



CONSUMER PRODUCTS SERVICES DIVISION

## LEGAMI SPA SB

**Technical Report:** (6622)083-0054(2<sup>nd</sup> REVISED)

December 13, 2023

Date Received: January 28, 2022

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This report is amendment of and supersedes the previous (6622)083-0054(REVISED) dated October 24, 2023

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

Sample Description:

BLACK ERASABLE INK  
BLACK ERASABLE PEN REFILL SET  
BLUE ERASABLE INK  
BLUE ERASABLE PEN REFILL SET  
RED ERASABLE INK  
RED ERASABLE PEN REFILL SET  
GREEN ERASABLE INK  
GREEN ERASABLE PEN REFILL SET  
PINK ERASABLE INK  
PINK ERASABLE PEN REFILL SET  
PURPLE ERASABLE INK  
PURPLE ERASABLE PEN REFILL SET  
TURQUOISE ERASABLE INK  
TURQUOISE ERASABLE PEN REFILL SET  
ORANGE ERASABLE INK  
ORANGE ERASABLE PEN REFILL SET

|                        |               |              |                                                                                                      |
|------------------------|---------------|--------------|------------------------------------------------------------------------------------------------------|
| Vendor:                | LEGAMI SPA SB | Sample Size: | 1 CARTON                                                                                             |
| 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.:    | REFEP0004<br>REFEP0005<br>REFEP0006<br>REFEP0007<br>REFEP0008<br>REFEP0009<br>REFEP0010<br>REFEP0011 |

|                             |             |                         |                             |
|-----------------------------|-------------|-------------------------|-----------------------------|
| Client Specified Age Grade: | 6+, NON-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/<br>NZ/GSO |
| Color:                      | N/A         |                         |                             |

### EXECUTIVE SUMMARY:

| TEST REQUESTED                   | CONCLUSION              | Remark |
|----------------------------------|-------------------------|--------|
| 1) TOXICOLOGICAL RISK ASSESSMENT | REFER TO<br>BELOW PAGES | /      |
| 2) ...                           | REFER TO<br>BELOW PAGES | /      |



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Note:

1. With the client's prior consent, the TRA & LHAMA were the subcontracted test items.
2. As client's request, added LHAMA evaluation in the revised report.

**BVCPS (SHANGHAI) GENERAL CONTACT INFORMATION FOR THIS REPORT**

TELEPHONE NO.: 86-21-24166888  
E-MAIL: [bvcpshtoy.sh@cn.bureauveritas.com](mailto:bvcpshtoy.sh@cn.bureauveritas.com)

**BUREAU VERITAS**  
**CONSUMER PRODUCTS SERVICE DIVISION (SHANGHAI)**  
No. 368, Guangzhong Road, Zhuanqiao Town, Minhang,  
Shanghai.  
No. 168, Guanghua Road, Zhuanqiao Town, Minhang,  
Shanghai.



LEON DENG  
PRODUCT LINE MANAGER (TOY DIVISION)

The following sample was submitted and identified by the client as Erasable Ink - Orange Color (1 formulation).

Net Weight/Volume : 0.8g/pc  
Style/Item No. : /  
Manufacturer : /  
Buyer : /  
Region of Origin : China  
Region of Destination : EU  
Receiving Date : 19 March 2022  
Test Period : 19 March 2022 ~ 25 March 2022

**Test Requested:**

Toxicological Risk Assessment (TRA) for the said product.

**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

The aim of this report is to assess the safety of the formulation of Erasable Ink - Orange Color under normal and reasonably foreseeable conditions of use. The formulation is intended to be preloaded in appropriate instruments for writing by the population of 6 years old and above.

**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:**

Local effects (skin/eye irritation, skin sensitization)

Systemic effects (acute toxicity, repeated dose toxicity, carcinogenicity, genotoxicity, reproductive and developmental toxicity, etc.)

**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

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### 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: liquid;
- Intended use (suggested use): to be applied for writing;
- Accessibility: this product may contact the consumer accidentally;
- Exposure route(s): primarily via dermal contact;
- Default body weight: 23 kg (child), 60 kg (adult);
- 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, which may be classified as hazardous mixture by the CLP Regulation. However, considering the ink will be released at a slow and stable rate and will not contact the consumer with significant amount during normal use, it is unlikely to result in skin irritation or sensitization by accidental skin contact due to limited contact duration, frequency and contact amount. Accidental exposure to the eye may produce irritation, but the chance to contact eyes under normal use is relatively low unless deliberately. Moreover, the formulation is not expected to induce adverse systemic health effects when used for its intended purpose.

### Section IV. CONCLUSION

Taking into account the way the product is used, it is considered that under normal condition of use, this product is unlikely to constitute significant health risks to the consumers.

#### 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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The following sample was submitted and identified by the client as ERASABLE GEL PEN REFILL (1 formulation and 7 additional colors).

|                       |   |                                     |
|-----------------------|---|-------------------------------------|
| Net Weight/Volume     | : | 0.8 g/pc/color                      |
| Style/Item No.        | : | AKR67K71                            |
| Manufacturer          | : | Shanghai M&G Stationery Inc         |
| Buyer                 | : | LEGAMI s.p.a                        |
| Region of Origin      | : | China                               |
| Region of Destination | : | EU                                  |
| Receiving Date        | : | 26 September 2023                   |
| Test Period           | : | 26 September 2023 ~ 24 October 2023 |

**Test Requested:**

Toxicological Risk Assessment (TRA) for the said product.

**Test Results:**

Please refer to the following pages.

**Conclusion:**

Please refer to *Section IV: CONCLUSIONS*.

Signed for and on behalf of

WUHAN FOCOTESTTECHNICAL SERVICES CO., LTD

Raul Xin

Ph.D., ERT, DABT

### TOXICOLOGICAL RISK ASSESSMENT

The aim of this report is to assess the safety of the formulation of ERASABLE GEL PEN REFILL in 8 assorted colors (black, blue, red, green, pink, purple, turquoise and orange) under normal and reasonably foreseeable conditions of use. The formulation is intended to be preloaded in pen for writing by the population of 6 years old and above.

**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:**

**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.

**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

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## **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: liquid;
- 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: 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, 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 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**

Based on available data, 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.

### **The assessment is valid under the following conditions:**

10. Potential physical, mechanical electrical and microbiological risks of the product have not been assessed or evaluated.
11. The formulation, description and other supporting documents of the product were assumed to be valid and accurate.
12. 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.
13. 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.
14. Heavy metal contents in the product were not assessed and evaluated.
15. This product has been assessed for compliance only with the regulation(s) specified herein.
16. In case of consumer's adverse reaction from using this formulation, the undersigned should be informed so that the formulation can be further reviewed.



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17. This product has been evaluated for human health only, environmental concern/eco-toxicity were not assessed in this report.
18. 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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The following sample was submitted and identified by the client as ERASABLE GEL PEN REFILL (1 formulation and 7 additional colors).

|                       |   |                                    |
|-----------------------|---|------------------------------------|
| Net Weight/Volume     | : | 0.8 g/pc/color                     |
| Style/Item No.        | : | AKR67K71                           |
| Manufacturer          | : | OMISSIS                            |
| Buyer                 | : | LEGAMI s.p.a                       |
| Region of Origin      | : | China                              |
| Region of Destination | : | USA                                |
| Receiving Date        | : | 1 December 2023                    |
| Test Period           | : | 1 December 2023 ~ 13 December 2023 |

**Test Requested:**

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:**

The said product conforms to the health requirements of ASTM-D4236 and requires no additional safety labeling in accordance with the CPSC's Regulations as amended by the LHAMA. This product must bear the following statement of **"Conforms to ASTM D-4236"**.

Signed for and on behalf of

WUHAN FOCOTESTTECHNICAL SERVICES CO., LTD

Raul Xin

Ph.D., ERT, DABT



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#### **Test Results:**

The formulation of ERASABLE GEL PEN REFILL in 8 assorted colors (black, blue, red, green, pink, purple, turquoise and orange) 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 referenced to evaluate the said formulation for chronic hazards and the health risk assessment approaches.

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.

The review is based only on the submitted formula (*APPENDIX-1*) including the CAS No. of each component and their concentration (% by weight). All the ingredients in this product are assumed to contain no contaminants or residues at level that would cause chronic toxicity among users when used as intended or under circumstances involving reasonably foreseeable misuse. If there is any alteration to this formula in this product, it will void this certification.

The formulation is intended to be preloaded in pen for writing by the population of 6 years old and above. 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 validity of this review depends on the validity of disclosure by both the manufacturer of the components and that of the finished products. In addition, best professional capabilities are used in performing this review and if the client wishes to use this opinion with any alterations to the submitted formula, WUHAN FOCO TEST TECHNICAL SERVICES CO., LTD. or any of its employees will not be held reliable for any injury or damage resulting from this product. This review will need to be updated **every five years** or upon reformulation or upon change of new significant safety information. In addition, the submitted sample should also be in compliance with US CPSC additional guidelines in all respects.

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