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*Compliance*BASE ™

- compliance management and risk assessment tool -

MDCTec's business intelligence system for enterprise technology and compliance planning (ETCP) runs under the trade mark *Compliance*BASE ™. This is a management and risk assessment tool which enables companies and professionals to organize and carry out all technology, compliance and sustainability related business operations starting from raw materials information and recipe management to compliance evaluation and certification.

The *Compliance*BASE ™ supports enterprises:
► in their strategic business planning
► to act sustainable
► to follow good manufacturing practice (GMP)
► to produce according to actual state of the art in technology and science
► to strengthen innovation processes and continuous improvement
► to react flexible in changes in day-to-day business
► to implement a systematic compliance strategy
► to identify and assess health, safety and environmental risks related to
   their raw materials, product and process portfolio.

The *Compliance*BASE ™ integrates the *Material*BASE ™, an innovative raw material, recipe and product management system and the *Process*BASE ™, a professional production process and processing management system, both in support of business, compliance and risk assessment which are linked to professional tools and a user friendly web based interface. High end functionalities like compliance check with applicable regulations, migration estimation and mass balance calculations or contamination risk assessment are one click away.

The *Compliance*BASE ™ forms together with a compliance module (C-MOD), e.g. for food contact materials (FCM) the *Compliance*BASE ™ - FCM dedicated to food contact materials and supports their legal or technical compliance management and evaluation.

The *Compliance*BASE ™ - FCM processes all business related information and links them ready to use for technology and compliance purpose. Professional tools and high end functionalities support the management, evaluation and innovation process:
● Recipe management and raw materials inventory
● Regulations and substance inventory including limitations for food contact materials (FCM)
● Migration and other test data management

- Worst case calculation based on mass balance and total transfer of components to food
- Migration modelling and functional barrier assessment in packaging systems
- Risk assessment for contaminants from food contact materials in processing and packaging
- Compliance check for food contact materials (FCM) with legal demands
- Compliance certificate generation and supporting documents management
- Full traceability of information, data processing and document management in the database
- Electronic communication with suppliers and customers through electronic questionnaires *eQ*™ and the food contact master file **FCMF**™
- Interface to enterprise resource planning systems like SAP, Axapta, Navision, etc.

The regulations and substance inventory **Chemprofiler**™ and the migration & other test data centre **Test**BASE™ are directly linked to the database system. Through **FCM Oracle**™ the application will identify the legal requirements based on composition and structure of the food contact materials (FCM) and supports in connection with available migration test data and migration estimation tool their compliance evaluation. Through **FCM Spec**™ and **FCM Comply**™ specifications respectively compliance certificates are issued on demand.
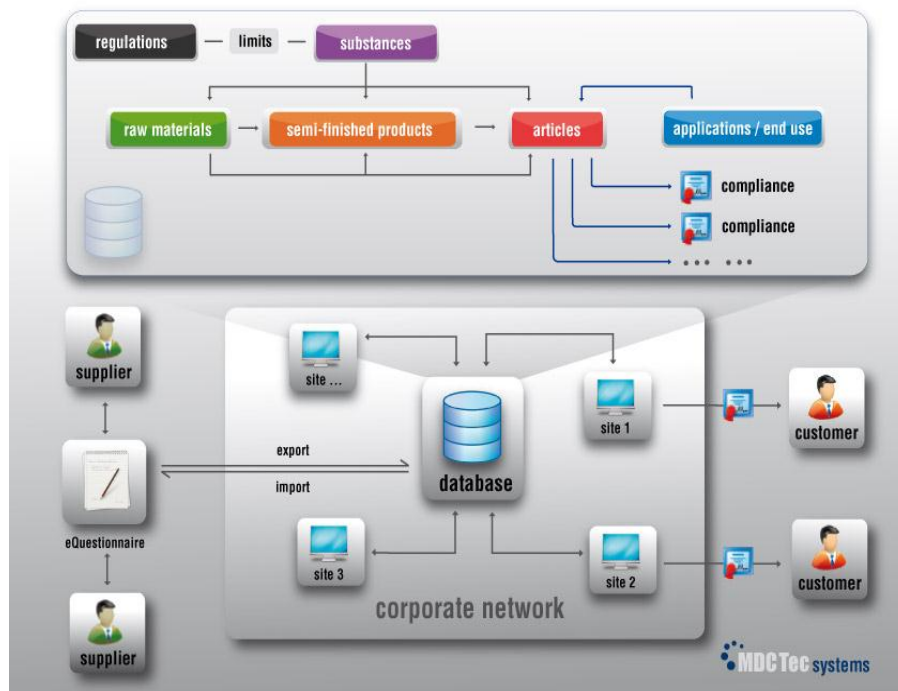
The concept for the **Compliance**BASE™ intends to be as flexible as possible to fulfil the needs of multinational enterprises as well as SME's.

Software tools linked to the database implement functionality's beyond simple queries. Results of database query are inputs for the software tools through which the **Compliance**BASE™ transforms information from the database into compliance certificates and specifications.

The **Material**BASE™ enables the users to build their own materials or articles (e.g. FCM) in a three level hierarchy from "raw materials" (= all you by) through "semi-finished products" (= internal production) to "final products" (= all you sell) which maps the existing enterprise resource planning system. Composition and structures are tracked as well as full mass balance on components and impurities. The **Material**BASE™ fully integrates all relevant information, related to technology, specifications, compliance, safety, etc. like reports, technical documents and supporting documentation. On the other hand the intended applications with all relevant requirements are implemented and linked to the final products.

The **FCM Oracle** ™ tracks the regulatory requirements (so far EU/DE/CH/US and others under construction) at any stage of the production, i.e. raw materials, semi-finished products or final products. If the application for the final article and corresponding migration data are implemented and the regulatory requirements specified and agreed with the customer, compliance of the final article with legal demands is evaluated (customer specific). Through the dynamic PDF functions **FCM Comply** ™ and **FCM Spec** ™ multilingual generation of compliance certificates or specifications or any other supporting documents based on the dynamic template system is possible.

The **eQ** ™ is an electronic questionnaire linked to the main database facilitating the communication of compliance related information between customers and suppliers along the value chain.
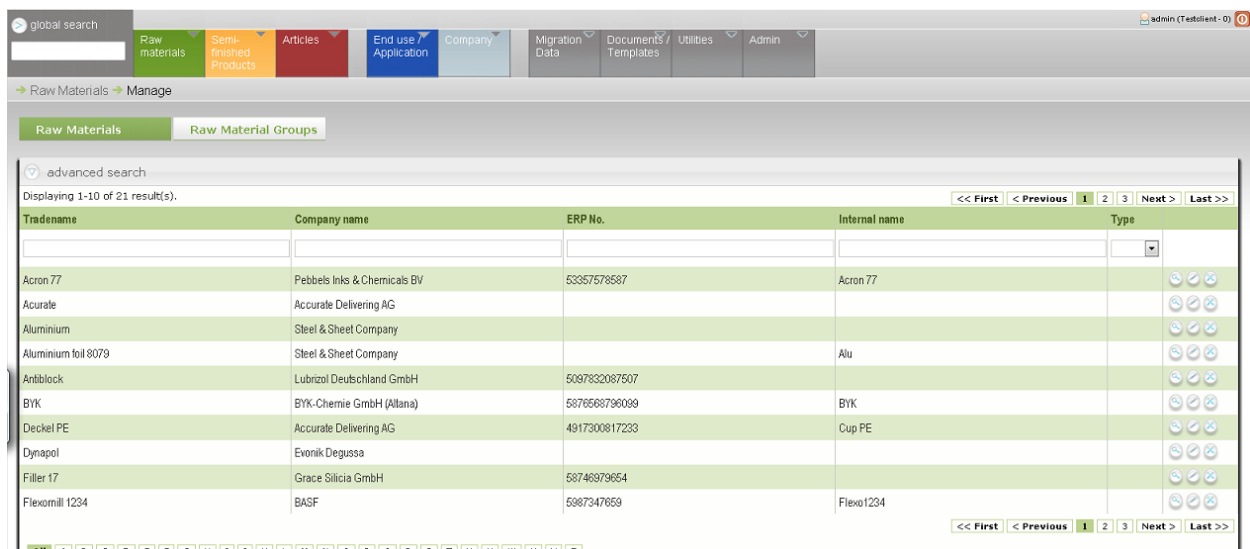
Compliance with specific migration limits is based on compositional information from the database and mass balance considerations (total transfer) or migration estimation by modelling (set-off, storage & aging, migration, etc.) as well as experimental data from laboratory testing. For safety reasons the experimental control of worst case or critical structures under worst case conditions is recommended based on worst case migration screening tests.

Access to the information from the database is limited to the confidentiality level attributed to individual information. Information can be shared between all sites in a corporate environment which have implemented the **Compliance**BASE ™ protected through a role based access system.

The **Compliance**BASE ™ gives the user the freedom of choice to make use of consultancy and testing services from any competent supplier. A link of the **Compliance**BASE ™ to the enterprise resource planning (ERP) system of the individual legal entities can be established by a customer specific data exchange interface. Split out of legal entities because of changes in the corporate structure is no problem.

Continuous update, maintenance and support of the **Compliance**BASE ™ will be provided by MDCTec based on the yearly rental fee and optional support packages.

Screen shot "Raw Materials" listing and search function

MDC Tec systems

Screen shot "Raw Materials" information and data

Screen shot "Article" (final product) information and data

Screen shot "Article" worst case calculation

Screen shot "Article" (final product) compliance tree

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            § FCN 749
            § FCN 865
            § CFR 176.170
            § CFR 176.180
        CH
            § Regulation SR 817.023.21
                SML 12 mg/kg
        DE
    Regulations
        § CFR 175.300 -
        § CFR 175.105 -
    Acron 77 | 53357578587 | Acron 77
    Substances
        00050-00-0 | FORMALDEHYDE -
            EU
                § Directive 2002/72/EC
                    SML 15 mg/kg
                § Regulation (EU) No 10/2011
                    SML 15 mg/kg
                § Guideline CEPI Guideline
                    SML 6.0 mg/kg
                    QMA 1.0 mg/dm²
            US
                § CFR 175.105
                § FCN 359
                § FCN 717
                § FCN 927
                § CFR 176.170
                § CFR 176.180
            DE
            CH
                § Regulation SR 817.023.21
                    SML 15 mg/kg
        00141-32-2 | ACRYLIC ACID, n-BUTYL ESTER -
    Flexomill 1234 | 5987347659 | Flexo1234
    Substances
        0000079-10-7 | ACRYLIC ACID -
        0002082-79-3 | OCTADECYL 3-(3,5-DI-tert-BUTYL-4-HYDROXYPHENYL) PROPIONATE -
        31566-31-1 | GLYCEROL MONOSTEARATE -
        00-00-0 | confidencial -
    Regulations
    Aluminium foil 8079 | Alu
    Heatseal 14A | 5865764986 |
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Implementation of the ***Compliance*BASE™** is not a trivial task reason for which a preliminary consultation to define customer specific requirements is strongly recommended. Because the ***Compliance*BASE™** is under continuous development, an early link of MDCTec's activities with user specific interests is of common interest.

Depending on the legal frame applicable for products and processing the following ***Compliance*BASE™** regulatory modules (C-MOD) exist:

FCM   - for food contact materials
PLANT   - for production plants
FOOD   - for foods
CHEM   - for chemicals and formulations
TOY   - for toys
COSMETIC   - for cosmetics
PHARMA   - for pharmaceuticals
CPDW   - for construction products and
                   materials in contact with drinking water

Our Vision

Compliance on Demand !