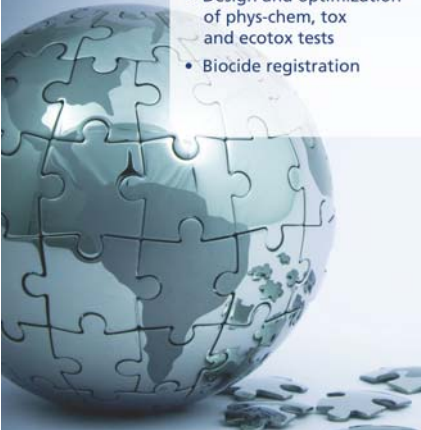


Intertek Expert Services

Partner of Choice for
Global Regulatory Support



- Worldwide notification of new chemicals
- Compliance with emerging regulations
- GHS / CLP
- Design and optimization of phys-chem, tox and ecotox tests
- Biocide registration

www.intertek.com/ies

Regulatory Services



Valued Quality. Delivered.

Regulatory Services

■ Overview:

- Specialises in Regulatory Consulting Services benefiting from Ciba heritage and long Cantox history in the market
- A focus on high-end services with two main core competencies:
 - Regulatory Affairs
 - Product Safety

■ Key Value Drivers:

- Strong relationships with regulatory authorities in Canada, USA, Europe, Switzerland, Australia/NZ, China, Korea, Philippines and Japan....and Taiwan, Turkey,and Serbia..... Brazil.....
- On the ground and at the forefront of emerging legislation: local network, local language, local culture – direct feedback to our clients globally
- *Practitioners* with decades of experience; not theoreticians
- Cantox; a leading internationally recognised brand in scientific & regulatory consulting



Expert Services



Intertek Regulatory Services

Main Business Areas



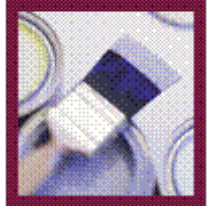
Valued Quality. Delivered.



- Food & Nutrition



- Pharmaceutical & Healthcare



- Specialty Chemicals & Performance Materials



- Agri, Biotech & Consumer (ABC) Products



Valued Quality. Delivered.

Substance-Specific Experience

absorbents / adsorbents

adhesives / binders / sealants
/ fillers

abrasives

antifreezes / coolants /
deicers

antioxidants / corrosion
inhibitors

asphalts

catalysts / initiators

chemical intermediates

paint & coating additives

photosensitive agents -
fluorescent agents / UV
absorbers

polymers - additives, crosslinking
agents

preservatives

refrigerants

rubbers

solvents / carriers

surfactants - detergents / wetting
agents / dispersants

viscosity adjusters

water and waste treatment
chemicals

colourants - pigments / stains /
dyes / inks

defoamers

flame retardants / fire
extinguishing agents

flocculating, precipitating,
clarifying agents

fragrances / perfumes /
deodourizers

fuels / fuel additives

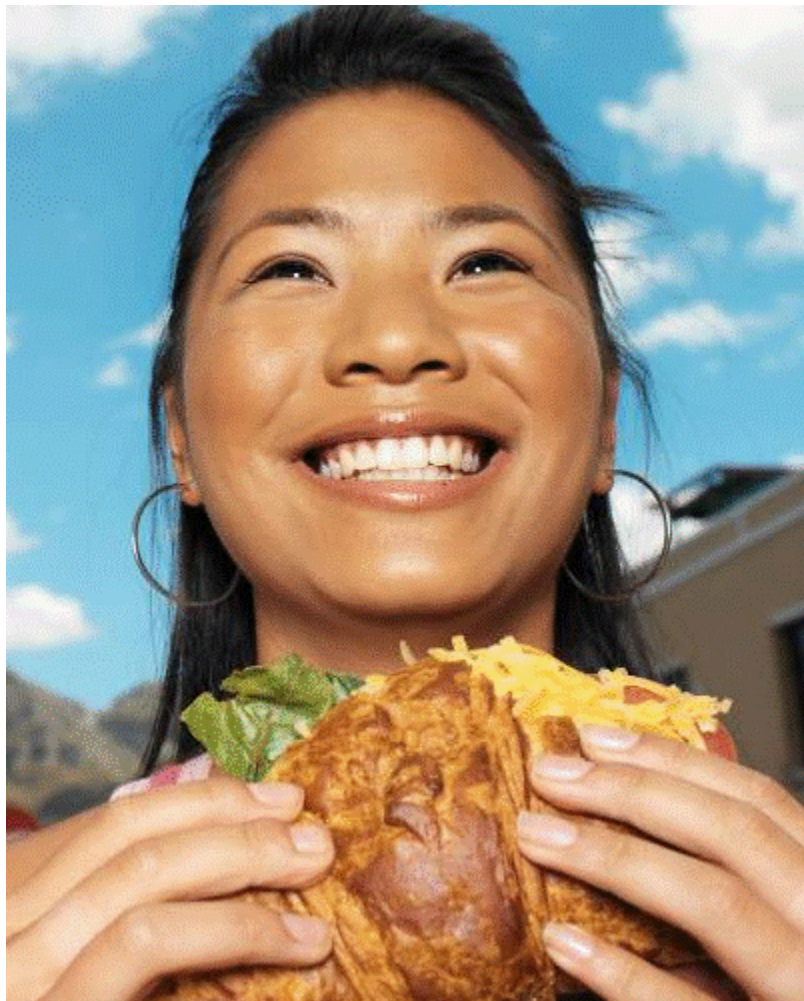
lubricating agents / lubricant
additives

monomers

Food & Nutrition

Intertek

Valued Quality. Delivered.



- Food Additive Submissions
- GRAS Determinations
- Dietary Supplement Notifications
- Novel Foods Submissions
- Health Claim Substantiation
- Non-clinical & Clinical Study Development and Monitoring
- Food Contact Notifications
- Food Application Biocides

...and more

Global Food Contact Program

- US Food Contact Notifications
- EFSA Dossiers
- Knowledge of Food Contact requirements in Japan, China, Canada, South America, etc.
- Regulatory & Testing Services include:
 - Development & Submission of dossiers for new materials intended to come into contact with foodstuff
 - Migration Studies (monomers, additives, heavy metals)
 - Protocol Design
 - Migration study
 - Preparation of Notification/Petition
 - Submission of Notification/Petition
 - Representation with Government Agency
 - Impurity Profiling and Complex formulation Identification



Pharmaceutical & Healthcare

Intertek

Valued Quality. Delivered.



- Non-clinical study design, CRO study placement, monitoring & report review
- Regulatory affairs
- Strategic planning
- Program management
- Toxicology consulting and expert reports
- Due diligence

...and more

Chemicals

Intertek

Valued Quality. Delivered.



- New Substance Notification, Strategic Planning, Dossier Preparation & Stewardship
- Hazcom Training & Support
- Materials Safety Data (MSDS) Preparation
- Workplace & Consumer Label Advice
- Hazard Classification, Product Safety Evaluation
- Product Chemistry Review
- Technical Support to Non-Compliance Resolution
- Supply Chain Mediation & Government Relations, EU REACH and BPD support
...and more

Global Chemical Notification

Intertek

Valued Quality. Delivered.

- New Chemical (Substance / Polymer) Notification Project Management +
 - USA (All TSCA Submissions: PMN, LVE)
 - EU REACH, CLP and the BPD
 - Turkey
 - Asia (China, Taiwan, Japan, South Korea, Philippines)
 - Australia & New Zealand
 - Canada
 - South America
- Design Testing Protocols, include country-specific testing
- Manage Required Toxicological Studies
- Dossier Preparation (in native language)
- Discussion and negotiation with authorities for possibilities of waiving strategies



H&E REACH Track Record

- involved with REACH since the White Paper
- multiple discussions with officials from the EU (eg Intertek seminars)
- participated with Danish authorities developing the legislation
- developed guidelines for the RIP's
- experienced with intelligent testing methods (ie grouping, waiving, (Q)SAR, read-across, etc)
- extensive knowledge on substance definition under REACH
- developed CSA for substances with extensive CSR's
- phase-in and non-phase-in substances experience
- dealt with large programs with dozens of substances (one client with >120 substances for 2010)
- managed > 40 lead registrant dossiers and > 500 co-registrations for 2010 deadline
- satisfied clients (zero failures in REACH)
- doing regulatory submissions for decades (not just REACH)

Regulatory Affairs and Product Safety is our business!



Toxicological Services



Valued Quality. Delivered.

- Toxicological and eco-toxicological evaluations
 - SAR Modelling (Structure Activity Relation)
 - Tox Literature Search
 - Design and optimization of toxicological and ecotoxicological protocols to meet global regulations
 - Placement and Monitoring of studies
 - Author Tox Narrative for Regulatory Submissions
 - Cancer Risk Assessment
 - Preparation of product safety reports
-
- | | | | |
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Classification, Packaging & Labelling



Valued Quality. Delivered.

UN GHS / EU CLP

- Consultancy re Interpretation & Implementation
- Seminars & In-house training (GHS & CLP)
- Reviewing and revising classification and labeling
- Safety Data Sheet Authoring
- CLP Notifications to ECHA



Transport of Dangerous Goods



Valued Quality. Delivered.

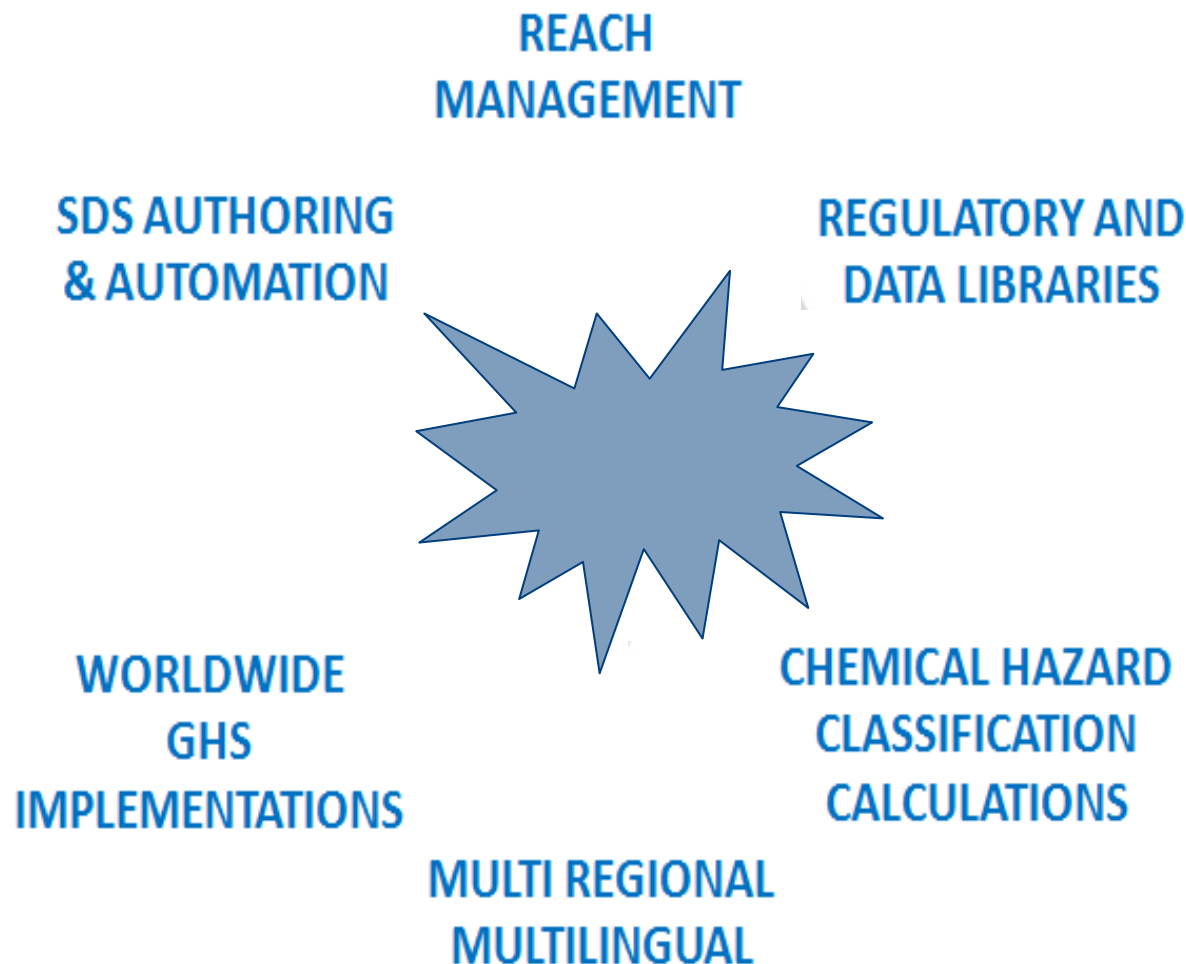
Comprehensive Dangerous Goods Training and support services for the supply and consignment of Dangerous Goods by Road, Air and Sea.

- Training for the consignment of dangerous goods by: Road (ADR) , Sea (IMDG) & Air (IATA)
- UK Civil Aviation Authority approved IATA courses
- Tailored courses available to suit individual company needs
- Act as a client's nominated Dangerous Goods Safety Advisor (DGSA)
- Auditing of a client's procedures to ensure compliance with the DGSA Regulations



Safety Data Sheet System

Valued Quality. Delivered.



SDS system offers full Chemicals and EH&S Management including :

- Chemicals inventory, expiry dates, stock & location, maintenance and inspection,...
- MSDS, labels, TremCards, Safety Instruction Cards
- Calculation of preparations, ADR, Seveso
- ISO14001, Responsible care, Waste management
- Risk Assessment
- REACH and GHS
- Environmental, Health and Safety management
- ...other

Agri, Biotech, & Consumer Products

Intertek

Valued Quality. Delivered.



- Developing regulatory strategy and submissions
- Product safety & efficacy evaluations for cosmetics/cosmeceuticals
- Substantiating waiver requests and read-across arguments
- Developing exposure limits and residue tolerances
- Conducting human health and environmental risk assessments & mechanistic evaluations of unique chemical hazards
- Third-party technical liaison

...and more

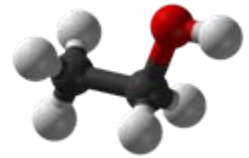
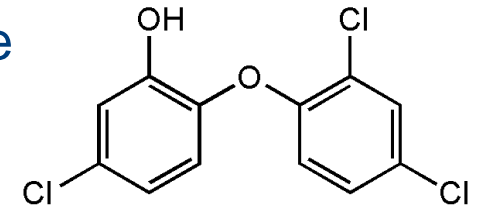
EU Biocides Regulation



Valued Quality. Delivered.

EU Biocidal Products Directive (BPD) & MS Requirements

- Consultancy re Interpretation & Implementation
- Dossier Preparation & Submission for biocide active substances
- Evaluation of existing data
- Design test protocols cost effectively and organize testing as per Directive guidelines
- Project management for test programmes and liaison between authorities and clients
- Toxicological evaluation support (with support from Cantox)
- Dossier Preparation & Submission for biocide product formulations





Valued Quality. Delivered.



Valued Quality. Delivered.
