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The following sample was submitted and identified by the client as Soap bubbles (1 formulation).

Net Weight/Volume : 30 ml/pc
Style/Item No. : 98076
Manufacturer : /
Buyer : /
Region of Origin : China
Region of Destination : EU
Receiving Date : 12 July 2022
Test Period : 12 July 2022 ~ 22 July 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

Raul Xin

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TOXICOLOGICAL RISK ASSESSMENT

The aim of this report is to assess the safety of the formulation of Soap bubbles under normal and reasonably foreseeable conditions of use. The formulation is intended to be applied for blowing bubbles by the population of 4 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)

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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

Ingredient Name	CAS RN	% By Weight
Water	7732-18-5	95.7996
Lauramidopropyl betaine	4292-10-8	2.85
2-phenoxyethanol	122-99-6	0.5
DMDM Hydantoin	6440-58-0	0.5
Hydroxyethyl cellulose	9004-62-0	0.35
Denatonium benzoate	3734-33-6	0.0004

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: bubble;
- Physical form: liquid;
- Intended use (suggested use): to be applied for blowing bubbles;
- Accessibility: this product may contact the consumer accidentally;
- Exposure route(s): primarily via dermal contact;

- Default body weight: 18.6 kg (child), 60 kg (adult);
- Target population: the population of 4 years old and above.

Section III. RISK EVALUATION

The submitted formulation is intended to be applied for blowing bubbles, which is unlikely to result in irritation or sensitization by incidental contact with intact skin. 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 produce adverse systemic health effects for this product when used for its intended purpose.

Section IV. CONCLUSION

Taking into account the way the product is used, it is concluded 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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***** End of Report *****