

TOXICOLOGICAL RISK ASSESSMENT FOR *HOT OR COLD GEL PACK*

Intertek Job Number: SHAH01468823

Applicant:

Date: July 5, 2022

Details of Product: Description: HOT OR COLD GEL BEAD PACK
Age grading on package, years: 3+
Physical form: Gel
Mass or volume: 100 g

Ingredients and %w/w composition are listed in the appendix (subject to valid request and approval by the formulation owner).

Scope of Evaluation:

The above-named product and the ingredients in the product formulation were assessed for the following toxicological potentials as defined in their respective regulations:

- acute oral toxicity;
- corrosivity and skin and eye irritation;
- strong sensitization; and,
- chronic toxicity.

as defined according to the following regulation:

- Title 16 of the United States *Code of Federal Regulations*, Section 1500.3 (16 CFR §1500.3) with consideration of Sections 16 CFR §1500.4, 1500.5, 1500.13, 1500.14 (excluding art materials), and 1500.135.

The sole purpose of this risk assessment is to assess the product for the above toxicological potentials under normal and reasonably foreseeable misuse and should not be misconstrued as an assessment of regulatory compliance. Compliance with regulations, other than as described above, are outside of the scope of this evaluation.

In completing this toxicological risk assessment, the following information was considered by the board-certified toxicologist:

- the composition of the product;
- the characteristics of the product including nature, physical form and size;
- the safety data identified for each ingredient obtained during literature searches in medical and toxicology databases;
- potential for synergistic or unpredictable adverse effects; and,
- the foreseeable conditions of use of the product.

Additional information pertaining to the assumptions made in completing this toxicological risk assessment can be provided as an addendum to this report, upon request.

No safety data have been generated by the applicant with the final product. However, due to the nature of the individual ingredients, it is considered by the safety assessor that the safety of the final product can be adequately assessed by considering the toxicological profiles of the individual ingredients and their levels of use in the final product. It was assumed that the formulation and all ingredients and concentrations provided by the applicant are accurate and complete, as listed in the appendix table, subject to valid request and approval by the formulation owner. Furthermore, it was assumed that neither this product, nor the ingredients used in the product, contained any impurities/contaminants, including those that would cause or contribute to toxicity in a consumer.

**Conclusion:**

Based on the available data and assumptions described in this report, the product, **HOT OR COLD GEL PACK**, is not considered to pose a risk of acute oral toxicity, eye irritation, skin irritation, corrosion, strong sensitization, or chronic toxicity when used under normal and reasonably foreseeable conditions of use.

The product was not evaluated by the toxicologist with respect to the following:

- Heavy metal or lead content;
- Compliance with the California EPA, Proposition 65 nor any other State or Federal Right to Know Legislation;
- Potential physical injury such as choking hazard, aspiration risk, or other mechanical hazards;
- Flammability, electrical, or auditory hazards of the product; and,
- Compliance or safety considerations for product packaging and labeling.

This evaluation is relevant solely to the conditions described herein. Any substitution or addition of ingredients, increase in concentrations of use, or change of use pattern will necessitate a new evaluation. Should occurrences of significant adverse reactions amongst consumers (e.g. high number of undesirable effects) be reported for **HOT OR COLD GEL PACK**, the board-certified toxicologist herein shall be informed and the necessity for a new evaluation will be determined.

This evaluation applies only to the formulation that has been provided in the corresponding confidential appendix to this report. This appendix is held on file at the Shanghai Intertek Office.

Signature of Board-Certified Toxicologist:

SH 2022-60 HOT OR COLD GEL PACK
SHAH01468823

Lois Haighton:
Diplomate, American Board of Toxicology
Intertek Health Sciences Inc. dba Intertek Assuris

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END OF MAIN REPORT



NOT TO BE DISCLOSED WITH REPORT UNLESS VALID REQUEST

APPENDIX: SUMMARY OF *HOT OR COLD GEL PACK* FORMULA

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Ingredient Name ¹	CAS #	Content of Product (%w/w)
Water	7732-18-5	65-77
Glycerin	56-81-5	20-25
Sodium Carboxymethylcellulose	9004-32-4	2-7
Sodium polyacrylate	9003-04-7	1-3

¹ Note: No independent testing of the formulation was conducted by the reviewer; thus, it is assumed that this formulation is accurate and complete. Furthermore, it is assumed that none of the ingredients contain impurities at levels that may cause harm to the consumer.

"Valid request" refers to a request that has been approved by the formulation owner, which may not always be the report applicant.

END OF APPENDIX