

# C3-B

## Alliance for Safety

### ONE SERVICE PROVIDER FOR ALL YOUR CHEMICAL REGULATORY NEEDS

#### What is C3-B?

C3-B is an international alliance of organisations that have come together to respond to the challenges of regulatory compliance. The four members of the Alliance work closely together to provide a full range of services in a seamless fashion. The areas of expertise include:

- Physico-Chemical Analysis
- Toxicology
- Eco-toxicology
- Dossier Preparation / Project Management

#### Why an Alliance?

Regulatory requirements such as Notification of New Substances (NONS) and Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) often need input from all of the specialities listed above. The ability to source all of these from a single point of contact is an important advantage and a time saving benefit.

The Alliance will do this for you while allowing you to choose the contact point with the appropriate member company.

#### How will the Alliance respond to my needs?

C3-B members co-ordinate their respective activities in response to your project requirements in a cost-effective and timely fashion.

#### What does the Alliance mean for me?

The Alliance means a co-ordinated response to regulatory issues, with access to experts in all four fields, each one able to contribute an enhanced level of expertise.

#### Will this affect my relationship with an Alliance member?

Hopefully the Alliance will help you to develop this relationship through the ability to provide a wider and more diverse number of products and services.

## Regulatory Services

C3-B is an international association of specialist organisations whose prime objective is to provide a high quality, rapid and cost effective response to chemical regulatory testing requirements. Each member of the consortium is a known and respected organisation in its own right and contributes the following areas of expertise;

### Chilworth Technology

Chilworth Technology brings together leading experts in the field of physico-chemical testing which has evolved from its deep involvement with process safety testing. Situated on the South Coast of the UK, its state-of-the-art, GLP compliant laboratories can provide physico-chemical data as required by the Dangerous Substances Directive 67/548/EEC, as well as data for transportation labelling and process safety risk assessments.



### CERB

CERB provides preclinical research and development services to the pharmaceutical, chemical and agro-chemical industries as well as provision of data for NONS and REACH from its state-of-the-art laboratories positioned in the centre of France. It specialises in toxicology, pharmacology and analytical chemistry and can offer all the toxicology skills necessary for inclusion into regulatory submissions.



### Brixham Environmental Laboratory

Understanding and delivering the environmental requirements for product registration in global markets is a vital part of Brixham Laboratory's continuing success. Located in the South West of the UK it evaluates new products, intermediates and effluents to increase understanding of their environmental fate and effects, and to help ensure that your business is compliant with current regulatory requirements.



### Chemsafe

Chemsafe is an independent consulting and project management company offering specialised services to the chemical and pharmaceutical industries.

Located just North of Milan, Italy, Chemsafe can assist in defining the most suitable programme of work by using the intrinsic characteristics of the test item and the commercial requirements of the sponsor. We manage projects from the initial approach, through the phases of submission and finally we provide post-submission assistance when supporting queries from a Competent Authority.



## PHYSICO-CHEMICAL PROPERTIES

When considering regulatory compliance for the Notification of New Substances (NONS) or the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) it is necessary to provide Physico-chemical data along with Toxicological and Ecotoxicological information. The amount of information required will depend upon the level of manufacture, ranging from an annual quantity of >10kg through to Level 2 with annual quantities of > 1000 tonnes. The majority of tests are performed according to Annex V, Part A of the Dangerous Substances Directive 67/548/EEC and follow OECD Guidelines. All work is performed in GLP certified laboratories.



### Chilworth Technology can also provide the following:

- Transportation labelling (UN, ADR, IMDG or IATA) and a qualified DGSA
- Process safety data (flammability of gas, vapours and dusts, thermal stability, electrostatics)
- Chemical Process Evaluation (DSC, ARC and reaction calorimetry)
- Consultancy assistance and training in all areas of process safety (CAD, ATEX and DSEAR).

Examples of base set tests are:

EU Ref	Description	EU Ref	Description	EU Ref	Description
N/A	U V-vis	A6	Water Solubility	A13	Pyrophoric properties
N/A	Dissociation Constant	A8	Partition Coefficient	A14	Explosive properties
A1	Melting point	A9	Flash Point	A15	Autoflammability (liquids)
A2	Boiling Point	A10	Flammability of Solids	A16	Autoflammability (solids)
A3	Relative Density	A11	Flammability of Gases	A17	Oxidising solids
A4	Vapour pressure	A12	Flammability in contact with water	A21	Oxidising liquids (draft)
A5	Surface Tension				



## IN-VIVO TOXICOLOGY TESTING

CERB is able to offer all of the in-vivo tests required for both the European Union Notification of New Substances (NONS) regulations and for the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). The tests are performed according to Annex V, Part B of the Dangerous Substances Directive 67/548/EEC and follow OECD Guidelines. All work is performed in GLP certified laboratories.



### CERB can also provide the following services:

- Formulation analysis, drug plasma analysis (HPLC, GC, LCMS/MS)
- Adaptation of the methodology according to the analytical technique and analytical validation or setup of new analytical methods

Examples of base set tests are:

EU Ref.	OECD Ref.	Test Description
B1	423	Acute oral toxicity study in the rat
B3	402	Acute dermal toxicity study in the rat
B4	404	Acute skin irritation study in the rabbit
B5	405	Acute eye irritation study in the rabbit
B6	406	Skin sensitisation study in the guinea-pig
B7	407	28-day oral toxicity in the rat

# Consortium Services

## ECO-TOXICOLOGICAL TESTING



Brixham Environmental Laboratory is able to offer the full range of environmental tests required for the Notification of New Substances (NONS). Many of the tests are also listed under the proposed REACH scheme. The majority of tests are performed according to Annex V, Part C of the Dangerous Substances Directive 67/548/EEC and also follow OECD Guidelines. All work is performed in GLP certified laboratories.

Examples of base set tests are:

EU Ref.	OECD Ref.	Test Description
C1	203	Acute toxicity fish
C2	202	Acute toxicity <i>Daphnia</i>
C3	201	Algal growth inhibition study
C11	209	Activated sludge respiration inhibition
C4	301	Ready Biodegradability
C7	111	Hydrolysis as a function of pH
C19	117	Adsorption/Desorption (HPLC test)

**Brixham Environmental Laboratory can also provide the following services:**

- Product Support - which can involve generating data for environmental safety dossiers that support new product registrations worldwide.
- Manufacturing Support - process development, waste minimisation programmes, effluent treatment process optimisation, discharge monitoring (DTA), rapid response for chemical incident/accidental release management. Site investigation and characterisation. Monitoring and data production to support Environmental Certification e.g. ISO 14001/PPC consent.
- Extensive field survey capabilities.

## DOSSIER ASSEMBLY AND SUBMISSION



Once all the tests are completed, the information is compiled into a dossier along with any toxicokinetic evaluation and safety risk assessments. This is then presented to the Competent Authority (CA) as a completed notification.

**Chemsafe can provide the necessary consultation services in support of regulatory testing in the following areas:**

- Project definition and planning
- Project management & Study Monitoring
- Regulatory Assistance
- Testing facility monitoring and inspections
- Dossier Preparation and submission
- Risk Assessment
- MSDS preparation
- Classification and labelling
- Toxicology Consultancy
- Data Search
- Professional on-site courses
- Sole representation for non-EU companies

Chemsafe can provide this service following the requirements of the Dangerous Substance Directive 67/548/EEC as updated in EEC 92/32 as well as providing post-submission assistance. Along with the notification there is also a responsibility to ensure that test programmes are specifically designed to avoid redundant studies and reduce in-vivo test requirements.



*Your Partners in Safety*

# Consortium Services Contacts

## Who do I talk to?

The first point of contact with C3-B can be made with any of the four organisations listed on the right. The consortium operates as a seamless alliance to provide you with a high level of service with the minimum of effort. If you have specific test requirements such as physico-chemical tests or eco-toxicity then please feel free to contact the appropriate organisation directly. Prices and formal quotations can be provided from any facility. In accordance with most regulatory work the normal operating language is English but if you wish to discuss your project, especially in the early stages, with a native language speaker such as French or Italian then please feel free to contact the specific company based in the chosen country.

The four centres of excellence cover the following aspects of work:

**Chilworth Technology Ltd (UK)** – Physico-chemical testing

**CERB (France)** – Toxicological testing

**Brixham Environmental Laboratory (UK)** – Eco-toxicological testing

**Chemsafe (Italy)** - Dossier preparation and submission

## How do you make an enquiry and progress a project?

After your initial enquiry with an Alliance member you will be presented with details of prices and time scales for the entire project. When this proposal is accepted then the sample and all documentation will be forwarded to the Alliance member who will then distribute the relevant material and information to the other Alliance members as appropriate. You are also at liberty to have direct access to any Alliance member to discuss their area of expertise. On completion of the work, all necessary documentation (reports, notification, risk assessments, etc.) will be forwarded to you in a single dossier.

All financial actions such as invoicing and payment will be directed through your Alliance member point of contact.

Please see the contact details to the right or email us at - [info@C3-B.com](mailto:info@C3-B.com)

## WWW.C3-B.COM

Please visit our website for up to date information, downloadable brochures and all the information you need to request a quotation for our services. One of the members of our alliance will respond to your query within 2 working days. Our experienced team will work behind the scenes to provide the most efficient and cost effective way of helping your business gain notification of your substances.



C3-B is an informal collaboration between AstraZeneca UK Limited (Brixham Environmental Laboratory), Chilworth Technology Limited, Centre de Recherches Biologiques (CERB) and Chemsafe S.a.S. No legal relationship exists between the aforementioned entities and none of them has the authority to contract on behalf of any other of the entities.

## CONTACT

C3-B Services are available from the following sites:-

### Chilworth Technology Ltd



Beta House,  
Chilworth Science Park,  
Southampton, SO16 7NS, UK  
Tel: +44 (0)23 8076 0722  
Fax: +44 (0)23 8076 7866  
Email: [marketing@chilworth.co.uk](mailto:marketing@chilworth.co.uk)  
Web: [www.chilworth.co.uk](http://www.chilworth.co.uk)

### CERB



Chemin de Montifault  
Baugy, 18800, France  
Tel +33 248 230023  
Fax. + 33 248 261187  
Email: [contact@cerb.fr](mailto:contact@cerb.fr)  
Web: [www.cerb.fr](http://www.cerb.fr)

### Brixham Environmental Laboratory



Freshwater Quarry, Brixham  
Devon, TQ5 8BA, UK  
Tel. +44 (0)1803 882882  
Fax. +44 (0)10803 882974  
Email: [infomaster.brixham@astrazeneca.com](mailto:infomaster.brixham@astrazeneca.com)  
Web: [www.brixham-lab.com](http://www.brixham-lab.com)

### Chemsafe



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*For further information visit [www.c3-b.com](http://www.c3-b.com)*