



CONSUMER PRODUCTS SERVICES DIVISION

LEGAMI SPA SB

Technical Report: (6624)071-0278

March 19, 2024

Date Received: March 11, 2024

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

Sample Description: SQUISHY GEL PEN – UNICORN
SQUISHY GEL PEN – DINO
SQUISHY GEL PEN – KITTY
SQUISHY GEL PEN – PENGUIN
SQUISHY GEL PEN – BUNNY

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

Sample Size: 1 CARTON
Style No(s): N/A
SKN/SKU No.: N/A
PO No.: N/A
Item No.: SQP0001
SQP0002
SQP0003
SQP0004
SQP0005
SQPKIT1
SQPKIT2
SQPKIT3
SQPKIT4
SQPKIT5

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

Country of Origin: MADE IN CHINA
Assortment No.: 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.

BVCPS (SHANGHAI) GENERAL CONTACT INFORMATION FOR THIS REPORT

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LEON DENG
PRODUCT LINE MANAGER (TOY DIVISION)



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The following sample was submitted and identified by the client as squishy gel pen (1 formulation and 1 additional color).

Net Weight/Volume	:	0.47-0.52 g/pc/color
Style/Item No.	:	/
Manufacturer	:	/
Buyer	:	/
Region of Origin	:	China
Region of Destination	:	EU & US
Receiving Date	:	11 March 2024
Test Period	:	11 March 2024 ~ 19 March 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 FOCOTESTTECHNICAL 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 squishy gel pen in 2 assorted colors (Black, Blue) 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.
2. The formulation of squishy gel pen in 2 assorted colors (Black, Blue) 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 I. FORMULATION REVIEW

According to the client's needs and to protect business secrecy, detailed formulation is NOT presented in this report, whereas they are recorded in the WUHAN FOCO Archives. In case of medical events, it is the client's responsibility to provide the formulation to a patient's physician, or WUHAN FOCO upon request may furnish relevant medical units, on a confidential basis, with information necessary to diagnose or treat cases of exposure without prior written authorization.

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

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 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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substitute for professional legal advice and Client should seek legal review to ensure compliance with any applicable laws and regulations.

End of report