



CONSUMER PRODUCTS SERVICES DIVISION

LEGAMI SPA SB

Technical Report: (6625)015-0747

March 13, 2025

Date Received: January 15, 2025

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NATASCIA GHILARDI /GABRIELE PIROVANO
LEGAMI SPA SB
VIA STEZZANO 18 AZZANO SAN PAOLO 24052 (BG) – ITALY

Sample Description:

LOVELY FRIENDS
REFILL LOVELY FRIENDS - BLACK
REFILL LOVELY FRIENDS - BLUE
REFILL LOVELY FRIENDS - RED
REFILL LOVELY FRIENDS - GREEN
REFILL LOVELY FRIENDS - PINK
REFILL LOVELY FRIENDS - NEON GREEN
REFILL LOVELY FRIENDS - NEON PINK
REFILL LOVELY FRIENDS - PURPLE
REFILL LOVELY FRIENDS - SKY BLUE
REFILL LOVELY FRIENDS – ORANGE

Vendor: LEGAMI SPA SB
Manufacturer: N/A
Buyer: N/A
Labeled Age Grade: N/A
Appropriate Age Grade: N/A

Sample Size: 1 PACK
Style No(s): N/A
SKN/SKU No.: N/A
PO No.: N/A
Item No.:
CPP0012
CPPKIT12
CPP0013
CPPKIT13
CPP0014
CPPKIT14
CPP0015
CPPKIT15
CPP0016
CPPKIT16
CPP0017
CPPKIT17
CPP0018
CPPKIT18
CPP0019
CPPKIT19
CPP0020
CPPKIT20
CPP0021
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CPP0022
CPPKIT22
CPP0023
CPPKIT23
CPP0024
CPPKIT24
CPP0025
CPPKIT25
REFCPP0001
REFCPP0002
REFCPP0003
REFCPP0004



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REFCPP0005
REFCPP0006
REFCPP0007
REFCPP0008
REFCPP0009
REFCPP0010
MADE IN CHINA
N/A
EU/UK/US/CAN/AUS/
NZ/GSO

Client Specified Age Grade: TOY 6+
Tested Age Grade: N/A
UPC Code: N/A

Country of Origin:
Assortment No.:
Country of Destination:

Color: N/A

EXECUTIVE SUMMARY:

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

Note:

1. With the client's prior consent, the LHAMA & TRA were the subcontracted test items.

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IDAFY ZHU
PROJECT MANAGER (HARDLINE DIVISION)



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The following sample was submitted and identified by the client as LOVELY FRIENDS (1 formulation and 9 additional colors).

Net Weight/Volume	:	1.1 g/pc/color
Style/Item No.	:	/
Manufacturer	:	Shanghai M&G Stationery Inc.
Buyer	:	LEGAMI S.p.A SB
Agent	:	Shanghai M&G Stationery Inc.
Region of Origin	:	China
Region of Destination	:	EU & US
Receiving Date	:	15 January 2025
Test Period	:	15 January 2025 ~ 13 March 2025

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 FOCOTEST 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 LOVELY FRIENDS in 10 assorted colors (Black, Blue, Red, Green, Pink, Orange, Sky blue, Neon green, Neon pink) under normal and reasonably foreseeable conditions of use. The formulation is intended to be preloaded in pen for writing and drawing.
2. The formulation of LOVELY FRIENDS in 10 Assorted Colors (Black, Blue, Red, Green, Pink, Orange, Sky blue, Neon green, Neon pink) were reviewed according to the US Consumer Product Safety Commission's Regulation- 16 CFR § 1500.14(b)(8)(i)(C)(7) and the criteria outlined in ASTM D-4236. In addition, 16 CFR 1500.3(c)(2)(ii) and 1500.135 were also referred to evaluate the said formulation for chronic hazards and the health risk assessment approaches.

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 I. FORMULATION REVIEW

Ingredient Name	CAS RN	% By Weight
omissis, due to industrial secret		

omissis, due to industrial secret

omissis, due to industrial secret

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: pen;
- Physical form: liquid;
- Intended use (suggested use): to be preloaded in pen for writing and drawing;
- Accessibility: this product may contact the consumer directly;
- Exposure route(s): primarily via dermal contact;
- Default body weight: 31.8 kg (child);
- Target population: the population of 6 years old and above.

Section III. RISK EVALUATION

The submitted formulation is intended to be preloaded in pen for writing and drawing, which is unlikely to result in irritation or sensitization via incidental and instant skin contact. Accidental exposure to the eye may produce slight and transient 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 is unlikely to constitute unreasonable risk to the health of consumers 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 this compliance checking did not include the evaluation of the compliance 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 D-4236.

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