COSMETIC REGULATORY SERVICES

Our regulatory services for cosmetics include:

- Ensuring right cosmetic product **CLASSIFICATION**
- **TOXICOLOGICAL PROFILE OF THE SUBSTANCES**
- **PRODUCT INFORMATION FILE (PIF) including COSMETICS SAFETY ASSESSMENT**
- Acting for all **COSMETOVIGILANCE** needs
- **CLAIMS SUBSTANTIATION AND EFFICACY TESTS**
- **PRODUCT LABELLING**
- **COSMETIC CHALLENGE TEST / MICROBIOLOGY TESTING**
- **STABILITY AND COMPATIBILITY TESTS**
- **COSMETIC PRODUCT NOTIFICATION PORTAL (CPNP) NOTIFICATION**
- Better understand who is the **RESPONSIBLE PERSON**
- **BREXIT:** UK market for your cosmetics
- **INTERNATIONAL SERVICES**
- **SUPPORT** during inspections and questions from authorities

All these services are detailed below and can be adjusted to your specific needs
Annual subscriptions to regulatory services may be the right solution to fit your regular needs over the year

Right cosmetic product **CLASSIFICATION** according to EU cosmetic definition to make sure your product is a cosmetic according to Regulation 1223/2009/EC and not a borderline product.

TOXICOLOGICAL PROFILE OF THE SUBSTANCES: as required by Regulation 1223/2009/EC, EUDRAC can provide you with a thorough toxicological analysis of your ingredients in order to calculate all margins of safety (MOS) for each ingredient of your formula.

COSMETOVIGILANCE: EUDRAC can undertake your cosmetovigilance as requested by all cosmetic regulations in the world.

INTERNATIONAL SERVICES: EUDRAC can help you to prepare adequate cosmetic dossiers mainly for the USA, Brazil, Australia and China.
EUDRAC has contacts with local consultancy companies in most countries in the world and can help you to update your dossiers according to local regulations in order to export your cosmetics.
Do not hesitate to ask us for any country where you may plan to market your cosmetics.

COSMETICS SAFETY ASSESSMENT: as required by Regulation 1223/2009/EC, each cosmetic product must be the subject of a safety assessment performed by a qualified person, before the product can be placed on the EU market.
Safety assessment forms part bof the cosmetic product safety report (CPSR), and therefore is a vital part of the product information file.

Moreover, EUDRAC can propose regulatory assistance services based on annual subscription adapted to your portfolio:

- Assessment of your current dossiers PIF
- Gap analysis versus Regulation 1223/2009/EC
- Answers to regulatory questions
- Assistance in case of inspections
- Assistance to the Responsible Person in EU and UK

PRODUCT INFORMATION FILE (PIF): each product placed on the EU market needs to have a product information file. EUDRAC can prepare the complete Part A on product safety information for your formula.
The product information file must be kept at one single address within the EU, even if the cosmetic product is marketed in various EU countries. This also means that there can only be one Responsible Person per product for the whole of the EU.

PRODUCT LABELLING: The regulation contains various cosmetic labelling laws requirements and very specific rules regarding labelling, which have to be followed and are described in article 19 of the Regulation 1223/2009/EC. EUDRAC can help you to get compliant labelling with Regulation 1223/2009/EC. This include all visuals: packaging, website, adds etc.

STABILITY AND COMPATIBILITY TESTS: required by EU Cosmetics Regulation 1223/2009/EC, all these tests can be subcontracted by EUDRAC.

BREXIT: Thanks to its local offices in UK, EUDRAC can help you to maintain your current cosmetics in UK or to export your products in the UK.

CLAIMS SUBSTANTIATION AND EFFICACY TESTS: EUDRAC can help you to determine which clinical test is necessary to support your desired claims and will review your claims wording to make sure they are compliant with Regulation 655/2013/EC and common criteria: legal compliance, truthfulness, evidential support, honesty, fairness, informed decision-making.

COSMETIC CHALLENGE TEST *(or Preservative Efficacy Test PET)* as required by Regulation 1223/2009/EC: Basically, challenge test checks how effective your preservative system is. EUDRAC can subcontract this mandatory test for your finished product.

MICROBIOLOGY TESTING: Microbiological specifications need to be provided for cosmetic products that are placed on the EU market. Microbiological testing is vital in ensuring cosmetic product safety. EUDRAC can undertake these tests for you.

COSMETIC PRODUCT NOTIFICATION PORTAL (CPNP) NOTIFICATION: Notification is a pre-marketing requirement where the Responsible Person informs the EU Commission and the EU member states that the new cosmetic product will be placed on the EU market. This notification means that the concerned product is compliant with the relevant legislation. EUDRAC can notify your products to the Commission through CPNP portal on your behalf.

EUDRAC can help you to better understand who is the **RESPONSIBLE PERSON:** EU cosmetics Responsible person is an EU based cosmetic product manufacturer, importer, distributor, or another person established within the EU who has to accept this role in writing. The role of the responsible person is to ensure that the cosmetic products placed on the EU market are safe for use and compliant with the EU Regulation 1223/2009. A Responsible Person is basically a legal representative of a cosmetic product in the EU. EUDRAC can act as your RP in EU and UK.

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EUDRAC

EUDRAC has also offices in UK and Germany