



BETA obchodní společnost, s.r.o.
Křižanská 1
460 10 Liberec

YOUR REF.: 24.10.2016
DATE: SZÚ 3476/2016
OUR REF.: CTZB 187- 3476/16-364 EX
161496
PROCESSED BY: RNDr. M. Rucki, PhD.
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DATE: 22.11.2016

Subject: **EXPERT OPINION on the health safety of box for cleaning the menstrual cups.**

SUBJECT OF THE REQUEST:

Our decision regarding your request from 24 October 2016 on evaluation of the health safety of infuser box under Act No. 102/2001 Sb., as amended, on General Product Safety is as follows:

SAMPLES PROVIDED: **1) Box for cleaning the menstrual cup (infuser box),
material: polypropylen**

Manufacturer: **BETA obchodní společnost, s.r.o., Křižanská 1, 460 10 Liberec**

DOCUMENTATION PROVIDED:

Specification of the product provided in the request from 24 October 2016.

TESTING PREFORMED:

Chemical analyses (presence of primary aromatic amines under ČSN 621156, total migration in the water solution measured under ČSN 621156, volume of reducing substances in the water solution under ČSN 621156) were carried out in Test Laboratories no 1206, certified by the Czech Accreditation Institute, in the Centre of Toxicology and Health Safety (CTZB). The analyses were carried out in the extent of the Methodological Guidelines of the National Institute of Public Health (SZÚ) No. 1/2000 on evaluation of products in direct contact with the human body by skin or by mucosa (AHM No. 3/2000).

The provided samples were used for the above analyses.

EXPERT OPINION:

The subject of the assessment was the analysis of possible undesirable effects of the material in contact with skin.

The presence of primary aromatic amines in the samples are below the detection limits.

The values of total migration in the water solution of the samples are below the limit for a safe product.

The volume of reducing substances in the water solution of the samples is also below the limit for a safe product.

CONCLUSION:

Based on the assessment of the provided documentation, chemical analysis and cytotoxicity assay, the decision was reached that the product Infuser box for cleaning the menstrual cups is safe for human health when in contact with skin. The results of the performed chemical analyses and cytotoxicity assays confirm health safety under Act No. 102/2001 Sb., as amended, on General Product Safety.

This statement applies is valid only for the provided samples and the conclusions drawn from their evaluation can only be applied on like products, whose content and properties correspond entirely to thus evaluated samples.

**NATIONAL INSTITUTE OF
PUBLIC HEALTH
Centre of Toxicology
and Health Safety
for Cosmetics
Šrobárova 48, 100 42 Praha 10**

MUDr. Dagmar Jírova, CSc.
Director of the Centre of Toxicology
and Health Safety

ATTACHEMENTS:

Chemical Analyses Protocol no. CTZB 187-3476/16-364

CHEMICAL ANALYSES PROTOCOL

National Reference Centre for Cosmetics
National Institute of Public Health Prague, Centre of Toxicology and Health
Safety Šrobárova 48, 100 42 Prague 10

Contracting Entity: BETA obchodní společnost, s.r.o., Křižanská 1, 460 10 Liberec

Protocol Number: CTZB 187-3476/16-364

Date of the test: 15.-16.11.2016

Sample description: 1) Infuser box for cleaning the menstrual cup

Manufacturer: BETA obchodní společnost, s.r.o., Křižanská 1, 460 10 Liberec

CHEMICAL ANALYSES

Measured parameters:

Determination of primary aromatic amine

Solution: 37 °C ± 2 °C, 24 h., 8 g in 100 ml, method according to CSN 62 1156
device: VARIAN CARY 1E

Volume of reducing substances in the water solution

solution: 37 °C ± 2 °C, 24 h., 8 g in 100 ml, method according to CSN 62 1156

Total migration in the water solution

solution: 37 °C ± 2 °C, 24 h., 100 sq cm in 100 ml, method according to CSN 62 1156

Results of the tests:

sample no.: 1) menstrual cap transparent (01052015) - silicone				
test	value measured	unit	unit	limit
chemical analyses				
Primary aromatic amine	<0,03*	mg.l ⁻¹	±15%	-
reducing substances in the water solution	0,5	ml KMnO ₄ (c = 3.10 ⁻³ mol.l ⁻¹).50ml ⁻¹	± 18%	30
total migration in the water solution	1,8	mg.dm ⁻²	± 12%	10

*values are lower than limits set for quantification

Chemical analyses were carried out in the extent of the Methodological Guidelines of the SZÚ no. 1/2000 on evaluation of products in direct contact with the human body by skin or by mucosa (AHM č. 3/2000).

Date: 21 November 2016
Test performed by: RNDr. Marián Rucki, PhD.

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