TOXICOLOGY RISK ASSESSMENT

APPLICANT	:	**YIWU JITENG TOYS CO.,LTD**
ADDRESS	:	NO.111 OF HUACHUAN NORTH ROAD,CHI'AN TOWN, YIWU,CHINA
TESTED SAMPLE DESCRIPTION	:	DOUGH
TESTED ITEM NO.	:	N/A
MANUFACTURER	:	YIWU JITENG TOYS CO.,LTD
COUNTRY OF ORIGIN	:	CHINA
COUNTRY TO IMPORT	:	USA
AGE REQUESTED ON APPLICATION FORM	:	3+
SAMPLE RECEIVED DATE	:	NOV. 10, 2021
TEST PERIOD	:	NOV. 10, 2021 TO NOV. 19, 2021
CONCLUSIONS	:	PLEASE REFER TO PAGE 3.

**********FOR FURTHER DETAILS, PLEASE REFER TO THE FOLLOWING PAGE(S)**********

1.0 Product Information

Description: Dough
Intended age: 3 years and older
Physical form: Semi - solid
Net weight or volume: 2 oz

2.0 Introduction

LHAMA: The product, *Dough*, was evaluated for compliance with ASTM D4236: determination of whether the product is expected to pose any significant chronic adverse health effects to humans when used as intended or under circumstances involving reasonable foreseeable misuse. This evaluation was conducted in general accordance with the US Code of Federal Regulations (CFR) Title 16 (CPSC) Part 1500.14(b)(8) "Art Materials", and ASTM Standard D 4236 "Standard Practice for Labeling Art Materials for Chronic Health Hazards". Chronic toxicity was evaluated in accordance with the guidelines specified by the Consumer Product Safety Commission in 16 CFR 1500.135.

TRA (US): The product, *Dough*, was evaluated for its potential to be flammable, toxic (acute/chronic), corrosive, a skin/eye irritant, or a strong sensitizer as defined in 16 CFR 1500.3(b)(5), (7)-(10) (Federal Hazardous Substances Act regulations). Chronic toxicity was evaluated in accordance with the guidelines specified by the Consumer Product Safety Commission in 16 CFR 1500.135.

In addition, the ingredients in the product were reviewed to determine whether the substances are included in the list of banned hazardous substances cited in 16 CFR 1500.17.

3.0 Disclaimer

This evaluation was conducted based solely on the product formulation and the information provided by the client between November 15th and 17th, 2021. It was assumed that all product formulation details are accurate and that there are no additional ingredients that are not listed. 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 or mechanical irritation) was not considered.

The following health endpoints are considered:

- Acute toxicity (oral, dermal, inhalation)
- Irritation/corrosion (eye, skin, respiratory tract)
- Sensitization (dermal, respiratory)
- Aspiration
- Chronic Toxicity (general organ and tissue toxicity, genotoxicity, carcinogenicity, neurotoxicity, reproductive and developmental toxicity)

Toxicity limits, incorporating appropriate safety factors and risk assessment models, are established based on a review of several regulatory and scientific databases including those provided by US EPA,

Health Canada, European Chemicals Agency, and California's Office of Environmental Health Hazard Assessment (OEHHA).

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.

4.0 Exposure Considerations

The product, *Dough,* consists of colored moldable dough formulations intended to be used by children 3 years and older for play purposes. 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 potential exposure to product ingredients is through the dermal route and possibly the oral route through accidental ingestion. Any volatile compounds within the product were evaluated for the inhalation route of exposure (acute and chronic).

5.0 Conclusions

LHAMA

Based on the available data, the submitted formulation would not be expected to pose any significant chronic adverse health effects to humans when used as intended or under circumstances involving reasonable foreseeable misuse. Chronic toxicity was evaluated in accordance with the guidelines specified by the Consumer Product Safety Commission in 16 CFR 1500.135. The product will not require any additional chronic health hazard labeling according to ASTM D4236.

The product must bear the following statement:

“Conforms to ASTM D4236.”

Other requirements of 16 CFR 1500.14 pertaining to proper labeling of the product including format and placement of statements and additional precautionary statements must also be adhered to.

TRA (US)

Based on available data, the product, *Dough* MEETS the requirements for classification as not flammable, toxic (acute/chronic), corrosive, a skin/eye irritant, or a strong sensitizer as defined in 16 CFR 1500.3, when used as intended or under circumstances involving reasonable foreseeable misuse.
In addition, the ingredients in the product are not included in the list of banned hazardous substances cited in 16 CFR 1500.17.

Additional Notes

- Individuals with an allergy to wheat may experience skin irritation or sensitization via direct or indirect contact with the product, *Dough*, due to the presence of the ingredient, wheat extract (CAS No. 84012-44-2).

- Assessment of paraffin CAS No. 8012-95-1) was based on the assumption that the ingredient used in the product formulation is “highly refined”. If this is not the case, reassessment of the product is required.

- Titanium dioxide (CAS No. 13463-67-7) (airborne, unbound particles of respirable size) is listed on the California Proposition 65 List, as chemicals known to the State of California to cause cancer; however, given the nature and physical form of the product (*i.e.*, semi-solid dough), airborne respirable titanium dioxide particles would not likely be released from the product and therefore the listed form titanium dioxide is not relevant for the product.

6.0 Approval

(Signature)	Charles Lambert, Ph.D., DABT, ERT (Name, printed)
Registered Toxicologist (Title)	November 19, 2021 (Date)

Attachment

Data issues or limitations that were identified during the assessment for each ingredient in the product are discussed below. Additional lines of evidence such as human experience that provide evidence for the safe use of the ingredient in the product are also described.

TRA (US TRA & LHAMA)

- Assessment of wheat (CAS No. 84012-44-2) was based on consideration of available animal data and human use/experince information. According to the European Chemicals Agency's Classification and Labelling Inventory database, wheat (listed as wheat, ext.) has been classifed for skin sensitization (Category 1) by the majority of industry notifiers. Product calssification for this effect is not warranted based on available data. However, it should be noted that individuals with an allergy to wheat may experience skin irritation or sensitization *via* direct or indirect contact with the product, *Dough*, due to the presence of wheat. According to the Cosmetic Ingredient Review, wheat (listed as triticum vulgare (wheat) flour extract) is considered safe as used in cosmetic products in rinse-off products at concentrations up to 2%. wheat (listed by varoius names) is listed in the EU Cosmetic Ingredients and Substances database with no use restrictions. Based on the available information, wheat is not considered to pose a safety concern at the concentration present in the product.

- Assessment of calcium chloride (CAS No. 10035-04-8) was based on consideration of limited available information and animal data and human experience/use information for the anhydrous form of calcium chloride (CAS No. 10043-52-4). According to the European Chemicals Agency's Classification and Labelling Inventory database, calcium chloride (CAS No. 10035-04-8) has been classified for eye irritation (Category 2) and acute oral toxicity (Category 4) by the majority of industry notifiers. According to the EU CLP Regulation (Regulation (EC) No 1272/2008), calcium chloride (CAS No. 10043-52-4; Index No. 017-013-00-2) has also been classified for eye irritation (Category 2). Product classification is not warranted for eye irritation or acute oral toxicity given the concentration of calcium chloride in the product and a review of the available data. Calcium chloride (CAS No. 10043-52-4) is listed in the EU Cosmetic Ingredients and Substances database with no use restrictions. Calcium chloride (CAS No. 10035-04-8) is listed in the Health Canada Natural Health Products Ingredients Database as a non-medicinal ingredient with no use restrictions. Based on the available information, calcium chloride is not considered to pose a safety concern at the concentration present in the product.

- Assessment of sodium chloride (CAS No. 7647-14-5) was based on consideration of available animal data and human experience/use information. According to the European Chemicals Agency's Classification and Labelling Inventory database, sodium chloride has not been classified for human health hazards by the majority of industry notifiers. It should be noted that a significant number of industry notifiers classified for eye irritation (Category 2); however, product classification is not warranted for eye irritation given a review of the available data and the concentration of sodium chloride in the product. Sodium chloride (listed as sodium chloride and sea salt) is listed in the EU Cosmetic Ingredients and Substances database with no use restrictions. Sodium chloride is listed as a direct food substance granted generally recognized as safe (GRAS) status by the US FDA (21 CFR 182.70). Sodium chloride is also listed in the Health Canada Natural Health Products Ingredients Database as a non-medicinal ingredient with no use restrictions. Based on the available information, sodium chloride is not considered to pose a safety concern at the concentration present in the product.

- Assessment of paraffin (CAS No. 8012-95-1) was based on consideration of available animal data and human experience/use information. Assessment of paraffin was also based on the assumption that the ingredient used in the product formulation was “highly refined”. If this is not the case, product reassessment is required. Paraffin (listed as paraffin oils) has been classified as an aspiration toxicant (Category 1) by the majority of industry notifiers according to the European Chemicals Agency’s Classification and Labelling Inventory database. Product classification for this effect is warranted given the concentration of paraffin in the product. It should be noted that a significant number of industry notifiers have not classified paraffin for other human health hazards. Paraffin (listed as mineral oil) is used as an inactive ingredient in US FDA approved topical products at concentrations up to 95%. Paraffin (listed as mineral oil) is listed in the Health Canada Natural Health Products Ingredients database as a non-medicinal ingredient with an acceptable daily intake of 20 mg/kg bw (high viscosity) and 1 mg/kg bw (medium and low viscosity). Paraffin (listed as paraffinum liquidum) is listed in the EU Cosmetic Ingredients and Substances database with no use restrictions. Based on the available information, paraffin is not considered to pose a safety concern at the concentration present in the product.
- Assessment of phenoxyethanol (CAS No. 122-99-6) was based on consideration of available animal data and human experience/use information. According to the EU CLP Regulation (Regulation (EC) No 1272/2008), phenoxyethanol (listed as 2-phenoxyethanol, Index No. 603-098-00-9) has been classified for acute oral toxicity (Category 4), eye damage (Category 1), and specific target organ toxicity (single exposure, Category 3, may cause respiratory irritation). Product classification is not warranted for these effects given the concentration of phenoxyethanol in the product. Phenoxyethanol (listed as 2-phenoxyethanol) is listed in the EU Cosmetics Regulation (Regulation (EC) No. 1223/2009) as a preservative allowed in cosmetic products with a maximum authorized concentration of 1%. According to the Cosmetic Ingredient Review, phenoxyethanol is considered safe for use in cosmetic products at concentrations up to 1%. Phenoxyethanol (listed as ethylene glycol monophenyl ether) is listed as an indirect additive used in food contact substances by the US FDA (21 CFR 175.105). Additionally, phenoxyethanol is listed in the Health Canada Natural Health Products Ingredients Database as a non-medicinal ingredient for topical application, with a maximum usage concentration of 1.0%. Based on the available information, phenoxyethanol is not considered to pose a safety concern at the concentration present in the product.
- Assessment of titanium dioxide (CAS No. 13463-67-7) was based on consideration of available animal data and human experience/use information. Titanium dioxide (in powder form containing 1% or more of particles with aerodynamic diameter ≤10 µm) (Index No. 022-006-00-2) has been classified for carcinogenicity (Category 2) through the inhalation route of exposure according to the EU CLP Regulation (Regulation (EC) No 1272/2008); however, given the nature/physical form of the product (*i.e.,* semi-solid dough), airborne respirable particles would not likely be released from this product and therefore the listed form of titanium dioxide is not relevant for the product. Titanium dioxide (listed as titanium dioxide) has not been classified for human health hazards by the majority of industry notifiers according to the European Chemicals Agency’s Classification and Labelling Inventory database. It should be noted that titanium dioxide (airborne, unbound particles of respirable size) is listed on the California Proposition 65 List as a chemical known to the State of California to cause cancer; however, given the nature/physical form of the product (*i.e.,* semi-solid dough), airborne respirable particles would not likely be released from this product and therefore the listed form of titanium dioxide is not relevant for the product. Titanium dioxide (listed as titanium dioxide) is approved for use in drugs and cosmetics generally, including those for the eye area by the US FDA (subject to Good Manufacturing Practices) (multiple 21 CFR listings). Titanium dioxide (listed as titanium dioxide and CI 77891) is a colorant allowed in cosmetic products according to the EU Cosmetics Regulation (Regulation (EC) No. 1223/2009), subject to purity criteria. Titanium dioxide (listed as E171) is approved in

the EU as a food additive. Titanium dioxide (listed as titanium dioxide) is also listed in the Health Canada Natural Health Products Ingredients Database as a non-medicinal ingredient for oral use and topical application. Based on the available information, titanium dioxide is not considered to pose a safety concern at the concentration present in the product.

- Assessment of Pigment Violet 23 (CAS No. 215247-95-3) was based on consideration of available animal data as well as human experience/use information for the related chemical, Pigment Violet 23 (CAS No. 6358-30-1), as considered appropriate by the European Food Safety Authority. According to the European Chemicals Agency's Classification and Labelling Inventory database, Pigment Violet 23 (CAS No. 215247-95-3) (listed as 2,20-dichloro-13,31-diethyl-4,22-dioxa-13,18,31,36-tetraazanonacyclo[19.15.0.03,19.05,17.06,14.07,12.023,25.024, 32.025,30]hexatriaconta-1(36),2,5,7,9,11,14,16,18,20,23,25,27,29,32,34-hexadecaene and Pigment Violet 23 (CAS No. 6358-30-1) (listed as 8,18-dichloro-5,15-diethyl-5,15-dihydrodiindolo[3,2-b:3',2'-m]triphenodioxazine) have not been classified for human health hazards by industry notifiers. Pigment Violet 23 (listed as carbazole violet, CAS No. 6358-30-1) is approved for use in contact lenses by the US FDA (21 CFR 73.3107), subject to Good Manufacturing Practices. Pigment Violet 23 (CAS No. 6358-30-1) (listed as 8,18-dichloro-5,15-diethyl-5,15-dihydrodiindolo[3,2-b:3',2'-m]triphenodioxazine and CI 51319, CAS No. 6358-30-1) is listed as a colorant allowed in rinse-off cosmetic products according to the EU Cosmetic Regulation (Regulation (EC) No. 1223/2009). Based on the available information, Pigment Violet 23, is not considered to pose a safety concern at the concentration present in the product.
- Assessment of Pigment Blue 15 (CAS No. 147-14-8) was based on consideration of available animal data, and human experience/use information. Pigment Blue 15 (listed as 29H,31H phthalocyaninato (2) N29,N30,N31,N32 copper) has not been classified for human health hazards by the majority of industry notifiers, according to the European Chemicals Agency's Classification and Labelling Inventory database. Pigment Blue 15 [listed as (29H,31H phthalocyaninato(2-)-N29,N30,N31,N32) copper and CI 74160)] is a colorant allowed in cosmetic products, except when used as a substance in hair dye products according to the EU Cosmetics Regulation (Regulation (EC) No 1223/2009). Pigment Blue 15 is also listed as an indirect food additive approved for human consumption by the US FDA (multiple 21 CFR citations). Pigment Blue 15 (listed as copper phthalocyanine) is listed in the Health Canada Natural Health Products Ingredients Database as a non-medicinal ingredient for dental and topical application. Based on the available information, Pigment Blue 15 is not considered to pose a safety concern at the concentration present in the product.
- Assessment of Pigment Red 181 (CAS No. 2379-74-0) was based on consideration of available animal data and human experience/use information. According to the European Chemicals Agency's Classification and Labelling Inventory database, Pigment Red 181 (listed as 6-chloro-2-(6-chloro-4-methyl-3-oxobenzo[b]thien-2(3H)-ylidene)-4-methylbenzo[b]thiophene-3(2H)-one) has not been classified for human health hazards by the majority of industry notifiers. Pigment Red 181 (listed as D&C Red No. 30) is allowed for use in drugs and cosmetics generally by the US FDA (subject to Good Manufacturing Practices). Pigment Red 181 (listed as 6-chloro-2-(6-chloro-4-methyl-3-oxobenzo[b]thien-2(3H)-ylidene)-4-methylbenzo[b]thiophene-3(2H)-one and CI 73360) is a colorant allowed in cosmetic products with no use conditions according to the EU Cosmetics Regulation (Regulation (EC) No. 1223/2009). Pigment Red 181 (listed as D&C Red No. 30) is listed in the Health Canada Natural Health Products Ingredients Database as a non-medicinal ingredient with no use restrictions. Based on the available information, Pigment Red 181is not considered to pose a safety concern at the concentration present in the product.

- Assessment of Benzidine Orange (CAS No. 3520-72-7) was based on consideration of available animal data and toxicological information provided by the European Chemicals Agency's Classification and Labelling Inventory database. Benzidine Orange (listed as 4,4'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one]) has not been classified for human health hazards by the majority of industry notifiers according to the European Chemicals Agency's Classification and Labelling Inventory database. Benzidine Orange is a benzidine-based dye; however, it is not classified as carcinogenic or mutagenic. Based on the available information, Benzidine Orange is not considered to pose a safety concern at the concentration present in the product.

Table 1: Product Formulation - Dough

Chemical Name	CAS No.	% By Weight in Product
Wheat	84012-44-2	52%
Calcium chloride	10035-04-8	8%
Sodium chloride	7647-14-5	7%
Paraffin	8012-95-1	4%
Phenoxyethanol	122-99-6	0.5%
Water	7732-18-5	27.4%
The product formulation may contain the following colorants:		
Titanium dioxide[a]	13463-67-7	up to 1%
Pigment violet 23	215247-95-3	up to 0.1%
Pigment Blue 15	147-14-8	up to 0.1%
Pigment Red 181	2379-74-0	up to 0.1%
Benzidine orange	3520-72-7	up to 0.1%

[a] Toxicological data for primary particles of titanium dioxide (*i.e.*, >100 nm in size) were used in the current product evaluation; toxicity associated with exposure to ultrafine grades (*i.e.*, nanoparticles) of titanium dioxide (*i.e.*, <100 nm) was not considered.

Other Information / Remark:

The assessment report was subcontracted to lab: C021.

END OF THE REPORT