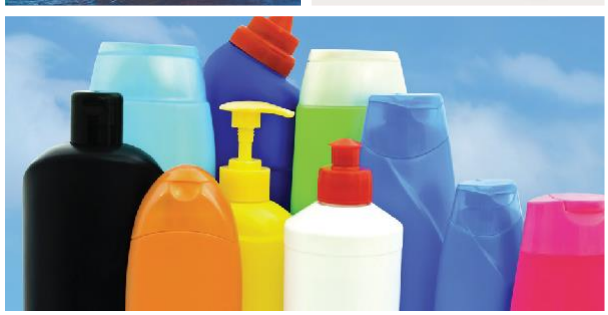
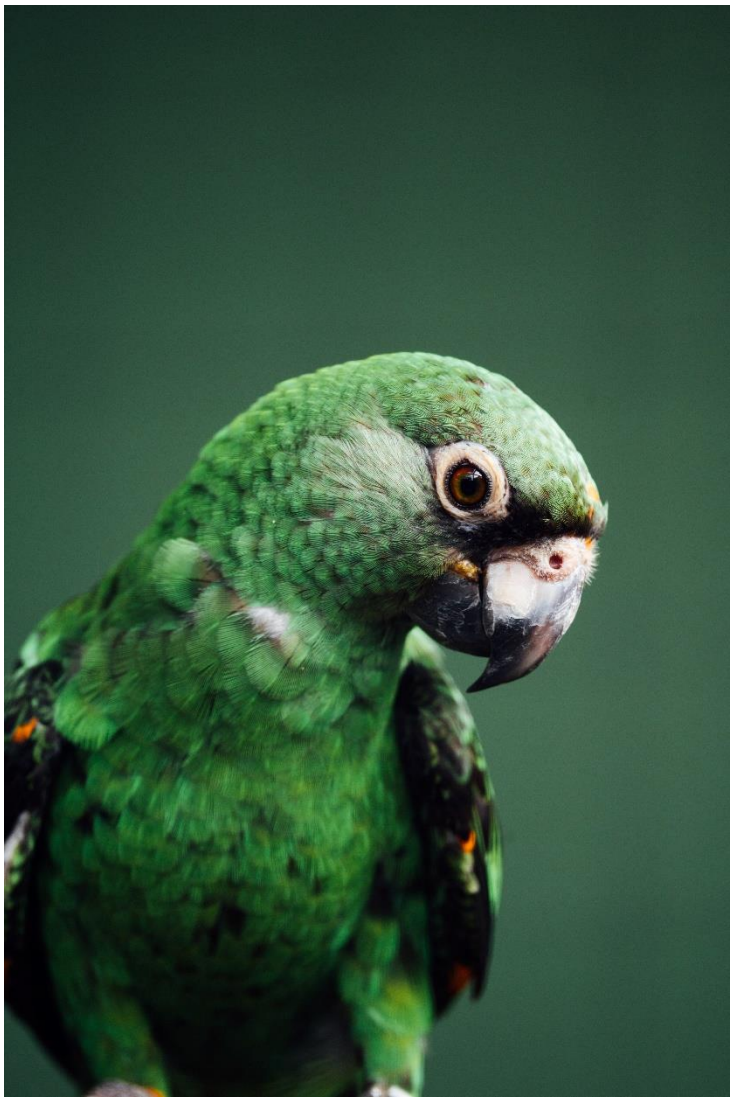


REACHUP®
Regulatory services

ARGCHEMICAL

TEAM mastery
Know the rules, play your market.



ABOUT US

REACHUP SRL

Reach Up provides Chemical Regulatory Affairs and Product Safety services as consultant.
Our consultancy to meet regulatory compliance in EU market, provides a comprehensive regulatory support for developing and implementing firm regulatory policy. It includes services related to new product introductions to market, data development as well compliance of existing products with local and EU regulations. The organization, born in 2010, is based in Italy with many correspondents offices located around the Europe and has established a strong relationships with local and Europeran trade associations, laboratories and government authorities.

Reach Up has already submitted several registrations approved by ECHA and manages or works with many European REACH Registration Consortia (eg EUROPEAN BIODIESEL BOARD, FEUC, CONCAWE, ERRC, REACH CENTRUM)

Reach Up wants to provide an effective and competent response to each company based in Europe by providing technical and management assistance within consortia and SIEFs as well as regulatory, analytical, toxicological and ecotoxicological required skills. We find sustainable customized solutions to their most challenging questions. Our network assistance combines technical and strategic skills, relying on the wide industrial experience and skills of our team.

THE NETWORK REACHUP

Our mission is to offer full Ready to use services to comply with all possible regulatory requests according to the EU regulations.

REACHUP has established a network of companies located in the North and Central Italy and with offices in Milan, Como and Rome.

The network of our partner companies will guarantee a robust level of service where for each specific tasks will provide the best expertise on the market.

REACHUP SERVICES: REACH

REACH & CLP are two independent pieces of chemical legislation in EU containing hazard communication tools. Labeling rules are set out in CLP whereas the Safety Data Sheet (SDS) rules are set out in REACH; a CLP label must always be used together with SDS.
The classification of a substance is one mandatory part of REACH registration dossier whereas the classification criteria are set out in CLP regulation.

REACH

Reach Up is dedicated to Regulatory Affairs and Product Safety.
Since the entry in force of the Regulation (EC 1907/2006), Reach Up provides assistance to customers in meeting the REACH regulatory requirements.
By the time we have gained the experience required to provide all related services: from substance identification management, to risk assessment and dossier compilation.
Reach Up also participates in administrative activities and scientific discussions at European level.

Our REACH services include:

- Information and training
- Regulatory consultancy
- Registration strategy
- Registration dossiers
  a. Assistance analytical identification and sameness evaluation
  b. Inquiry dossier preparation
  c. Collection and evaluation of data (Klimisch score)
  d. Data gap analysis
  e. Testing strategy proposal and development
  f. IUCLID compilation
  g. Completeness checks assistance
  h. Toxicological and Eco-toxicological assistance
  i. No Testing Methods (NTMs) assessment (QSARs; read-across; grouping)
  j. Proposing and monitoring of new studies
  k. Data waiving
  l. Classification and labelling (C&L)
  m. PBT assessment
  n. Risk Assessment, Chemical Safety Assessment and Reports (CSA/CSR)
  o. Post Registration monitoring and assistance
- Exemption statement according the EU regulations
- Harmonised Classification and Labelling (CLH) dossier, preparation & reviewing
- Assistance and dossier compilation in authorization process
- Registration Consortia management and SIEF/Consortia representation
- Third Party Representative (TRP) services
- Legal representation in the EU (Only Representative)
- Support in litigation by law firm partners

This expertise is available to issue specific customer requirements and our team work judgement will offer the best available solutions.

REACHUP SERVICES: CLP/SDS & BIOCIDES

The Biocidal Product Regulation (BPR, Regulation (EU) 528/2012) concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms, like pests or bacteria, by the action of the active substances contained in the biocidal product.

CLP/SDS

We are able to support companies to achieve the compliance with the CLP Regulation (EC 1272/2008) and with art.31 of REACH Regulation (EC 1907/2006), preparing SDS/e-SDS.

- Individuation of the obligations required under CLP/GHS
- Classification and Labelling according CLP/GHS
- Notification of Classification and Labelling to ECHA
- Italian National C&L Notification of dangerous mixture & biocides to Istituto Superiore di Sanità
- Review and revising of exiting classifications depending of CLP amendments and/or updates in available hazard information.
- Compilation of complete SDS (16 sections) for substances and mixtures according to CLP Regulation (EC 1272/2008) in all main European Languages/Countries
- Creation of extended SDS from a complete CSR in the main European Languages
- Compilation of SDS for substances and mixtures according to extra-EU Regulations following customer needs.
- Compilation of informative data sheet for not dangerous substances and mixtures following customer needs.

This expertise is available to issue specific customer requirements and our team work judgement will offer the best available solutions.

BIOCIDES

Our services include also the national authorization for biocidal products according to each National Member State law, to enjoy the transitional period (art. 89 BPR) in EU/EEA and Switzerland without any market interruption.

Reach Up is able to support customers during the authorization of biocides product and/or active substances by evaluating existing data, data gap analysis and testing strategy proposals.

We have gained the expertises to manage toxicological and ecotoxicological testing activities and to develope exposure scenarios required by authorization.

Our R4BP services include:

- Advice on regulatory obligations
- Comunication with Authorities
- Dossier strategy evaluation
- Collection and/or evaluation of available data
- Use of no testing methods (NTMs: QSARs, Read-Across, grouping...)
- Proposal and/or management of new studies
- Human health and environmental risk assessment
- Exposure assessment and refinement
- Dossier creation (IUCLID 6 compilation and R4BP assessment)
- Assistance and monitoring post submission

This expertise is available to issue specific customer requirements and our team work judgement will offer the best available solutions.

REACHUP SERVICES

The European Union (EU) Cosmetics Directive 76/768/EEC was replaced by Regulation (EC) No 1223/2009 (the "CosmeticProducts Regulation"), which harmonizes and simplifies the cosmetics regulations across the EU member states. Cosmetics suppliers (manufacturers/importers/exporters) must provide to the designated competent authority prior to placing notification dossier and a Product Information File (PIF) for each cosmetic product must be maintained and made available upon request.

PPP/AGROCHEMICALS

Fulfil dossier for Plant Protection Active Substances and Products requires a broad variety of knowledges. REACH mastery provides the guidance and experience to make sure that clients have all the necessary data or waivers on human health effects, environmental toxicity and efficacy of a substance in order to the compilation of a plant protection dossier.

We perform data gap analysis, study monitoring and dossier preparation and have extensive experience in communication and negotiations with regulatory authorities.

1. Advice on regulatory requirements
2. Communication with regulatory authorities
3. Dossier strategy evaluation
4. Contracting and monitoring of new tests
5. Human health risk assessment
6. Environmental risk assessment
7. Higher tier testing strategies
8. Exposure assessment and exposure refinement
9. QSARs
10. Literature study and read-across
11. Dossier preparation
12. Dossier follow-up

COSMETICS

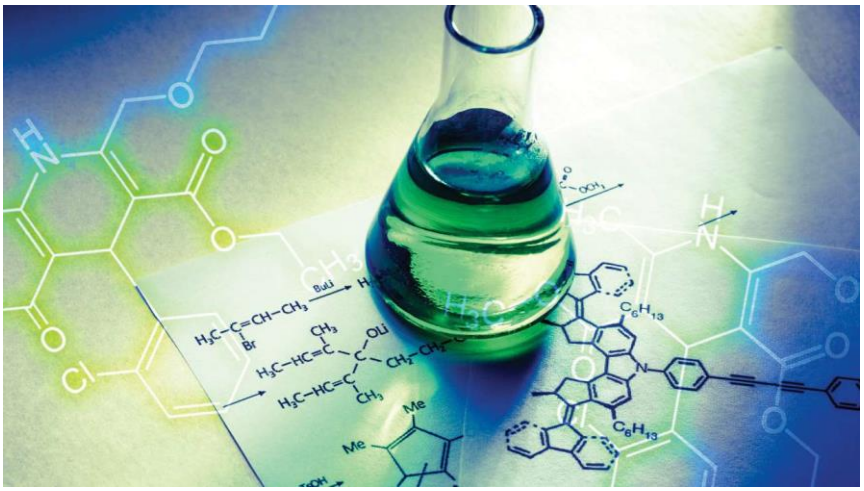
Reach Up provides the assistance required to meet the obligations of the cosmetic industry by EC Regulation 1223/2009 and its modifications. Our testing strategies include the use of No testing methods, making cost-effective evaluations possible.

Our services include:

- Advice on regulatory obbigations
- Ecotoxicological impact of cosmetic ingredients and cosmetic products
- Toxicological assessment of cosmetic products
- Use of no testing methods (NTMs: QSARs, Read-Across, grouping...)
- Proposal and/or managment of new studies
- Creation of Product Information Files (PIF)
- Creation of Cosmetic Product Safety Reports (CPSR)
- Electronic notification of cosmetic products by the dedicated portal (CPNP)

This expertise is available to issue specific customer requirements and our team work judgement will offer the best available solutions.

REACHUP SERVICES



REACH UP srl offers assistance to pharma companies from the development of drugs still their registration according the law. The protection of workers requires the determination of occupational exposure level (OEL) and the protection of enduser requires the derermination of the per- mitted daily exposure (PDE) according EMA Guideline.

FOOD

Reach Up provides the assistance required to meet the EU-obligations on Food products, including additives and food and contact materials (FCM), pesticides and their residues. Our network can provide analytical information about products composition and impurities.
Reach Up also participates in administrative activities and scientific discussions at European level.

Our services include:
- Advice on regulatory obbigations
- Planning of dossier compilation strategy
- Re-authorization dossier compilation
- Use of no testing methods (NTMs: QSARs, Read-Across, grouping...)
- Proposal and/or management of new studies
- Calculation of the Acceptable Dietary Intake (ADI)
- Food Safety assessment
- Risk assessment for workers and consumers
- Assistance and monitoring post submission

This expertise is available to issue specific customer requirements and our team work judgement will offer the best available solutions.

PHARMACEUTICALS

Reach Up offers assistance to pharma companies from the development of drugs still their registration according the law. The presence of pharmacologically active substances should be limited to a level toxicologically considered safe for all those who will be exposed (operators / end users). The protection of workers requires the determination of occupational exposure level (OEL) and the protection of enduser requires the determination of the permitted daily exposure (PDE) according:

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2014/11/WC500177735.pdf.

Our services include:
- Assistance on regulatory obligations
- Reviewing and/or revising of toxicological available data during screening phase for new molecules and derivates
- Planning of dossier compilation strategy
- Use of no testing methods (NTMs: QSARs, Read-Across, grouping...)
- Proposal and/or managment of new studies
- Human health risk assessment
- Determination of the permitted daily exposure (PDE)
- Authorization process
- Creation of the dossier

This expertise is available to issue specific customer requirements and our team work judgement will offer the best available solutions.

REACHUP SERVICES

EXTRA EU REGULATORY SERVICES

Reach Up gained the expertise in fields as well as toxicological and ecotoxicological assessment and risk evaluation, helpful to support our costumers in regulatory compliance extra-EU. Our team, thank to a strong cooperation with our local partners, can manage the most relevant regulatory tasks in compliance with regulatory requirements of the main geographical areas **worldwide**.

This expertise is available to issue specific customer requirements and our teamwork judgement will offer the best available solutions.

Services with use of alternative methods (NTMs) Reduction of animal testing

Reach Up can also provides No Testing Methods (NTMs) toxicologic assessment evaluations and reports on molecules, precurors and residues. The term NTMs includes multiple and/or integrated approaches: structure–activity relationship (QSARs), grouping and read-across, weight of evidence and expert systems. These methods provides results in short time and reduced cost in comparison with standard experimental strategies.

REACH Regulation states that NTMs can be used within, because before making an animal experiment the industry should verify if alternative methods exist. Authorities promotes officially alternative methods for regulatory purposes, as example ECHA advises the use of QSARs in the Pratical Guide n.5 and in the Chapter R.6 of the Guidance of information requirements and Chemical Safety assessment.

ONLY REPRESENTATIVE SERVICE (OR) NO- EU/EEA

Our Network provides regulatory consultancy on products for non-European markets. In these cases, the fulfillment of local obligations is allowed only to legal entities established in the territory of the relevant market.
It is in these cases that the appointment of an Exclusive Representative is appropriate for all market exporters who want to keep information on their products confidential, without having to transfer the burden of compliance to importing customers.
Reach Up provides this service to companies interested in the **UK (GB), Switzerland, Turkey and many other NO EU/EEA** markets, through expert and qualified local entities that can support the customer throughout the process of achieving regulatory compliance.

UK - BREXIT (GB COUNTRIES: ENGLAND, SCOTTLAND AND WALLES)

With the end of the transitional period (31.12.2020), the United Kingdom has ceased to be part of the European Union according to Article 50 of the EU Treaty and following the internal referendum of March 2017.

Our services support the processes of maintaining and placing products on the market, the production, research and collection of data, the verification of compliance of products with EU and UK regulations. (DUIN, GRANDFATHERING, GB REACH Registration) for Chemical, Detergent, Cosmetic, biocide, Medical Device, Pharma, Food / Feed.

The services offered by Reach Up are:

• Legal entity change to other offices / companies IN EU by 31.12.2020
• Grandfathering for GB legal entities and EU REACH registrations in the UK
• DUIN notification for GB importers of substances and mixtures
• New GB REACH registrations according to new deadlines
• Compliance with new GB regulations (REACH, CLP; BPR, PIC, Cosmetic, MDR, Pharma, Food/Feed etc.)
• Exclusive Representation Services in GB for Italian / EU companies (OR service)

TURKEY – KKDIK TURKEY REACH

Our services that deal with the Fulfillments of the KKDIK and SEA Regulation and cover:

- Substance pre-registration by 31.12.2023
- Substance registration by 31.12.2023
- CSA / CSR approval by a qualified expert (CAE)
- Turkish language SDS certified by chemical expert
- SEA notification of dangerous and classified monomers and polymers
- OR services

HOW TO CONTACT US

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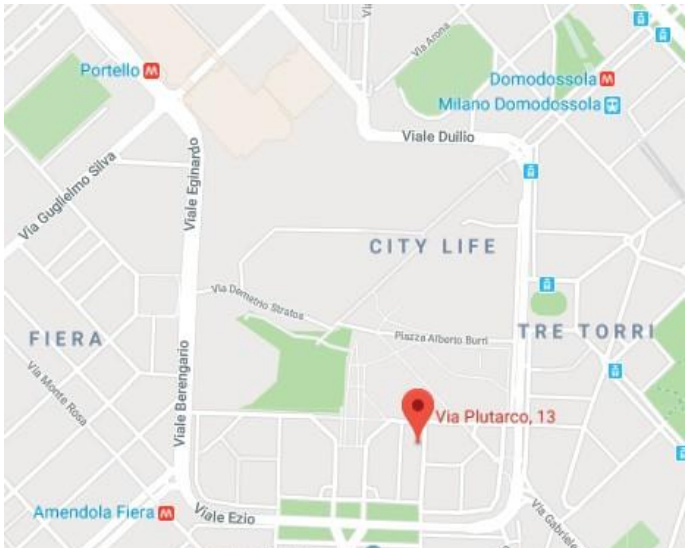

HOW TO REACH US

Our offices are located in Milan, into the new Busines Center Area of City Life.

You can r
each us from FN Cadorna Station by metro M1 to Amendola Fiera or Buonarroti stops;

from Milano Porta Garibaldi and FN Domodossola Stations by metro M5 to Tre Torri stop.

Underground parking areas are available in the closer Piazza Giulio Cesare and at the City Life Shopping District.