NATIONAL INSTITUTE OF PUBLIC HEALTH
Šrobárova 48 Prague 10 100 42

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

YOUR REF..:	4.5.2015
DATE:	SZÚ 1598/2015
OUR REF.:	CTZB 187- 1598/15-126 EX 150569
PROCESSED BY:	RNDr. M. Rucki, PhD.
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DATE:	27.5.2015

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

SUBJECT OF THE REQUEST:
Our decision regarding your request from 4 May 2015 on evaluation of the health safety of menstrual cups under Act No. 102/2001 Sb., as amended, on General Product Safety is as follows:

SAMPLES PROVIDED: **1) Menstrual cup transparent (01052015) - silicone**
2) Menstrual cup transparent (B-2251) - silicone

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

DOCUMENTATION PROVIDED:
Specification of the product provided in the request from 4 May 2015.

TESTING PREFORMED:
Chemical analyses (pH of the solution from the sample measured under the ČSN EN ISO 3071, total migration in the water solution measured under ČSN 621156, volume of reducing substances in the water solution under ČSN 621156) and the cytotoxicity assay (under ČSN EN ISO 10993-5:2005, Part 5) 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 (AHEM 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 pH of the products is within the safe range for contact with mucosa.
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.
The results of the cytotoxicity assay showed that the products are not toxic for tissue-culture cells.

Results:

Sample (extract)	Viability (% control)
VZ1 - 25%	107.3
50%	99.0
100%	104.9
VZ2 - 25%	105.9
50%	101.5
100%	104.8
NK	100.0
PK - LS 1 µg/ml	105.5
LS 10 µg/ml	47.2
LS 20 µg/ml	9.6

Assessment based on the results:

Samples VZ1 and VZ2 are not toxic for tissue-culture cells under the test conditions.

Date: 26 May 2015

Analysis performed by: RNDr. K. Kejlová, Ph.D.

CONCLUSION:
Based on the assessment of the provided documentation, chemical analysis and cytotoxicity assay, the decision was reached that the products menstrual caps are 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.

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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 187-1598/15-126
Cytotoxicity Assay Protocol no. CTZB 187-1598/15-126

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 187-1598/15-126**
Date of the test: **18 May – 20 May 2015**

Sample description: **1) menstrual cap transparent(01052015) - silicone**
2) menstrual cap transparent(B-2251) - silicone

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

CHEMICAL ANALYSES

Measured parameters:

pH value of the solution

CSN ISO 4045

device: inoLab pH Level 1

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				
pH extraction agent	7.0	-	±0.1	5.0 - 7.5
PH	5.6	-	±0.1	4.5 - 7.5
reducing substances in the water solution	2.1	ml $KMnO_4$ ($c = 3.10^{-3}$ $mol.l^{-1}$).50ml^{-1}	± 18%	30
total migration in the water solution	5.6	$mg.dm^{-2}$	± 12%	10

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sample no.: 2) menstrual cap transparent(B-2251) - silicone				
test	**value measured**	**unit**	**unit**	**limit**
chemical analyses				
pH extraction agent	7.0	-	±0.1	5.0 - 7.5
pH	5.7	-	±0.1	4.5 - 7.5
reducing substances in the water solution	1.05	ml $KMnO_4$ ($c = 3.10^{-3}$ $mol.l^{-1}$).50ml^{-1}	+ 18%	30
total migration in the water solution	7.6	$mg.dm^{-2}$	± 12%	10

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 (AHEM č. 3/2000).

Date: 27 May2015
Test performed by: RNDr. Marián Rucki, PhD.

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

Test laboratory no. 1206, certified by the Czech Accreditation Institute

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

Protocol Number: CTZB 187-1598/15 -126

Date of the test: 18 May – 20 May 2015

List of samples: VZ 1 - Menstrual cap sample 01052015, silicone, colour transparent

VZ 2 - Menstrual cap sample B-2251, silicone, colour transparent

The test was carried out according to CSN EN ISO 10993-5:2010 – Biological assessment on medical devices - Part 5: Tests for in vitro cytotoxicity.

Cell line: Mouse fibroblast - line Balb/c 3T3
Culture medium: DMEM containing antibiotics (PNC 100 IU/ml, STM 100 µg/ml) with 10 % of inactive bovine serum
Positive control: Sodium laureth sulphate (SLS)
Negative control: Hydro - poly[(2-hydroxyethyl) methacrylate]
Preparation of the extract: 0.1 g of the sample in 1 ml of the extraction agent (DMEM without serum), 24 hours at 37°C. 100% extracts were then diluted by DMEM without serum.

Procedure: After 24-hour pre-culture, the cellular culture was exposed to 25%, 50% and 100% extracts of the tested samples VZ1 and VZ2 for the period of 24 h. (37°C, 7.5% CO_2).Then the viability of the cellular culture was determined based on incorporation of vital dye (neutral red) by the fluorometric method. The viability of the culture exposed to the tested sample was then compared to the viability of the negative control.

Cytotoxicity level of the extract:

viability equal and above 70 % .....non-cytotoxic
viability equal and above 50% and below 70 %.....mildly cytotoxic
viability equal and above 30% and below 50 %..... medium cytotoxic
viability below 30 % ..... strongly cytotoxic

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