

CONSUMER PRODUCTS SERVICES DIVISION

# NINGBO LOFOS STATIONERY CO., LTD.

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**REN GUANG ZE** 

NINGBO LOFOS STATIONERY CO., LTD.

NO. 529, MINGZHOU WEST ROAD, BEILUN, NINGBO, CHINA

Sample Description: ACRYLIC INK

Vendor: N/A Sample Quantity: N/A

Manufacturer: N/A Style No(s) PMK900-PMK935

SKN/SKU No.: Buyer: N/A N/A PO No.: Labeled Age Grade: N/A N/A Appropriate Age Grade: N/A Ref #: N/A Client Specified Age N/A Country of Origin: N/A

Grade:

Tested Age Grade: N/A Assortment No.: N/A UPC Code: N/A Country of N/A

Destination:

# **EXECUTIVE SUMMARY:**

The sample(s) MEETS the following requirement(s):

TEST REQUESTED	CONCLUSION	Remark
LHAMA	REFER TO PAGE 2-5	/

# BVCPS (Shanghai) Nanjing branch contact information for this report

#### **Technical Questions:**

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# **Concerns About Billing and General Inquires:**

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## **RESULTS:**

Client:



# **Toxicological Risk Assessment & LHAMA**

Report 17-11248-RA74160

# Art white

> NINGBO LOFOS STATIONERY CO.,LTD NO.529, MINGZHOU WEST ROAD, BEILUN, NINGBO, CHINA

> > PHYSICAL / CHEMICAL CHARACTERISTICS

 Appearance:
 Liquid
 Viscosity:
 Not Provided

 Odour:
 Characteristic
 Water Solubility:
 Not Provided

 Melting Point:
 Not Provided
 Log Kow:
 Not Provided

 pH:
 Not Provided
 Particle Size:
 Not Provided

Specific Gravity: Not Provided

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

### FORMULATION OVERVIEW

The formulation of this product has not been disclosed, and is held in confidence by Delphic HSE Solutions Ltd.

For information concerning the formulation of this product, please refer any enquiries to the manufacturer.

SAFETY WARNINGS / INSTRUCTIONS

Use of this product by children should be supervised by an adult. Do not ingest.



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#### **RESULTS:**

#### **IMPURITIES & TRACE MATERIALS**

The formulation of this product has not been disclosed, and is held in confidence by Delphic HSE Solutions Ltd.

For information concerning the formulation of this product, please refer any enquiries to the manufacturer.

#### EXPOSURE SCENARIO

Intended Consumer: Children 6+ Minimum Expected Body Weight 20.5kg
Single Exposure: 1 q | 1 x Day Diluted in use: No

Retention Factor: 1 Retained Exposure: 48.780 mg/kg/day

Exposure to Neat Product: Exposure to Diluted Product: Product Not Diluted in Use

Exposure to Neat Product:

Body Site(s): Hands

Surface Area: 517 cm<sup>2</sup>
Exposure Level: 1.934 mg/cm<sup>2</sup>
Exposure Time: Removed at end of day.

#### Manufacturers Instructions for Use

No specific instructions for use were provided for review.

#### Information on Previous Sales / Complaints

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

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

### Information on User Trials / Product Testing

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



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## **RESULTS:**

#### TOXICOLOGY & REGULATORY ASSESSMENT

#### **Product Review**

A formulation of a white paint (1g) intended for use by children of 6 years and above, for distribution to EU and US.

The ingredients used in the formulation are either not classified as hazardous, or if the particular substance is known to be hazardous on their own, the levels used in the formulation will not make the whole product classified as a health hazard and would be considered unlikely to pose a significant toxicological risk to a majority of individuals under normal conditions of use.

There is an ingredient for which the calculated Margin of Safety (MoS) is below the recommended 100-fold value. However, the calculation is based on animal toxicological data concerning oral exposure, which is not a significant route of exposure for this product type. Whilst some dermal contact is expected during normal use, dermal absorption of this substance is suggested to be limited, hence the resultant systemic exposure would be minimal that would not pose an undue risk to the user. Moreover, this substances is widely used in cosmetics. Therefore, together with the fact that it does not trigger any health hazard classifications, its current usage is considered acceptable. Nevertheless, the product is advised to be labelled with 'Use of this product by children should be supervised by an adult' and 'Do not ingest' to minimise incidental oral exposure when used by children.

The manufacturer must ensure that a main polymer ingredient used in this product must be free from benzene.

All the colorants used are permitted for use in fingerpaint or cosmetic products within EU, except for a red pigment, and without restriction for use in consumer product within US and as such would not be expected to pose an undue risk of significant adverse effects in an item of this nature.

The Naphthol AS-PH (CAS No. 92-74-0) content in the red pigment should be lower than 1%

It is noted that the updated ASTM F963—17 includes specific microbiological requirements for the cleanliness of cosmetics, liquids, pastes, putties, gels, powders, and avian feather products used in toys. As a formulation containing water it is believed that such requirements would be applicable to this product. It is noted that there are no preservative materials listed as present within this product. The manufacturer / organisation placing the product on the market must ensure these items meet the required specifications.

The manufacturer must ensure that all the raw materials are of suitably safe EU and US grade.

Assuming this is the case and the product is labelled appropriately, overall the product is expected to present a minimal toxicological risk to the majority of consumers under normal conditions of use.

There are no chronic hazard warning statements that are required on the product label in order to comply with the LHAMA regulations.

#### Skin Toxicity - Neat Product

Not expected to cause skin irritation following prolonged or repeated use Exposure to this product is unlikely to result in photo-toxic effects,

Unlikely to cause sensitisation following repeated skin contact.

Unlikely to produce systemic toxicity following skin contact.

## Eye Toxicity - Neat Product

May cause slight transient eye irritation.

#### Oral Toxicity - Neat Product

All materials if swallowed in large amounts have the potential to cause injury.

If incidentally swallowed in small amounts, the formulation as supplied is unlikely to cause any adverse effects.

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

#### **Inhalation Toxicity**

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



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## **RESULTS:**

#### CONCLUSIONS & RECOMMENDATIONS\*

## Required Safety Labelling

Use of this product by children should be supervised by an adult. Do not ingest.

# Overall Safety & Compliance

Taking into account typical exposure of children during use, the toy is unlikely to cause harm.

The use of the product as an art material will not pose a significant risk to health.

This toy is not classified as a Hazardous Substance or Mixture as per the health criteria of European CLP Regulation (EC) No 1272/2008. Provided that suitable safe grades of chemicals are used, this toy will comply with the EU Toy safety Directive 2009/48/EC and as implemented by EN71 from a toxicological perspective.

Review of the documented information for the ingredients in the formulation for this product suggests that it is not expected to be Toxic, Highly Toxic, Corrosive, Irritant or a Strong Sensitiser as defined in 16 CFR 1500.3(b)(5), 1500.3(b)(6), 1500.3(b)(7), 1500.3(b)(8) and 1500.3(b)(9) and ASTM F963-17 Standard Consumer Safety Specification for Toy Safety.

This product is considered unlikely to be of health concern for use as an artist material and will not present any serious adverse health effects following long term use as set out in the Labelling of Hazardous Art Materials Act (Public Law 100- 695). It complies with the safety requirements of ASTM D-4236-94(2016).



Toxicological & Regulatory Assessor

Dr J Wakefield, BSc(Hons), MSd, PhD, Eurotox Registered Toxicologist

27 Nov 2020

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