



## THE NATIONAL INSTITUTE OF PUBLIC HEALTH

Contributory organisation

Šrobárova  
48 Praha 10  
100 42

**Jaguara, s.r.o.**  
**Jeruzalémská 5**  
**110 00 Praha 1**

YOUR LETTER MARK:

DATED **10 November 2008**  
OUR MARK **SZÚ 3719/08**  
**CZŽP 13-3719/08-297, EX 081525**  
ATTENDED BY: **M.Sc. M. Rádlová**  
TEL./FAX: **267 08 23 76**  
E-MAIL: [radlova@szu.cz](mailto:radlova@szu.cz)

DATE: 17 December 2008

Re: **EXPERT OPINION to the health safety of the LadyCup menstrual cups**

### SUBJECT-MATTER OF THE APPLICATION:

To your application of 10 November 2008 to assess the health safety of the LadyCup menstrual cups in accordance with the requirements of Act No. 102/2001 Coll., on General Safety of Products, we wish to inform you as follows:

### SUBMITTED SAMPLES: LadyCup menstrual cups in the colour design:

- **blue (under the designation BlueCup)**
  - **lilac (under the designation LilacCup)**
  - **orange (under the designation OrangeCup)**
  - **green (under the designation GreenCup)**
  - **yellow (under the designation YellowCup)**
- (silicone Elastosil LR 3003 A,B)**

Country of origin: EU

### DOCUMENTS SUBMITTED:

Certificate of the company IQNet and CQS No. CZ-2161/2006 for the silicone materials used for the menstrual cup production of the company Silroc CZ, a.s. of 19 June 2006.

Specification of the silicone material Elastosil LR 3003 A, B from the producer, the company Wacker Silikones (Germany).

Technical drawings B-2235 and B-2236 for the menstrual cups with the diameter of 40 and 46 mm were given in the documentation to the file of the Centre of Health and Life Conditions CZŽP 13-1184/08-156 dated 3 July 2008.

Certificates of the company Bioservice Scientific Laboratories GmbH (Munich) for biological tests of the silicone material Elastosil LR 3003 A, B dated 10 July 1998 and 28 December 1998.

Results of the microbiological tests of the material Elastosil LR 3003/ 30-70 shore A of 23 February 2004.

Instructions for use of the menstrual cup.

Opinion of CZŽP (the Centre of Health and Life Conditions) 13-246/08-36, EX 080221 dated 12 March 2008 for the LadyCup menstrual cup of colourless silicone and CZŽP 13-1184/08-156, EX 080850 dated 3 July 2008 for the LadyCup menstrual cup of silicone in the pink design PinkCup.

### **PERFORMED TESTS:**

Chemical examinations (Determination of primary aromatic amines and content of reducing substances in the water extract in accordance with modified ČSN 621156, Determination of heavy metal content in the extract of plastic in accordance with SOP 8/21) and Cytotoxicity test (in accordance with ČSN EN ISO 10993-5:2005, Part 5) were carried out in the testing Laboratories of the Centre of Health and Life Conditions accredited by the Czech Accreditation Institute No. 1206.3.

The submitted samples were used for the mentioned examinations.

### **EXPERT ASSESSMENT:**

The subject-matter of the assessment is determination of possible undesirable biological effects of the menstrual cup material in the various colour designs in contact with the skin.

The examination was carried out to the extent of Methodical Recommendation of the National Institute of Public Health No. 1/2000 for assessment of the products coming into direct contact with human organism through skin or mucous membranes (AHEM No. 3/2000).

### **CONCLUSION:**

Based on the assessment of the documents submitted and the chemical examinations and the cytotoxicity determination, we come to a conclusion that the menstrual cup material in the mentioned colour design is, within the extent of the performed test, safe for human health in contact with the skin. It fulfils the basic requirements for the material safety in accordance with Act No. 102/2001 Coll., on General Safety of Products, as amended.

This expression relates only to the samples submitted, and the conclusions derived from their assessment may be applied only for the other products of the same kind that completely correspond, with their composition and properties, to the samples examined by us.



M.Sc. Jitka Sosnovcová  
Head of the Centre of Laboratory  
Activities in Public Health Protection  
and Support

**STÁTNÍ ZDRAVOTNÍ ÚSTAV**  
Centrum laboratorních činností  
v ochraně a podpoře veřejného zdraví  
Šrobárova 48  
100 42 Praha 10

*Stamp:* THE NATIONAL INSTITUTE OF PUBLIC HEALTH  
Centre of Laboratory Activities  
in Public Health Protection and Support  
Šrobárova 48  
100 42 Praha 10

### **ANNEX:**

Report on Chemical Examination No. CLČ 13-3719/08-297

Report on Determination of Heavy Metal Content in the Extract No. CLČ-3719/08-297

Report on Cytotoxicity Determination No. CLČ 13-3719/08-297



**THE NATIONAL INSTITUTE OF PUBLIC HEALTH**

*Contributory organisation*

Šrobárova 48  
Praha 10 100 42

**Jaguara, s.r.o.**  
**Jeruzalémská 961/5**  
**110 00 Praha 1**

YOUR LETTER MARK:

DATED **16 June 2008**

OUR MARK **SZÚ 1986/08**

**CZŽP 13-1184/08-156, EX 080850**

ATTENDED BY: **M.Sc. M. Rádlová**

TEL/FAX **267 08 23 76**

E-MAIL: [\*\*radlova@szu.cz\*\*](mailto:radlova@szu.cz)

DATE: **3 July 2008**

**Re: EXPERT OPINION to the health safety of the LadyCup menstrual cup  
in pink design**

**SUBJECT-MATTER OF THE APPLICATION:**

To your application of 16 June 2008 to assess the health safety of the LadyCup menstrual cup in the pink design in accordance with the requirements of Act No. 102/2001 Coll., on General Safety of Products we wish to inform you as follows:

**SUBMITTED SAMPLES: LadyCup menstrual cups in pink design - PinkCup  
(silicone Elastosil LR 3003 A,B)**

Country of origin: EU

**DOCUMENTS SUBMITTED:**

Specification of the menstrual cup material was mentioned by the producer in the order.  
Certificate of the company IQNet and CQS No. CZ-2161/2006 for the silicone materials used for the menstrual cup production of the company Silroc CZ, a.s. of 19 June 006.  
Specification of the silicone material Elastosil LR 3003 A,B from the producer, the company Wacker Silikones (Germany).  
Technical drawings B-2235 and B-2236 for the menstrual cups with the diameter of 40 and 46 mm.  
Certificates of the company Bioservice Scientific Laboratories GmbH (Munich) for biological tests of the silicone material Elastosil LR 3003 A,B dated 10 July 1998 and 28 December 1998.  
Results of the microbiological tests of the material Elastosil LR 3003/ 30-70 shore A.  
Documentation to SpecTruLite colours – Hydro-Glaze.  
Instructions for use of the menstrual cup.  
Opinion of CZŽP (the Centre of Health and Life Conditions) 13-246/08-36, EX 080221 dated 12 March 2008 for the LadyCup menstrual cup of colourless silicone.

**PERFORMED TEST:**

Chemical examination (Determination of primary aromatic amines - method in accordance with ČSN 62 1156) was carried out in the testing Laboratories of the Centre of Health and Life Conditions accredited by the Czech Accreditation Institute No. 1206.3.

The submitted samples were used for the mentioned examination.

TELEPHONE NUMBER OF THE EXCHANGE: 267 081111  
FAX: 272 744 354

BANK CONNECTION: 1730101/0710 Company identification No.: 75010330

**EXPERT ASSESSMENT:**

The subject-matter of the assessment is determination of possible undesirable biological effects of the menstrual cup material in the pink execution in contact with the skin.

The examination was carried out to the extent of Methodical Recommendation of the National Institute of Public Health No. 1/2000 for assessment of the products coming into direct contact with human organism through skin or mucous membranes (AHEM No. 3/2000).

**CONCLUSION:**

Based on the assessment of the documents submitted and the chemical examination, we come to a conclusion that the menstrual cup material in the pink colour is, within the extent of the performed test, safe for human health in contact with the skin. It fulfils the basic requirements for the material safety in accordance with Act No. 102/2001 Coll., on General Safety of Products, as amended.

This expression relates only to the samples submitted and the conclusions derived from their assessment may be applied only for the other products of the same type that completely correspond, with their composition and properties, to the samples examined by us.

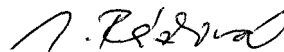
Stamp: THE NATIONAL INSTITUTE OF PUBLIC HEALTH

The Centre of Health and Life Conditions

Šrobárova 48

100 42 Praha 10

**STÁTNÍ ZDRAVOTNÍ ÚSTAV**  
Centrum zdraví  
a životních podmínek  
Šrobárova 48  
100 42 Praha 10



M. D. Jarmila Rážová, Ph.D.

Head of the Centre of Health and Life  
Conditions

**ANNEX:**

Report on Chemical Examination No. CZŽP 13-1184/08-156

**REPORT ON CHEMICAL EXAMINATION**

**The National Reference Centre for Cosmetics**  
The National Institute of Public Health Prague, the Centre of Health  
and Life Conditions  
Šrobárova 48, 100 42 Praha 10

**Submitter: Jaguara, s.r.o., Jeruzalémská 961/5, 110 00 Praha 1****Report number: CZŽP 13-1184/08-156**  
**Test date: 24 June 2008****Sample description: LadyCup menstrual cup in pink design**  
**(silicone Elastosil LR 3003 A,B)****Country of origin: EU****CHEMICAL EXAMINATION****Parameter assessed:**Determination of primary aromatic amines

extract in accordance with ČSN EN ISO 14184-1, method in accordance with ČSN 62 1156  
apparatus: VARIAN CARY 1E

**Test result:**

sample: Silicone Elastosil LR 3003 A,B in pink colour				
test	determined value	unit	uncertainty	limit
Chemical examinations				
Primary aromatic amines	<0.03*	mg.l <sup>-1</sup> (recalculated on aniline hydrochloride)	± 15 %	0.05

\* the values are lower than the determination limit of the method

The chemical examinations were carried out to the extent of the Methodical Recommendation of the National Institute of Public Health No. 1/2000 for assessment of the products coming into direct contact with human organism through skin or mucous membranes (AHEM No. 3/2000).

**Date: 3 July 2008****For performance of the test: M.Sc. Marie Rádlová**

Signature:

Stamp:

THE NATIONAL INSTITUTE OF PUBLIC HEALTH  
The National Reference Centre  
for Cosmetics

  
**STÁTNÍ ZDRAVOTNÍ ÚSTAV**  
Národní referenční centrum  
pro kosmetiku



## THE NATIONAL INSTITUTE OF PUBLIC HEALTH

Contributory organisation

Šrobárova 48  
Praha 10  
100 42

Jaguara, s.r.o.  
Jeruzalémská 5  
110 00 Praha 1

YOUR LETTER MARK:

DATED: **10 November 2008**

OUR MARK: **SZÚ3719/08**  
**CZŽP 13-3719/08-297, EX 081525**

ATTENDED BY: **M.Sc. M. Rádllová**

TEL./FAX: **267 08 23 76**

E-MAIL: [radlova@szu.cz](mailto:radlova@szu.cz)

DATE: **17 December 2008**

Re: **EXPERT OPINION to the health safety of the LadyCup menstrual cups**

### SUBJECT-MATTER OF THE APPLICATION:

To your application of 10 November 2008 to assess the health safety of the LadyCup menstrual cups in accordance with the requirements of Act No. 102/2001 Coll., on General Safety of Products, we wish to inform you as follows:

### SUBMITTED SAMPLES: LadyCup menstrual cups in the colour design:

- blue (under the designation BlueCup)
  - lilac (under the designation LilacCup)
  - orange (under the designation OrangeCup)
  - green (under the designation GreenCup)
  - yellow (under the designation YellowCup)
- (silicone Elastosil LR 3003 A,B)

Country of origin: EU

### DOCUMENTS SUBMITTED:

Certificate of the company IQNet and CQS No. CZ-2161/2006 for silicone materials used for the menstrual cup production of the company Silroc CZ, a.s. of 19 June 2006.

Specification of the silicone material Elastosil LR 3003 A, B from the producer the company Wacker Silikones (Germany).

Technical drawings B-2235 and B-2236 for the menstrual cups with the diameter of 40 and 46 mm were given in the documentation to the file of the Centre of Health and Life Conditions CZŽP 13-1184/08-156 dated 3 July 2008.

Certificates of the company Bioservice Scientific Laboratories GmbH (Munich) for biological tests of the silicone material Elastosil LR 3003 A, B dated 10 July 1998 and 28 December 1998.

Results of the microbiological tests of the material Elastosil LR 3003/ 30-70 shore A of 23 February 2004.  
Instructions for use of the menstrual cup.

Opinion of CZŽP (the Centre of Health and Life Conditions) 13-246/08-36, EX 080221 dated 12 March 2008 for the LadyCup menstrual cup of colourless silicone and CZŽP 13-1184/08-156, EX 080850 dated 3 July 2008 for the LadyCup menstrual cup of silicone in the pink design PinkCup.

**PERFORMED TESTS:**

Chemical examinations (Determination of primary aromatic amines and content of reducing substances in water extract according to modified ČSN 621156, Determination of heavy metal content in the extract of plastic according to SOP 8/21) and Cytotoxicity test (according to ČSN EN ISO 10993-5:2005, Part 5) were carried out in the testing Laboratories of the Centre of Health and Life Conditions accredited by the Czech Accreditation Institute No. 1206.3.

The submitted samples were used for the mentioned examinations.

**EXPERT ASSESSMENT:**

The subject-matter of the assessment is determination of possible undesirable biological effects of the menstrual cup material in the various colour designs in contact with the skin.

The examination was carried out to the extent of Methodical Recommendation of the National Institute of Public Health No. 1/2000 for assessment of the products coming into direct contact with human organism through skin or mucous membranes (AHM No. 3/2000).

**CONCLUSION:**

Based on the assessment of the documents submitted, the chemical examinations and the cytotoxicity determination we come to a conclusion that the menstrual cup material in the mentioned colour design is, within the extent of the performed test, safe for human health in contact with the skin. It fulfils the basic requirements for the material safety in accordance with Act No. 102/2001 Coll., on General Safety of Products, as amended.

This expression relates only to the samples submitted, and the conclusions derived from their assessment may be applied only for the other products of the same kind that completely correspond, with their composition and properties, to the samples examined by us.

**STÁTNÍ ZDRAVOTNÍ ÚSTAV**  
Centrum laboratorních činností  
v ochraně a podpoře veřejného zdraví  
Šrobárova 48  
100 42 Praha 10



M.Sc. Jitka Sosnovcová  
Head of the Centre of  
Laboratory Activities in Public  
Health Protection and Support

*Stamp:* THE NATIONAL INSTITUTE OF PUBLIC HEALTH  
Centre of Laboratory Activities  
in Public Health Protection and Support  
Šrobárova 48  
100 42 Praha 10

**ANNEX:**

Report on Chemical Examination No. CLČ 13-3719/08-297

Report on Determination of Heavy Metal Content in the Extract No. CLČ-3719/08-297

Report on Cytotoxicity Determination No. CLČ 13-3719/08-297



## THE NATIONAL INSTITUTE OF PUBLIC HEALTH

Contributory organisation

Šrobárova 48  
Praha 10  
100 42

**Jaguara, s.r.o.**  
**Jeruzalémská 961/5**  
**110 00 Praha 1**

YOUR LETTER MARK:

DATED: **8 February 2008**

OUR MARK: **SZÚ 465/08**

**CZŽP 13-246/08-36, EX 080221**

ATTENDED BY: **M.Sc. M. Rádlová**

TEL/FAX: **267 08 23 76**

E-MAIL: [\*\*radlova@szu.cz\*\*](mailto:radlova@szu.cz)

DATE: **12 March 2008**

**Re: EXPERT OPINION to the health safety of the LadyCup menstrual cup**

### **SUBJECT-MATTER OF THE APPLICATION:**

To your application of 8 February 2008 to assess the health safety of the LadyCup menstrual cup in accordance with the requirements of Act No. 102/2001 Coll., on General Safety of Products, we wish to inform you as follows:

**SUBMITTED SAMPLES: 1. LadyCup menstrual cup (silicone)**  
**2. Textile bag in light pink colour (packing of the menstrual cup)**

Country of origin: EU

### **DOCUMENTS SUBMITTED:**

Specification of the menstrual cup material was mentioned by the producer in the order.  
Certificate of the company IQNet and CQS No. CZ-2161/2006 for silicone materials used for the menstrual cup production of the company Silroc CZ, a.s. of 19 June 006.  
Specification of the silicone material Elastosil LR 3003 A, B from the producer the company Wacker Silikones (Germany).  
Technical drawings B-2235 and B-2236 for the menstrual cups with the diameter of 40 and 46 mm.  
Certificates of the company Bioservice Scientific Laboratories GmbH (Munich) for biological tests of the silicone material Elastosil LR 3003 A, B dated 10 July 1998 and 28 December 1998.  
Results of the microbiological tests of the material Elastosil LR 3003/ 30-70 shore A.  
Instructions for use of the menstrual cup.

### **PERFORMED TESTS:**

Chemical examinations (Determination of pH of the extract in accordance with ČSN EN ISO 3071, Determination of free and hydrolysable formaldehyde in accordance with ČSN EN ISO 14184-1 and Cytotoxicity test (in accordance with ČSN EN ISO 10993-5:2005, Part 5) were carried out in the testing Laboratories of the Centre of Health and Life Conditions accredited by the Czech Accreditation Institute No. 1206.3.

The submitted samples were used for the mentioned examinations.

### **EXPERT ASSESSMENT:**

The subject-matter of the assessment is determination of possible undesirable biological effects of the menstrual cup material and of the protective bag in contact with the skin.



The examinations were carried out to the extent of Methodical Recommendation of the National Institute of Public Health No. 1/2000 for assessment of the products coming into direct contact with human organism through skin or mucous membranes (AHEM No. 3/2000).

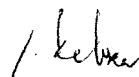
**CONCLUSION:**

Based on the assessment of the documents submitted, the chemical examination and the cytotoxicity determination, we come to a conclusion that

the mentioned materials of the menstrual cup and the protective bag are, within the extent of the performed tests, safe for human health in contact with the skin. They fulfil the basic requirements for the material safety in accordance with Act No. 102/2001 Coll., on General Safety of Products, as amended.

This expression relates only to the samples submitted, and the conclusions derived from their assessment may be applied only for the other products of the same kind that completely correspond, with their composition and properties, to the samples examined by us.

**STÁTNÍ ZDRAVOTNÍ ÚSTAV**  
Centrum zdraví  
a životních podmínek  
Šrobárova 48  
100 42 Praha 10



Reader V. Kebza, Ph.D., app. Ph.D.  
Head of the Centre of Health and Life Conditions

Stamp: THE NATIONAL INSTITUTE OF PUBLIC HEALTH  
The Centre of Health and Life Conditions  
Šrobárova 48  
100 42 Praha 10

**ANNEXES:**

Report on Chemical Examination of the Textile Bag No. CZŽP 13-246/08-36  
Report on Cytotoxicity Determination No. CZŽP 13-246/08-36

# REPORT ON CYTOTOXICITY TEST IN VITRO METHOD

## The National Reference Centre for Cosmetics

The National Institute of Public Health Prague, the Centre of Health and Life Conditions  
Šrobárova 48, 100 42 Praha 10

Laboratories of the Centre of Health and Life Conditions  
Accredited testing laboratory No. 1206.3

**Submitter:** Jaguara, s.r.o., Jeruzalémská 961/5, 110 00 Praha 1

**Report number:** CZŽP 13-246/08 - 36

**Date of test:** 13 February – 15 February 2008

**List of samples:** VZ 1 – LadyCup Menstrual cup

**The test was performed in accordance with ČSN EN ISO 10993-5:2005 – Biological assessment of the medical devices – Part 5: Cytotoxicity tests in vitro.**

**Cell-line:** Mouse fibroblasts - line Balb/c 3T3

**Culture medium:** DMEM with antibiotics content (PNC 100 IU/ml, STM 100 µg/ml) with 10% of inactivated veal serum

**Positive check:** Sodium lauryl sulphate (LS)

**Negative check:** Hydron - poly[(2-hydroxyethyl) methacrylate]

**Preparation of the extract:** 0.1 g of the sample weight per 1 ml of the extraction agent (DMEM without the serum), 24 hours at 37°C. 100% extract was further diluted with DMEM without the serum.

**Procedure:** After 24 hours of pre-culturing, the cellular structure was exposed to 10%, 25%, 50% and 100% extract of the VZ1 sample tested for the period of 24 hours. (37°C, 7.5% CO<sub>2</sub>). Subsequently, the lifetime of the cellular culture was determined on the basis of incorporation of the vital dyestuff (neutral red) by fluorimetric method, and the lifetime of the culture influenced by the tested sample with the lifetime of the negative check was compared.

Cytotoxicity degree of the extract:

lifetime 80% and more..... non-cytotoxic  
lifetime higher or equal to 60% and lower than 80% ..... low cytotoxic  
lifetime higher or equal to 40% and lower than 60%..... medium cytotoxic  
lifetime lower than 40%..... strongly cytotoxic

**Results:**

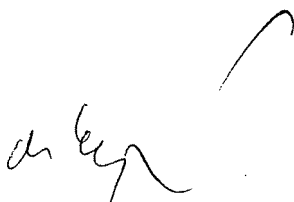
<b>Sample (extract)</b>	<b>Lifetime (% of check)</b>
VZ1- 10%	103.7
25%	94.4
50%	105.4
100%	99.8
NK	100.0
PK - LS 1 µg/ml	86.3
LS10 µg/ml	13.5
LS 20 µg/ml	12.1

**Evaluation of the results:**

The VZ1 sample is not toxic for the tissue culture cells under the conditions of the test of the extract. This value is usual for the products of this kind.

**Date:** 3 March 2008

**For performance of the test:**  
M.Sc. K. Kejlová

  
**STÁTNÍ ZDRAVOTNÍ ÚSTAV**  
Národní referenční centrum  
pro kosmetiku 3

*Signature*

*Stamp:*

THE NATIONAL INSTITUTE  
OF PUBLIC HEALTH  
The National Reference Centre  
for Cosmetics 3

**REPORT ON CHEMICAL EXAMINATION**

**The National Reference Centre for Cosmetics**  
The National Institute of Public Health Prague, the Centre of Health and Life Conditions  
Šrobárova 48, 100 42 Praha 10

**Submitter: Jaguara, s.r.o., Jeruzalémská 961/5, 110 00 Praha 1****Report number: CZŽP 13-246/08-36****Test date: 4 March 2008****Description of samples: Textile bag in light pink colour (packing of the menstrual cup)****Country of origin: EU****CHEMICAL EXAMINATIONS****Parameters assessed:**Determination of the extract pH value

ČSN EN ISO 3071

apparatus: inoLab pH Level 1

Determination of free and hydrolysable formaldehyde

ČSN EN ISO 14184-1

apparatus: VARIAN CARY 1E

**Test results:**


<b>Sample No. Textile bag in light pink colour (menstrual cup packing)</b>				
<b>test</b>	<b>determined value</b>	<b>unit</b>	<b>uncertainty</b>	<b>limit</b>
<b>Chemical examinations</b>				
<b>pH</b>	<b>6.5</b>	-	± 0.1	4.5 – 7.5
<b>formaldehyde</b>	<b>&lt;20*</b>	mg.kg <sup>-1</sup>	±8%	75

\* the values are lower than the determination limit of the method

The chemical examinations were carried out to the extent of the Methodical Recommendation of the National Institute of Public Health No. 1/2000 for assessment of the products coming into direct contact with human organism through skin or mucous membranes (AHM No. 3/2000).

**Date: 12 March 2008****For performance of the test: M.Sc. Marie Rádlová***Stamp:*

THE NATIONAL INSTITUTE OF PUBLIC HEALTH  
The National Reference Centre  
for Cosmetics

  
**STÁTNÍ ZDRAVOTNÍ ÚSTAV**  
Národní referenční centrum  
pro kosmetiku