Cabex.

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Expertise Cosmético Badr Raïs

REPORT ON THE SAFETY OF COSMETIC PRODUCT

(According to the European Cosmetic Regulation, EC 1223/2009)

"WATER TEMPORARY TATTOO MOD STANDARD & WHITE"
(Formula/Reference F-000219/2013)

Certificate Nº 17-787-GRI-02

Document elaborated by:

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On the request of the company:

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PART II.B – Cosmetic product safety assessment

II.B.1 – Assessment conclusion

At the request of the company INDUSTRIAS DECORMARKET, SA, we have assessed the safety to human health from use of the product **WATER TEMPORARY TATTOO MOD STANDARD & WHITE** Formula/Reference **F-000219/2013** within the framework of the European Regulation (EC) No. 1223/2009 on Cosmetic products, published in the Official Journal of December 22, 2009 and its updates, the Guidelines adopted by the Scientific Committee on Consumer Safety during the 11th plenary meeting of 29 September 2015: "The SCCS's Notes of guidance for the testing of cosmetic substances and their safety evaluation" (9th revision) and its addendum of October 22, 2014 and the Guidelines on Annex I to Regulation (EC) No 1223/2009 (Commission Implementing Decision 2013/674/EU of 25 November 2013).

We have examined the documents and the results mentioned in part II.A of the cosmetic file and it allows us to appreciate that, in the present state of our knowledge, the product designated as "**WATER TEMPORARY TATTOO MOD STANDARD & WHITE - F-000219/2013**" does not present with any recognized toxic effect, which could affect human health, under the normal or reasonably predictable conditions of use: it can thus be marketed on the European market.

Nevertheless, if within the framework of cosmeto-vigilance and in conformity with the European Commission Guidelines about the management of the adverse effect (SUE REPORTING GUIDELINES) of August 2012, if any undesirable events, defined as "adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product", in reference to the Articles 2.1(o) and 21, of Cosmetics Regulation (EC) No 1223/2009, attributable to this product have been registered, we should be informed about it and possibly request for a new evaluation of its no-toxicity. The same applies in case of any variation in the formula of the product examined for this assessment, in its instructions of use, in its target, in its claims or in any other datum which may affect its safety for human health.

II.B.2 – Labelled warnings and instructions of use

- Precautions relative to regulated substances: *none.*
- Particular precautions to be observed in use:
  - *external use,*
  - *use immediately after opening,*
  - *do not use on sensitive or irritated skin,*
  - *do not apply near the eyes,*
  - *not suitable for children under three years. Small parts,*
  - *use under adult supervision.*
- Special precautionary information on cosmetic products for professional use: *not applicable.*

II.B.3 – Reasoning

The reasoning which enabled to obtain the assessment conclusion is based in particular on the analysis of the following elements:

- for the purposes of the Annexes II to VI of the Cosmetics Regulation (EC) No. 1223/2009, the product is considered as a leave on skin product;
- the quantitative and qualitative composition of the cosmetic product:
  - absence of substances prohibited and concentrations not authorised by the European cosmetic legislations in force;

- analysis of the presence of substances and combinations of substances limited in concentrations or classified (specially Xi), in particular those likely to cause a sensitization risk (H317 - R43);
- analysis of substances which can be labelled, known as « allergenic »;
- analysis of the presence of substances, whose recent publication of scientific information requires a new safety evaluation, such as the endocrine disruptors, taking into account the recommendations of the SCCS and the following elements:
  - type of product, conditions of use;
  - relevance of their presence in the formula («benefit/risk balance», substitute considered...);
  - analysis of the other formula components likely to change their bioavailability and to increase or limit the toxicity risk;

- the physical and chemical characteristics of the substances or mixtures and the product, as well as the physicochemical and microbiological (challenge test) stability of cosmetic product;
- the attestation made by the manufacturer, specifying that this formula was elaborated according to the European legislations in force, as regards cosmetic manufacturing;
- the absence of significant impurities and the stability of the packaging materials (absence in the present state of our knowledge of substances or concentrations likely to present a known toxicological risk induced by the substance itself, by the packaging materials or by the manufacturing process);
- relevant characteristics of the packaging material, in particular the nature, the purity and the stability of the packaging material, compatibility of the formula with the packaging:
  - inertia and safety of the packaging material constituents: the materials PAPER met the regulatory requirement on materials in contact with foodstuffs - Regulation (EC) 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come in contact with food and Council Europe Resolution AP 2002/1 on paper and board, within the restrictions limits for cadmium, lead, mercury and pentachlorophenol;
- the toxicological profile of substances, their chemical structure and their direct or indirect secondary level of exposure (in the present case: no identified risk), in particular that of the perfuming composition:
  - evaluation of the elements of the material safety data sheets (MSDS) and of the technical sheets of those substances and mixtures of substances;
  - the product does not contain fragrance;
- the specific analysis of the toxicological data and of the **Margin of Safety** (MoS) of the formula substances, and especially of the substances and mixtures of substances classified according to the modalities specified by the SCCS. *(Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation – 9th revision, September 2015)*:
  - the MoS calculated for those substances in this finished product, when the NOAEL is available, are all higher than 100;
  - for the substances whose NOAEL has not been, a priori determined, the analysis of toxicological data from the **MSDS**, technical sheets and, if necessary, of the bibliographical references or toxicological databases (Toxnet, Toxline, CIR., Europe / CosIng…), as well as the calculation of the SED (systemic exposure dosage, in mg/kg/day), enables to conclude that there is no foreseeable hazard in normal or reasonably predictable conditions of use for the concerned target given the maximising conditions used for the computations (daily applied amount and cutaneous penetration factor of 100%);
  - toxicological assessment of Tattoos transfer glue - Intertek Toxicology Assessment report n° LECTA000 69664 ver. 1, of April 19, 2010 – under normal and foreseeable conditions of use, the product is unlikely to produce an abnormally high number of adverse reactions. The product will give users the level of safety they can reasonably expect;
  - toxicological risk assessment of temporary tattoos ingredients - Delphic HSE Solutions report n° 5144 - 9307 of January 18, 2013 – under normal and foreseeable conditions of use, the product is unlikely to produce an abnormally high number of adverse reactions. The product will give users the level of safety they can reasonably expect;

- the calculated LD_{50}, according to oral toxicity calculation of a mixture based on ingredients (additivity formula) - Regulation (EC) No 1272/2008, is greater than 2,000 mg/kg bw and the product is not classified as dangerous;

- analysis of the incidence on the toxicological profile in particular of:
  - particles size: unexpected presence of nanomaterials in the formula;
  - the impurities: presence of heavy metals and other impurities at concentrations which do not present, in the present state of our knowledge, known toxicological risk;
  - the interaction of substances: substances do not present, in the present state of our knowledge, any risk of molecular interaction likely to induce a known toxicological risk (confirmed one hand by the analysis of the toxicological profiles and chemical structures in particular for the generation of nitrosamines and on the other hand by the results of the *in vitro* and clinical tests carried out on the product);
- the specific characteristics of the corporal areas where the product will be applied, the amount, duration and frequency of use or the population to whom the product is intended:
  - the product has been designed to be used some times, but not on a repeated basis and applied as such on the body skin area;
  - the targeted people is children over three years old and adults with normal skin;
- the normal and reasonable foreseeable conditions of use. Unintentional ingestion is also considered;
- the experience gained on similar formula and products;
- the available data on the undesirable and serious undesirable effects;
- the results of the analysis performed on the product object of the present certificate (**F-000219/2013**) allow to conclude the product fulfils the Directive 2009/48/EC on the safety of toys:
  - determination of Cadmium (Cd) and Lead (Pb) in substrates, paints and coatings - AIJU report n° L/0038456-1 of 3/11/2011=> Cadmium fulfills the requirements according to Annex XVII of the REACH Regulation, Section 23 and Lead fulfills the requirements according to CPSIA 2008, Section 101 "Children's Products containing Lead";
  - Phthalates determination - AIJU report n° L/0038456-2 of 7/11/2011=> Tested Phthalate Plasticizers concentration detected in the product is less than 0,1% by weight. The product fulfills with phthalate content, according to Annex XVII of the REACH Regulation (CE) n° 1907/2006, sections 51 and 52, and with the requirements related to phthalates as set in CPSI Section 108;
  - EN-71-3:2013 Safety of toys - Part 3: Migration of certain elements (Al, As, B, Ba, Cd, Co, Cr, Cu, Hg, Mn, Ni, Pb, Sb, Se, Sn, Sr, Zn) – AIJU report n° L/0048407-1 of September 8, 2014. The product satisfies the requirements;
  - determination of Cadmium (Cd) in substrates, paints and coatings by Fluorescence and/or microwave digestion and ICP analysis - AIJU report n° L/0048407-1 of 8/9/2014=> Cadmium fulfills the requirements according to Annex XVII of the REACH Regulation, Section;
  - EN 71-3:2013 + A1:2014 Safety of toys - Part 3: Migration of certain elements (Al, As, B, Ba, Cd, Co, Cr total, Cu, Hg, Mn, Ni, Pb, Sb, Se, Sn total, Sr, Zn, Cr (VI)) – AIJU report n° L/0053351-1 of July 7, 2015. The product satisfies the requirements of the Standard;
  - EN-71:2005/9 Safety of toys - Part 9: Organic chemical compounds. Requirements – AIJU report n° L/0053351- 2 of July 14, 2015. The product satisfies the requirements of the Standard;
  - EN 71-3:2013 + A1:2014 Safety of toys - Part 3: Migration of certain elements (Al, As, B, Ba, Cd, Co, Cr total, Cu, Hg, Mn, Ni, Pb, Sb, Se, Sn total, Sr, Zn) – AIJU report n° L/0056270-1 of March 29, 2016. The product satisfies the requirements;
  - EN-71:2005/9 Safety of toys - Part 9: Organic chemical compounds. Requirements – AIJU report n° L/0056270- 2 of April 15, 2016. The product satisfies the requirements;

- EN 71-3:2013 + A1:2014 Safety of toys - Part 3: Migration of certain elements (Al, As, B, Ba, Cd, Co, Cr total, Cu, Hg, Mn, Ni, Pb, Sb, Se, Sn total, Sr, Zn,) – AIJU report n° L/0059964-1 of January 24, 2017. The product satisfies the requirements;
- EN-71:2005/9 Safety of toys - Part 9: Organic chemical compounds. Requirements – AIJU report n° L/0059964- 2 of January 26, 2017. The product satisfies the requirements;
- Impurities analysis: analysis of ACID 2-ETHYLHEXANOIC – CROMLAB S.L. report n° 1819 of May 14, 2012 with satisfactory results;
- Impurities analysis: analysis of NONILFENOL – CROMLAB S.L. report n° 2305 of July 3, 2012 with satisfactory results;
- Impurities analysis: analysis of VINYL ACETATE – CROMLAB S.L. report n° 4050 of January 10, 2013 with satisfactory results;
- Determination of Polycyclic Aromatic Hydrocarbon (PAH) in "*Tattoo black*" and "*Tattoo adhesive*" – AIJU. report n° L/0058702-1 of October 11, 2016. No concentrations of polycyclic aromatic hidrocarbons (PAH) higher than the limit of quantification (0.1 mg/kg) have been detected in analysed samples. The results for these samples can be classified in Category I of document AfPS GS 2014:01 PAK (test and assessment of polycyclic aromatic hidrocarbons (PAH) for the endorsement of mark GS) for materials intended to be put in the mouth, or materials of toys with intended to long-term skin contact (longer than 30 seconds).

  No concentrations higher than 0.5 % by weight of polycyclic aromatic hidrocarbons (PAH) limited by REACH Regulation (EC) no. 1907/2006, have been detected in the analysed samples. Therefore, these samples meet point 50 of Annex XVII in REACH Regulation (EC) no. 1907/2006;
- Determination of Polycyclic Aromatic Hydrocarbon (PAH) in "*Tattoo (without adhesive) Lot 215.964*" and "*Tattoo (final product) Lot 215.964*" – AIJU. report n° L/0059071-1 of November 11, 2016. No concentrations of polycyclic aromatic hidrocarbons (PAH) higher than the limit of quantification (0.1 mg/kg) have been detected in analysed samples. The results for these samples can be classified in Category I of document AfPS GS 2014:01 PAK (test and assessment of polycyclic aromatic hidrocarbons (PAH) for the endorsement of mark GS) for materials intended to be put in the mouth, or materials of toys with intended to long-term skin contact (longer than 30 seconds).

  No concentrations higher than 0.5 % by weight of polycyclic aromatic hidrocarbons (PAH) limited by REACH Regulation (EC) no. 1907/2006, have been detected in the analysed samples. Therefore, these samples meet point 50 of Annex XVII in REACH Regulation (EC) no. 1907/2006;

- the results of the clinical study of cutaneous acceptability performed on the formula object of the present certificate (**F-000219/2013**):
  - **cutaneous in-use test** (I.E.C. Espagne report n° E130301RE, of September 20, 2013): evaluation of the cutaneous acceptability on adult human subjects in normal conditions of use (tested under Dermatological control); the results observed during the study allows to conclude to a very good cutaneous acceptability;
- the fact that **this formula** has been launched on the market since 2009 with more than 250,946,362 units sold, and no undesirable event (classified as «very likely» or «likely to happen») resulting from the use of this product and that could harm human health has been communicated to the Company (see cosmetovigilance report done by **INDUSTRIAS DECORMARKET, SA** in conformity with the recommendations of the European Commission on the management of serious undesirable effects (SUE REPORTING GUIDELINES) version August 2012);
- the results obtained from the in-use test performed on 26 adult human subjects, individually examined by a Dermatologist, allow justifying the claim "Tolerance tested under Dermatological control".

This evaluation allows us to appreciate, that in the current state of our knowledge, **this product, under normal or reasonably foreseeable conditions of use, does not present any revealed toxicological effect on the human health**: thus it could be commercialized respecting the usual or legal labelling conditions for this kind of product.

Nevertheless, within the limits of the cosmeto-vigilance and in conformity with the European Commission Guidelines about the management of the adverse effect (SUE REPORTING GUIDELINES) of August 2012, if any undesirable effect, defined as "adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product", in reference to the Articles 2.1(o) and 21, of Cosmetics Regulation (EC) No 1223/2009, attributable to this product have been registered, we should be informed about it and eventually ask for a new evaluation of its no-toxicity.

II.B.4 – Assessor's credentials and approval of part B

. Name and address of the safety assessor:

Badr RAIS
Ph.D. Biological and Medical Sciences, Health Biology Option
European Registered Toxicologist - EUROTOX

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. Proof of qualification of safety assessor: see following pages (copies of the **State Diploma** for the **Doctorate** and of the registration on the Eurotox List).

. Date and signature of the safety assessor

Barcelona March 16, 2017

Badr RAIS

RÉPUBLIQUE FRANÇAISE

Ministère de la jeunesse, de l'éducation nationale et de la recherche

UNIVERSITE BORDEAUX 2

DOCTORAT DE L'UNIVERSITE BORDEAUX 2
MENTION SCIENCES BIOLOGIQUES ET MEDICALES - OPTION BIOLOGIE SANTE

Vu le code de l'éducation, et notamment son article L.613-1

Vu le décret n° 84-573 du 5 juillet 1984 modifié relatif aux diplômes nationaux de l'enseignement supérieur

Vu l'arrêté du 30 mars 1992 modifié relatif aux études du troisième cycle

Vu le procès-verbal du jury attestant que l'intéressé a soutenu, le 05 juillet 1995 une thèse portant sur le sujet suivant :
Contrôle de la chaîne de biosynthèse de la threonine chez escherichia coli.
devant un jury présidé par M. le Professeur M. AIGLE et composé de M. A. DESCHAMPS, M. R. HEINRICH, M. J.P. MAZAT, Professeurs, de M. B. KUDLA Directeur de Recherche et de M. N. LINDLEY, Chargé de Recherche.

Vu la décision dudit jury prononçant l'admission de l'intéressé

le DOCTORAT DE L'UNIVERSITE BORDEAUX 2
Mention SCIENCES BIOLOGIQUES ET MEDICALES Option BIOLOGIE SANTE *Mention très honorable*

est conféré à **Monsieur Badr RAÏS**

né le 6 août 1963 à CASABLANCA (Maroc) pour en jouir avec les droits et prérogatives qui y sont attachés.

Fait à Bordeaux, le 4 septembre 2003

Le titulaire

Le Président

Bernard BEGAUD

Le Recteur d'Académie
Chancelier des universités

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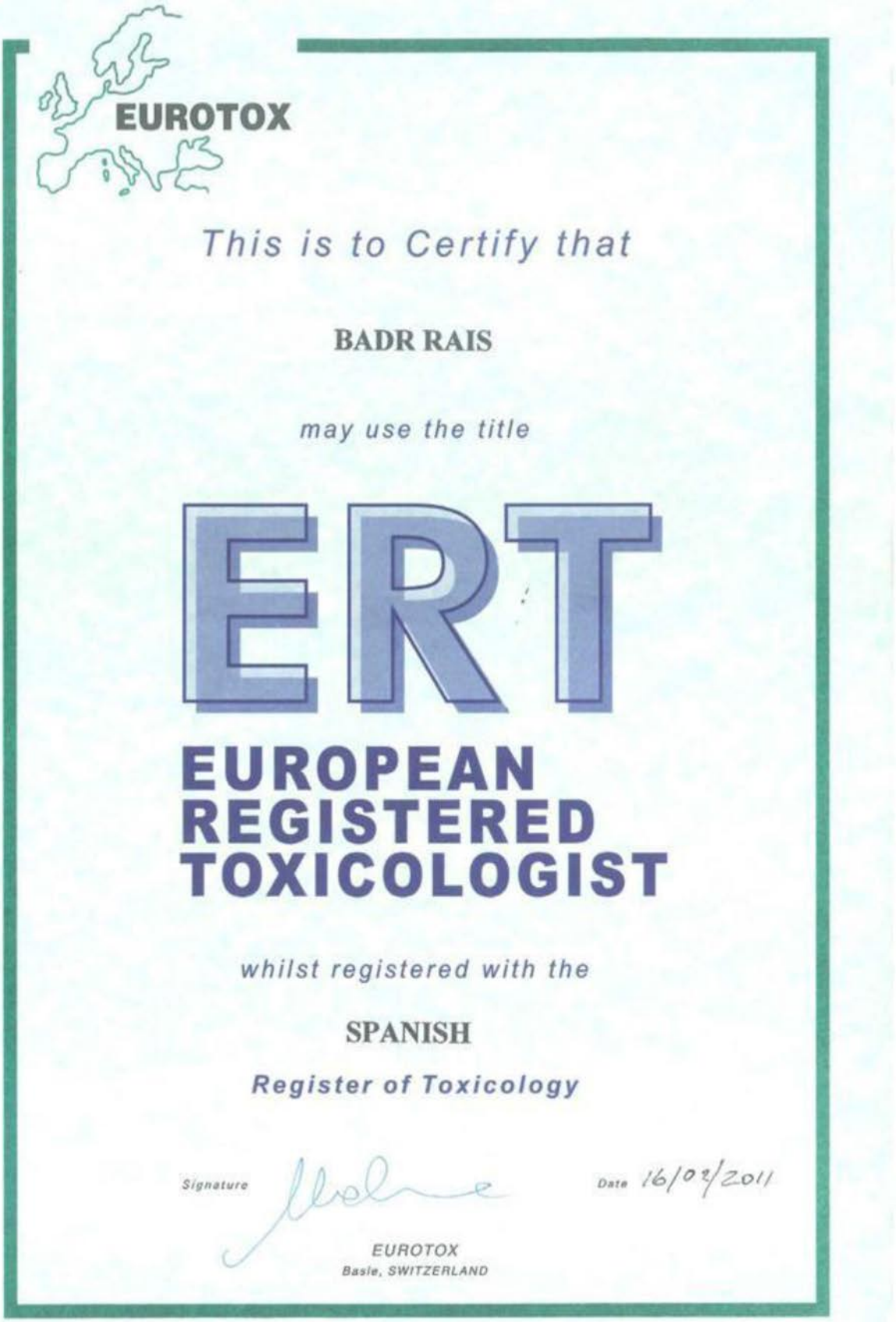

EUROTOX

This is to Certify that

BADR RAIS

may use the title

ERT

EUROPEAN REGISTERED TOXICOLOGIST

whilst registered with the

SPANISH

Register of Toxicology

Signature

Date 16/02/2011

EUROTOX
Basle, SWITZERLAND