Chementors
chemical safety consulting

www.chementors.eu

WE MENTOR YOU FOR SUCCESS!

- ***ONE-STOP SERVICE IN EUROPEAN CHEMICALS AND COSMETICS REGULATION***
- ***EFFICIENT AND RELIABLE PARTNER TO ENTER EU MARKETS***
- ***COST-EFFICIENT PROCESS***
- ***COMMITTED TO SERVE***
- ***LOCATED IN FINLAND, OFFICE IN HONG KONG***
- ***GOOD RELATIONS WITH EUROPEAN CHEMICALS AGENCY (ECHA)***

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One-Stop Service

Our ultimate mission is to enable you to focus on your own profitable business, leaving all regulatory issues to us, on a turnkey basis. This gives you the competitive edge you need for your success in the European market.

Efficient and Reliable

Our specialist team in Finland is highly qualified and experienced in the field of chemical and cosmetic regulations. We work in close co-operation with our customers and the authorities. We have expertise in various fields of industrial operations and we may also utilise our network of company contacts, enabling each order to be handled efficiently, smooth and reliably.

Cost-efficient Process

Our quotations do not have any hidden costs. Should there be some extra costs we will inform and negotiate about them in advance.

APPROVED MEMBER OF ORO©
ONLY REPRESENTATIVE ORGANISATION

REACH Ready Approved Supplier

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Chemical safety consulting for Europe

Committed to Serve

We strive constantly to learn and grow our know-how every single day. Therefore customer feedback is our most valuable tool to measure our success.

Offices in Hong Kong and in Finland

We are a global service provider. The utilisation of modern communication tools allows us to be present at the customers convenience. We realize meetings face-to-face are also important. Our personnel is available for customer meetings - whenever this is required.

Good relations with the European Chemicals Agency (ECHA)

One major asset contributing to our efficiency is the knowledge how to co-operate with ECHA. This enables fast communication between our specialists and the government authorities. Clients of Chementors´ can be assured of expert interpretation and expert statements that will satisfy authorities such as ECHA.

Backed by Finnish Government

Our business is considered having a high value for international trade of Finland and the EU markets. As an indication of significance we are enjoying funding from Finnish Centre for Economical Development, Transport and Environment. In addition we also enjoy funding from the Ministry of Employment and the Economy.

REACH Registration due to EU Regulation

Manufacturers and importers of substances have an obligation to communicate to the European Chemicals Agency (ECHA) on uses and properties of the substances they trade at an amount of 1 tonne per year or more within the European Economic Area (EEA). The hazards related to the handling and use of the substances have to be assessed and the control of risks must be adequately demonstrated. Communication with ECHA is carried out by submitting a registration dossier containing all the required information.

1. Analytical testing/ Substance identification

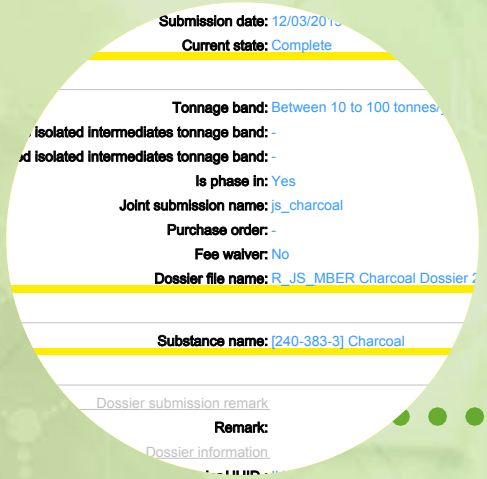
Each potential registrant needs to provide sufficient analytical information prescribed in Annex VI of REACH (Section 2: Identification of the Substance) to thoroughly characterise the substance and correctly determine the substance identity in order to verify substance sameness and appropriateness of the registration.

2. ECHA inquiry or (late) pre-registration (1-100t/a)

Companies wishing to register “phase in” substances (i.e. existing substances) had the opportunity to preregister these substances until the end of June 2008. In some instances, it may still be possible to submit a late preregistration. For “new” substances and phase in substances where companies did not preregister them in time, an Inquiry has to be submitted to ECHA. ECHA establishes if there are other companies who will register the same substance then the company who sent the inquiry can join those other companies in a Joint Submission.

3. Data sharing negotiations/’Letter of Access’ Fee

Each registration needs to contain certain data according to Annex VII-X of REACH depending on the tonnage threshold. Companies are expected to gather all relevant existing data plus fill any identified data gaps. All companies registering the same substance share this data as well as the costs of the data. This process reduces unnecessary testing plus reduces the costs for companies. Companies purchase a ‘Letter of Access’ to have legitimate right to the data used in the registration.



4. Dossier compiling/submission

The technical registration dossier is prepared using IUCLID software. The IUCLID file is submitted to ECHA via the REACH-IT Portal. The submission undergoes Business rules check, technical completeness check, a financial completeness check and overall completeness check. The lead registrant submits a lead dossier containing all the required joint information for the substance and the members of the Joint Submission submits their Joint Submission Member dossier with their individual information.

5. ECHA communication

Official communication between ECHA and the company registering takes place within REACH-IT. ECHA issues the invoice and other communications regarding the status of the submission. Finally following a successful submission ECHA sends company in REACH-IT the letter containing the registration number.

6. Follow-up and future dossier updates

Companies are expected to keep their registrations up-to-date and where necessary updates need to be made without undue delay. The data contained within registraions are subject to inspection and evaluation by ECHA and if they deem it necessary further information including new tests may be requested by ECHA.

The Only Representative (OR) responsibilities

- Accept the role as OR following appointment by the supplier
- Make the pre-registration on behalf of the supplier
- Accept official role on SIEFs
  - -Agree upon new testing strategies
  - -Agree upon hazard assessment for single registration
  - -Agree upon missing data (data gaps)
  - -Agree upon costs of sharing data
- Cooperation with the European importers
- Consider exposure scenarios of all Downstream Users in the supply chain
- Organise Chemical Safety Report (necessary for registrations >10t)
- Organise and agree on Safety Data Sheet's to be consistent with Registration details
- Monitor supply patterns (import volumes and 'SDS check' with each importer)
- Check risk management measures are being communicated

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REACH does not end when the Registration is submitted. This applies to all those involved in REACH and not just the OR. The exposure scenarios, CSR and CSA are on-going 'live' documents which need updating with new test data or new exposure details as necessary and similarly the SDS is a live document that will need updating and revision as required.

Chementors Ltd is located in Finland and is a member of ORO (Only Representatives Organisation).

COSMETIC SAFETY ASSESSMENT

The Cosmetic Product Safety Report (CPSR) is divided into two parts. Part A provides information on safety and important properties of the product, in addition to an evaluation of the toxicological profile of its components. Part B comprises an overall safety assessment of the product, taking into account known hazards and exposures leading to an evaluation of risks and 'margin of safety' (MoS) in order to determine acceptable use. A CPSR needs to be compiled for all cosmetic products on the market.

1. Data search
We gather the information about the product: Product formula and SDS- documents of each raw material. In case a product contains forbidden substances or substances at too high concentrations we can assist to re-formulate the product.

2. Stability testing
The product under inspection is held under three different temperatures (5 °C, 23 °C and 40 °C) usually for 4 months. This will give the stability validation for 12 months. To get longer validation for stabilisation the inspection period may have to be extended.

3. Microbiological challenge test
This test is executed under the requirements of European Pharmacopeia (Ph. Eur 5.1.3). Completing this test takes 2 months.

4. Compiling Product Information File (PIF)
Includes: Product description, Cosmetic Product Safety Report (CPSR), GMP authentication, proof of claimed effects, data on animal testing.

5. Labelling
Checking the labels in cooperation with the manufacturer. Product label has to meet the legal requirements.

6. Notification to CPNP/ Opening the CPNP account
All information will be submitted to Cosmetic Product Notification Portal. Also information about Responsible Person is required from non-EU companies at this stage.

7. Responsible person
Usually the manufacturer or importer assumes the identity of the "responsible person". The distributor within the European Economic Area (EEA) could also be required to take on the role of the responsible person, if they place a cosmetic product on the market under their own name or trademark or if they modify a product already on the market. Alternatively, the manufacturer or importer may authorise a representative to act on their behalf as a responsible person. A foreign manufacturer cannot act as a responsible person on their own within the EEA. The obligations of the responsible person are to ensure that the product is safe for its intended use and that it is used in a safe way, and to ensure that all r equirements under the regulation are fulfilled. The obligations are detailed in articles 4 and 5 of the Cosmetics Regulation.

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CERTIFICATE

Cosmetic Product Safety Assessment

CHEMENTORS LTD, FINLAND

Business ID: FI24575706
Address: Smart Chemistry Park, Raisionkaari 55, 21200 Raisio, Finland

has assessed the following Cosmetic Products according to Regulation (EU) No 1223/2009 of the European Parliament and of the Council (Cosmetics Regulation), for

COMPANY LTD, CHINA

Business ID:
Address:

Assessment conclusion:
Based on the information provided by the manufacturer and the toxicity data compiled for Cosmetic Products

xxxxxxxx CPNP No.: xxxxxx
xxxxxxxx CPNP No.: xxxxxx
xxxxxxxx CPNP No.: xxxxxx
xxxxxxxx CPNP No.: xxxxxx

are concluded to be safe for use under normal or reasonably foreseeable conditions of use.

xxth January, 2016

CEO Jani Määttä
CHEMENTORS LTD

Chementors
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CERTIFICATE

Responsible Person

CHEMENTORS LTD, FINLAND

Business ID: FI24575706
Address: Smart Chemistry Park, Raisionkaari 55, 21200 Raisio, Finland

acts as a Responsible Person according to Regulation (EU) No 1223/2009 of the European Parliamentand of the Council (Cosmetics Regulation), for

COMPANY LTD, CHINA

Business ID:
Address:

for Cosmetics Products:

xxxxxxxx CPNP No.: xxxxxx
xxxxxxxx CPNP No.: xxxxxx
xxxxxxxx CPNP No.: xxxxxx
xxxxxxxx CPNP No.: xxxxxx

The Responsible Person is the foreign manufacturers' representative within the European Union.

Company Ltd is allowed to use CHEMENTORS ' logo and name in connection to labelling of the certified products and thereto related materials.

xxth January, 2016

CEO Jani Määttä
CHEMENTORS LTD

"As we came up with the thought to open EU markets with our cosmetic products we realized that requirements by European regulations would be strict and complicated. Without special consultancy the mission would have been impossible. We contacted Chementors Ltd and ever since our cooperation has been efficient and profitable. We have launched a variety of cosmetic products in Europe and under process doing more. Chementors is covering all regulatory issues for us and also acting as our Responsible Person in Europe. Responsible Person service is valuable and mandatory for us since we do not have any establishment in Europe. Being dynamic and customer caring company we have been really lucky to find Chementors as our partner. – Sanjeev Bhatt – Radico, India "

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