



WWW.ENVMED.COM

01309-1009

ENVIRONMENTAL MEDICINE, INC.
CONSULTANTS IN TOXICOLOGYRUDOLPH J. JAEGER, PH.D. DABT
PRESIDENT AND CHIEF TOXICOLOGIST778 CARVER AVENUE
WESTWOOD, NJ 07675
U.S.A.
TEL. +1-201-666-7929
FAX. +1-201-666-8611Date of Certification: April 23, 2018
Revised:Project Code: **BOKSAIEKI**Nobuyoshi Matsui
Boku-Undo Co., Ltd
5-35 ROKUJYO 1-CHOME
Nara-Shi 630-8043
JAPAN**ART MATERIAL CERTIFICATION to ASTM D-4236 & 16CFR1500.14(b)(8) (LHAMA) FOR CHRONIC HAZARDS AND COMPLIANCE WITH THE FEDERAL HAZARDOUS SUBSTANCES ACT (FHSA) FOR ACUTE HAZARDS.**

Dear Nobuyoshi Matsui,

This letter constitutes my certification that your product(s),

SAIEKE - SERIES 404

complies with the regulations cited above. As a qualified Toxicologist as defined by ASTM D-4236, I hereby confirm compliance of this product with the American Society for Testing and Materials (ASTM) Standard of Practice for Labeling Art Materials for Chronic Health Hazards. I conducted this review in a manner consistent with the Consumer Product Safety Commission (CPSC) Guidelines as found in 16CFR1500.135. The procedures and regulations that I followed are described separately and have been filed with the CPSC. This product was reviewed according to 16CFR1500.14(b)(8) (LHAMA) for chronic hazards and the whole of 16CFR1500 (FHSA) for acute hazards.

This certification is based on a product(s) review and includes any changes to your label statements which are required under the regulations. My review as stipulated by LHAMA considered the product as a whole as well as the components, their formulae, the SDS's for the ingredients and any other information provided to me by you. Other applicable sections of the FHSA found in 16CFR1500 were reviewed for acute hazard standards and are reflected on the label statement page.

If the formula or intended uses change, it will be necessary for me to evaluate the new data in order for this certification to be valid. In any case, under LHAMA requirements, this certification must be reviewed every five (5) years. The re-certification date for this product is **April 23, 2023**. This certification is not transferrable.

Be advised that the Consumer Product Safety Commission may choose a different determination about this product line than I made. Since the Commission is mandated by Congress to enforce these regulations, their opinion, not mine, is final.

ENVIRONMENTAL MEDICINE INC.

Rudolph J. Jaeger, Ph.D. DABT., ERT (UK)
Certifying Toxicologist

April 23, 2018

**LHAMA CERTIFICATION PROCEDURE AND APPLICABLE REGULATIONS
FOR ARTS & CRAFT MATERIALS (16 CFR 1500.135)**

Boku-Undo Co., Ltd SAEIKE - SERIES 404

The Federal Hazardous Substances Act (FHSA), as amended by Public Law 100-695 (15USC 1227), names the American Society for Testing and Materials (ASTM) Standard Practice for Labeling Art Materials for Chronic Health Hazards, Designation 4236, as applicable under federal law, to art materials. This US Federal requirement applies in addition to the labeling and certification requirements of various states. The referenced ASTM standard previously established certain procedures which are to be used by qualified persons to use in health labeling review and compliance certification for art materials. The statement of compliance with the standard can only be performed by a Toxicologist or a Physician who is certified by a nationally recognized certification board. For ASTM, the Toxicologist shall use the current ASTM standard practice, while FHSA requires ASTM D-4236-88. This certification is conducted in accord with the Consumer Product Safety Commission procedure detailed at 16 CFR 1500.135 as applicable and as data are available.

For the Toxicologist to assure labeling compliance as required by ASTM and to conclude that a material is suitable for use, i.e., to certify a material as being free of chronic health hazard or that it is adequately labeled to warn of such hazards under conditions of use, the Toxicologist shall conduct those investigations which, the Toxicologist's professional opinion, are sufficient to develop the information required for such a judgment. These investigations include manufacturing formula review, biologic testing (as warranted), and review of the toxicologic literature. Biologic availability and anticipated exposures, as well as acceptable levels of intake, are considerations used by the Toxicologist in his or her evaluation. Incorporated by reference are the determination of the presence of substances which may be carcinogenic, neurotoxic or otherwise toxic to the reproductive systems of men, women and children. Proper Labeling considers the assessment of exposure by ingestion, inhalation and dermal contact. As data are available, direct monitoring, modeling or surrogate data may be used. Assessment of bioavailability and the application of suitable margins of safety are an integral part of this evaluation.

In the present case, the general formula for your product was reviewed by Dr. Rudolph J. Jaeger, Consulting Toxicologist. Dr. Jaeger is a Diplomate of the American Board of Toxicology. As defined by ASTM, a Toxicologist is qualified by training and experience to evaluate the toxicity of art materials. The product in question has been evaluated for its intended use as an art or craft material. To fill a gap in information or to confirm the data provided, the Toxicologist may arrange for the performance of toxicity testing. Test results from similar products, certification for equivalent product and information provided by the supplier of the components used, will also be judged to be applicable. Exposures which are foreseeable and reasonable form the basis for the certification. For reasonable and foreseeable uses of the product, that is, its intended and likely use as an art material, the Toxicologist will rely on the label as well as the statements of the manufacturer, formulator, or the packager.

Your representative(s), employees, and others assigned by you have described the product(s), the intended distribution, and expected uses. The description of the art material, as of this date, suggests that the material is generally available for sale to a variety of customers. It is understood that similar products or formulations have been sold by your firm. To the present date and for the product that is named below, the Toxicologist is given to understand that no significant chronic harm or contents-attributable injury has been reported to you by customers or by other responsible authorities. As the manufacturer, such reports must be provided to the Toxicologist for review if and when they are received. The product labels will be registered with a Poison Information System so that reports of adverse effects can be documented.

Based on professional judgment, scientific and regulatory literature, and the reasonable foreseeable use of the products, it is judged that this product meets the current ASTM D-4236 requirements and, thus, it may be certified for compliance.

***This product SAEIKE - SERIES 404 may be labeled as follows:
"CONFORMS TO ASTM D-4236".***

ENVIRONMENTAL MEDICINE INC.



Rudolph J. Jaeger, Ph.D., DABT
Certifying Toxicologist

ENVIRONMENTAL MEDICINE INC.
778 Carver Avenue
Westwood, NJ 07675

April 23, 2018
BOKSAIEKI

Cindy Fronsoe
Data Specialist
Truven Health Analytics
6200 South Syracuse Way, Suite 300
Englewood, CO 80111-4740
Phone: 303-486-6673

Attention: New Data Submission

Dear Cindy,

Attached is a new submission for the following company

Boku-Undo Co., Ltd
SAIEKE - SERIES 404
SEE LIST

Kindly confirm receipt of this information and send us a log number.

Sincerely yours,

ENVIRONMENTAL MEDICINE, INC.

Enc.

ENVIRONMENTAL MEDICINE, INC.
778 Carver Avenue
Westwood, NJ 07675

April 23, 2018
BOKSAIEKI

Ms. Mary F. Toro, Assoc. Director
United States C.P.S.C.
Office of Compliance and Recalls
4330 East West Highway, Room 613F
Bethesda, MD 20814-4408

Dear Ms. Toro,

Kindly accept the enclosed Art Material Certification paperwork for the following company and its product line:

Boku-Undo Co., Ltd
SAIEKE - SERIES 404
SEE LIST

Contact us if you need any additional information.

Sincerely yours,

ENVIRONMENTAL MEDICINE, INC.

Enc.

Product List**SAIEKE - SERIES 404**

Date:	4/23/2018	Product Age Group:	Adult
Certification Date:	4/23/2018	Flash Point:	NOT APPLICABLE
Project Code:	BOKSAIEKI	PH:	N/A
Company Name:	Boku-Undo Co., Ltd	Viscosity:	N/A
Product No.(s):	SEE LIST	Weight:	SEE LIST
Country Of Origin:	JAPAN		

	PRODUCT #	COLOR	UPC Code	Formula	Notes
1	404	RED	N/A		SIZE: 5 mL; 12 mL; 70 mL; 200 mL; 500 mL
2	404	ORANGE	N/A		SIZE: 5 mL; 12 mL; 70 mL; 200 mL; 500 mL
3	404	GREEN	N/A		SIZE: 5 mL; 12 mL; 70 mL; 200 mL; 500 mL
4	404	BLUE	N/A		SIZE: 5 mL; 12 mL; 70 mL; 200 mL; 500 mL
5	404	YELLOW	N/A		SIZE: 5 mL; 12 mL; 70 mL; 200 mL; 500 mL
6	404	BLACK	N/A		SIZE: 5 mL; 12 mL; 70 mL; 200 mL; 500 mL

LABEL INFORMATION FOR Container - USA**Product Identity: SAIEKE - SERIES 404**


Certification Date:	4/23/2018	Package Type:	Container
Project Code:	BOKSAIEKI	Area Of Display:	NOT PROVIDED
Company Name:	Boku-Undo Co., Ltd	Product Age Group:	Adult
Product No.(s):	SEE LIST	Flash Point:	NOT APPLICABLE
Label Size:	NOT APPLICABLE	PH:	N/A
Country Of Origin:	JAPAN	Viscosity:	N/A
		Size:	5 mL; 12 mL; 70 mL; 200 mL; 500 mL

[For a two-panel label designed to be consistent with ANSI Z129.1-2000]

Principal Display Panel

Signal Word	NO STATEMENT REQUIRED.
Principal Hazards	NO STATEMENT REQUIRED.
Small Parts Statement	 WARNING: CHOKING HAZARD - Small Parts. Not for children under 3 years.
Refer	NO STATEMENT REQUIRED.

Other Display Panel

Hazardous Ingredients	NO STATEMENT REQUIRED.
Hazard Statement	NO STATEMENT REQUIRED.
Precaution Statement	NO STATEMENT REQUIRED.
First Aid Statements	NO STATEMENT REQUIRED.
Children's Statement	ADULT USE PRODUCT.
Conformity Statement	CONFORMS TO ASTM D-4236
California	 WARNING: Cancer and Reproductive Harm - www.P65Warnings.ca.gov

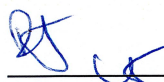
NOTE: The warning must have the symbol. According to 27 CCR § 25603 (a)(1) A symbol consisting of a black exclamation point in a yellow equilateral triangle with a bold black outline. Where the sign, label or shelf tag for the product is not printed using color yellow, the symbol may be printed in black and white.

Notes and Statements This information does not need to appear on the product label. For Reference Only.

Notes or Statements	Labeling information is based on the review of the reasonable foreseeable use of the product, formulation and on the submitted information by the manufacturer, as of April 23, 2018 . Label updates are required upon any changes to formulation or raw ingredients.
----------------------------	---

NOTES OR STATEMENTS

The bold and case style is per labeling regulation guidelines. Please consult regulation 16 CFR §1500.121 (c.) Table 1 for specific sizing requirements


 Initials

LABEL INFORMATION FOR Container - USA**Product Identity: SAIEKE - SERIES 404**

Certification Date:	4/23/2018	Package Type:	Container
Project Code:	BOKSAIEKI	Area Of Display:	NOT PROVIDED
Company Name:	Boku-Undo Co., Ltd	Product Age Group:	Adult
Product No.(s):	SEE LIST	Flash Point:	NOT APPLICABLE
Label Size:	W: in H: in (in ²)	PH:	N/A
Country Of Origin:	JAPAN	Viscosity:	N/A
		Size:	5 mL; 12 mL; 70 mL; 200 mL; 500 mL

[For a two-panel label designed to be consistent with ANSI Z129.1-2000]

Notes and Statements - Disclaimer**Disclaimer****Disclaimer:**

EMI's responsibility rest solely in the certification of the product as defined in the documents provided. We are empowered to interpret and define the hazards present in a product based on the formulation provided, intended user as well as other criteria. The final authority lies with the federal regulatory agencies of each sovereign nation. EMI can only confirm the hazards statements are correct from a toxicological perspective and that general guidelines have been observed. EMI is not responsible for the final label copy. It is the responsibility of the manufacturer to ensure proper labeling of their products according to the rules and regulations set forth by each country.



Initials

LABEL INFORMATION FOR Kit - USA**Product Identity: SAIEKE - SERIES 404**

Certification Date:	4/23/2018	Package Type:	Kit
Project Code:	BOKSAIEKI	Area Of Display:	NOT PROVIDED
Company Name:	Boku-Undo Co., Ltd	Product Age Group:	Adult
Product No.(s):	SEE LIST	Flash Point:	NOT APPLICABLE
Label Size:	NOT APPLICABLE	PH:	N/A
Country Of Origin:	JAPAN	Viscosity:	N/A
		Size:	SET

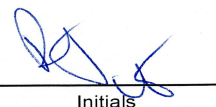
[For a two-panel label designed to be consistent with ANSI Z129.1-2000]

Principal Display Panel**Warning Statement** (NO STATEMENT REQUIRED).**Small Parts Statement** ⚠ WARNING: CHOKING HAZARD - Small Parts. Not for children under 3 years.**Sharp Point or Edges Statement** (NO STATEMENT REQUIRED).**Age Grading ASTM D-4236** ADULT USE ONLY.**Refer** Refer to side/back panel.**Other Display Panel****Hazardous Ingredients** NO STATEMENT REQUIRED.**Hazard Statement** (NO STATEMENT REQUIRED).**Precaution Statement** (NO STATEMENT REQUIRED).**First Aid Statements** (NO STATEMENT REQUIRED).**Children's Statement** Not intended to be used by children.**Conformity Statement** CONFORMS TO ASTM D-4236**California** ⚠ WARNING: Cancer and Reproductive Harm - www.P65Warnings.ca.gov

NOTE: The warning must have the symbol. According to 27 CCR § 25603 (a)(1) A symbol consisting of a black exclamation point in a yellow equilateral triangle with a bold black outline. Where the sign, label or shelf tag for the product is not printed using color yellow, the symbol may be printed in black and white.

Special Instructions**Instruction Pamphlet Statement** Add any cautionary statements.**NOTES OR STATEMENTS**

The bold and case style is per labeling regulation guidelines. Please consult regulation 16 CFR §1500.121 (c.) Table 1 for specific sizing requirements



Initials

LABEL INFORMATION FOR Kit - USA**Product Identity: SAIEKE - SERIES 404**

Certification Date:	4/23/2018	Package Type:	Kit
Project Code:	BOKSAIEKI	Area Of Display:	NOT PROVIDED
Company Name:	Boku-Undo Co., Ltd	Product Age Group:	Adult
Product No.(s):	SEE LIST	Flash Point:	NOT APPLICABLE
Label Size:	W: in H: in (in ²)	PH:	N/A
Country Of Origin:	JAPAN	Viscosity:	N/A
		Size:	SET

[For a two-panel label designed to be consistent with ANSI Z129.1-2000]

Notes and Statements This information does not need to appear on the product label. For Reference Only.**Notes or Statements****Recommended:** For emergency health information, call your Poison Control Center 1-800-222-1222.**Notes or Statements**

Labeling information is based on the review of the reasonable foreseeable use of the product, formulation and on the submitted information by the manufacturer, as of April 23, 2018 . Label updates are required upon any changes to formulation or raw ingredients.

Notes and Statements - Disclaimer**Disclaimer****Disclaimer:**

EMI's responsibility rest solely in the certification of the product as defined in the documents provided. We are empowered to interpret and define the hazards present in a product based on the formulation provided, intended user as well as other criteria. The final authority lies with the federal regulatory agencies of each sovereign nation. EMI can only confirm the hazards statements are correct from a toxicological perspective and that general guidelines have been observed. EMI is not responsible for the final label copy. It is the responsibility of the manufacturer to ensure proper labeling of their products according to the rules and regulations set forth by each country.



Initials