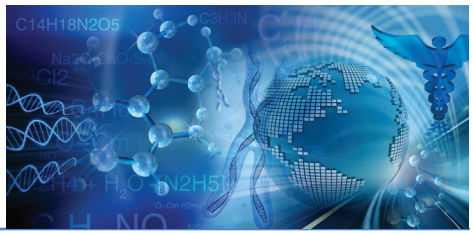
BioReliance

Toxicology Services



REACH Compliance Testing

REACH is Here! Are You Prepared?

– BioReliance is your partner for REACH compliance

– We offer an extensive line of services for the toxicology testing required by REACH Regulations

In June 2007 a new European Union (EU) regulation on the management of chemicals came into force. This regulation is known as REACH (Registration, Evaluation, Authorisation and Restriction of Chemical Substances).[1]

REACH was enacted to ensure that all chemicals on the market in the EU do not adversely affect human health or the environment

The REACH system set forth seven objectives to ensure a high level of chemicals safety and a competitive chemicals industry:

- Protection of human health and environment
- Maintenance and enhancement of the competitiveness of the EU chemical industry
- Prevention of fragmentation of the internal market
- Increased transparency
- Integration with international efforts
- Promotion of non-animal testing
- Conformity with EU international obligations under the WTO

REACH applies to all chemicals imported or produced in the EU and is enforced by the European Chemicals Agency (ECHA). All chemicals over 1 metric ton are required to be registered and implementation will be phased in over the next decade.

With over 60 years of testing experience for the chemicals, consumer health care, cosmetics, medical device, vaccine and pharmaceutical industries, BioReliance is the world's most trusted CRO.

Advantages of the BioReliance REACH Testing Program

- Unsurpassed knowledge
  - Over 50 years of toxicology testing experience
  - Industry-lauded scientific experts
- Focused expertise in genetic toxicology
- Close relationship and extensive familiarity with regulatory bodies
- State-of-the-art Facilities
- Dedicated animal facility for mammalian studies
- Fully validated and audited procedures
- Compliant with all regulatory bodies and regulations

BioReliance has all the Knowledge and Experience to help you register and ensure your products comply with REACH

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BioReliance

Toxicology Services

BioReliance offers an extensive array of testing services to assist in all phases of the REACH regulation

ECHA supports registration of chemicals by providing a software application (IUCLID) which assists in the process of submitting data on chemical properties and effects. BioReliance's team of experts provide testing and consultation to guide you through the registration process.

Genetic Toxicology Assays

Our services include a broad spectrum of *in vitro* and *in vivo* toxicology testing services designed in accordance with international guidelines and are conducted in full compliance with all applicable GLP regulations.

Assay Name	OECD Guideline	REACH Annex Number	REACH Test Method[3]
In Vitro Chromosome Aberration Assay	473	VII, VIII, IX	B10
In Vivo Metaphase Analysis (Bone Marrow)	475	VII, VIII, IX	B11
In Vivo Micronucleus Assay (Bone Marrow)	474	VIII, IX	B12
In Vitro Micronucleus Assay	487 (draft)	VIII, IX	B12
Bacterial Mutation Assay (Ames)	471	VII, VIII,	B13/14
L5178 $TK^{+/-}$ Mouse Lymphoma Assay	476	VIII, IX	B17
CHO/HGPRT Gene Mutation Assay	476	VIII, IX	B17
In Vitro Unscheduled DNA Synthesis (UDS)	482	VII, VIII, IX	B18
In Vitro Sister Chromatid Assay (SCE)	479	VII, VIII, IX	B19
In Vitro Transformation of Syrian Hamster Embryo Cells (SHE)	N/A	VII, VIII, IX	B21
Mouse Spermatogonial Cells	483	VII, VIII, IX	B23
In Vivo Unscheduled DNA Synthesis (UDS)	486	VII, VIII, IX	B39

Mammalian Toxicology Assays

BioReliance has extensive experience in the development and application of toxicological methodologies using rodent and other small laboratory animals. Full analytical chemistry support is available for dose formulation, homogeneity, stability and dose analysis.

Assay Name	OECD Guideline	REACH Annex Number[2]	REACH Test Method[3]
Acute Oral Toxicity – Fixed Dose	420	VII	B1
Acute Toxicity (Dermal)	434	VIII, IX	B3
Repeated Dose (28 Day) Toxicity (Oral)	407	VIII, IX	B7
Repeated Dose (28 Day) Toxicity (Dermal)	410	VIII, IX	B9
Sub-chronic Repeated-Dose Oral Toxicity 90-Day (Rodent)	408	IX	B26
Sub-chronic Repeated-Dose Oral Toxicity 90-Day (Rabbit)	409	IX	B27
Sub-chronic Repeated-Dose Dermal Toxicity 90-Day	411	IX	B28

References

[1] "REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENTAND OF THE COUNCIL of 18 December 2006," Official Journal of the European Union, December 30, 2006, 1-849.

[2] Regulation (EC) No 1907/2006, 316-359.

[3] "COUNCIL REGULATION (EC) No 440/2008 OF 30 May 2008," Official Journal of the European Union, May 30, 2008.

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