

Report No.: NB2024056063-R1

Date: May 30, 2024

Page:1/4

Product Name: Hand Boilers
Reference No.: EG7860
Region of Destination: EU
Target consumers: All ages
Applicant Name: Funtime Gifts Ltd
Applicant Address: Unit 1409, 14th Floor, Nan Fung Commercial Centre, No.19 Lam Lok Street, Kowloon Bay, Kowloon
Receiving Date: May. 22, 2024


Summary of Ingredient Review:

Based on the information provided by the client and when used under intended use of reasonably foreseeable misuse, the product conforms the following requirements:

Items	Result
EU market	
EU REACH (Registration, Evaluation and Authorization of Chemical Substances) Regulation (EC) 1907/2006	Ingredients used in Hand Boilers are not listed on EU REACH's Annex XVII, Annex XIV & Substances of Very High Concern for Authorization candidates (SVHC).
EU CLP Regulation (Classification, Labelling and Packaging) Regulation (EC) No 1272/2008	Hand Boilers are not classified as a hazardous mixture according to the health criteria of EU CLP regulation.
EU Toy Safety Directive 2009/48/EC	Hand Boilers are compliant with toxicological requirements defined by 2009/48/EC.

Signed for and on behalf of Guangdong NewBest Testing Service Co., Ltd.

Approved by:


Wen SUN
B. Pharm, M. Pharm, ERT, UKRT, DCST
Registered Toxicologists



This report cannot be reproduced partly, without prior written permission of Laboratory. Any unauthorized alteration, forgery or falsification of the content of this document is unlawful. Unless otherwise stated the results shown in this test report refer only to the sample (s) tested. Items marked with "#" means they are not accredited by CNAS, "s" means the item of subcontractor, and the test items was/were not in CMA scope and the result cannot be as social justice proof data

Background

Hand Boilers were evaluated by a toxicologist according to the above requirements.

No impurities or contaminants from the product and packaging were provided for assessment. Potential physical injury (e.g., choking hazard or mechanical irritation), environmental hazard and detailed labelling requirements (i.e., label content, prominence, placement, and conspicuousness, and any relevant exemptions) beyond any necessary hazard warning guidance on the product were not evaluated.

This TRA is based on information disclosure by the client at the time of this assessment. It should be updated upon any change in the formulation, change in use pattern or upon knowledge of additional toxicological information. We will not be held reliable for any injury or damage resulting from the use of this product.

Composition of the product

The names of the ingredients and its maximum composition are listed below. Detailed information on the safety, and toxicology of the ingredients has been reviewed.

Ingredient name provided by the client	CAS No.	% w/w
Ethanol	64-17-5	2.9
Dichlorofluoroethane	1717-00-6	2
Water	7732-18-5	95.06
Brilliant Blue FCF	3844-45-9	0.044
Fast green FCF	2353-45-9	0.04
Carmine	1390-65-4	0.04
Amaranth	915-67-3	0.036

This report cannot be reproduced partly, without prior written permission of Laboratory. Any unauthorized alteration, forgery or falsification of the content of this document is unlawful. Unless otherwise stated the results shown in this test report refer only to the sample (s) tested. Items marked with “#” means they are not accredited by CNAS, “s” means the item of subcontractor, and the test items was/were not in CMA scope and the result cannot be as social justice proof data

Exposure assessment

The following assumptions have been made for assessment of exposure based on EU Scientific Committee on Consumer Safety (SCCS) opinion notes of guidance 11th revision, EPA exposure handbook 2011 and A.S. Fichoux et al. 2016 table 5:

- Target consumers: All ages
- Physical form: liquid
- Intended use and reasonably foreseeable use: This product is toy product played by children
- Exposure Route(S): Dermal contact
- Net quantity: 10g (8ml)
- Exposure area: 180cm²
- Exposure duration: To be removed after played
- Body weight:4.8kg
- Retention factor: 0.01
- Calculated relative daily exposure: 20.8 mg/kg bw/day

Toxicological risk assessment

Available data from the U.S. National Toxicology Program, the World Health Organization's International Agency for Research on Cancer IARC, the U.S. National Cancer Institute, U.S. National Library of Medicine's toxicology databases, EU Scientific Committee on Consumer Safety (SCCS) opinions, Cosmetic Ingredients Review (CIR), ECHA registration dossier and widely accepted scientific literatures were compiled for assessment. Apart from that, the physical & chemical form of the product, chemical composition of the product, concentration in the product, bioavailability and potential exposure to users under the intended and foreseeable conditions of use were also considered for the assessment.

All significant toxicological routes of absorption have been considered as well as the systemic effects. Where applicable, Margin of Safety (MoS) has been calculated for all ingredients except those which No Observed Adverse Effect Levels (NOAELs), or other suitable Points of Departure (PoD) were not available for review. The MoS values for these ingredients were well above 100 to indicate they are systemically safe for use in the product. For those materials where a Margin of Safety (MoS) was not derived, they are all common cosmetic & food ingredients with extensive history of safe usage and considered to be Generally Recognized as Safe (GRAS) in either direct food use or indirect food uses. Furthermore, a number of ingredients are present at or below the recommended safe levels as established by bodies such as the Scientific Committee on Consumer Safety (SCCS) or Cosmetic Ingredients Review (CIR) expert panel, or maximum legal limits from the relevant regulations.

The Responsible Person/manufacturer must ensure that all ingredients are of suitably grade and manufactured to ensure that any residues and impurities are not exposed at level that would cause local and/or chronic toxicity on humans.

This report cannot be reproduced partly, without prior written permission of Laboratory. Any unauthorized alteration, forgery or falsification of the content of this document is unlawful. Unless otherwise stated the results shown in this test report refer only to the sample (s) tested. Items marked with "#" means they are not accredited by CNAS, "s" means the item of subcontractor, and the test items was/were not in CMA scope and the result cannot be as social justice proof data

Report No.: NB2024056063-R1

Date: May 30, 2024

Page:4/4

- **Acute toxicity**

It is considered as non-toxic.

- **Skin irritation**

It is not expected to cause the skin irritation under the normal and foreseeable condition of use.

- **Eye irritation**

It is not expected to cause the eye irritation under the normal and foreseeable condition of use.

- **Skin Sensitization**

It is not expected to cause the skin sensitizer under the normal and foreseeable condition of use.

- **Inhalation toxicity**

It is unlikely to cause inhalation toxicity under the normal and foreseeable condition of use.

- **Systemic toxicity**

It is unlikely to cause chronic effect through skin under normal and reasonably foreseeable conditions of use. If swallowed in large amounts, it may have the potential to cause injury.

Conclusion

Based on the available data, ingredients used in this product are not on the lists of restriction, authorization and SVHCs candidates under EU REACH. No health hazard is classified on this product according to the EU CLP regulation. It is compliant with the safety requirements in the toxicological perspective as defined by EU Toy Safety Directive.

Remark: This report is to supersede NBTS report No. NB2024056063 dated on May 29, 2024.

Reason for modification:

Update the test result.

*** End of Report ***

This report cannot be reproduced partly, without prior written permission of Laboratory. Any unauthorized alteration, forgery or falsification of the content of this document is unlawful. Unless otherwise stated the results shown in this test report refer only to the sample (s) tested. Items marked with "#" means they are not accredited by CNAS, "s" means the item of subcontractor, and the test items was/were not in CMA scope and the result cannot be as social justice proof data