



CONSUMER PRODUCTS SERVICES DIVISION

## COOL GEAR INTERNATIONAL INC

**Technical Report:** (5118)080-0005 REVISION  
Date Received: March 21, 2018

April 3, 2018  
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10 CORDAGE PARK CIRCLE  
PLYMOUTH, MA 02360  
UNITED STATES

Sample Description:	FREEZER GEL (CLEAR)	Sample Size:	1
Manufacturer:	NINGBO LISI HOUSEWARE CO., LTD & CHINA GIANT INDUSTRIAL LTD.		
Buyer:	N/A	Style No(s):	N/A
Labeled Age Grade:	N/A	SKN/SKU No.:	N/A
Appropriate Age Grade:	N/A	PO No.:	N/A
Client Specified Age Grade:	N/A	Ref #:	N/A
Tested Age Grade:	N/A	Country of Origin:	CHINA
UPC Code:	N/A	Assortment No.:	N/A

### EXECUTIVE SUMMARY:

The sample(s) MEETS the following requirement(s):

- Classification of not being toxic (acute), corrosive, a skin/eye irritant, or strong sensitizer as defined in the 16 CFR 1500.3(b)(5), (7) – (9) (FHSA regulations), when used as intended or under circumstances involving reasonable foreseeable misuse, based on a Toxicological Risk Assessment of the submitted product formulation by a Diplomat of the American Board of Toxicology (DABT). Chronic toxicity was not evaluated for this product as chronic exposure was not expected.
- Classification of not being very toxic, toxic or harmful (acute), corrosive or a skin/eye irritant per the requirements set forth in the Canadian Consumer Chemicals and Containers Regulations, 2001 (SOR/2016-170), when used as intended or under circumstances involving reasonable foreseeable misuse, based on an assessment of the submitted product formulation by a Diplomat of the American Board of Toxicology (DABT).
- Classification of not being acute toxic, skin corrosive, serious eye-damaging, germ cell mutagenic, carcinogenic, reproductive toxic, respiratory/skin sensitizing or specific target organ toxic (single or repeated exposure) as defined in Annex I of sections 3.1.1, 3.2.1, 3.3.1, 3.4.1, 3.5.1, 3.6.1, 3.7.1, 3.8.1, 3.9.1 of Regulation (EC) no. 1272/2008.



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### **Exposure Assessment:**

The Freezer Gel (Clear) is a liquid formulation that is contained between the two walls of a double walled food container or drinking bottle. The container or bottle is intended to be placed in the freezer and, once frozen, can be used for cold storage of food or drink. Consideration was given to consumer exposure with intended product use and under circumstances involving reasonable foreseeable misuse. Intentional product misuse was not considered within the scope of the assessment. This evaluation was conducted under the assumption that with the intended use of the product, no intentional exposure to the liquid inside the product is anticipated (i.e., the liquid formulation is encased within the product, which is not permeable and represents a structural barrier to exposure). This evaluation was conducted under the assumption that acute exposure to product ingredients through the dermal route and possibly the oral route via accidental ingestion could occur if the product is broken or damaged (foreseeable misuse). Misuse of the product is not expected to occur on a regular or consistent basis, and thus chronic exposure is not foreseeable. The inhalation route was not evaluated since none of the chemicals in the product formulation were considered sufficiently volatile for inhalation exposure.

### **Considerations:**

It was assumed that all product formulation details are accurate and that there are no additional ingredients that are not listed (note: chemical testing was not conducted as part of this product evaluation and chemical analyses data were not provided in support of this evaluation). It was also assumed that any ingredients provided in the product formulation do not contain any impurities and/or contaminants (e.g., heavy metal(s) or lead) or infectious agents that would cause toxicity in a consumer who may be exposed to them. This product was not evaluated for toxicological considerations related to physical or chemical properties of the formulation (e.g., pH, viscosity, volatility) and potential for physical injury (e.g., choking hazard, aspiration risk, or mechanical irritation) was not considered.

- Note: This evaluation does not constitute a regulatory review and does not address the requirements for labeling, unless otherwise indicated.
- Note: This evaluation is relevant solely to the conditions described herein. Any substitution of ingredients, increase in ingredient concentrations, or change in use pattern will necessitate a new evaluation.
- Note: Assessment of sodium polyacrylate (CAS No. 9003-04-7) was based on the assumption that sodium polyacrylate is a high molecular weight polymer with minimal residual monomers. If this is not the case, reassessment of the product is required.
- Note: While methylisothiazolinone (CAS No. 2682-20-4) is a potential skin sensitizer at the concentration present in the product formulation, product classification is not warranted for this effect given the nature of the product (i.e., repeat exposure is not anticipated).
- Note: The Toxicological Risk Assessments were performed at a Bureau Veritas CPS approved subcontract lab on March 27, 2018
- Note: This report has been revised to list both factories as the Manufacturers.**



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