# Barbara Figura, Janusz Pluta

# EVALUATION OF PURITY OF CERTAIN PAEDIATRIC PREPARATIONS OF PLANT ORIGIN AND ITS SIGNIFICANCE FOR THE SAFETY OF PHARMACOTHERAPY Part 1. Heavy metals contamination of certain paediatric preparations of plant origin

Department of Pharmaceutical Technology, Wroclaw Medical University

## INTRODUCTION

Chemical contamination with heavy metals in preparations of plant origin is associated with increasing environmental pollution. For this reason plant material for production of drugs is more and more commonly obtained from areas of special cultivation in which the levels of toxic substances are limited. On the other hand, dynamic development of industry and motorization cause constant increase of pollution of our natural environment with various gases and dusts with high level of chemical toxicity.

The consequences of pollution of the atmosphere, soil and water include heavy metals contamination of the world of plants and animals, and at the same time, of food and drugs. On the other hand, the administration of pharmaceutical products with low chemical purity levels to patients with already compromised immunity, apart from the desired therapeutic effect, may at the same time cause intoxication of the organism with noxious substances (PLUTA et al. 1984, FIGURA et al. 1998).

dr n. farm. Barbara Figura, prof. dr hab. Janusz Pluta, Department of Pharmaceutical Technology, Wroclaw Medical University, Szewska 38/39, 50-139 Wroclaw, Poland

Paediatric products should be the subject of especially careful analysis of the level of contamination, since child's organism is exceptionally sensitive to the toxic effects of many substances, including heavy metals.

The aim of the study was to determine the level of heavy metals contamination in certain paediatric herbal preparations. The investigations involved both, herbs, so-called herbal tea-bags which are used to prepare infusions, as well as granulated teas – dissolved in hot water and gels for teething problems.

The rate of passing of the substances to prepared infusions was determined. The presence of mercury was also investigated in powder, tablets and juice.

## MATERIALS AND METHODS

### Materials

Perchloric acid 60% (POCH Gliwice, Poland), Nitric acid 65% (POCH,Gliwice, Polska), bi-distilled water, lead acetate (POCH, Gliwice, Polska), zinc chloride (Merck, Germany), cuprum acetate (POCH, Gliwice, Poland), tea bags: Bobofen fix (Herbapol Lublin), Fructus

Myrtilli fix (Herbapol Lublin), Bronchial fix (Herbapol Lublin), Flatuvit fix (PhytoPharm, Klęka), Fito-mix 9 fix (Herbapol Lublin), Fructus Foeniculi fix (Herbapol Lublin), Anthodium Chamomillae fix (PhytoPharm, Klęka), Inflorescentia Tiliae fix (PhytoPharm, Klęka), Folium Melissae fix (Herbapol Lublin), Folium Menthae piperitae fix (Herbapol Lublin), Folium Menthae piperitae fix (PhytoPharm, Klęka), Nervinum fix (Herbapol Lublin) Fructus Rubi idaei fix (Herbapol Lublin), Fito-mix 4 fix (Herbapol Lublin), Folium Menthae piperitae cum malus fix (Herbapol Lublin), Anthodium Chamomillae cum mell et lemon fix (Herbapol Lublin); instant granulated teas: Sedative HIPP, Lemon with vit C Impress, Foeniculi Impress, Foeniculi HIPP, Fruit with vit. C Impress, Orange with vit. C Impress, Chamomile HIPP, Chamomile Impress, Digestive HIPP, Herbal Impress, Plantex (Lek Poland); teething gels: Aperisan (Dentinox), Bobodent (Hasco-Lek); Other: Pulvis Magnesie cum Rheo, Echinapur - tabulettae (Herbapol Poznań), Succus Echinacaeae (Herbapol Poznań).

### **Preparation of samples**

Herbal mixtures were mineralized by means of a dry method and a 1:1 mixture of perchloric acid and nitric acid was added. Tea bags were brewed according to the leaflet and the brew was mineralized with acid mixture.

### Measurements

The determination of the content of Cu, Zn, Fe, Mn, Cd, Pb was performed by means of a ASA spectrophotometer – Spectro Lab.

Hg of the sample was determined in raw material after mixing and crumbling, without diluting. The determinations were performed by means of mercury selective ASA method with the use of AMA -254 analyzer (AL-TECH) (SZCZEPANIAK 1999, *Determination of mercury...*).

## **RESULTS AND DISCUSSION**

The results of measurements of heavy metals levels in herbal teas and teething gels (Tables 1–5) indicated that the investigated metals were present in all the products.

It should be remembered that if the herbal raw material contains certain amounts of natural microelements, which form so-called background, their excess together with the presence of cadmium, lead or mercury is harmful for human organism. Especially dangerous for the organism are Pb, Cd, Hg, and As and for this reason their permissible levels have been determined (*Order of the Minister of Health...2003*).

According to the recommendations of the Ministry of Health and Social Welfare (MZiOS) of 2003, the allowable levels of Pb in herbal and fruit teas for adults are 1 mg·kg<sup>-1</sup>, for Cd – 0.1 mg·kg<sup>-1</sup>, Hg – 0.2 mg·kg<sup>-1</sup> and As 0.3 mg·kg<sup>-1</sup>. In case of the products for infants and young children, the allowable levels of heavy metals contamination are much more restrictive and are: 0.1 mg·kg<sup>-1</sup> – Pb, 0.01 mg·kg<sup>-1</sup> – Cd, 0.005 mg·kg<sup>-1</sup> – Hg and 0.1 mg·kg<sup>-1</sup> – As (Order of the Minister of Health...2003).

As indicated by data presented in Table 1, cadmium was present in all the investigated herbal and herbal-fruit tea bags, although in trace amounts. Cadmium does not have any physiological activity, and its presence in the organism disturbs metabolic cycles, decreases production of insulin, causes hypochromic anaemia (SEŃCZUK 1999). Allowable daily intake of this element according to WHO (NIKONOROW 1997) is 0.2 mg for an adult person. This means that the investigated tea bags are basically safe as regards cadmium.

Lead was also found in all the investigated tea bags, although in five of them in trace amounts. The remaining tea bags contained much higher levels of lead than allowed by Ministry of Health and Social Welfare RP norms, 0.1 mg·kg<sup>-1</sup>, the highest levels being found in Fructus Myrtilli tea bags  $- 8 \text{ mg·kg}^{-1}$  and slightly lower, 5 mg·kg<sup>-1</sup> – in Inflorescentia Tiliae and Nervinum. The above data demonstrate that the allowable level of lead was many times exceeded in seven teas. This must arise concern, the more

Table 1 Tabela 1

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Name of the preparation Nazwa preparatu	Batch and manufacturer Nr partii	Cd	Pb	Cu	Mn	Zn	Fe
Bobofen	1012002L	+	1.400	9.000	50.830	47.000	95.900
	Herbapol		±0.2331	±0.3622	±0.9866	±1.0232	±1.6321
Fructus	3012004L	+	8.100	11.000	93.080	79.750	150.550
Myrtylli	Herbapol		±0.03214	±0.3654	±2.2975	$\pm 2.5511$	±7.3301
Bronchial	1032002L	+	+	3.950	18.430	32.250	42.000
	Herbapol			±0.02145	±0.01527	±1.3952	±1.1244
Fito-mix 9	2022002L	+	3.700	10.000	62.180	46.500	306.800
	Herbapol		±0.0232	±0.3654	±0.1254	±1.7351	±3.1022
Flatuvit	2065211	+	2.600	2.350	1.080	35.000	90.900
	PhytoPharm		±0.0143	±0.0361	±0.0233	±0.5230	±1.6914
Fructus	2022003L	+	+	37.250	61.930	49.000	255.300
Foeniculi	Herbapol			±0.2412	±1.3354	±1.4023	±6.2112
Anthodium	101131111	+	+	8.750	89.030	95.750	165.500
Chamomillae	PhytoPharm			±0.1254	±1.3214	±1.2751	±2.5133
Inflorescentia	10041706	+	5.700	2.900	16.430	42.500	90.650
Tiliae	PhytoPharm		±0.2234	±0.0236	±0.3561	$\pm 1.9724$	±1.7385
Folium	6032002B	+	2.700	12.000	40.400	69.500	182.200
Melissae	Herbapol		±0.0334	±0.3654	±0.9630	±1.7802	±1.7440
Folium	4032003B	+	+	14.250	88.080	61.500	175.250
Menthae pip.	Herbapol			±0.2365	±1.1121	±2.9631	±1.8404
Folium	1004805	+	+	12.250	88.230	66.500	193.400
Menthae pip.	PhytoPharm			±0.6547	±1.2563	±2.4332	±3.0800
Nervinum	2022002L		5.600	24.000	56.180	128.000	343.450
	Herbapol		±0.1231	±1.3655	±1.3654	$\pm 2.5633$	±3.2711

Content of heavy metals in tea bags (mean $\pm$ SD) (mg $\cdot$ kg<sup>-1</sup>) Zawartość metali ciężkich w herbatach ekspresowych (mg $\cdot$ kg<sup>-1</sup>)

+ trace amounts – ilości śladowe

that lead is especially dangerous as it exerts harmful effects already at low doses and the effects are more noxious the younger the affected organism. Accumulation of this element leads to severe neurological lesions, anaemia, lead-poisoning and developmental disturbances in the young organism (SEŃCZUK 1999).

Mercury is another heavy metal which has been considered especially harmful for the organism by WHO and the Ministry of Health and Social Welfare. Clinical symptoms of toxic effect of mercury depend on the type of compound. Organic compounds dissolve in lipids and readily pass through

Table 2 Tabela 2

	Zawai tose Ttęci w preparatacii zie	Now yen			
Kind of preparation	Name of the preparation Nazwa preparatu	$\begin{array}{c} Hg \\ (mg \cdot kg^{-1}) \end{array}$			
Rodzaj preparatu	Folium Melissae	$0.03304 \pm 0.000147$			
Tea in tea bags	Fructus Rubi idei	$0.03263 \pm 0.000365$			
	Nervinum	0.02272±0.001123			
	Fito-mix 9	0.01855±0.000332			
	Folium Menthae piperitae	0.01727±0.0004423 0,003265			
	Fructus Myrtilli	0.01418±0.001841			
	Folium Menthae piperitae cum malus	0.01339±0.000232			
	Fructus Cerasi	0.01251±0.000365			
	Anthodium Chamomillae cum malus et lemon	0.00804±0.000221			
	Anthodium Chamomillae	$0.00619 \pm 0.00033$			
	Bobofen	0.00536±0.000321			
	Fructus Foeniculi	0.00511±0.000651			
Granulated teas	Sedative HIPP	0.01799±0.006956			
	Phoeniculi HIPP	0.01016±0.004587			
	Digestive HIPP	0.00645±0.000725			
	Chamomile Impress	0.00823±0.000963			
	Fruit with wit. C	0.00639±0.000511			
	Plantex	0.0086±0.0002236			
Teething gels	Aperisan	0.00239±0.000369			
	Bobodent	0.00165±0.000112			
Other	Pulvis Magnesiae cum Rheo	0.00803±0.000123			
	Echinapur	0.00781±0.000655			
	Succus Echinacaeae	0.00012±0.000087			

### The content of mercury in preparations of plant origi (mean $\pm$ SD) Zawartość rtęci w preparatach ziołowych

cell membranes, cross the placenta and get to the foetus and to the milk of lactating women (Seńczuk 1999, Clarkson 1997). The most severe consequences of mercury include neurotoxicity, teratogenicity and embryotoxicity (NIKONOROW 1997, *Kryteria zdrowotne*...1983, Clarkson 1997). As indicated by data presented in Table 2, eight out of 12 teas contained mercury at levels higher than 0.01 mg·kg<sup>-1</sup>, which is considered an allowable norm. The highest levels of mercury were found in the following products: Folium Melissae, Fructus Rubi idei and Nervinum – in which the levels of mercury were higher than 0.02 mg·kg<sup>-1</sup>. Apart from so far discussed elements, other elements were determined, i.e. cuprum, manganese, zinc and iron, which are indispensable for normal functioning of the organism, but in higher concentrations may be harmful.

Cuprum is considered to be one of the most significant microelements necessary for normal oxidation and reduction processes. It affects iron and collagen metabolism.

Average daily requirements for an adult person are 2–3 mg, and doses higher than mg·kg<sup>-1</sup>·day<sup>-1</sup> are considered the maximum tolerated intake from all sources (Seňczuk 1999, Nikonorow 1997, GERTING 1998). The symptoms of cuprum intoxication include among others kidneys and liver damage, diarrhoea, intestinal spasms, inflammation of mucous membranes (Seńczuk 1999, Nikonorow 1997, GERTING 1998).

The highest levels of cuprum (Table 1) were found in Fructus Foeniculi brew – 37.25 mg·kg<sup>-1</sup> and Nervinum – 24 mg·kg<sup>-1</sup>. The remaining teas contained lower levels of cuprum, which ranged from 2.35 mg·kg<sup>-1</sup> in Flatuvit to 14.25 mg·kg<sup>-1</sup> in Folium Menthae piperitae. However these are not very high levels, taking into account natural levels of cuprum in plants, which are referred to as "background" and range from 5 to 15 mg·kg<sup>-1</sup> (RUMIŃSKA 1983).

In case of zinc, the allowable levels in food products containing over 50% of solid mass according to regulations of the year 1990 ((*Order of the Minister of Health*...1990), are up to 30 mg·kg<sup>-1</sup>, while the daily recommended dietary intake is 12 mg and differs in relation to age, gender and physiological condition of the organism. An average level of zinc in herbs ranges from 16-47 mg·kg<sup>-1</sup> (RUMIŃSKA 1983).

Zinc in trace amounts activates enzymatic processes and is a component of some enzymes. Zinc in excess is considered harmful. The mechanism of toxic effect consists in competing in metabolic processes with other metals, e.g. with calcium, cuprum and iron. Chronic intoxication is characterized by gastrointestinal disturbances, changes in blood count, hearing loss and sleep disturbances (SEŃCZUK 1999).

The levels of zinc in the investigated teas (Table 1) were from 128 mg·kg<sup>-1</sup> in Nervinium to 32.25 mg·kg<sup>-1</sup> in Bronchial. These are levels higher than background, but the final assessment should consider the fact that the teas are not administered per os, but are drunk in the form of brew.

Manganese plays a very important role in carbohydrates and lipids metabolism. As a component of an enzyme responsible for decreasing the concentration of free radicals, it prevents the development of carcinogenesis. Investigations have shown that deficit of manganese may contribute to diabetes mellitus, while its excess causes Parkinson-like symptoms. Allowable daily intake of manganese is 5 mg (SENCZUK 1999).

The highest levels of manganese in tea bags (Table 1) were found in the following products: Fructus Myrtilli – 93 mg·kg<sup>-1</sup>, Anthodium Chamo-

millae, Folium Menthae piperitae – about 89 mg·kg<sup>-1</sup> each. The lowest levels of manganese were detected in Flatuvit tea – 1 mg·kg<sup>-1</sup>. The measured levels do not exceed the natural content of this element in herbs and thus they should not pose any chemical hazards even for the youngest organisms.

Iron is a permanent and a very important component of human organism. Its ions participate in the synthesis of haemoglobin, myoglobin and ferroporphyrin enzymes. However when the therapeutic dose is exceeded,

> Table 3 Tabela 3

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Name of preparation Nazwa preparatu	Cd	Pb	Cu	Mn	Zn	Fe
Bobofen	-	+		6.670 ±0.2230	4.680 ±0.2241	2.180 ±0.0642
Fructus Myrtylli	-	+	0.120 ±0.0122	0.360 ±0.0783	6.560 ±0.3263	12.000 ±0.7790
Bronchial	-		0.160 ±0.0051	1.740 ±0.1424	2.080 ±0.0968	14.330 ±0.6522
Fito - mix 9	-	+	0.610 ±0.1301	0.930 ±0.0654	6.660 ±0.1425	33.830 ±1.1124
Flatuvit	-	+	0.230 ±0.1107		3.000 ±0.0678	4.100 ±0.1476
Fructus Foeniculi	-	-	0.610 ±0.1232	1.930 ±0.3212	3.750 ±0.0232	10.500 ±0.7454
Anthodium Chamomillae	-		0.500 ±0.0683	11.040 ±0.9881	3.750 ±0.0699	16.870 ±0.7791
Inflorescentia Tiliae	-		0.160 ±0.0523	0.940 ±0.0365	5.000 ±0.0663	$1.600 \pm 0.0556$
Folium Melissae	-	+	0.700 ±0.0987	14.080 ±0.7475	3.750 ±0.0412	13.250 ±0.9984
Folium Menthae pip. Herbapol	-	-	1.000 ±0.1251	14.950 ±0.8660	3.750 ±0.0996	9.250 ±0.7981
Folium Menthae pip. PhytoPharm	-	-	+	12.580 ±0.6992	3.750 ±0.1244	14.800 ±1.1125
Nervinum	-	+	1.000 ±0.0665	5.990 ±0.0222	7.500 ±0.3353	30.750 ±1.3651

The content of heavy metals in brewed teas (mean±SD) (mg·kg<sup>-1</sup>) Zawartość metali ciężkich w naparach (mg·kg<sup>-1</sup>)

+ trace amounts – ilości śladowe

it may be the reason of acute intoxication especially in children. Daily intake of iron for an adult person is 15 mg, while the natural content in herbs may reach even up to 1000 mg $\cdot$ kg<sup>-1</sup> (SEŃCZUK 1999, RUMIŃSKA 1983).

Among the investigated products, the highest content of iron (Table 1) was found in Nervinium – 343.45 mg·kg<sup>-1</sup>, in Fito-Mix-9 – 306.8 mg·kg<sup>-1</sup> and in Folium Menthae piperitae – 193.4 mg·kg<sup>-1</sup>. The levels do not arise and reservations from the toxicological point of view.

Evaluating the potentially dangerous consequences of increased levels of heavy metals in herbal mixtures for the patient's organism, it should be borne in mind that the teas are brewed.

The process of brewing significantly decreases the levels of microelements taken in by the patient in comparison to the initial product, what is evidenced by data presented in Table 3.

As indicated by the data, the presence of cadmium was not confirmed in any of the brews, while lead was found in seven products and only in trace amounts. This means that even if the recommended doses are exceeded, the element gets to the patient's organism in trace amounts and it does not any danger to the health.

The remaining heavy metals displayed significant differences in their levels in brews (Table 4). This was due to the differentiated qualitative and quantitative composition of herbal mixtures. The lowest degree of passing to a brew was observed in cuprum – from 1% to 10%, while the highest was observed in case of iron and manganese – from 2% to 34%. However in neither of the cases administration of a brew even to a baby will cause a significant increase of daily intake of cuprum, manganese, zinc and iron. Mercury only slightly dissolves in water, from 0.6 mg·dm<sup>-3</sup> to 4 mg·dm<sup>-3</sup> depending on the kind of compound and availability of oxygen (SENCZUK 1999, SZPADT 1994, GALAL-GORCHEV 1993).

This means that when a patient drinks e.g. a glass of Folium Melissae brew, about 0.0001 mg of mercury is introduced to his organism, which does not cause any hazards to his health, even if it is a baby.

On the other hand, herbal teas should not be yet another source of toxic substances, which accumulate in the tissues and are the more harmful the younger organism is affected.

Table 5 presents the findings of examinations of the level of heavy metals in granulated – instant herbal teas and teething gels.

None of them contained cadmium. Lead was present in all the granulated preparations in amounts similar to those which were found in tea bags. The highest level of lead was found in Plantex – 7.7 mg·kg<sup>-1</sup> and Chamomile tea Impress – 6.5 mg·kg<sup>-1</sup>. The remaining teas contained on an average 3 mg·kg<sup>-1</sup> of lead. This means that the level of lead is higher that allowable norm recommended by MZiOS, i.e. 0.1 mg·kg<sup>-1</sup>. These preparations are given to children in the form of a drink after dissolving a determined dose in water. Usually, from 4 to 10 g of the granulate and about 150 ml of water are used. Thus the administration of one dose of tea to a baby means that on an average 0.01 to 0.07 mg of lead are introduced to the organism. This is not little, taking into account that an adult person can safely absorb 0.3 mg without any effect on the organism. The norms for children are usually ten times lower. Thus the investigated instant teas cannot be considered safe in relation to small children, for whom they are indicated.

Cuprum, manganese, zinc, iron and mercury (Tables 2 and 5) were present in granulated teas in significantly lower amounts than in tea bags. After preparing a drink according to the instruction on a leaflet, we do not introduce to the organism of small children any significant amounts of the microelements.

Comparing data presented in Tables 3 and 4, we can observe that the process of brewing tea is able to reduce significantly the level of microelements in comparison to the initial product. Taking into account the allowable

> Table 4 Tabela 4

Name of preparation	Cd	Pb	Cu	Mn	Zn	Fe		
Nazwa preparatu	(%)							
Bobofen	-	-	+	13.120	9.950	2.270		
Fructus Myrtylli	-	+	1.090	0.360	8.280	7.900		
Bronchial	-	-	4.050	9.450	6.450	34.110		
Fito - mix 9	-	+	6.100	1.490	14.320	11.020		
Flatuvit	-	+	9.780	-	8.570	5.400		
Fructus Foeniculi		-	1.630	3.200	7.650	4.120		
Anthodium Chamomillae	-	-	5.710	12.400	3.910	10.200		
Inflorescentia Tiliae	-	+	5.510	5.720	11.760	1.760		
Folium Melissae	-		5.830	34.780	5.390	7.270		
Folium Menthae pip. Herbapol	-	-	7.010	16.970	6.090	5.270		
Folium Menthae pip. PhytoPharm		-	-	12.550	5.640	5.040		
Nervinum	-	+	4.160	10.660	5.850	8.950		

The percentage of heavy metals extraction to brewed teas
Procent ekstrakcji metali ciężkich do naparów

+ trace amounts - ilości śladowe

# Table 5

Tabela 5

			-	•			
Name of preparation Nazwa preparatu	Bath and manufac- turer Nr partii	Cd	Pb	Cu	Mn	Zn	Fe
Lemon with vit. C Impress	L-91472 Kruger	-	3.000 ±0.2365	3.000 ±0.1788	2.730 ±0.2244	+	42.500 ±1.0221
Foeniculi Impress	L-181731 Kruger	-	3.350 ±0.0353	5.000 ±0.0269	0.730 ±0.02554	+	40.500 ±1.3321
Foeniculi HIPP	L-93142 HIPP GmbH	-	4.200 ±0.0236	5.500 ±0.0487	1.550 ±0.0689	5.700 ±0.3265	25.000 ±0.8799
Fruit with vit. C Impress	L-00731 Kruger	-	3.450 ±0.0412	2.500 ±0.0635	1.130 ±0.0611	+	11.750 ±0.7456
Orange with vit. C Impress	L-9265 Kruger	-	3.100 ±0.0089	11.300 ±0.5840	0.900 ±0.0325	7.500 ±0.0224	20.750 ±0.6699
Chamomile HIPP	L-181771 HIPP GmbH	-	3.550 ±0.0042	4.500 ±0.0322	5.870 ±0.2236	7.500 ±0.1133	53.250 ±1.0123
Chamomile Impress	L-92651 Kruger	-	6.500 ±0.0298	2.350 ±0.0244	+	13.750 ±0.3365	66.000 ±0.8989
Sedative HIPP	L-181932 HIPP GmbH	-	3.550 ±0.0513	2.500 ±0.0392	0.200 ±0.0042	2.500 ±0.0221	13.500 ±0.7532
Digestive HIPP	L-1811932 HIPP GmbH	-	3.550 ±0.0411	3.000 ±0.0421	0.230 ±0.0096	+	147.500 ±1.9636
Herbal Impress	L-00041 Kruger	-	4.900 ±0.0223	4.500 ±0.2112	1.480 ±0.0321		12.250 ±0.0556
Plantex	1012003 Lek	-	7.700 ±0.6325	1.600 ±0.0415	+	19.500 ±0.2214	41.050 ±0.4411
Aperisan	Dentinox 1001	-	2.400 ±0.0653	8.750 ±0.1452	1.830 ±0.0784	23.750 ±0.2236	45.750 ±0.6398
Bobodent	HascoLek 11003	-	1.850 ±0.0069	0.500 ±0.0041	2.080 ±0.0142	23.750 ±0.6523	32.750 ±0.4112

The content of heavy metals in instant granulated teas and teething gels (means  $\pm$  SD) (mg·kg<sup>-1</sup>) Zawartość metali ciężkich w herbatach granulowanych i żelazach na ząbkowanie (mg·kg<sup>-1</sup>)

+ trace amounts – ilości śladowe

daily intake of heavy metals and their content in brews for immediate consumption, we can conclude that tea bags do not cause any danger to an adult organism. However in the case of babies and small children this means that a significant portion of allowable daily intake is delivered with the tea. This is the more disturbing that the major intake of bioelements should be from food and not herbal teas. Moreover, vegetable food contains less bioavailable form of microelements than meat and fish (GALAL-GORCHEV 1993, PLUTA et al. 1984, GERTING 1998).

The investigations also included two dental gels used in teething babies: Aperisan and Bobodent. As shown in Table 2 and 5, none of the gels contained cadmium, but both of them contained lead and mercury. Also, a relatively high dose of iron – 45.75 mg·kg<sup>-1</sup> and 32.75 mg·kg<sup>-1</sup> as well as zinc – 23.75 mg·kg<sup>-1</sup> in both products and 8.75 mg·kg<sup>-1</sup> of cuprum in Aperisan may arise restrictions.

However, taking into account dosage regimen of both products, the delivered amounts of heavy metals are insignificant for the organism.

The level of mercury was additionally assessed in Pulvis Magnesiae cum Rheo, Echinapur tabl. and Succus Echinacaeae (Table 2). The determined levels of mercury were insignificant in all of the drug forms – they did not exceed the level of  $0.01 \text{ mg} \cdot \text{kg}^{-1}$ .

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### Barbara Figura, Janusz Pluta

### EVALUATION OF PURITY OF CERTAIN PAEDIATRIC PREPARATIONS OF PLANT ORIGIN AND ITS SIGNIFICANCE FOR THE SAFETY OF PHARMACOTHERAPY

# Part 1. Heavy metals contamination of certain paediatric preparations of plant origin

Keywords: heavy metals, preparation of plant origin, contaminations, paediatric preparations.

Abstract

The main reason responsible for the presence of contaminations such as heavy metals in plant products is increasing environmental pollution. As a consequence of contamination, the elements penetrate the plant and animal world as well as food and drugs. The presence of heavy metals was traced in all the investigated herbal preparations, the highest levels being found in tea bags, slightly lower – in granulated teas and gels for difficult teething. The passage of the metals to tea bags varied from 1% to 35%. Many of the investigated preparations cannot be recognized as safe as regards the levels of heavy metals, especially in relation to young children.

### OCENA CZYSTOŚCI PEDIATRYCZNYCH PREPARATÓW POCHODZENIA ROŚLINNEGO I JEJ ZNACZENIE DLA BEZPIECZEŃSTWA FARMAKOPTERAPII

# Cz. I. Zanieczyszczenie metalami ciężkimi wybranych pediatrycznych preparatów roślinnych

Słowa kluczowe: metale ciężkie, preparaty ziołowe, zanieczyszczenia, preparaty pediatryczne.

#### Abstrakt

Główną przyczyną obecności w preparatach pochodzenia roślinnego zanieczyszczeń, takich jak metale ciężkie, jest wzrastające zatrucie środowiska. Konsekwencją skażenia jest ich przenikanie do świata roślin i zwierząt, a tym samym do żywności i leków. We wszystkich badanych preparatach ziołowych stwierdzono obecność metali ciężkich, przy czym najwięcej znajdowało się w herbatach ekspresowych, nieco mniej w herbatach granulowanych i żelach na ząbkowanie. Przechodzenie metali do naparów z herbat ekspresowych było zróżnicowane i wynosiło od 1% do 35%. Wielu spośród przebadanych preparatów nie można uznać za bezpieczne pod względem poziomu metali ciężkich, szczególnie w odniesieniu do małych dzieci.