

TEST REPORT

Test Report No.: 021985-01/01

Issued: 10. 9. 2020

Name of product: Toothbrush
Type of product: IONICKISS
Ratings: -
Serial number: -
Manufacturer: ORTUS HEALTH s. r. o.
Nad Oborou 514, 252 42 Jesenice - Osnice,
Czech Republic
Production site: -
Ordering firm: ORTUS HEALTH s. r. o.
Nad Oborou 514, 252 42 Jesenice - Osnice,
Czech Republic
Number of tested samples: 3
Samples submitted on: 17. 8. 2020
Location of testing: Elektrotechnický zkušební ústav, s. p.
Tests performed from 18. 8. 2020 through 8. 9. 2020
Other data: -
Tested according to: RoHS DIRECTIVE 2011/65/EU as amended,
NV 481/2012 Sb. as amended,
ZP 344/02 – The Method for determination of substances
in materials using X-ray fluorescent spectrometry (See
ČSN EN 62321-1:2014 and ČSN EN 62321-3-1:2014.)

Compiled by: Tereza Medová

Approved by: Jiří Bažant
Testing laboratory technical manager

No. of pages: 6

No. of annexes: 2

No. of annexes pages: 8

The test results stated in the test report apply only to the tested subject and unless specified otherwise in the test report, the tests were performed using the method and under the conditions determined in the test regulations, technical norm, instructions for use and information provided by the manufacturer on the tested subject and using accessories required by the manufacturer.
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• **Description of the sample:**

The following samples were submitted: Toothbrush IONICKISS with two heads – soft and medium.

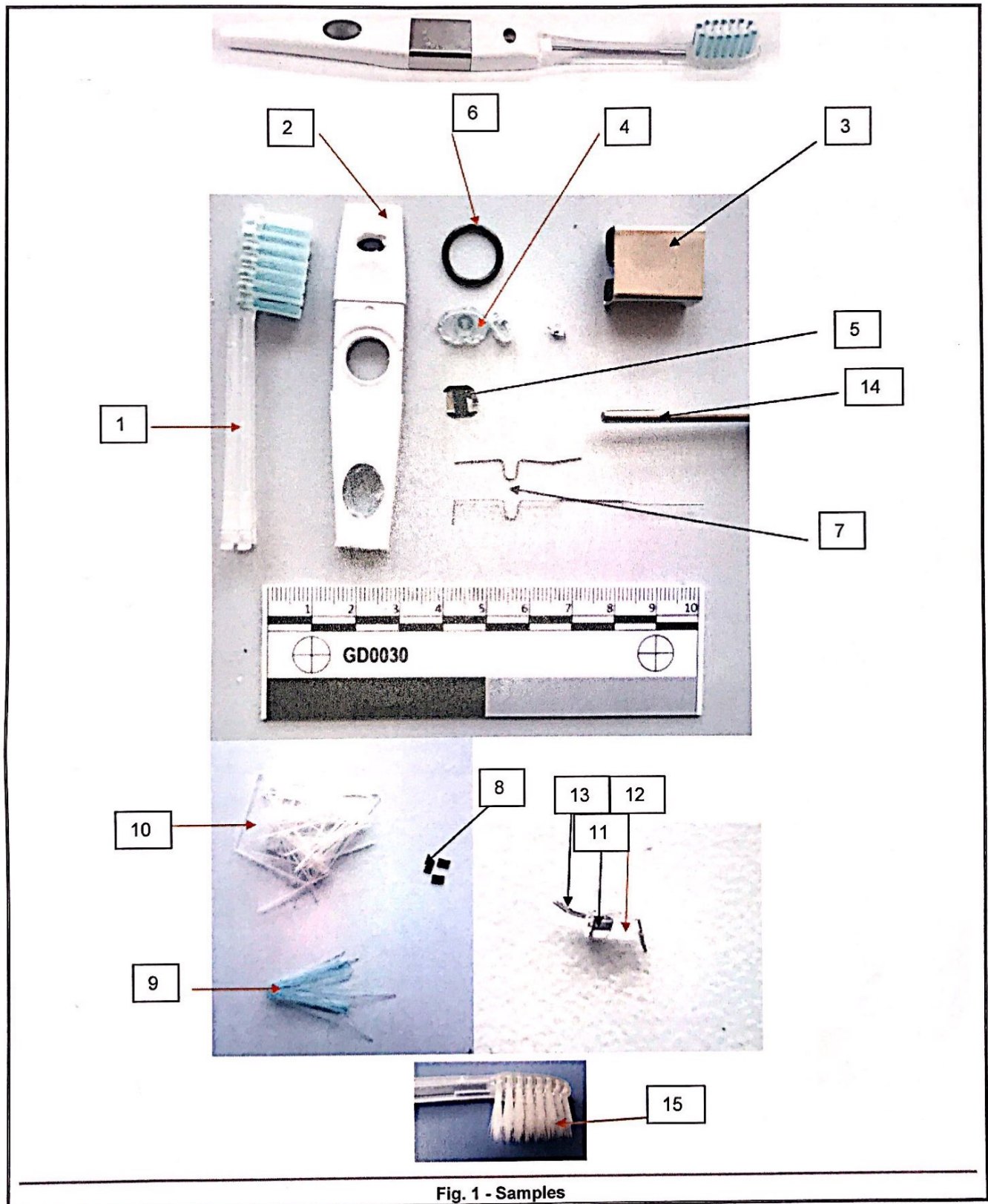


Fig. 1 - Samples

Testing:**1 Determination of Pb, Cd, Cr, Hg, Br - spectral analysis:**

ZP 344/02 – The Method for determination of substances in materials using X-ray fluorescent spectrometry (see ČSN EN 62321-1:2014 and ČSN EN 62321-3-1:2014).

Principle of the method: EDXRF, energetic dispersion X-ray fluorescent spectrometry.

Instruments used: Analyzer MESA-50K HORIBA, inv. No: 110324

Conditions: Temperature (23 ± 3) °C, RH (35 ± 5) % (Comet S3120E, inv. No: 500011)

2 Determination of hexavalent chromium in the leachate by the method according to EPA 3060A and 7196A:

Measurement of the substances was performed at Institute of Chemical Technology in Prague, Independent Packaging Laboratory. Test report No.: EZU 14-en/20 of 28. 8. 2020 (see Annex 1).

3 Determination of Phthalates (DEHP, BBP, DBP and DIBP) - GC/MS, Method ZM-14:

Measurement of four phthalates was performed at University of Chemistry and Technology, Prague, Independent Packaging Laboratory of UCT Prague. Test Report No.: EZU 13-en/20 of 8. 9. 2020 (see Annex 2).

Evaluation:

The limit concentrations of hazardous substances in homogeneous material according to the requirements of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2) and its amendment Directive (EU) 2015/863:

Test item(s)	Limit concentration (% w/w)	Limit concentration (mg/kg)	Name
Pb	0,1 %	1000 mg/kg	Lead
Hg	0,1 %	1000 mg/kg	Mercury
Cr ^{VI}	0,1 %	1000 mg/kg	Hexavalent chromium
PBB, PBDE	0,1 %	1000 mg/kg	Polybrominated biphenyls and polybrominated diphenyl ethers
Cd	0,01 %	100 mg/kg	Cadmium
DEHP	0,1 %	1000 mg/kg	Bis(2-ethylhexyl) phthalate
BBP	0,1 %	1000 mg/kg	Butyl benzyl phthalate
DBP	0,1 %	1000 mg/kg	Dibutyl phthalate
DIBP	0,1 %	1000 mg/kg	Diisobutyl phthalate

XRF screening threshold values:

Element	Plastic material	Metal material	Complex material
Cd	$BL \leq (70-3\sigma) < X < (130+3\sigma) \leq OL$	$BL \leq (70-3\sigma) < X < (130+3\sigma) \leq OL$	$BL \leq (50-3\sigma) < X < (150+3\sigma) \leq OL$
Pb	$BL \leq (700-3\sigma) < X < (1300+3\sigma) \leq OL$	$BL \leq (700-3\sigma) < X < (1300+3\sigma) \leq OL$	$BL \leq (500-3\sigma) < X < (1500+3\sigma) \leq OL$
Hg	$BL \leq (700-3\sigma) < X < (1300+3\sigma) \leq OL$	$BL \leq (700-3\sigma) < X < (1300+3\sigma) \leq OL$	$BL \leq (500-3\sigma) < X < (1500+3\sigma) \leq OL$
Br	$BL \leq (300-3\sigma) < X$	-	$BL \leq (250-3\sigma) < X$
Cr	$BL \leq (700-3\sigma) < X$	$BL \leq (700-3\sigma) < X$	$BL \leq (500-3\sigma) < X$

Note: BL: Below Limit, OL: Over Limit, X: Further examination required, -: Not regulated, σ : Standard deviation of instrument, units: mg/kg

Results of EDXRF screening:

No.	Pb (mg/kg)	3 σ	Cd (mg/kg)	3 σ	Cr (mg/kg)	3 σ	Hg (mg/kg)	3 σ	Br (mg/kg)	3 σ	Result
1	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	BL
2	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	BL
3	ND	32,3	0,1	23,8	173616,1	655,4	5,1	37,8	94,0	18,0	X
4	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	BL
5	ND	35,8	0,1	21,4	181799,7	549,9	0,0	72,7	87,2	21,3	X
6	ND	ND	ND	ND	6,9	10,0	ND	ND	ND	ND	BL
7	32,5	36,9	12,0	29,2	180919,8	838,9	10,3	38,5	21,1	15,8	X
8	64,8	107,4	8,5	23,0	134,2	205,5	100,7	187,4	5,7	37,6	BL
9	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	BL
10	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	BL
11	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	BL
12	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	BL
13	47,9	117,8	0,6	40,9	587,9	771,5	54,8	114,2	0,4	23,1	X
14	23,7	51,4	3,8	48,9	184069,1	1217,4	10,0	65,0	37,3	33,1	X
15	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	BL

Note:

BL: Below Limit. OL: Over Limit. X: Inconclusive. Further examination required. ND: Not detected, <10 ppm (MDL)

Br: Determination of total bromine. To determine presence of PBB, PBDE is necessary to use another analytical method.

Cr: Determination of total chromium content. It is necessary to use another analytical method to determine hexavalent chromium.

Determination of hexavalent chromium in the leachate by the method according to EPA 3060A and 7196 A:

Measured samples (3, 5, 7, 13, and 14) do not contain excessive amount of hexavalent chromium (see Annex 1).

Results of GC/MS- Determination of Phthalates:

No.	DIBP % (w/w)	DBP % (w/w)	BBP % (w/w)	DEHP % (w/w)	Result
1	<0,0001	<0,0001	<0,0001	<0,0001	BL
2	<0,0001	<0,0001	<0,0001	<0,0001	BL
4	0,0007 ± 0,0002	0,0006 ± 0,0002	<0,0001	<0,0027 ± 0,0002	BL
6	0,0006 ± 0,0002	0,0008 ± 0,0002	<0,0001	<0,0195 ± 0,0002	BL
9+10	<0,0001	<0,0001	<0,0001	<0,0001	BL
12	<0,0001	0,0001 ± 0,0002	<0,0001	<0,0001	BL
15	0,0003 ± 0,0002	0,0006 ± 0,0002	<0,0001	<0,0001	BL

Note:


The values are taken from Test report No.: ECU 13-en/20 of 8. 9. 2020 (see Annex 2).

BL: Below Limit

OL: Over Limit

Test results:

The results of measuring the concentration of substances prohibited under the Directive 2011/65/EU (RoHS 2) and its amendment Directive 2015/863/EU (RoHS 3) for the samples measured did not show exceeding levels of $Pb \leq 0.1\%$, $Cd \leq 0.01\%$, $Cr^{VI} \leq 0.1\%$, $Hg \leq 0.1\%$, $PBB+PBDE \leq 0.1\%$, $DEHP \leq 0.1\%$, $BBP \leq 0.1\%$, $DBP \leq 0.1\%$ and $DIBP \leq 0.1\%$.


 Compiled by: T. Medová

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