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# ComplianceBASE™

## - compliance management and risk assessment tool -

MDCTec's business intelligence system for enterprise technology and compliance planning (ETCP) runs under the trade mark **ComplianceBASE™**. 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 **ComplianceBASE™** 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 **ComplianceBASE™** integrates the **MaterialBASE™**, an innovative raw material, recipe and product management system and the **ProcessBASE™**, 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.

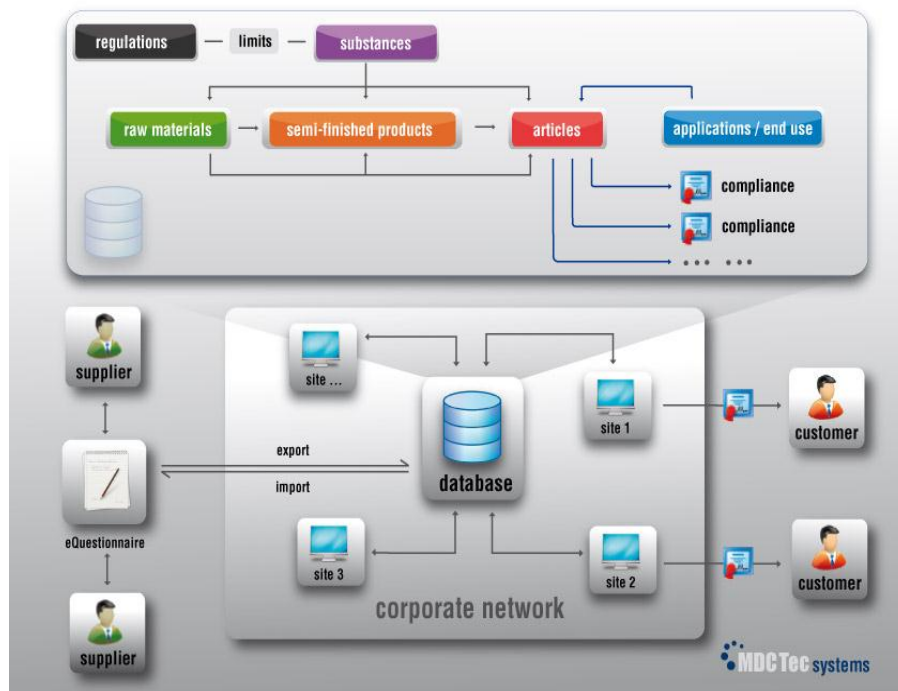
The **ComplianceBASE™** forms together with a compliance module (C-MOD), e.g. for food contact materials (FCM) the **ComplianceBASE™ - FCM** dedicated to food contact materials and supports their legal or technical compliance management and evaluation.

The **ComplianceBASE™ - 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 **TestBASE™** 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 **ComplianceBASE™** 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 **ComplianceBASE™** transforms information from the database into compliance certificates and specifications.

The **MaterialBASE™** enables the users to build their own materials or articles (e.g. FCM) in a three level hierarchy from "raw materials" (= all you buy) 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 **MaterialBASE™** 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.

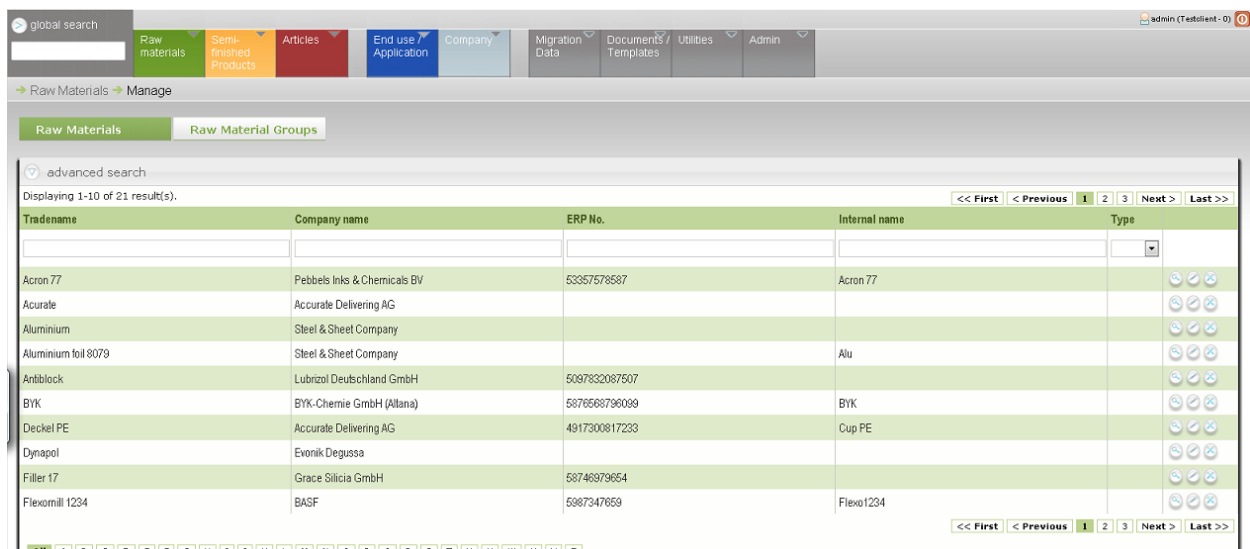
Compliance with specific migration limits is based on compositional information from the database and mass balance considerations (total transfer) or migration estimation by modelling (set-off, storage & aging, migration, etc.) as well as experimental data from laboratory testing. For safety reasons 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 **ComplianceBASE™** protected through a role based access system.

The **ComplianceBASE™** gives the user the freedom of choice to make use of consultancy and testing services from any competent supplier. A link of the **ComplianceBASE™** 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 **ComplianceBASE™** will be provided by MDCTec based on the yearly rental fee and optional support packages.

### Screen shot "Raw Materials" listing and search function



Tradename	Company name	ERP No.	Internal name	Type
Acron 77	Pebblets Inks & Chemicals BV	53057578587	Acron 77	
Acurate	Accurate Delivering AG			
Aluminium	Steel & Sheet Company			
Aluminium foil 8079	Steel & Sheet Company		Alu	
Antiblock	Lubrizol Deutschland GmbH	5087832087507		
BYK	BYK-Chemie GmbH (Allana)	5876688736039	BYK	
Deckel PE	Accurate Delivering AG	4917300817233	Cup PE	
Dynapol	Evonik Degussa			
Filler 17	Grace Silicia GmbH	58746873654		
Flexomill 1234	BASF	5987347859	Flexo1234	

## Screen shot "Raw Materials" information and data

global search [input] Raw materials | Semi-finished Products | Articles | End use / Application | Company | Migration Data | Documents / Templates | Utilities | Admin | admin (Testclient - 0)

Raw Materials -> Flexomill 1234

Tradename **Flexomill 1234** | ERP No. **5987347659** | Internal name [input] | [Back to Raw Materials list](#)

overview

- general data
- technical data
- documents
- composition
- substances
- exclusion list
- regulatory
- groups
- functions
- migration data
- other testdata
- supplier
- upper tree
- compliance tree

general data	
Tradename	Flexomill 1234
ERP No.	5987347659
Internal name	Flexo1234
Other name	
Another name	
CAS	
Food Approval	Yes
Company name	BASF
Type	
Comment	
Created	Apr 19, 2011
Changed	Sep 27, 2011

technical data	
Density	1.04 g/cm³
Solids content	100 %
Solids content tolerance	
Thickness	Not set
Unitmass	Not set
Area	Not set
Volume	Not set
Weight	Not set

documents		
File	Name	Type
	Merkblatt D001	Produktblatt
	Synoflag CC regulatory datasheet	Regulatory datasheet

substances						
CAS no.	name eu	ref no.	Content [%]	File	Confidential	Comment
0000079-10-7	ACRYLIC ACID	10630			No	
0002062-78-3	OCTADECYL 3-(β,5-DI-tert-BUTYL-4-HYDROXYPHENYL) PROPIONATE	68320	0.03		No	
31566-31-1	GLYCEROL MONOSTEARATE	18115, 57520	0.1		No	
00-00-0	confidential				Yes	

regulatory			
Regulatory Type	Regulatory No	Date	Comment
Recommendation	XIVBIR	01.06.2009	
List	EuPIA Exclusion List	01.04.2011	
Directive	2002/72/EC	13.02.2003	
CFR	176.180	01.04.2009	

exclusion list	

Actions

- edit general data
- edit technical data
- edit documents
- edit regulatory
- edit composition
- edit substances
- edit migrationdata
- edit other testdata
- add to a group
- edit supplier
- delete Raw Material
- copy this Raw Material
- copy Raw Material data
- history
- create Raw Material
- create Raw Material Group
- manage Raw Material
- manage exclusion list

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

global search [input] Raw materials | Semi-finished Products | Articles | End use / Application | Company | Migration Data | Documents / Templates | Utilities | Admin | admin (Testclient - 0)

Articles -> Aluminium Lid

Tradename **Aluminium Lid** | ERP No. **32858797858** | Internal name [input] | [Back to Articles list](#)

overview

- general data
- technical data
- documents
- composition
- substances
- regulatory
- compliances
- customer
- groups
- functions
- migration data
- other testdata
- applications
- worst case calculation
- upper tree
- compliance tree

general data	
Tradename	Aluminium Lid
ERP No.	32858797858
Internal name	No174418
Other name	
Another name	
Article group	Not set
Market	
Created	Apr 20, 2011
Changed	Sep 20, 2011
Comment	

technical data	
Density	1.02 g/cm³
Solids content	100 %
Solids content tolerance	
Thickness	Not set
Unitmass	Not set
Area	Not set
Volume	Not set
Weight	Not set

documents		
File	Name	Document Date
	Tst	-

composition				
Order	Name	Date	File	Comment
1	Printing Ink 3887			Unit mass 1.4 g/m²
2	Primer XRD06   1477465323   XRD06			Unit mass 0.45 g/m²
3	Aluminium foil 8079   Alu			Thickness 31 µm
5	Heatseal 14A   5865764986			Unit mass 6.2 g/m²

regulatory			
Regulatory Type	Regulatory No	Date	Comment
Regulation	1935/2004	13.11.2004	
Regulation	2023/2006	29.12.2006	

compliance						
<a href="#">&lt;&lt; First</a>   <a href="#">&lt; Previous</a>   1   2   <a href="#">Next &gt;</a>   <a href="#">Last &gt;&gt;</a>						
Customer	Language	Valid	Created	Expires	Comment	
Customer AG	DE	No	Jul 7, 2011	Jul 5, 2012		
Customer AG	DE	No	Jul 7, 2011	Jul 5, 2012		
Customer AG	DE	No	Jul 7, 2011	Jul 5, 2012		
Customer AG	DE	No	Jul 7, 2011	Jul 5, 2012		
Customer AG	DE	No	Jul 7, 2011	Jul 5, 2012		
Customer AG	DE	No	Jul 7, 2011	Jul 5, 2012		
Customer AG	DE	No	Jul 7, 2011	Jul 5, 2012		
Customer AG	DE	No	Jul 7, 2011	Jul 5, 2012		
Customer AG	DE	No	Jul 7, 2011	Jul 5, 2012		
Customer AG	DE	No	Jul 7, 2011	Jul 5, 2012		
Customer AG	DE	No	Jul 7, 2011	Jul 5, 2012		
Customer AG	DE	No	Jul 7, 2011	Jul 5, 2012		
Customer AG	DE	No	Jul 7, 2011	Jul 5, 2012		

Actions

- create compliance
- edit general data
- edit technical data
- edit customers
- edit documents
- edit regulatory
- edit composition
- edit substances
- edit migrationdata
- edit other testdata
- edit applications
- add to a group
- copy this Article
- copy Article data
- history
- find similar Articles
- delete Article
- create Article
- create Article group
- manage Articles

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### Screen shot "Article" worst case calculation

The screenshot displays the 'worst case calculation' tab for the article 'Aluminium Lid'. The interface includes a navigation menu on the left, a main content area with a table of substances, and an 'Errors' section at the bottom.

Item	Substance	Unit	Value	Unit	Value
000104-76-7	2-ETHYL-1-HEXANOL	n.a. mg/kg Food	n.a.	mg/dm <sup>2</sup>	n.a. mg/kg Packaging
00108-05-4	ACETIC ACID, VINYL ESTER	0.002 mg/kg Food	n.a.	mg/dm <sup>2</sup>	0.451 mg/kg Packaging
0000079-10-7	ACRYLIC ACID	n.a. mg/kg Food	n.a.	mg/dm <sup>2</sup>	n.a. mg/kg Packaging
00141-32-2	ACRYLIC ACID, n-BUTYL ESTER	0.002 mg/kg Food	n.a.	mg/dm <sup>2</sup>	0.542 mg/kg Packaging
0007429-90-5	Aluminium	4833.582 mg/kg Food	805.597	mg/dm <sup>2</sup>	1150852.857 mg/kg Packaging
00106-99-0	BUTADIENE	0.001 mg/kg Food	n.a.	mg/dm <sup>2</sup>	0.249 mg/kg Packaging
00050-00-0	FORMALDEHYDE	0.018 mg/kg Food	0.003	mg/dm <sup>2</sup>	4.338 mg/kg Packaging
31566-31-1	GLYCEROL MONOSTEARATE	0.012 mg/kg Food	0.002	mg/dm <sup>2</sup>	2.94 mg/kg Packaging
00110-16-7	MALEIC ACID	n.a. mg/kg Food	n.a.	mg/dm <sup>2</sup>	n.a. mg/kg Packaging
0002082-79-3	OCTADECYL 3-(3,5-DI-tert-BUTYL-4-HYDROXYPHENYL) PROPIONATE	0.004 mg/kg Food	0.001	mg/dm <sup>2</sup>	0.882 mg/kg Packaging
0000100-42-5	STYRENE	0.03 mg/kg Food	0.005	mg/dm <sup>2</sup>	7.181 mg/kg Packaging
0014807-96-6	TALC	70.378 mg/kg Food	11.73	mg/dm <sup>2</sup>	16756.757 mg/kg Packaging
00077-90-7	TRI-n-BUTYL ACETYL CITRATE	3.36 mg/kg Food	0.56	mg/dm <sup>2</sup>	800 mg/kg Packaging
00-00-0	confidential	n.a. mg/kg Food	n.a.	mg/dm <sup>2</sup>	n.a. mg/kg Packaging

**Errors:**

Item	Substance	Message
Printing Ink 3887	00-00-0 // confidential	No Substance content defined
Flexomil 1234	0000079-10-7 / 10690 / ACRYLIC ACID	No Substance content defined
Flexomil 1234	00-00-0 // confidential	No Substance content defined
Polybind	00110-16-7 / 19540; 64800 / MALEIC ACID	No Substance content defined
Polybind	000104-76-7 / 17050 / 2-ETHYL-1-HEXANOL	No Substance content defined

### Screen shot "Article" (final product) compliance tree

The screenshot displays the 'compliance tree' tab for the article 'Aluminium Lid'. The tree structure shows regulatory requirements for various substances and regions.

- Aluminium Lid | 32858797858 | No 174418
  - Regulations
    - Regulation 1935/2004 -
    - Regulation 2023/2006 -
  - Printing Ink 3887
    - Substances
      - 00-00-0 | confidential -
      - 00077-90-7 | TRI-n-BUTYL ACETYL CITRATE -
        - EU
          - Directive 2007/42/EC
            - QMA 6 mg/dm<sup>2</sup>
          - Directive 2007/19/EC
            - Regulation (EU) No 10/2011
              - SML 60 mg/kg
          - US
            - CFR 175.300
            - CFR 175.300
            - CFR 175.105
          - CH
            - Regulation SR 817.023.21
    - Regulations
      - Guideline EuPIA Guideline -
      - List EuPIA Exclusion List -
    - Primer XR/06 | 14777465323 | XR/06 |
      - Regulations
        - CFR 175.300 -
      - Vinos 4MC | 541777556596 | Vinos
        - Substances
          - 00108-05-4 | ACETIC ACID, VINYL ESTER -
            - EU
              - Directive 2002/72/EC
                - SML 12 mg/kg
              - Regulation (EU) No 10/2011
                - SML 12 mg/kg
            - US
              - CFR 175.300
              - CFR 175.105
              - FCN 203



Implementation of the **ComplianceBASE™** is not a trivial task reason for which a preliminary consultation to define customer specific requirements is strongly recommended. Because the **ComplianceBASE™** 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 **ComplianceBASE™** regulatory modules (C-MOD) exist:

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

***Our Vision***  
***Compliance on Demand !***