



Report

No.: T52410300107TA

Date: JUL 06, 2024

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BTL DIFFUSION
16, RUE ANATOLE MOUSSU - ZA MÉRÉ NORD EST 78490 MÉRÉ, FRANCE

Toxicological Risk Assessment (TRA) Cover Page

The following samples were submitted and identified on behalf of the client as:

- WOODEN MEDALLION KEEPSAKE
- 2 MAGNETIC KEEPSAKES
- BABY BOX ROUND - RAINBOW TERRACOTTA
- BABY BOX ROUND - LITTLE PRAIRIE
- BABY BOX SQUARE - PRETTY HEARTS
- BABY BOX SQUARE - OLIVE TREE
- CLASSIC FRAME - DAISY OCHRE
- CLASSIC FRAME - IVY GREY
- PRINT BOX - PRETTY HEARTS
- PRINT BOX - RAINBOW
- 2 PRINTS FRAME - BLUE ABSTRACT
- 2 PRINTS FRAME - RAINBOW TERRACOTTA
- DOUBLE FRAME - PRETTY HEARTS
- DOUBLE FRAME - OLIVE TREE
- DUO FRAME - PRETTY HEARTS
- DUO FRAME - DAISY OCHRE
- PUZZLE FRAME - OLIVE TREE
- PUZZLE FRAME - IVY GREY
- IMPRINTS MODELING CLAY - 35G
- IMPRINTS MODELING CLAY - 50G
- IMPRINTS MODELING CLAY - 85G

(1 formula)

Net Weight : 35G / 50G / 85G

Item No. : PA1000, PA1100, PA1305, PA1307, PA1401, PA1403, PA1502,
PA1506, PA1601, PA1605, PA1704, PA1705, PA1801, PA1803,
PA1901, PA1902, PA2003, PA2006, PA2235, PA2250, PA2285

Region of Destination : EUROPE

Sample Information Received : FORMULATION WITH CHEMICAL NAME, CAS NO. AND PERCENTAGE

Order Receiving Date : JUN 21, 2024

Last Information Date : JUL 03, 2024

Assessment Period : JUN 21, 2024 TO JUL 06, 2024

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Shenzhen Branch Testing Center Hardlines.

Service Requested

Toxicological Risk Assessment (TRA) for the said product per information provided.

Conclusion

Please refer to *the section "CONCLUSION"*

Sample Photo:

Pic.1



SGS authenticate the photo on original report only

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***** For Further Details, Please Refer to the Following Page(s) *****

Signed for and on behalf of
SGS-CSTC Standards Technical
Services Co., Ltd. Shenzhen Branch Testing Center

Jia Fengjuan, Shelly
Dept. Manager



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TOXICOLOGICAL RISK ASSESSMENT REPORT

The formula of
 WOODEN MEDALLION KEEPSAKE
 2 MAGNETIC KEEPSAKES
 BABY BOX ROUND - RAINBOW TERRACOTTA
 BABY BOX ROUND - LITTLE PRAIRIE
 BABY BOX SQUARE - PRETTY HEARTS
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 PUZZLE FRAME - OLIVE TREE
 PUZZLE FRAME - IVY GREY
 IMPRINTS MODELING CLAY - 35G
 IMPRINTS MODELING CLAY - 50G
 IMPRINTS MODELING CLAY - 85G
 WHITE CLAY is reviewed. The product is for EU market and intended for it is for creating the foot model or hand model, you can refer to the user guide for the usage by children of 0-3 years old and above as client claims. The net weight of paste (The formula under assessment) is 35g / 50g / 85g.

This risk assessment takes account of:

- Corrosivity
- Skin irritation
- Eye irritation
- Strong sensitization
- Oral toxicity
- Inhalation toxicity (if applicable)

According to:

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures and its following amendments, referred as the CLP Regulation

The followings were considered in this toxicological assessment

- Ingredient toxicological profile
- Potential ingredient interaction
- Consumer exposure scenario

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Section I. FORMULATION REVIEW

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

The formulation is not classified for human health according to the CLP Regulation. None of the ingredients in the formulation is classified as carcinogenic, mutagenic and toxic to reproduction (CMR) Cat. 1A, 1B or 2 under the CLP Regulation.

No allergenic fragrance has been indicated to be present in the formulation.

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: WOODEN MEDALLION KEEPSAKE
 2 MAGNETIC KEEPSAKES
 BABY BOX ROUND - RAINBOW TERRACOTTA
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 IMPRINTS MODELING CLAY - 50G
 IMPRINTS MODELING CLAY - 85G
- Physical form: paste
- Intended use (suggested use): It is for creating the foot model or hand model, you can refer to the user guide for the usage
- Accessibility: this product will contact with the consumer directly
- Exposure route(s): primarily via dermal contact, potentially hand to mouth transfer
- Default body weight: 5-15 kg

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- Target population: children of 0-3 years old and above as client claims

Section III. RISK EVALUATION

This product is unlikely to cause damage to internal organs through skin and accidental oral contact in majority of consumers under normal and reasonably foreseeable conditions of use. However, this product should also comply with applicable toy regulation, e.g., choking to substantiate its safety.

Section IV. CONCLUSION

The formulation is not classified as a Dangerous Mixture as per the human health criteria of the CLP Regulation. Provided the manufacturer’s instructions are followed, it is considered that, in the present state of knowledge, the submitted formulation put on the market is unlikely to pose a significant risk to the health of intended consumer under normal and reasonably foreseeable conditions of use.

Recommended Safety Labelling

Caution: avoid contact nose and eyes.

The TRA assessment is valid under the following conditions:

1. Potential physical, mechanical, electrical and microbiological risks of the product have not been assessed and evaluated.
2. The formulation, description and other supporting documents of the product were submitted and identified by/on behalf of the client, assumed to be valid and accurate.
3. It was assumed that either the ingredients, or the finished product contain no contaminants or residues that cause toxicity to a consumer who may be exposed. All polymers should be well-cured if they are present in the formulation.
4. The risk evaluation can solely be applied to and 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, should therefore 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. If there is an adverse reaction from using this formulation then 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/ ecotoxicity is not assessed in this report.
9. The assessment is performed by in-house method, taking reference of available consumer product exposure database, literature data to the best of knowledge by the time of assessment.



HONGJING XU MB, MPH,
Diplomate, American Board of Toxicology,
European Registered Toxicologist,
Certified Toxicologist of CSOT
Certified Cosmetic Safety Assessor

***** End of Report *****

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