

## Toxicological Risk Assessment

Product Name: Liquid floor tiles

Region of Destination: EU

Target consumers: Age above 3 years old

Applicant Name: Dongguan Heng Fu plastic products Co., LTD

Applicant Address: Room 201, Building 2, No. 9, Yifeng Yinling Road, Zhangmu Town, Dongguan City, Guangdong Province

Receiving Date: Nov 10, 2023

### 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
<b>EU market</b>	
<b>EU REACH (Registration, Evaluation and Authorization of Chemical Substances) Regulation (EC) 1907/2006</b>	Ingredients used in Liquid floor tiles are not listed on EU REACH's Annex XVII, Annex XIV & Substances of Very High Concern for Authorization candidates (SVHC).
<b>EU CLP Regulation (Classification, Labelling and Packaging) Regulation (EC) No 1272/2008</b>	Liquid floor tiles are not classified as a hazardous mixture according to the health criteria of EU CLP regulation.

Reviewer

Signed on behalf of Standards compliance and technology (International) and Technology CO Limited



Wen SUN

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

Date: 17-11-2023

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**Background**

Liquid floor tiles 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. SCTC 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
Polyvinyl chloride resin	9002-86-2	84.27
Mineral oil	8012-95-1	12.49
Fatty acids, castor-oil, caustic-oxidized, distn. residues, esters with 1,3-butanediol	113669-95-7	0.37
Ethylene-vinyl acetate copolymer	24937-78-8	2.87

**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 11<sup>th</sup> revision, EPA exposure handbook 2011 and A.S. Ficheux et al. 2016 table 5:

- Target consumers: Age above 3 years old
- Physical form: Solid
- Intended use and reasonably foreseeable use: This is a children's product
- Exposure Route(S): Dermal contact
- Net quantity: 630g
- Product use per day: As per net quantity of the product
- Exposure area: 460cm<sup>2</sup>
- Exposure duration: To be removed after used
- Body weight: 18.6kg
- Retention factor: 0.01
- Calculated relative daily exposure: 338.7 mg/kg bw/day

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**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.

Polyvinyl chloride and Ethylene-vinyl acetate copolymer are assumed to be manufactured without using toxic chemicals like phthalates which is associated with adverse reproductive & developmental effects and restricted in the toy regulation. It is also assumed to be well-cured or fully polymerized without leaching any toxic. As such, it is not expected to contain residues or contaminants at level that would cause health effect on human.

Paraffinum Liquidum (mineral oil) is a mixture of hydrocarbons obtained from mineral or petroleum sources. The potential for genotoxicity or carcinogenicity of petrolatum is associated with the presence of polycyclic aromatic constituents (PAC) found in the entrained oil and the degree of refining of feedstock. So, the Responsible Person must ensure that they are of pharmaceutical/food grade or sufficiently refined to remove PAC constituents especially saturated crystalline & liquid hydrocarbons having carbon numbers predominantly > C25. They must have full known refining history or to indicate that the substance from which it is produced is not a carcinogen.

- **Acute toxicity**

It is considered as non-toxic.

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- **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.

- **Sensitization**

Exposure to the formulation as supplied is unlikely to produce sensitization by skin contact in the majority of the consumers under normal and reasonably foreseeable conditions of use.

- **Inhalation toxicity**

It is unlikely that inhalation will be a route of exposure.

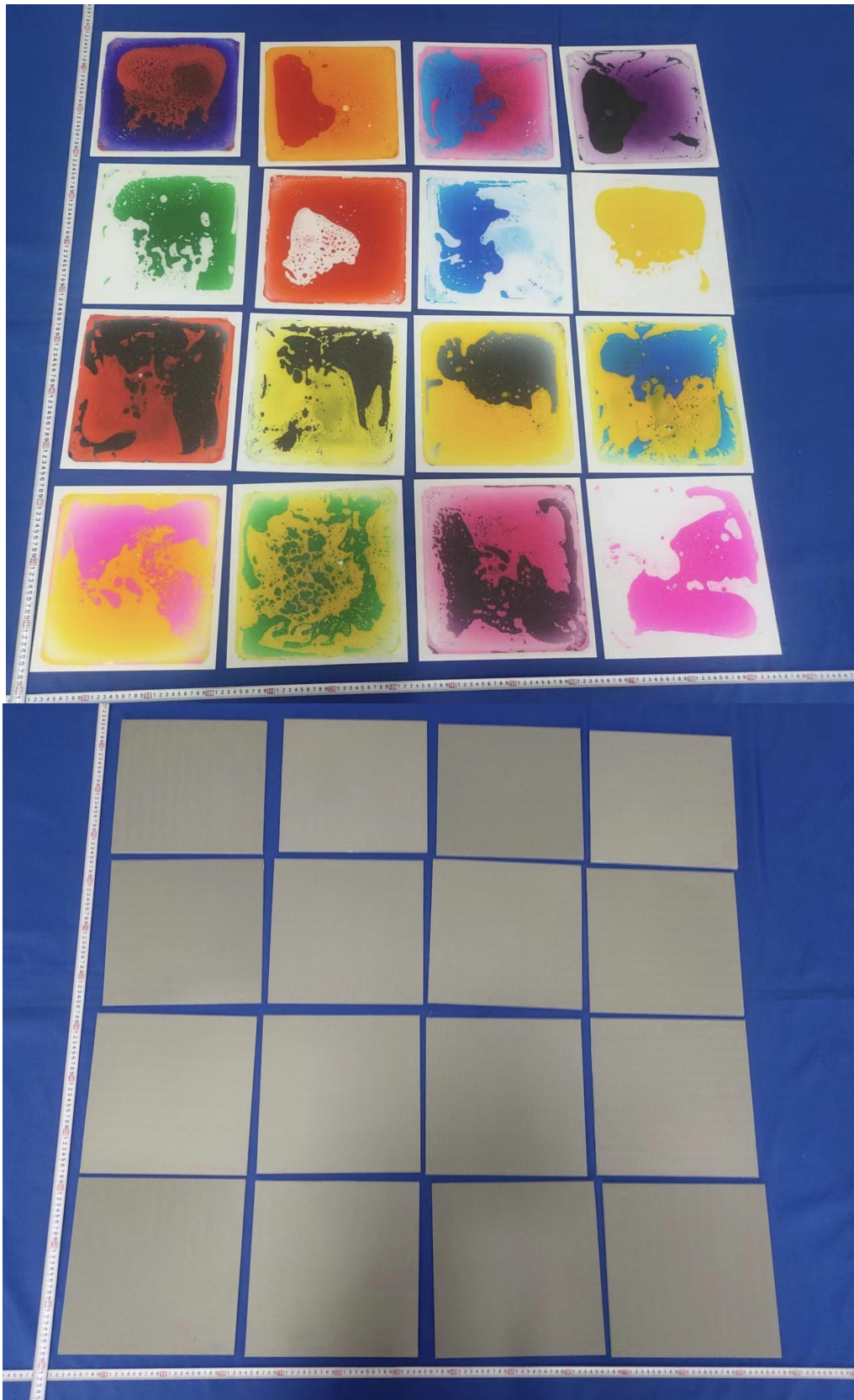
- **Systemic toxicity**

It is unlikely to cause chronic effect through skin under normal and reasonably foreseeable conditions of use.

## **Conclusion**

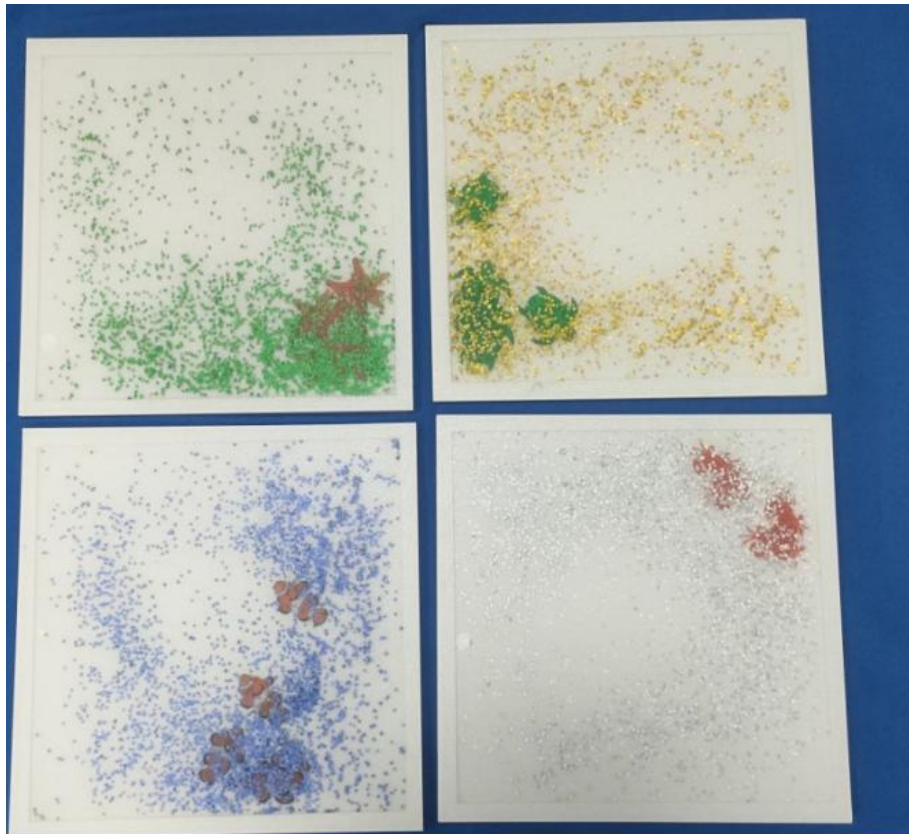
Based on the available data, ingredients used in Liquid floor tiles are not on the lists of restriction, authorization and SVHCs candidates under EU REACH. No health hazard is classified on this product according to the EU CLP regulation. It is compliant with the safety requirements in the toxicological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

**Product images:**



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