



CONSUMER PRODUCTS SERVICES DIVISION

LEGAMI S.P.A SB

Technical Report: (6623)347-0279(5th REVISED)

April 3, 2025

Date Received: December 13, 2023

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This report is amendment of and supersedes the previous report (6623)347-0279(4th REVISED) dated on March 27, 2025

NATASCIA GHILARDI /GABRIELE PIROVANO

LEGAMI S.P.A SB

VIA STEZZANO 18 AZZANO SAN PAOLO 24052 (BG) – ITALY

Sample Description:

WRITING IS MAGIC – DINO
WRITING IS MAGIC – CHRISTMAS TREE;
WRITING IS MAGIC – SANTA CLAUS;
WRITING IS MAGIC – KITTY;
WRITING IS MAGIC – UNICORN;
WRITING IS MAGIC – PUMPKIN
WRITING IS MAGIC – HEART
WRITING IS MAGIC – SPIDER

Vendor:

LEGAMI S.P.A SB

Sample Size:

1 PACK

Manufacturer:

N/A

Style No(s):

N/A

Buyer:

N/A

SKN/SKU No.:

N/A

Labeled Age Grade:

N/A

PO No.:

N/A

Appropriate Age Grade:

N/A

Item No.:

DP0001, DPKIT1
TPE0001, TPEKIT1
SPE0001, SPEKIT1
KP0001, KPKIT1
UP0001, UPKIT1
PP0001, PPKIT1
HPL0001, HPLKIT1
SPP0001, SPPKIT1
MADE IN CHINA
EU/UK/US/CAN/AUS/
NZ/GSO

Client Specified Age Grade:

3+, TOY

Country of Origin:

MADE IN CHINA

Tested Age Grade:

N/A

Assortment No.:

N/A

UPC Code:

N/A

Country of Destination:

EU/UK/US/CAN/AUS/
NZ/GSO

Color:

N/A

EXECUTIVE SUMMARY:

TEST REQUESTED	CONCLUSION	Remark
1) LHAMA	REFER TO BELOW PAGES	/
2) TOXICOLOGICAL RISK ASSESSMENT	REFER TO BELOW PAGES	/



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Note:

1. With the client's prior consent, the LHAMA & TRA were the subcontracted test items.
2. As per client's request, updated the result and data in the 5th revised report.

BVCPS (SHANGHAI) GENERAL CONTACT INFORMATION FOR THIS REPORT

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LEON DENG
PRODUCT LINE MANAGER (TOY DIVISION)

The following sample was submitted and identified by the client as Writing is magic - Dino, Christmas tree, Santa Claus, Kitty, Unicorn, pumpkin, Heart, Spider (1 formulation and 2 additional colors).

Net Weight/Volume	:	0.1 g/pc/color
Style/Item No.	:	DP0001, DPKIT1 TPE0001, TPEKIT1 SPE0001, SPEKIT1 KP0001, KPKIT1 UP0001, UPKIT1 PP0001, PPKIT1 HPL0001, HPLKIT1 SPP0001, SPPKIT1
Manufacturer	:	/
Buyer	:	/
Region of Origin	:	China
Region of Destination	:	EU & US
Receiving Date	:	31 January 2024
Test Period	:	31 January 2024 ~ 19 February 2024

Test Requested:

1. Toxicological Risk Assessment (TRA) for the said product.
2. For compliance with Labeling of Hazardous Art Materials Act (LHAMA) and the criteria outlined in ASTM D-4236.

Test Results:

Please refer to the following pages.

Conclusion:

Please refer to *Section IV: CONCLUSIONS*.

Signed for and on behalf of
WUHAN FOCO TEST TECHNICAL SERVICES CO., LTD

Signed for and on behalf of
WUHAN FOCO TEST TECHNICAL SERVICES CO., LTD



Raul Xin
Ph.D., ERT, DABT

TOXICOLOGICAL RISK ASSESSMENT

1. The aim of this report is to assess the safety of the formulation of Writing is magic - Dino, Christmas tree, Santa Claus, Kitty, Unicorn, pumpkin, Heart in 3 assorted colors (Blue, Black, Pink) under normal and reasonably foreseeable conditions of use. The formulation is intended to be packaged by appropriate instruments to be preloaded in pen for writing by the population of 3 years old and above.
2. The formulation of Writing is magic - Dino, Christmas tree, Santa Claus, Kitty, Unicorn, pumpkin, Heart in 3 assorted colors (Blue, Black, Pink) were reviewed according to the US Consumer Product Safety Commission's Regulation-16 CFR 1500.135 and the criteria outlined in ASTM D-4236.

The report takes the risk-based approach to evaluate the safety of the said formula covering if the risk of following health hazards is acceptable for this product:

1. TRA (EU):

Local effects (skin/eye irritation; skin sensitization)

&

Systemic effects (acute toxicity, repeated dose toxicity, carcinogenicity, genotoxicity, reproductive and developmental toxicity, etc.) as defined in Annex 1, Part 3 (Health Hazards) of regulation 1272/2008/EC concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labeling of substances and mixtures.;

2. LHAMA:

In this review, the available data including the relevant data from the National Toxicology Program (NTP), International Agencies for Research on Cancer (IARC) and other sources in the National Library of Medicine Data Bank were considered to assess the need for chronic health hazard warning. In the case of absence of relevant information from public toxicity data resources, data-gap filling methods such as read-across or exposure-based waiving approaches will be employed to evaluate the potential health risk for chronic health hazards of concerned ingredients in given products under normal conditions of use.

Hence, the followings were considered in this toxicological risk assessment:

Ingredient toxicological profile

Known potential interaction among ingredients

Consumer exposure scenario

Section II. CONSUMER HEALTH RISK ASSESSMENT

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

Exposure assessment

The following assumptions have been made for assessment of exposure:

- Product category: ink;
- Physical form: gel;
- Intended use (suggested use): to be preloaded in pen for writing;
- Accessibility: this product may contact the consumer incidentally;
- Exposure route(s): primarily via dermal contact;
- Default body weight: 15.1 kg (child);
- Target population: the population of 3 years old and above.

Section III. RISK EVALUATION

The submitted formulation is intended to be preloaded in pen for writing, which is unlikely to result in irritation or sensitization via incidental contact with intact skin due to insignificant amount of dermal uptake and limited contact frequency and duration. Accidental exposure to the eye may produce irritation, but the chance to contact eyes under normal condition of use is relatively low unless deliberately. Exposure to the chemicals contained in the said formulation is considered to be short term and intermittent. Moreover, it is not expected to produce adverse systemic health effects for this product when used for its intended purpose.

Section IV. CONCLUSION

1. TRA (EU):

Taking into account the intended way the product is used, it is concluded that, under the present state of knowledge, this product does not give rise to safety concerns under normal condition of use. Thus, the product MEETS the essential safety requirements outlined in Chapter III, Article 10 of European Toy Safety Directive 2009/48/EC (relating to chemical hazards) and DOES NOT require warnings for safe use (described in Article 11). In addition, the product complied with Section III. of Annex II (Particular Safety Requirements) towards the chemical properties, but it did not include the compliance checking of the migration amount of certain elements with the specified limits as no relevant testing results were submitted for review.

2. LHAMA:

None of ingredients at levels found in this product would be expected to cause chronic toxic effects in consumers during its normal and foreseeable use conditions according to the searches of the data sources and other information sources mentioned above. Based on the available data, the submitted formulation would not be expected to produce chronic toxicity health effects on consumers when used as intended or under circumstances involving reasonably foreseeable misuse. Risk of chronic toxicity effects was evaluated in accordance with the guidelines specified by the Consumer Product Safety Commission in 16 CFR 1500.135. Hence, the product will not require any additional chronic health hazard labeling according to ASTM D4236.

Labeling Practice:

CONFORMS TO ASTM D-4236

The assessment is valid under the following conditions:

1. Potential physical, mechanical electrical and microbiological risks of the product have not been assessed or evaluated.
2. The formulation, description and other supporting documents of the product were assumed to be valid and accurate.
3. It was assumed that, neither the ingredients, nor the finished product contain contaminants or residues, which could cause adverse effect to a consumer who may be exposed, above the level set in the applicable legislation.
4. The risk evaluation can solely be applied to and is appropriate for, the product described above under the stated conditions. Modification of any components of the finished product, such as net weight, adjustment of ingredient concentrations, would require re-evaluation.
5. Heavy metal contents in the product were not assessed and evaluated.
6. This product has been assessed for compliance only with the regulation(s) specified herein.
7. In case of consumer's adverse reaction from using this formulation, the undersigned should be informed so that the formulation can be further reviewed.
8. This product has been evaluated for human health only, environmental concern/eco-toxicity were not assessed in this report.
9. The assessment is performed by using in-house method, to consumer product exposure database, public information and literature data available at the time of this assessment.

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End of report