BALONEVİ SANAYİ VE TİCARET A.Ş.
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To the attention of Mustafa Oğuz Vanlı

The following sample(s) was (were) submitted and identified by/on behalf of the client as:

Sample No.	Sample Description
A	Foam Liquid Mix

Client's reference No.	:	TR 2338767
Colour	:	COLORLESS
Manufacturer	:	BALONEVİ SANAYİ VE TİCARET A.Ş.
Sample Receiving Date	:	17 July 2023
Test Performing Period	:	17 July 2023~25 October 2023
Overall Conclusion	:	**SEE RESULTS**
Test Results	:	Please refer to the next page(s).
Performed Test Summary:		Selected test(s) as requested by client against Client's performance standard.

Test Parameters	Result
Chemical tests	**A**
TOXICOLOGICAL RISK ASSESSMENT	*

Remarks	M = Meets client's requirement
	F = Does not meet client's requirement
	I = Inconclusive
	* = No specified requirement
Notes:	Conclusions on meet/fail are based on the test result from the actual sampling of the received sample(s).
	Residual sample can be returned to client if requested.

The test results relate to the tested items only.
Test reports without SGS seal and authorised signatures are invalid.

Issued in Istanbul
Signed for and on behalf of
SGS Supervise Gözetme Etüd Kontrol Servisleri A.Ş.

RAVİYE MUTLU Customer Services Supervisor	Bora Şirinbilek Hardline C&H Testing Services Manager
	

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Test Results

TOXICOLOGICAL RISK ASSESSMENT

The formulation of FOAM LIQUID MIX – bubble solution is reviewed. The product is for EU market and intended for making bubble for fun during party by children of 3 years old or above. The net weight of bubble solution (The formula under assessment) is 50 ± 5 g per consumer product.

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

Ingredient Name	CAS RN	% By Weight
Water	7732-18-5	94.20
SINAR GLUSP Glycerin	56-81-5	2.57
Glucopon® 650 EC D-Glucopyranose, oligomers, decyl octyl glycosides (20-30%) & D-Glucopyranose, oligomeric, C10-16(even numbered) alkyl glycosides (20-30%) & Sodium Hydroxide (> 0.3- < 1%)	68515-73-1 & 110615-47-9 & 1310-73-2	2.05
Dehyton ® PL Dodecyldimethylamine oxide & Amines, C12-16-alkyldimethyl, N-oxides (30-50%)	1643-20-5 & 85408-49-7	1.02
Tylose HS 100000 YP2 Hydroxyethylcellulose (> 88%) & Glyoxal (<0.01%)	9004-62-0 & 107-22-2	0.16

Taking reference of the submitted product MSDS, the formulation is classified according to Regulation (EC) No 1272/2008 as following:

Eye irrit. 2 H319 Causes serious eye irritation

None of the disclosed 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: Bubble solution
- Physical form: Transparent liquid with a pH value of 6.5-7
- Intended use (suggested use): Making bubble for fun / partying
- Accessibility: This product will contact with the consumer directly
- Exposure route(s): Primarily via dermal contact, potential oral contact via hand to mouth transfer.
- Default body weight: 15.1 kg
- Target population: Children of 3 years old or above

Section III. RISK EVALUATION
This bubble solution is intended for making bubbles for playing by children of 3 years old or above. The bubble solution is expected to contact the skin, mainly the hands, under normal and reasonably foreseeable conditions of use. Accidental exposure of the eye would cause serious eye irritation. Inhalation of ingredients, except water, is not a significant route of administration during handling of bubble solution and bursting of bubble. Small amount of the bubble solution may be ingested via hand-to-mouth transfer but the amount is expected to be very limited.

The formulation consisted of solvents, surfactants, thickener and buffer. It is classified as “Causes serious eye irritation” due to a mixture of surfactants. The bubble solution should be rinsed off immediately in case of direct eye contact. First aid information, warning label and precautionary statement is required to ensure its proper use. The submitted SDS for Hydroxyethylcellulose, in the trade name of Tylose HS 100000 YP2, indicated the presence of glyoxal (< 0.01%), resulting in up to 0.16 ppm of glyoxal in the final product. Glyoxal is classified as Suspected of causing genetic defects as well as skin sensitizing, skin and eye irritancy, acute toxicity by inhalation. However, the maximum concentration of glyoxal, as impurity, in cosmetic is 100 ppm according to the EU Cosmetic Regulation. The trace amount of glyoxal is hence not expected to pose a significant health concern. Several of the submitted SDS, Glucopon® 650 EC, Dehyton ® PL and Tylose HS 100000 YP2, did not add up to 100%. It is assumed that the remaining components in the respectively mixture are non-hazardous / classified substances. If it is not the case, it will void this assessment.

Provided the manufacturer's instructions are followed and all the ingredients used are of acceptable chemical purity while the polymer is well-cured, this product 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. Only the safety of the formulation of the bubble solution is evaluated in this assessment, the container and the accompanied bubble-making tools have not been assessed. The product, as a whole, is a toy and should comply with Toy Safety Directive 2009/48/E and applicable EN71 standards to be put on the market. It should also be labelled according to EU CLP which is not covered in this assessment.

Section IV. CONCLUSION

The formulation is classified as a hazardous mixture according to Regulation (EC) No 1272/2008. However, provided the manufacturer's instructions are followed and the ingredients used are of acceptable grade while the polymer is well-cured, 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 consumers when used as instructed. Due to potential eye damage of the formulation, first aid information, warning label and precautionary statement is required to ensure the proper use of the product.

Required Safety Labelling

Use under adult supervision.
Avoid contact with eyes. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.
Rinse hands thoroughly after use.
If skin irritation or rash occurs, get medical advice. (Recommended)

The TRA assessment is valid under the following conditions:

1. Potential physical risk such as choking hazard, aspiration risk, mechanical, electrical, flammability and microbiological risks of the product have not been assessed and evaluated.
2. The formulation, description and other supporting documents of the product were 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.

10. This product has not been assessed for compliance with Regulation (EC) No. 1272/2008 Labelling requirement, product packaging and labelling.

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).

****This test has been performed as subcontracted at SGS Hong Kong.**

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* * * End of Test Report * * *