



Report

No.: T52410300104TA

Date: JUL 04, 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:

PETIT ARTICHAUT HAND PAINTS (1 formula and 4 additional colors)

Net Weight : 9G
Item No. : PA1200
Region of Destination : EUROPE

Sample Information : FORMULATION WITH CHEMICAL NAME, CAS NO. AND
Received PERCENTAGE
Order Receiving Date : JUN 21, 2024
Last Information Date : JUL 04, 2024
Assessment Period : JUN 21, 2024 TO JUL 04, 2024

Service Requested

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

Conclusion

Please refer to *the section "CONCLUSION"*

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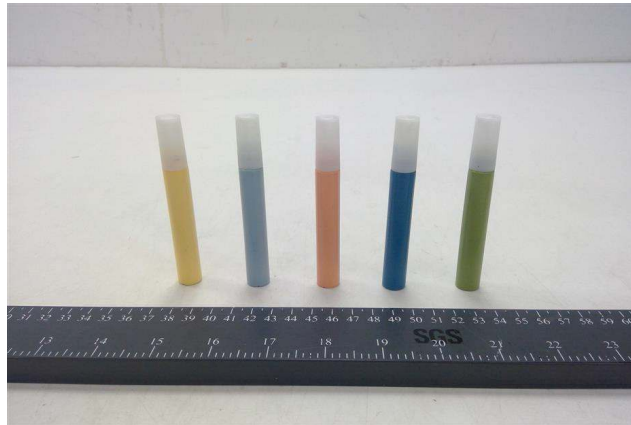
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Sample Photo:

Pic.1



SGS authenticate the photo on original report only

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The validity of this review depends on accurate disclosure by both the manufacturer(s) of the components and of the finished products. Best professional capabilities are used in performing this review. If client wishes to use this opinion with any alterations to the submitted formula, SGS-CSTC Standard Technical Services Co., Ltd. Shenzhen Branch- Hardlines or any of its employees will not be held liable for any injury or damage resulting from this product. A review of this assessment should be programmed at regular and frequent intervals (upon reformulation of the components or the finished products or upon any change to health and safety regulations).

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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 PETIT ARTICHAUT HAND PAINTS (GRASS GREEN, YELLOW, ORANGE, LIGHT BLUE, BLUE) is reviewed. The product is for EU market and intended for it is for creating the hand model. Please refer to the user guide. Attached is the updated BOM for the Prints by children of 0-3 years old and above as client claims. The net weight of liquid (The formula under assessment) is 9 g.

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

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.

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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: petit artichaut hand paints
- Physical form: liquid
- Intended use (suggested use): It is for creating the hand model. Please refer to the user guide. Attached is the updated BOM for the Prints.
- 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
- 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.

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

Not Applicable.

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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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