.2 The relevant characteristics of packaging material

The relevant characteristics of packaging materials in direct contact with the finished product are important for the safety of the cosmetic product.

According to Appendix X, the packaging is compliant with EU REACH Regulation and does not contain any substances mentioned in the candidate list of SVHC.

The product is offered in two packaging formats, the material compositions of the two container (or primary packaging) types are as follows.

Table 3 - Packaging composition

MO2807

Raw material name	Description	CAS	Supplier
Polystyrene (PS)	Plastic lid, colorless transparent hard plastic	9003-53-6	
Polypropylene (PP)	Plastic holder, white hard plastic	9003-07-0	
Polypropylene (PP)	Plastic case, white hard plastic	9003-07-0	

MO28274

Raw material name	Description	CAS	Supplier
Polystyrene (PS)	Plastic case, colorless transparent hard plastic	9003-53-6	

Acrylonitrile utadiene Styrene (ABS)	Plastic lid and case, beige hard plastic with silvery coating	97048-04-9	
Acrylonitrile utadiene Styrene (ABS)	Plastic knob, black hard plastic	97048-04-9	
Polypropylene (PP)	Plastic holder, translucent hard plastic	9003-07-0	

4.2.1 Chemical purity of the packaging materials

The analytical testing result of container indicated Cadmium, Lead, Mercury, Hexavalent Chromium complies with the limit of European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste and its amended directives. The original report is given in Appendix XI.

4.2.2 Compatibility of package

The formulations of the Face paint series are similar, and the primary packaging materials are identical. Therefore, Packaging compatibility tests was performed only on the red paintstick. The original report is given in Appendix VI.

The products were stored for 3 month at -5±1°C, room condition, and 40 ± 2°C, 60 ± 5% humidity. The appearance, odor, colour, pH and appearance of the package of the products no significant changes have occurred at 3 months.

5 Normal and reasonably foreseeable use

This product is a face paint used for makeup.

The normal use of this product is intended to be applied as face paint by 3 years old and above. Other usage is not foreseeable.

As the printed instructions of use and warning is clear to describe the product usage and apporiate enough to avoid misuse, no special warnings or instructions of use are further required.

Please refer to the product label attached in Appendix XII for further reference.

6 Exposure to the cosmetic product

Area of application	Face
Surface area of application (cm^2)	565
Amount applied (g) per day	0.51
Duration	Leave-on
Retention factor	1
Frequency	$1/day^2$
Possible exposure routes	Dermal
Target group for use	Adult and children over 3 years

No nanomaterials are used in the product, so the effect of particle size on exposure is not considered.

7 Exposure to the substances

The assessment of the exposure to each of the substances contained in the cosmetic product is necessary in order to assess the risk associated with each individual substance.

Exposure levels to the substances are generally calculated based on the following equation, as outlined in the SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation (12th Revision, 2023).

$$SED = E_{product} \times \frac{C(\%)}{100} \times \frac{DAp(\%)}{100} \times Rf$$

Where,
SED (mg/kg bw/day): Systemic exposure dose
Eproduct (mg/kg bw/day): Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application.
C(%): Concentration of the substance under study in the finished cosmetic product on the application site
DAp (%): Dermal absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions. Calculated as 100 %.
Rf: Retention factor

Default values for body weights of children is 23.1kg.

Table 4 - systemic exposure dose of each ingredient

Red paintstick

INGREDIENT (INCI)	% (W/W)	Retention factor	Amount applied (g) per day	Eproduct (mg/kg bw/day)	SED (mg/kg/day)
PARAFFINUM LIQUIDUM	27.90	1	0.51	510	6.15974026
CERA MICROCRISTALLINA	26	1	0.51	510	5.74025974
BEESWAX	15	1	0.51	510	3.311688312
MICA	12	1	0.51	510	2.649350649
CERESIN	10	1	0.51	510	2.207792208
METHYLHEPTYL PALMITATE	5	1	0.51	510	1.103896104
CI 15850	4	1	0.51	510	0.883116883
PHENOXYETHANOL	0.1	1	0.51	510	0.022077922

White paintstick

INGREDIENT (INCI)	% (W/W)	Retention factor	Amount applied (g) per day	Eproduct (mg/kg bw/day)	SED (mg/kg/day)
PARAFFINUM LIQUIDUM	27.90	1	0.51	510	6.15974026
CERA MICROCRISTALLINA	26	1	0.51	510	5.74025974
BEESWAX	15	1	0.51	510	3.311688312
MICA	12	1	0.51	510	2.649350649
CERESIN	10	1	0.51	510	2.207792208
METHYLHEPTYL PALMITATE	5	1	0.51	510	1.103896104
CI 77891	4	1	0.51	510	0.883116883
PHENOXYETHANOL	0.1	1	0.51	510	0.022077922

Blue paintstick

INGREDIENT (INCI)	% (W/W)	Retention factor	Amount applied (g) per day	Eproduct (mg/kg bw/day)	SED (mg/kg/day)
PARAFFINUM LIQUIDUM	27.90	1	0.51	510	6.15974026
CERA MICROCRISTALLINA	26	1	0.51	510	5.74025974
BEESWAX	15	1	0.51	510	3.311688312
MICA	12	1	0.51	510	2.649350649
CERESIN	10	1	0.51	510	2.207792208

METHYLHEPTYL PALMITATE	5	1	0.51	510	1.103896104
CI 42090	4	1	0.51	510	0.883116883
PHENOXYETHANOL	0.1	1	0.51	510	0.022077922

8 Toxicological profile of the substances

Table 5 - safety assessment conclusion of all ingredients

Red paintstick

No.	INGREDIENT (INCI)	%(w/w)	Max. allowed conc. in reference	Margin of Safety	Assessment Conclusion	Reference
1	PARAFFINUM LIQUIDUM	27.90	87.95	n.a.	Conforms to accepted external review in a cosmetic product.	China NIFDC: Raw Material Usage Information for Marketed Products
2	CERA MICROCRISTALLINA	26	50	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
3	BEESWAX	15	56	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel.Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 2005,24(Suppl. 1) : 1–102
4	MICA	12	Mica, a silicate mineral with generally negligible transdermal absorption and potential systemic toxicity. And it can be used as coloring agent for cosmetics in EU, USA, China and other regions without restriction requirements.			
5	CERESIN	10	25	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
6	METHYLHEPTYL PALMITATE	5	n.a.	855.15	MOS > 100, the raw material is considered acceptable for safety evaluation.	QSAR Toolbox. Detailed information can be found in the description below and Appendix XVII
7	CI 15850	4	n.a.	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex IV
8	PHENOXYETHANOL	0.1	1.0	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex V

White paintstick

No.	INGREDIENT (INCI)	%(w/w)	Max. allowed conc. in reference	Margin of Safety	Assessment Conclusion	Reference
1	PARAFFINUM LIQUIDUM	27.90	87.95	n.a.	Conforms to accepted external review in a cosmetic product.	China NIFDC: Raw Material Usage Information for Marketed Products

2	CERA MICROCRISTALLINA	26	50	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
3	BEESWAX	15	56	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel.Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 2005,24(Suppl. 1) : 1–102
4	MICA	12	Mica, a silicate mineral with generally negligible transdermal absorption and potential systemic toxicity. And it can be used as coloring agent for cosmetics in EU, USA, China and other regions without restriction requirements.			
5	CERESIN	10	25	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
6	METHYLHEPTYL PALMITATE	5	n.a.	855.15	MOS > 100, the raw material is considered acceptable for safety evaluation.	QSAR Toolbox. Detailed information can be found in the description below and Appendix XVII
7	CI 77891	4	n.a.	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex IV
8	PHENOXYETHANOL	0.1	1.0	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex V

Blue paintstick

No.	INGREDIENT (INCI)	%(w/w)	Max. allowed conc. in reference	Margin of Safety	Assessment Conclusion	Reference
1	PARAFFINUM LIQUIDUM	27.90	87.95	n.a.	Conforms to accepted external review in a cosmetic product.	China NIFDC: Raw Material Usage Information for Marketed Products
2	CERA MICROCRISTALLINA	26	50	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005
3	BEESWAX	15	56	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel.Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 2005,24(Suppl. 1) : 1–102
4	MICA	12	Mica, a silicate mineral with generally negligible transdermal absorption and potential systemic toxicity. And it can be used as coloring agent for cosmetics in EU, USA, China and other regions without restriction requirements.			
5	CERESIN	10	25	n.a.	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. International Journal of Toxicolgy, 24(Suppl. 1):1–102, 2005

6	METHYLHEPTYL PALMITATE	5	n.a.	855.15	MOS > 100, the raw material is considered acceptable for safety evaluation.	QSAR Toolbox. Detailed information can be found in the description below and Appendix XVII
7	CI 42090	4	n.a.	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex IV
8	PHENOXYETHANOL	0.1	1.0	n.a.	Complies with cosmetic regulations.	EU Cosmetics Regulation EC 1223/2009 Annex V

Toxicological profile of METHYLHEPTYL PALMITATE (CAS# 1341-38-4, Isooctyl palmitate)

Toxicological endpoints[1]:

Acute toxicity: The acute oral LD_{50} value of the test item methylheptyl palmitate was estimated > 5000 $mg/kg^{-1}$of body weight for female rats.

Skin irritation: The test item 1341-38-4 Isooctyl palmitate is considered non-irritant to skin in the Reconstructed human Epidermis (RhE) Test Method.

Eye irritation: The test item 1341-38-4 Isooctyl palmitate showed no effects on the cornea of the bovine eye.

Skin sensitization: The skin sensitizing potential of Isooctyl palmitate was assessed using the murine local lymph node assay. Based on the results of the study, Isooctyl palmitate is not considered a skin sensitizer under the conditions of the LLNA study.

Genetic toxicity: Based on the results of the study it is concluded that 1341-38-4 Isooctyl palmitate is not mutagenic in the Salmonella typhimurium strains TA97a, TA98, TA100, TA102 and TA1535 in the absence and presence of metabolic activation under the experi-mental conditions in this study.

Repeated dose toxicity: No available data. Using the QSAR Toolbox for read-across analysis, the predicted NOAEL value is 944 mg/kg bw/d[2].

Conclusion:

A calculated Margin of Safety (MoS) value more than 100 is deemed acceptable for safety evaluation.

9 Undesirable effects and serious undesirable effects

None reported.

10 Information on the cosmetic product

No other relevant information.

PART B - Cosmetic Product Safety Assessment

1 Assessment conclusion

This cosmetic product can be considered as safe to human health and compliant with the EU Cosmetics Regulation (EC) 1223/2009 when used under normal and reasonably foreseeable use.

This assessment is conditional on the Responsible Person complying with the conditions in the notes and any other purity restrictions listed.

2 Labelled warnings and instructions of use

Detailed warnings and instructions of use are labelled on the product packaging.

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[1]ECHA. REACH registered subatances factsheets of Isooctyl palmitate (CAS no. 1341-38-4)
https://echa.europa.eu/registration-dossier/-/registered-dossier/29334/11

[2] Prediction of NOAEL of Read-across prediction report from QSAR TOOLBOX.

Warning: Not suitable for children under 3 years. Small parts.
Achtung: Nicht für Kinder unter drei Jahren geeignet. Kleine Teile.
Attention. Ne convient pas aux enfants de moins de 3 ans. Petites pièces.
Advertencia. No conveniente para niños menores de 3 años. Piezas pequeñas.
Avvertenza. Non adatto a bambini di età inferiore a 3 anni. Contiene parti piccole.
Waarschuwing: Niet geschikt voor kinderen jonger dan 3 jaar. Kleine onderdelen.
Ostrzeżenie. Nieodpowiednie dla dzieci w wieku poniżej 3 lat. Male części.

3 Reasoning

This study evaluated the Face paint.

None of the ingredients used in the formulation are classified as hazardous substances. Based on the assessment in Part A, Section 8 "Toxicological Profile of the Substances", the use of all substances in the product is safe.

Provided the manufacturer's instructions are followed and all the ingredients used are of cosmetic grade or other appropriate, 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.

4 Assessor's credential and approval of Part B

Assessor: Xiaopeng Zhang, PhD, DABT, DCST

Name: Xiaopeng Zhang
Address: 288 Qiuyi Road, Binjiang District, Hangzhou, Zhejiang Province, China

Signature: Xiaopeng Zhang

Date: 31/10/2025

The curriculum vitae of the assessor can be found in Appendix XIII.

SECTION 3:

Method of manufacture, statement of compliance with GMP

The manufacturing process for the product can be found in Appendix XIV.

The product is manufactured in accordance with ISO 22716, standards developed for and by the cosmetic industry. Please refer to the ISO certificate in Appendix XV.

SECTION 4:

Proof of effect claimed

This product is a face paint used for makeup.

The intended use of the product can be identified through sensory evaluation. As the product label

does not include any efficacy claims beyond those stated above, no substantiation documents for efficacy are required.

SECTION 5:

Data on animal testing

According to the manufacturer's declaration, neither the product nor the substances contained have been tested on animals. The declaration can be found in Appendix XVI.

The manufacturer does not conduct animal testing on finished products unless required by regulatory authorities in a few countries.

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