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Izvješće o sigurnosti kozmetičkog proizvoda

CLEOPATRA ŠEĆERNA PASTA ZA EGIPATSKU DEPILACIJU SA ČOKOLADOM

Šifra proizvoda: 3859892429232

Proizvođač/Odgovorna osoba: Luxury Cosmetics d.o.o, Korzo 8, 51000 Rijeka, Hrvatska

Kontakt osoba i telefonski broj: Dijana Čuzela, dijana.cuzela@luxury-cosmetics.eu Tel: 00-385 (0) 51-371-418, Fax: 00-385 (0) 51-371-244

Kategorija proizvoda: proizvod za kožu/proizvod koji se odstranjuje

Cosmetic Product Safety Report

CLEOPATRA CHOCOLATE SUGAR PASTE FOR ORIENTAL EPILATION

Product code: 3859892429232

Company („Responsible Person“): Luxury Cosmetics d.o.o, Korzo 8, 51000 Rijeka, Croatia

Contact person and contact telephone number: Dijana Čuzela, dijana.cuzela@luxury-cosmetics.eu

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Category /application of product: skin product, leave off

17. lipnja 2014.

17th June 2014.

A. IZVJEŠTAJ O PROIZVODU/ COSMETIC PRODUCT SAFETY INFORMATION

U svrhu izrade procjene sigurnosti za kozmetički proizvod „Cleopatra“ čokoladna šećerna pasta za egipatsku depilaciju, dostavljena je dokumentacija od Luxury Cosmetics d.o.o, Korzo 8, 51000 Rijeka, Hrvatska koja sadrži sljedeće:

- Rješenje Ministarstva zdravlja Klasa UP/I-530-01/12-01/04, Ur.br: 534-09-1-1-1/2-13-9, Zagreb od 9. rujna 2013. o ispinjavanju uvjet za proizvodnju prema Pravilniku o posebnim uvjetima za proizvodnju i stavljanje na tržište predmeta opće uporabe (NN 082/2010) odnosno smjernicama za dobru proizvođačku praksu (HRN EN ISO 22716)
- kvalitativni i kvantitativni sastav kozmetičkog proizvoda sa specifikacijom sirovina i certifikatima o njihovoj čistoći
- fizikalno-kemijska svojstva gotovog proizvoda i mikrobiološka čistoća gotovog proizvoda
- stabilnost proizvoda
- Ugovor o kontroli zdravstvene ispravnosti sa Nastavnim zavodom za javno zdravstvo Primorsko-Goranske Županije od 5.02.2013
- Ugovor o izradi procjene sigurnosti s Hrvatskim zavodom za javno zdravstvo
- Izvješće o zdravstvenoj ispravnosti
- proizvodni postupak s in – process kontrolom
- Analitičko Izvješće LRN P 00262/11 (101585) za sekundarnu ambalažu izdano od Hrvatskog zavoda za javno zdravstvo za proizvođača Velpapir d.o.o, 10090 Zagreb, Croatia
- certifikati sirovina za ambalažu proizvođača Borealis A/S, Danska Parallevej 16, DK-2800 Kongens Lyngby prema Uredbi (EZ) br. 1935/2004, direktivama 2002/72/EC, 2004/1/EC, 2004/19/EC i 2005/79/EC
- deklaracija gotovog proizvoda

With a view to assessing the safety of cosmetic product Cleopatra Chocolate sugar paste for oriental epilation, the following documentation was submitted by Luxury Cosmetics d.o.o, Korzo 8, 51000 Rijeka, Croatia:

- *Decision by the Ministry of Health regarding registration of entity for production of cosmetics according to the HRN EN ISO 22716, and special purpose cosmetics, dated 18 January 2012, Class: UP/I-530-01/12-01/04, Ref.no: 534-09-1-1-1/2-13-9, Zagreb 9. September 2013.*
- *Qualitative and quantitative content of cosmetic product with raw material specification and purity certificates;*
- *Physical and chemical composition of products and microbiological purity*
- *Product stability at storage temperature*
- *Agreement between the Institute of Public Health Rijeka and Luxury Cosmetics regarding the product health safety and microbiological purity*
- *Agreement between the Croatian National Institute of Public Health, Rockefellerova 7, Zagreb, and Luxury Cosmetics regarding the safety assessment*
- *Analytical report regarding health safety*
- *Manufacturing Process with in-process control*
- *Analytical Report LRN P 00262/11 (101585) by Croatian National Institute of Public Health on packaging material by Velpapir d.o.o, 10090 Zagreb, Croatia*
- *Attached Certificate of Conformity for packaging materials from manufacturer Borealis A/S, Danska Parallevej 16, DK-2800 Kongens Lyngby according to EU Regulation 1935/2004, 2002/72/EC, 2004/1/EC, 2004/19/EC and 2005/79/EC*
- *Declaration of Final Product*

1. Kvantitativni i kvalitativni sastav kozmetičkoga proizvoda/ *The qualitative and quantitative composition of a cosmetic product*

Tablica 1. Sastav proizvoda/ *Ingredients*

INCI name	m/m % (% w/w)
Sucrose	90
Citrus Medica Limonum	5
aqua	4,5
Theobroma Cacao Fruit Powder	0,5

2. Fizikalno-kemijska svojstva i stabilnost kozmetičkoga proizvoda/ *Physical-chemical characteristic of the product and stability of the cosmetic products*

Organoleptika: homogena, ljepljiva masa, smeđe boje, karakterističnog mirisa na čokoladu

pH vrijednost 10% vodene otopine : 3.5-4.0

Ubrzani test stabilnosti proveden je pri temperaturama od +4°C, 37°C, 40°C i 45°C tijekom 15 dana pri čemu nije bilo organoleptičkih promjena.

Predviđeni rok valjanosti iznosi 36 mjeseci i 12 mjeseci nakon otvaranja.

Organoleptics: homogenous, sticky mass of brown color and characteristic chocolate odor

pH value (10% aqua solution) 3.5-4.0

Accelerated stability (during a period of 15 days at +4oC, 37oC, 40oC i 45oC) where the requirements are fulfilled.

Results of stability testing: stable up to 36 months and 12 months after opening

3. Mikrobiološka čistoća/ *Microbiological quality*

Kontrolirana prema Ugovoru o zdravstvenoj ispravnosti sa Nastavnim zavodom za javno zdravstvo Primorsko-Goranske županije na ukupne mezofilne bakterije, kvasci i plijesni, *Pseudomonas aeruginosa*, *Escherichia coli*, *Staphylococcus aureus*, *Candida albicans* gotovog proizvoda te briseve radnih površina.

Controlled according the Contract with Institute for Public Health, Rijeka regarding the product health safety Total Mesophilic Bacteria, Yeasts and Molds, *Pseudomonas aeruginosa*, *Escherichia coli*, *Staphylococcus aureus*, *Candida albicans* of the final product and microbiological purity of work surfaces.

4. Nečistoće, tragovi, podaci o ambalažnom materijalu/ *Impurities, traces, information about the packaging material*

Proizvod je pakiran je u plastičnu teglicu od 120g, 700g i 1400g, izrađenoj iz polipropilena. Ambalaža ispunjava zahtjeve prema Uredbi (EZ) br. 1935/2004, direktivama 2002/72/EC , 2004/1/EC, 2004/19/EC i 2005/79/EC.

It is packaged in plastic polypropylen jar with plastic lid, mass of 120g, 700g and 1400g. Packaging meets requirements according to EU Regulation 1935/2004, 2002/72/EC , 2004/1/EC, 2004/19/EC and 2005/79/EC.

5. Uobičajeni i razumno predvidljivi uvjeti uporabe/*Normal and reasonably foreseeable use/instructions*

Označen na deklaraciji: Cleopatrina šećerna pasta ručno se nanosi u suprotnom smjeru rasta dlačica, a uklanja se u smjeru njihovog rasta. Na taj način dlačice se ne lome, već se u cijelosti izvlače iz korijena.

Depilacija Cleopatrinom šećernom pastom:

- a) mogućnost uklanjanja dlačica već od 2mm
- b) dlačice se uklanjaju iz korijena što omogućuje dugotrajnu glatkoću bez neželjenih posljedica

Indicated on the label: Cleopatra sugar paste is applied in the opposite direction of hair growth, and it is removed in the direction of their growth. In this way the hairs are not broken but fully extracted from their roots.

Epilation done by Cleopatra Sugar paste

- a) Cleopatra sugar paste has the capacity to remove 2 mm long body hair
- b) Hairs are removed from their roots which provides a long-lasting smoothness without side effects.

Other waxing methods:

- a) cannot guarantee removal of hairs shorter than 3 mm
- b) break the hairs causing hair ingrowth

6. Izloženost kozmetičkom proizvodu/*Exposure to the cosmetic product*

Scenario: noge

Mjesto aplikacije/*The site of application:* dermalna aplikacija, kratkotrajan kontakt/ *dermal application, short-term contact*

Površina zahvaćenekože/*The surface area(s) of application :* 5530cm²

Tjelesna masa žene/*Body weight female:* 60 kg

Količina koja se nanosi/*The amount of product applied :* 5,5g

Učestalost uporabe/*Frequency of application:* 17/godišnje (17/times per year)

Vrijeme izloženosti/*Exposure time :* 15min

Retencijski faktor/*Retention factor:* 1.0

Populacija/*The target populations:* žene i muškarci, mlađe i starijedom / *women and men, younger and older age*

Scenarij izloženosti je napravljen prema The SCCP-s Notes of guidance for the testing of cosmetic ingredients and their Safety evaluation (2012), and RIVM report 320104001/2006 Cosmetic Fact Sheet To assess the risks for the consumer , H.J. Bremmer, L.C.H., Prud homme de Lodder, J.G.M van Engelen.

Exposure scenario was made on the basis of the SCCP-s Notes of guidance for the testing of cosmetic ingredients and their Safety evaluation (2012), and RIVM report 320104001/2006 Cosmetic Fact Sheet To assess the risks for the consumer , H.J. Bremmer, L.C.H., Prud homme de Lodder, J.G.M van Engelen.

7. Toksičnost sastojaka/ *Local Toxicity Effects of 100% active ingredient*

INCI name	Nagrizajuće Corrosivity	Nadražujući za kožu Skin irritation	Nadražujuće za oči/ Eye irritation	Senzibilizacija kože Skin sensitisation	Fotoosjetljivost Photosensitivity	Alergeni legislativa IFRA regulation apply?
Sucrose	n/a	n/a	n/a	n/a	n/a	n/a
Citrus Medica Limonum Juice	-	n/a	Iritirajući/ Irritants	n/a	n/a	-
aqua	n/a	n/a	n/a	n/a	n/a	n/a
Theobroma Cacao (Cocoa) Fruit Powder	-	-	-	-	-	-

-..... Nema opasnosti kod normalne uporabe/no hazard in normal use

n/a --- nema podataka/ not available

Podaci o toksičnosti sastojaka odnosno smjese napravljeni su prema podacima proizvođača i podacima iz Sigurnosno-tehničkog lista.

Toxicity data are based on suppliers documents and data on the safety data sheet.

8. Izloženost sastojcima / *Exposure of the substances*

Proizvod sadrži sastojke koji u uporabljenim koncentracijama prema stručnoj i znanstvenoj literaturi smatraju se sigurnim za uporabu.

The product contains ingredients that, in used concentrations are considered safe for use, according to professional and scientific literature.

9. Neželjeno djelovanje i ozbiljni učinci na zdravlje / *Undesirable effects and serious side-effects on health*

Prema Izjavi proizvođača do sada nisu zabilježeni ozbiljni učinci na zdravlje. U uvjetima pravilne primjene mala je mogućnost neželjenog djelovanja osim u slučaju kada se smjesa pregrije kada mogu nastati opekotine.

Stated by the manufacturer until now there were no serious health effects. When properly applied, there is small risk of undesirable side-effects, except in the case of paste overheating which may cause burns.

10. Podaci o kozmetičkom proizvodu / *Human studies on the finished product*

Nije proveden test dermatološke prihvatljivosti gotovog proizvoda
No human studies have been carried out on the finished product.

B. PROCJENA SIGURNOSTI/COSMETIC PRODUCT SAFETY ASSESSMENT

ZAKLJUČAK

Uvidom u dokumentaciju proizvođača Luxury Cosmetics d.o.o, Korzo 8, 51000 Rijeka, Hrvatska za proizvod **Cleopatra šećerna pasta za egipatsku depilaciju sa čokoladom** smatramo da je u skladu sa Uredbom(EZ) br. 1223/2009 Europskog Parlamenta i Vijeća od 30.studenog 2009 o kozmetičkim proizvodima te Zakonom o predmetima opće uporabe (NN 39/2013, 47/2014).

Potrebna upozorenja i uputa za uporabu:

Deklaracija i upozorenja na proizvodu u skladu su sa zahtjevima za kozmetičke proizvode iz članka 19 stavak d) Uredbe o kozmetičkim proizvodima (EC) br. 1223/2009.

Obrazloženje:

Cleopatra šećerna pasta za egipatsku depilaciju s čokoladom prema postavljenim zahtjevima u dokumentaciji uz kontrolu gotovog proizvoda smatra se sigurnim za predviđenu namjenu ako se koristi na predviđen način i prema uputi proizvođača.

Napomena: Procjena sigurnosti odnosi se na ovu formulaciju i dopušta varijaciju koncentracija sirovina (osim konzervansa i eteričnih ulja) unutar +/-20% od deklariranog udjela ukoliko je granica sigurnosti 100 ili viša. Svaka promjena sirovina, boje, mirisa ili eteričnog ulja zahtijeva novu procjenu sigurnosti. Kontrola gotovog proizvoda i praćenje stabilитета obveza je proizvođača.

Assessment conclusion

By inspection of the documentation by the manufacturer Luxury Cosmetics d.o.o, Korzo 8, 51000 Rijeka, Croatia concerning the product **Cleopatra Chocolate sugar paste for oriental epilation** is found to be in

conformity with Regulation (EC) No. 1223/2009 of the European Parliament and of The Council of 30 November 2009 on cosmetic products and Act on General Use Items (OG 39/2013, 47/2014).

Required warnings and instructions for use

Declarations and warnings on the product in accordance with the requirements for cosmetic products in the Regulation (EC) No. 1223/2009 of the European Parliament and of The Council of 30 November 2009 on cosmetic products.

Reasoning:

In regard to requirements defined in said documents, and upon an end product examination, **Cleopatra Chocolate sugar paste for oriental epilation** is found to be SAFE for the specified purpose, if applied in a suitable manner and as recommended by the manufacturer.

Note: Except for preservatives and essential oil, this assessment is valid for concentration variations of +/- 20% of the declared percentage as long as the margin of safety for the ingredients is 100 or greater. Any changes of raw materials, colours, fragrance or essential oils requires new Safety assessment. The control of cosmetic products and stability testing is obligation of manufacturer.



MSc. Ivona Vidić Štrac, Biol.sci.toxicology

Head of Consumer Product Unit
Croatian National Institute of Public Health
Rockefellerova Street 7, 10000 Zagreb
Croatia

Curriculum Vitae of Safety assessor

Personal Information	
First name/ Surname	Ivona Vidić Štrac
Nationality	Croatian
Date of birth	01.07.1969
Gender	Female, married, mother of two sons
Work experience	
Dates	1 June 1995 Croatian National Institute of Public Health 1994 - 1995 Medical Center Peščenica, Biochemical/Hematological Laboratory, probation
Occupation	Head of Objects of Common Use
Name and address of employer	Croatian National Institute of Public Health, Rockefellerova 7, Zagreb
Telephone	00385 14863258
Fax	0038514683907
E-mail	ivona.vidic-strac@hzjz.hr
Position held	From December 2008 Head of Consumer Products Unit
Main activities and responsibilities	Analyst, participated in drafting of legislation for Ministry of Health and Social Welfare, giving expert opinion, member of working group for AcquisCommunaute, Chapter 1. Free Movement of Goods, member of EDQM Consumer Health Protection Committee of Experts on Cosmetic Products, member of Expert Group on Toys, DG SANCO
Education and training	
Dates	December 2008, degree of Master of Science, University of Zagreb, Faculty of Science, Division of Biology, field: toxicology, thesis "Presence of phthalates esters in intravenous solution" 23 Feb 1995. state exam at the Ministry of Health and Social Welfare 29 Oct 1993. graduate of Medical biochemistry at Faculty of Pharmacy and Biochemistry University of Zagreb
Level in national or international classification	Master of Science in Biology, field: toxicology
Personal skills and competences	
	Experience in drafting legislation in the field of cosmetics, toys and detergents
Mother tongue	Croatian
Other language	English, German

Participations	1996 1st Croatian Congress on Pharmacy, poster section «Health Safety of Pharmaceutical Packaging» Zagreb 1998 Environmental Health Section, Croatian Pharmaceutical Society, oral presentation «Health of powdered detergents», Stubičketoplice 2000 Symposium Environmental Health Section, Croatian Pharmaceutical Society, poster section «Liquid washing agents and cleaners», Trogir 2000 2nd Croatian Toxicology Congress, Crotox «Health Safety of Toys», Pula 2003 Eurotox, poster section «Acute poisoning with caustic corrosives in Croatia», Florence, Italy 2003 Continuing Education Course: Safety testing of cosmetic ingredients and cosmetic formulations, Eurotox Florence 2003 1st Croatian Congress on Preventive Medicine and Health Promotion, poster section Zagreb, title 2004 Symposium Environmental Health Section, Croatian Pharmaceutical Society, Child poisoning with caustic corrosives in Croatia, Zadar 2007 Croatian Society of Cosmetic Chemists, Legislation on detergents, oral presentation, Šibenik 2007 Symposium Environmental Health Section, Croatian Pharmaceutical Society, Šibenik title 2007 Workshop DDDi Dubrovnik Acute poisoning with pesticides in Croatia 2000-2005 2008 Symposium Environmental Health Section, Croatian Pharmaceutical Society, Labeling of Consumer Products according to the Ordinance - problems 2009 Eurotox „Migration of Di-(2-Ethylhexyl) phthalate in normal saline during one year” poster section, symposium, oral presentation, Dresden 2010 4th Croatian Congress on Pharmacy, oral presentation “Safety Assessment of Cosmetic Products”, Opatija 2011 1s Croatian Environmental health Congress , oral presentation “Cosmetic claims or how to select the right claim” Strac IV, Pušić M, Gajski G, Garaj-Vrhovac V. Presence of phthalate esters in intravenous solution evaluated using gas chromatography–mass spectrometry method, J Appl Toxicol. 2011 Oct 28. 2012 2013 2s Croatian Environmental health Congress , oral presentation “Cosmetovigilancevs.Toxicology” 2013 Vidić Štrac I. Žuntar I, Dimitrov N, Puklek M. Ethylene glycol and diethylene glycol in toothpaste on Croatian market, Farm.glas., vol 69, 319-331 (2013) 2013 13th CSCC Meeting 2013 Cosmetics and detergents up to date, oral presentation legislation overview concerning Cosmetic Products Regulation 1223/2009, Poreč Training Course Safety Assessment, Vrije Universiteit Brussel, 3.02.-8.02.2014
Member	Croatian Toxicological Society, Croatian Standards Institute: member TO 217 Cosmetic, TO 181 Safety of toys and child use, TO 539 Chemical disinfectants and antiseptics
Social skills and competences	Participation in activities of Croatian Society of Cosmetic Chemists
Organizational skills and competences	Good team leadership in a laboratory comprising diverse experts and professional staff with secondary education Organization of conferences and congresses
Technical skills and competences	Use of a variety of analytical equipment (such as GC-FID, GC-MS) and computer equipment