HDN
Chemical
Consultancy

HDN CHEMİCAL
www.hdnchemical.com

HANDAN KAVİ

HANDAN KAVİ

CHEMICAL EVALUATION SPECIALIST

TURKEY

OUR SERVICES INCLUDING THE COSMETICS REGULATION

COSMETIC PRODUCT SAFETY REPORT

APPOINTMENT OF RESPONSIBLE MANAGER

APPOINTMENT OF A REPRESENTATIVE

PRODUCT SAFETY FILE

ENGLISH LABEL

COMPANY REGISTRATION IN PRODUCT TRACKING SYSTEM

PRODUCT NOTIFICATION TO PRODUCT TRACKING SYSTEM

LABEL NOTICE IF ANY SPECIAL CLAIM IS

SDS SERVICE

INFORMATION ABOUT COSMETIC PRODUCTS REGULATION

IMPORTANT DEFİNİTİONS

- **IUPAC name:** The name of the substance given by the International Union of Fundamental and Applied Chemistry.

- **Manufacturer:** The natural or legal person who manufactures a cosmetic product or has the product designed or manufactured and puts it on the market under its own name or trademark.

- **Importer:** The natural or legal person who imports a cosmetic product and supplies it to the market,

- **Good manufacturing practices:** All standardized planned and systematic activities necessary to provide adequate confidence in the production, control, storage and shipment of cosmetic products to meet quality requirements.

- **Cosmetic product:** external parts of the human body; All substance prepared for application to the epidermis, nails, hair, hair, lips and external genitalia, or the teeth and oral mucosa, whose sole or primary purpose is to clean, scent, change their appearance, protect them, keep them in good condition or correct body odours. or mixtures,

- **Institution:** Turkish Medicines and Medical Devices Agency,

- **End user:** The consumer who uses the cosmetic product or the person who applies it professionally, Putting on the market: Providing a cosmetic product to the domestic market for distribution, consumption or use, with or without charge, through a commercial activity,

- **Placing on the market:** Making a cosmetic product available in the domestic market for the first time.

- **Harmonized standard:** It refers to a European standard adopted upon the request of the European Commission in order to implement the Harmonized European Union Legislation.
- Safety
- Responsibility
- Free Movement
- Security
- **(1)** A commercially available cosmetic product is safe for human health when used under normal or reasonably foreseeable conditions of use, in particular taking into account:
- **a)** Presentation of the product in accordance with Article 24/A of the Law No. 4822 Amending the Law on the Protection of the Consumer, published in the Official Gazette dated 14/03/2003 and numbered 25048,
- **b)** Labeling,
- **c)** Instructions for use and disposal,
- **d)** Any other data or information provided by the authorized representative defined in Article 6.

- **Authorized representative**
- **(1)** Cosmetic products are offered to the market only on condition that the natural or legal person residing in the country is appointed as the authorized representative.
- **(2)** The authorized representative ensures compliance with the relevant obligations set forth in this Regulation for each cosmetic product placed on the market.
- **a)** In case the manufacturer is resident abroad, a resident in the country is authorized by written agreement and appointed as the authorized representative.
- Translation of information about a cosmetic product that has already been placed on the market is not considered a change that could affect compliance with the product-applicable requirements of this Regulation.
- The authorized representative employs responsible technical staff. The responsible technical staff is responsible for controlling the compliance of the product to be placed on the market with the cosmetic legislation, good manufacturing practices and other relevant legislation. A chemist, biochemist, chemical engineer, biologist or microbiologist may be appointed as the responsible technical staff, provided that he/she certifies that he/she has actually worked in the field of pharmacist or cosmetics for two years.

- **Obligations of the authorized representative**
- **(1)** Authorized representatives; It ensures compliance with the 5th, 10th, 12th and 20th articles, the first, second and fifth paragraphs of the 21st article, and the 22nd, 23rd, 25th and 26th articles.
- **(2)** Authorized representatives shall immediately take the necessary corrective measures to bring this product into conformity, to withdraw or to recall it if it considers that a cosmetic product placed on the market is not in conformity with this Regulation or has a justification for it. The cosmetic product poses a risk to human health.
- In such cases, the authorized representatives shall immediately notify the Agency regarding any non-compliance and any corrective action taken.
- **(3)** Authorized representative; cooperates with the Agency to eliminate the risks related to the cosmetic products it has on the market. The authorized representative provides all the information and documentation required to prove the conformity of certain aspects of the product in Turkish or English, especially upon the request of the Authority.

- **Distributor's Obligations**

- **Distributors:**

- If it considers that a cosmetic product does not comply with the requirements set forth in this Regulation or has reasons for this, it does not keep the product on the market until it is brought into compliance with the relevant requirements,

- Distributors cooperate with the Agency in any activity aimed at eliminating the risks posed by the products they hold on the market. Distributors, upon the request of the Agency, in particular, transmit to the Agency in Turkish or English all necessary information and documents to demonstrate the conformity of the product with the conditions listed in the second paragraph.

- **Identification within the supply chain:**
- At the institution's request, for a period of three years from the date of presentation of a cosmetic product lot/batch to the distributor:
- Authorized representatives, to the distributors to whom they give cosmetic products,
- Distributors provide information about the distributors or authorized representative from which they receive the cosmetic product and the distributors from which they give the cosmetic product.

- **Good Manufacturing Practices:**
- **(1)** The manufacture of cosmetic products shall comply with good manufacturing practices in order to achieve the purposes specified in Article 1.
- **(2)** Where the manufacture complies with the relevant harmonized standards whose reference numbers have been published in the Official Journal of the European Union, it is deemed to comply with good manufacturing practices.

- **Free Roaming**
- **(1)** Cosmetic products that meet the requirements set forth in this Regulation shall not be refused, prohibited or restricted from being made available on the market for reasons related to the requirements in this Regulation.
- **Safety Assessment**
- **Product Information File**
- **Notice**

- **Safety Assessment**
- **(1)** The authorized representative shall ensure that a cosmetic product is subjected to a safety assessment on the basis of relevant information prior to placing on the market and a cosmetic product safety assessment report is prepared in accordance with Annex I to demonstrate compliance with Article 5.

- **(2) Authorized representative:**
- **a)** The intended use of the cosmetic product and the expected systemic exposure for each ingredient in the final formulation are taken into account in the safety assessment,
- **b)** In safety assessment, an appropriate weight-of-evidence method is used to examine data from all available sources,
- **c)** It ensures that the cosmetic product safety evaluation report is kept up-to-date in the light of the relevant additional information obtained after the product is placed on the market.
- **(3)** The Authority prepares guidelines when necessary to ensure compliance with the requirements set out in Annex I.
- **(4)** the safety assessment of the cosmetic product detailed in Annex I; It is made by a person who has a diploma or other official proof of qualification showing that he has completed a theoretical and practical university education in pharmacy, toxicology, medicine or a similar discipline or another education program whose equivalence is accepted by the Institution.
- **(5)** The non-clinical safety studies referred to in the safety assessments specified in the first paragraph are in accordance with the Principles of Good Laboratory Practices, Harmonization of Test Units, Regulation on the Supervision of Good Laboratory Practices and Studies published in the Official Gazette dated 9/3/2010 and numbered 27516 or the EU Commission's regulations. or other standards recognized as equivalent by the European Chemicals Agency (ECHA).

Product Information File

- **1)** When a cosmetic product is placed on the market, the authorized representative keeps the product information file for that product for ten years following the placing of the last batch/batch of the cosmetic product on the market.
- **(2)** The product information file contains the following information and data and is updated as necessary.
- Description of the cosmetic product, which ensures that the product information file is clearly attributed to the cosmetic product.
- The cosmetic product safety report referred to in the first paragraph of Article 12, the explanation of the manufacturing method and the declaration of compliance with the good manufacturing practices specified in Article 10.
- Evidence of the alleged effect of the cosmetic product, where justified on the basis of the nature or effect of the cosmetic product.
- Data on all kinds of animal tests performed by the manufacturer, its representatives or suppliers in connection with the development or safety assessment of cosmetic products or ingredients, including those carried out to meet legal or regulatory requirements of countries other than Turkey and EU member states.
- **(3)** The authorized representative makes the product information file available to the Institution in electronic or other format at the address indicated on the label.
- **(4)** The product information file is prepared in Turkish or English.

- **Sampling and Analysis**
- **(1)** Sampling and analysis for cosmetic products are performed reliably and reproducibly.
- **(2)** The method used in sampling and analysis processes shall comply with the guidelines published by the Institution. In addition, the method is considered reliable and reproducible if it complies with the relevant harmonized standards whose reference numbers have been published in the Official Journal of the European Union.
- **Notification**
- Before a cosmetic product is placed on the market, the authorized representative notifies the Agency with the following information via the national electronic registration system.
- The category and name(s) in Annex 1 of the Communiqué, which makes it possible to specifically identify the cosmetic product,
- Name and address of the authorized representative with the product information file, Product origin in imported products, If necessary, the contact information of a real person to be contacted,
- The presence of substances in the form of nanomaterials and:
- Definitions of these substances, including their chemical names (IUPAC) and other identifiers in Article 4 of the Communiqué,

- **Reasonably foreseeable exposure conditions.**
- In cosmetic products, including substances classified as carcinogens, mutagens or toxic for reproduction within the scope of category 1A or 1B in accordance with the Third Part of Annex VI of the Regulation on Classification, Labeling and Packaging of Substances and Mixtures published in the Official Gazette dated 11/12/2013 and numbered 28848 the name of the substances used and the CAS or EC number,
- Formulation in which volume or amount ratios are specified in intervals, including frame formulation, to provide prompt and appropriate medical treatment in emergencies.
- **(1)** While making a cosmetic product notification pursuant to the first paragraph, the authorized representative presents the original label of the product, the Turkish label and the product packaging to the Agency in a legible manner through the national electronic registration system.
- **(2)** The Institution transmits the information specified in the first and second paragraphs electronically to the National Poison Information Center, to be used only for medical treatment, without delay.
- **(3)** The authorized representative updates the information without delay in case any of the information in the first paragraph changes.

- **Prohibited substance residues**
- (1) The presence of a small percentage of prohibited substances unintentionally, which is technically unavoidable within the scope of good manufacturing practices, resulting from impurities of natural or synthetic components, manufacturing process, storage and transitions from packaging, is allowed if the product complies with Article 5.
- **INFORMATION FOR CONSUMERS LABELİNG**
- **(1)** Without prejudice to the other provisions in this article, cosmetic products can only be made available on the market if the following information on their inner and outer packaging is indelible, easily readable and visible.
- Name or registered title and address of the authorized representative. This information can be shortened to make it possible to identify the authorized representative and his address. If more than one address is specified, the address where the authorized representative has the product information file is indicated. The origin of imported cosmetic products is indicated.
- The list of product components is indicated on the outer packaging. In addition, it may be specified on the inner packaging. At the beginning of this list, the expression “product components” or a Turkish or English expression with the same meaning is written.

- **PRODUCT CLAİMS**
- **1)** Texts, names, trademarks implying that there are features or functions that these products do not have in the labeling, placing on the market, promotion and advertisement of cosmetic products,
- Images and figurative or other marks may not be used.
- **(2)** The Institution establishes a list of common criteria regarding the claims that can be used in cosmetic products and takes the necessary measures to ensure the conformity of products contrary to this.
- **INFORMİNG THE PUBLİC**
- The authorized representative shall, in particular, without prejudice to the protection of trade secrets and intellectual property rights, the quantitative and qualitative composition of the cosmetic product, in the case of perfume and aromatic compositions, the name and code number of the compositions together with the name of the supplier, the undesirable effects and serious undesirable effects resulting from the use of the cosmetic product. ensures that data is available to the public by appropriate means.

MARKET SURVEİLLANCE AND INSPECTİON

- **Market Control**
- **(1)** The Institution monitors that cosmetic products placed on the market comply with this Regulation and do not endanger human and public health and safety through internal market controls. For this purpose, the Authority carries out market surveillance and inspection activities and controls cosmetic products and economic operators at an appropriate scale, by means of the product information file and, where possible, the relevant physical controls and laboratory tests on appropriate samples.
- **(2)** The organization also monitors compliance with good manufacturing practices.
- **(3)** Production site inspections of cosmetic products, market surveillance and inspection, and sampling, warning, withdrawal, destruction, rehabilitation and closure of the production site are determined by the Authority.
- **(4)** The Authority periodically reviews its market surveillance activities, at least once every four years, and reports the results to the Commission and EU Member States. This review is made available to the public electronically and by other means as needed.
- Notification of serious undesirable effects(1) In case of serious undesirable effects, authorized representatives and distributors shall immediately notify the Agency and the manufacturer of the product.

- **PROTECTİON MEASURES**
- **(1)** The Institution takes all necessary measures to ensure that cosmetic products that pose or may pose a serious risk to human health are withdrawn from the market, recalled or access to the product is restricted, although they comply with the requirements of this Regulation.
- **(2)** The Authority shares information with the EU Commission through the Ministry of Trade, when necessary, regarding the activities and supporting data carried out within the scope of this article.
- **COOPERATİON**
- The Institution participates in the organization of the Commission for the necessary information exchange to enable the uniform application of this Regulation and cooperates with the competent authorities of the EU member states and the Commission in this direction.
- **NATİONAL POİSON INFORMATİON CENTER**
- The Agency notifies the Commission of the contact details of the National Poison Advisory Centre.
- For those who do not comply with this Regulation and the provisions of the legislation put into force for the implementation of this Regulation, the Cosmetic Law dated 24.03.2005 and numbered 5324, the Product Safety and Technical Regulations Law dated 05.03.2020 and numbered 7223 and the relevant provisions of the Turkish Penal Code are applied.

HARMONİZED EUROPEAN UNİON LEGİSLATİON

- This Regulation has been prepared within the framework of harmonization with the European Union legislation, taking into account the Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products.

EXECUTİVE

- The provisions of this Regulation are executed by the President of the Turkish Medicines and Medical Devices Agency.

- # COSMETİC PRODUCT SAFETY REPORT
- The cosmetic product safety report includes, as a minimum, the following elements:
- ## SECTION A
- ## Cosmetic Product Safety Information
- 1. Quantitative and qualitative composition of the cosmetic product
- 2. Physical/chemical properties and stability of the cosmetic product
- 3. Microbiological Quality
- 4. Information on impurities, residues, packaging material
- 5. Normal and reasonably foreseeable use
- 6. Exposure to cosmetic product, exposure information:
- 7. Exposure to substances in the formula
- 8. Toxicological profile of the substances in the formula
- 9. Undesirable Effects and Serious Undesirable Effects
- 10. Cosmetic product information.

- **PART B - Cosmetic Product Safety Assessment**
- 1. Evaluation result
- 2. Warnings and instructions for use on the label
- 3. Justification
- 4. Information on safety assessor and approval of Part B