



## Test Report

No.: T31620212376SC

Date: AUG 01, 2016

Page 1 of 5

BIC GRAPHIC  
14421 MYERLAKE CIRCLE  
CLEARWATER PINELLAS  
FL 33760 UNITED STATES

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

RECTANGULAR WARM / COLD PACK

SGS Case No.	: CA316202142309
Style / Item No.	: 41042
Ref. No / P.O. No.	: 7456
Quantity Submitted	: 9 PCS OF 3 STYLES
Manufacturer Date	: 2016
Country of Origin	: CHINA
Country of Destination	: US & CANADA
Sample Receiving Date	: MAY 23, 2016
Test Performing Date	: MAY 23 – JUL 29, 2016

### 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.

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Ka-Yiu YIP  
PhD, MRSB, MBTS, AMSOT  
Cosmetic Safety Assessor

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### TOXICOLOGICAL RISK ASSESSMENT

The formulation of RECTANGULAR WARM / COLD PACK – Encapsulated gel beads in red, blue, and transparent color is reviewed. The product is for US market and intended for physical cooling by adults. The net weight of the encapsulated gel beads (The formula under assessment) is 106 – 110 g per consumer product.

**This risk assessment takes account of:**

Corrosivity  
Skin irritation  
Eye irritation  
Strong sensitization  
Oral toxicity  
Inhalation toxicity

**According to:**

16 CFR 1500.3(c)(4), 1500.3(c)(2), 1500.3(c)(3) and 1500.3(c)(5)

**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 (Max)
Water	7732-18-5	83.02247
Glycerin	56-81-5	23.00000
Sodium carboxymethylcellulose	9004-32-4	2.00000
DMDM Hydantoin	6440-58-0	0.04800
Bronopol	52-51-7	0.01200
Dipropylene Glycol	25265-71-8	0.00500
Methylchloroisothiazolinone	26172-55-4	0.00100
Methylisothiazolinone	2682-20-4	0.00035
Iodopropynyl Butylcarbamate	55406-53-6	0.00010
Acid Red 27 (CI 16185)	915-67-3	0.06500
Acid Blue 9 (CI 42090)	3844-45-9	0.06500

The formulation is not classified according to OSHA Hazard Communication Standard 29 CFR 1900.1200 taking reference of the submitted product SDS.

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.

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**Exposure assessment**

The following assumptions have been made for assessment of exposure:

- Product category: Encapsulated gel beads
- Physical form: Gel beads in red, blue, and transparent colors
- Intended use (suggested use): gel beads in a well-sealed PVC clear plastic cover
- Accessibility: the gel beads are not expected to contact the consumer under normal and reasonably foreseeable conditions of use
- Exposure route(s): only contact the consumer when there is a leakage. Primarily via dermal contact.
- Default body weight: 65 kg
- Target population: adults

**Section III. RISK EVALUATION**

The formulation contains low concentrations of Methylchloroisothiazolinone (CAS RN 26172-55-4), Methylisothiazolinone (CAS RN 2682-20-4), and Iodopropynyl Butylcarbamate (CAS RN 55406-53-6), which themselves are capable of causing skin sensitization. Furthermore, the nitrosating agent Bronopol (CAS RN 52-51-7) might lead to the formulation of carcinogenic nitrosamines with amines/amides of other ingredients although the rate is not expected to be high. However, the encapsulated gel beads are sealed inside the PVC plastic cover, in which the gel beads should not come out under normal use and possible abusive use (i.e. drop, torque/tension and pressure). As a result, there is no chance of consumers contacting the gel beads 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 and, consider testing for nitrosamine formation after prolonged storage or introducing inhibitors of nitrosation to ensure that carcinogenic nitrosamines are not formed through the product's life cycle.

Provided that the manufacturer's instructions are followed, the encapsulated gel beads are 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 should be labeled accordingly to provide safety information in case of leakage of the product.

**Section IV. CONCLUSION**

The formulation is not expected to cause acute or chronic skin and eye irritation, acute or chronic oral, dermal or inhalation toxicity or be a strong sensitizer or corrosive as defined in 16 CFR 1500.3(c)(4), 1500.3(c)(2), 1500.3(c)(3) and 1500.3(c)(5). 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 should be labeled accordingly to provide safety information in case of leakage of the product.

**Recommended Safety Labeling**

Discard the product if it leaks.

Wash eyes/skin immediately in case of contact with the content.

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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 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 California Proposition 65 & TSCA inventory list.

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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Page 5 of 5

Only the Encapsulated gel beads in red, blue, and transparent color are assessed in this report



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

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