

No.T31820190011TA

Date: JAN 22, 2018

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4M INDUSTRIAL DEVELOPMENT LIMITED 2104, SHUI ON CENTRE,6-8 HARBOUR ROAD,WANCHAI,HONG KONG

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

THERMOMETER (1 formulation).

Net Weight : 0.05 G OF ENCAPSULATED LIQUID PER CONSUMER PRODUCT

SGS Case No. : CA318201913419

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

Country of Origin : CHINA Country of Destination : EU Labelled Age Grading : 8+

Sample Receiving Date : JAN 08, 2018 Last Information Date : JAN 16, 2018

Test Period : JAN 08, 2018 TO JAN 19, 2018

Test Requested

Toxicological Risk Assessment (TRA) for said product.

Test Results

Please refer to the following pages.

Conclusion

Please refer to Section IV: CONCLUSION.

Signed for and on behalf of SGS Hong Kong Ltd.

Alec Eng Dar KOR

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PhD, MRSB, MBTS

Toxicological Safety Assessor

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TOXICOLOGICAL RISK ASSESSMENT

The formulation of THERMOMETER – Encapsulated liquid in red is reviewed. The product is for EU market and intended for playing by children of 8 years old or above. The net weight of encapsulated liquid (The formula under assessment) is 0.05 g of encapsulated liquid per consumer product. Detailed formulation is submitted by the client. Ingredients are not presented in the report, whereas they are recorded in the SGS Archives.

This risk assessment takes account of:

Corrosivity Skin irritation Eye irritation Strong sensitization Oral toxicity Inhalation toxicity

According to:

Regulation (EC) No 1272/2008

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 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 classified according to Regulation (EC) No 1272/2008 as follow:

Asp. Tox. 1 H304 May be fatal if swallowed and enters airways

None of the ingredients in the formulation is classified as carcinogenic, mutagenic and toxic to reproduction (CMR) Cat. 1A, 1B or 2 under Regulation (EC) No. 1272/2008. 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: Thermometer liquid

- Physical form: Encapsulated liquid in red
 Intended use (suggested use): Playing; Checking ambient temperature
 Accessibility: the liquid is not expected to contact the consumer unless there is leakage.
- Exposure route(s): Only contact the consumer when there is a leakage. Default body weight: 28.1 kg
- Target population: Children of 8 year old and above

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rwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only



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Section III. RISK EVALUATION

The formulation is classified as "May be fatal if swallowed and enters airways" due to high concentration of a solvent ingredient. Although the formulation is classified as such, the encapsulated liquid is expected to be sealed inside the container, in which the liquid should not come out under normal use and possible abuse use (i.e. drop, torque/tension and pressure). As a result, there is no chance of consumers contacting the liquid under normal and reasonably foreseeable conditions of use during the whole product life cycle. Manufacturer should ensure the durability of the product by performing relevant test on its robustness. The product is also recommended to be labelled accordingly to provide safety information in case of leakage of the product.

Provided that the manufacturer's instructions are followed and the robustness of the encapsulation can withstand normal and reasonably foreseeable conditions of use, the encapsulated liquid is unlikely to cause damage to internal organs through skin, ingestion and inhalation in majority of consumers under normal and reasonably foreseeable conditions of use. However, the product is recommended to be labelled accordingly to provide safety information in case of leakage of the product.

Section IV. CONCLUSION

The formulation is classified as a hazardous mixture according to Regulation (EC) No 1272/2008. 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. However, the product is recommended to be labelled accordingly to provide safety information in case of leakage of the product. The following labelling is suggested from the point of safety.

Recommended Safety Labelling

Dispose the product if it leaks.

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Do not ingest the leaked liquid. Call physician immediately if swallowed.

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.
- The formulation, description and other supporting documents of the product were assumed to be valid and accurate.
- 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.
- 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.
- 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.
- 10. This product has not been assessed for compliance with Regulation (EC) No. 1272/2008 Labelling requirement.

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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 (HK) Ltd. 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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Sample Photo:

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Only the encapsulated liquid in red is assessed in this report



SGS authenticate the photo on original report only

*** End of Report ***

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