

Food contact materials database: data content & database description

The purpose of this document is to explain the structure and content of the database.

If you have questions, please contact Sanco-fcm@ec.europa.eu.

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A) Data content

(last update: 22/04/2010)

The database contains the data on :

- a) substances authorised to be used in plastics (Union list of substances to be used in plastics; listed in the plastic implementing measure)
- b) substances *not yet* authorised to be used in plastics

The database is continuously being updated with substances which are now being risk assessed by EFSA: the database informs if there is/are any ongoing application procedure(s) and the status of risk assessment.

- c) substances authorised to be used in plastics but not appearing in the plastics legislation because their authorisation is covered by the authorisation of another / other substance(s). For example:

- salts of aluminium, ammonium, barium, calcium, cobalt, copper, iron, lithium, magnesium, manganese, potassium, sodium and zinc of authorised acids that were listed in 2002/72/EC and are not anymore listed in the plastic implementing measure are authorised if the free acid is authorised (EFSA Journal 2009; 7(10):1364)
- such as substances covered by more generic substances

- d) components of mixtures; these substances also got a unique FCM substance No

The database does not (yet) contain data on :

- a) substances risk assessed by the Scientific Committee of Food and not authorised to be used in plastics or other categories of food contact materials
- b) substances risk assessed by EFSA for use in other categories of food contact materials than plastics

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B) Database description (user manual)

Webpage and section	Description
Webpage Substance – section Search Criteria	<p>In order to help facilitate your search for a particular food contact material substance, you may specify one or more filters to limit your results.</p> <p>Substance No. This is the unique FCM (Food Contact Materials) identification number of a substance</p> <p>Ref. No. This is the EEC packaging material reference number. The Ref. No. was the previous identification system used under the Plastics Directives 2002/72/EC. The reference number is a 5 digit number and indicate if the use is as monomer or other starting substance (from 10000 to 29999) or if the substance is used as an additive or a polymer production aid (from 30000 to 99999).</p> <p>Important: You can search for a plastic Ref No by means of the field Ref No and also by means of the field "Substance name and Synonym".</p> <p>Substance name and Synonym This is the chemical name or a synonym. You may enter any value into this field which may help to retrieve the substance you wish to find. Also an abbreviated name can be searched, e.g. BADGE.</p> <p>About 25 substances mentioned in the Plastics Directives 2002/72/EC appeared with more than one name and corresponding Ref No (the Ref No was related to their use). One of these names was inserted as the chemical name, the other name(s) as synonym name(s). For the synonym names, the corresponding Ref No was added. For that reason, two fields can be used to search for a Ref No: the field Ref No and also the field "Substance name and Synonym".</p> <p>CAS No. This is the Chemical Abstracts Service (CAS) registry number. It has a structural format like 1234567-89-0. For more information visit: http://www.cas.org/expertise/cascontent/registry/regsys.html Note : If a substance is not registered in the CAS registry or if the substance in the CAS registry does not exactly correspond to the authorised substance, in that case no CAS No is assigned. Where there is an inconsistency between the CAS No and the chemical name, the chemical name shall take precedence over the CAS No.</p> <p>EC No. The European Commission number, or EC number, also known as EC-No and EC#, is the seven-digit code that is</p>

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Webpage and section	Description
	<p>assigned to chemical substances that are commercially available within the European Union. It has the following format: 123-456-7.</p> <p>It includes the substances in the following inventories:</p> <ul style="list-style-type: none"> - European Inventory of Existing Commercial Chemical Substances, EINECS - European List of New Chemical Substances, ELINCS - The "No-longer Polymers" list, NLP-list <p>More information can be found in the European Chemical Substances Information System of the EC JRC: http://ecb.jrc.ec.europa.eu/esis/</p>
<p>Webpage Substance – Section Results</p>	<p>The results panel retrieves substances based upon the filters added in the search criteria panel.</p> <p>△ When no filter is applied, <i>all</i> substances in the database are listed: authorised and not yet authorised substances, components of mixtures, substances covered by another substance, etc.</p> <p>The list can be ordered by:</p> <ul style="list-style-type: none"> - substance No - substance name <p>Clicking on either of the above links will allow you to view all information regarding the specified substance and provide you with an overview of all authorisations of use for a particular substance in food materials. It will also provide information regarding applications for authorisation for a substance which in turn will show you the status of a particular application.</p>
<p>Webpage of a particular substance – Section General Data</p>	<p><u>Fields displayed in the General data include:</u></p> <p>Substance No. This is the Food Contact Materials Substance number, a unique identifier given to each particular substance.</p> <p>CAS No. This is the Chemical Abstracts Service registry number. It has the following format: 1234567-89-0. For more information visit: http://www.cas.org/expertise/cascontent/registry/regsys.html.</p> <p>△ Note on the Substance Name and Cas No The substance name and CAS No displayed may not be the final as it may still be subject to changes in later steps of the authorisation procedure. The substance name and CAS No are final, when the substance is authorised to be used in one type of food contact</p>

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	<p>materials.</p> <p>EC No. The European Commission number, or EC number, also known as EC-No and EC#, is the seven-digit code that is assigned to chemical substances that are commercially available within the European Union. It has the following format: 123-456-7.</p> <p>It includes the substances in the following inventories:</p> <ul style="list-style-type: none"> - European Inventory of Existing Commercial Chemical Substances, EINECS - European List of New Chemical Substances, ELINCS - The "No-longer Polymers" list, NLP-list <p>More information can be found in the European Chemical Substances Information System of the EC JRC: http://ecb.jrc.ec.europa.eu/esis/</p> <p>Substance name The chemical name of the substance. It is assigned by the Commission services based on the suggestion of the applicant and verified by the European Food Safety Authority, EFSA.</p> <p>Synonym name(s) This is a synonym chemical name. It can also be an abbreviation, e.g. BADGE.</p> <p>△ Note: About 25 substances in the Plastics Directives 2002/72/EC had more than one name and corresponding Ref No. One of these names is here inserted as chemical name, the other names as synonym name. For these synonym names of substances authorised to be used in plastics, the corresponding Ref No is added between brackets.</p> <p>FRF applicable FRF applicable (yes/no) contains an indication if for the substance the migration results can be corrected by the FRF (yes) or if they cannot be corrected by the FRF (no). Substances for which the FRF is applicable are assigned by the Commission services based on the advice by EFSA. Criteria for the decision are based on the SCF opinion Scientific Committee on Food on the introduction of a Fat (Consumption) Reduction Factor (FRF) in the estimation of the exposure to a migrant from food contact materials. (Expressed on 4 December 2002). The criteria are the following: The substance is lipophilic ($\log P_{o/w} > 3$). The value of its migration into non-fatty simulants should not exceed 1/10 of its SML.</p>

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Webpage and section	Description
	<p>Mixture This flag denotes whether the substance is a mixture or not.</p> <p>Mixture type Values can be defined/undefined.</p> <p>Composition of the mixture The components of the mixture: their substance No, Substance name and percentages or ranges.</p> <p>△ Note As regards mixtures, the database is incomplete for what concerns (1) the identification of mixtures (2) definition of the type of mixture and its composition. If you have more information, we would appreciate if you could inform us by e-mail.</p>
<p>Webpage of a substance – Section Name and reference number(s) assigned to this substance for which an application for authorisation for use as a monomer and/or additive in plastic has been submitted.</p>	<p>The aim of this table is to show the link between the plastic packaging material reference number and the FCM substance No, both used as substance identifiers mentioned in European Legislation on Food contact materials. It also shows the most recent name, monomer reference number and additive reference number assigned to the substance.</p> <p>Substances authorised to be used in plastics under the Plastics Directives 2002/72/EC got a EEC packaging material reference number, also called Ref No. This Ref No did not identify unique substances, but was different depending on their use as monomer or additive in plastics and the alphabetical order of their name in the EC list of substances to be used in food contact materials. The reference number is a 5 digit number and indicate if the use is as monomer or other starting substance (from 10000 to 29999) or if the substance is used as an additive or a polymer production aid (from 30000 to 99999).</p> <p>With the Plastic Implementing Measure, the FCM substance No was assigned to all unique substances. During a transitional period, the plastic Ref No may still be assigned to substances to be used in plastics.</p> <p>In the future, when the legislation for other types of food contact materials than plastics will be harmonised, only the new unique identification system (FCM substance No) will be used .</p> <p>The aim of this table is to show the link between the plastic packaging material reference number and the FCM substance No. It shows the most recent name, monomer reference number and additive reference number assigned to the substance.</p>

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Webpage and section	Description
<p>Webpage of a substance – section Message</p>	<p>Messages provide additional information on the substance or explanation on the interpretation of the data in the webpage of the substance.</p> <p>The following fields may appear:</p> <p>Type The type of a message can be an informational message or an emergency measure. An informational message may be displayed if it is necessary to provide extra information on how data on a specific substance should be interpreted.</p> <p>Message The actual message.</p> <p>Entry into force (only in case of an emergency measure) The date on which the emergency measure became effective. An informational message has neither <i>entry into force date</i> nor <i>until date</i>.</p> <p>Until (only in case of an emergency measure) The date on which an emergency measure will become out of date.</p>
<p>Webpage of a substance – Section Authorisation of the use of this substance in Food Contact Materials</p>	<p>This section displays the current authorized use of the substance by category(ies). This section is directly linked with the section “applications for authorisation”. When an application procedure leads to the authorisation/prohibition of the use of a substance and this is published in legislation, then this section is updated on the date of entry into force.</p> <p>Note: "Information messages" for this substance may give additional information on the 'Authorisation of the use of this substance'.</p> <p>The authorisation of the use of this substance is displayed by category of food contact materials (e.g. Plastics – monomer; Plastics – additive; etc).</p> <p><u>The authorised use of a substance is shown by means of the following fields:</u></p> <p>Individual restriction(s) SML: The specific migration limit applicable to the substance. It is expressed in mg of substance per kg food. In the</p>

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	<p>case that there is more than one SML, the applicability of the field Restrictions and specifications. If migration is not detectable, this is indicated with ND. If the specific migration limit is non-detectable (ND) a detection limit of 0.01 mg substance per kg food is applicable unless specified differently for an individual substance.</p> <p>Other types of individual restrictions: TDI, QMA, etc.</p> <p>Restrictions and Specifications This field contains other restrictions than the specific migration limit and specifications related to the substance. Other restrictions can be for example residual content of the substance in the final product, restriction of use to certain polymers or in contact with only certain types of food. It can restrict the use to only certain functions or behind a barrier layer. It contains only general specifications related to the substance such as properties as molecular weight, viscosity, etc.</p> <p>Group restriction(s) This field contains the identification number of the group of substances for which the group restriction applies. Group restrictions are listed in the webpage Group Restrictions.</p> <p>Biocide A substance can be authorised to be used as surface biocide, to be used as protection agent during production, not to be used as a biocide.</p> <p>In the section <i>General data</i>, the field "biocide" is meant to <i>inform</i> about the characteristics of the substance, and not about its authorised use.</p> <p>This substance is covered by the following indicates that the authorisation of the substance is covered by the authorisation of another substance. Then the FCM substance Number of the covering substance is displayed.</p>
<p>Webpage of a substance - Section Application for authorisation</p>	<p>The general procedure for authorisation of substances in food contact materials is laid down in Article 8 - 12 of the Framework Regulation (EC) No 1935/2004.</p> <p>The aim of the <i>Applications for authorisation</i> section is to give an overview of the applications for risk assessment and authorisation of substances to be used in one or more category/ies of food contact materials. The application procedures are ordered by date. The most recent one is at the top.</p> <p>This section informs you about:</p>

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	<p>1. the categories (and subcategories): the intended use of the application 2. the application reference nr. assigned by EFSA 3. the date of the application 5. the AAP decision (positive or negative) indicates if the applicant's dossier is administratively acceptable 6. the AAP date is the date when the AAP decision was taken 7. the status of application 8. the Legislative reference</p> <p>The procedure is finished when a legislative reference is mentioned or when the procedure status is "stopped". A link on the field "status of the application" opens a pop-up containing more information about the last step of the application procedure. Possible statuses are:</p> <p><u>- application received</u> <i>a new application was received.</i></p> <p><u>- application accepted / refused</u> If the AAP decision is positive, the application is accepted. If the AAP decision is negative, the application is refused and the procedure is stopped.</p> <p><u>- risk assessment ongoing</u> The risk assessment of the substance will be scheduled or is being discussed at one or more EFSA working group / Plenary meetings.</p> <p><u>- EFSA Opinion adopted</u> EFSA expresses its scientific opinion on the use of the substance in an EFSA Opinion list or EFSA Scientific Report. The pop-up shows the EFSA Opinion on this substance.</p> <p><u>- procedure completed</u> The application procedure was completed. The pop-up informs about the conclusions of the application procedure:</p> <ul style="list-style-type: none"> - a substance may be authorised - a substance may be forbidden to be used in one/more category/ies - in case of a re-evaluation, the authorised use may be modified - in case of a re-evaluation, the authorised use may be revoked - the authorised use may be corrected (corrigendum) - no decision on the authorisation of the use of the substance was taken

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	<p>△ Note: It is the date of entry into force of the legislation when the <i>Authorisation of the use of this substance</i> part " is updated. This happens in the following cases:</p> <ul style="list-style-type: none"> - the substance is authorised to be used in the selected category/ies or - the authorised use was modified as result of an re-evaluation - the substance is forbidden to be used in the selected category/ies <p><u>- procedure stopped</u> The reason why and when the procedure was stopped, is specified.</p>
<p>Webpage Categories</p>	<p>There are 17 categories of Food Contact Materials. A substance may be authorized to be used in one or more food contact material categories.</p> <p>Categories can contain sub-categories. A small plus icon appears next to categories which have their own hierarchy.</p> <p>Clicking on a particular category/subcategory will allow you to drill down on the data held on that particular grouping and show you which substances are linked to a particular category.</p> <p>Each node in the category structure is given a number to help identify it within the structure's hierarchy. This number is given in brackets after each category name.</p> <p>For example, Plastics(9) has two child elements Additive or polymer production aid (PPA) (9.1) and Monomer or other starting substance or macromolecule obtained from microbial fermentation (9.2). The first number inside the bracket indicates it belongs to the parent category (9) i.e. Plastics. The second number identifies its position as a child element within this structure.</p> <p>By selecting a category name, you can view the definition or description:</p> <p>△ Note: the category "additive" is defined as "Additive or polymer production aid (PPA)" and the category "monomer" is defined as "Monomer or other starting substance or macromolecule obtained from microbial fermentation" (9.2).</p>
<p>Webpage Group restrictions –</p>	<p>In order to facilitate your search for a particular group restriction or to search which group restriction(s) is/are applicable to a particular substance, you may specify one or more filters to limit your results:</p>

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Webpage and section	Description
section search group restriction	<ul style="list-style-type: none"> - the group restriction No - category - type of group restriction (SML(T); QMA(T); etc) - Substance No (to which GR(s) is applicable).
Webpage Group restrictions – section Results	<p>The results panel retrieves group restrictions based upon the filters added in the search criteria panel.</p> <p>When no filter is applied, <i>all</i> group restrictions are displayed:</p> <p>(1) group restrictions applicable to substances authorised to be used in food contact materials have the status "valid"</p> <p>(2) group restrictions applicable to substances not yet authorised to be used in food contact materials*</p> <p>* the status of those group restrictions is "draft". The status is "draft", when that version of the group restriction is not yet authorised or included in EU legislation. Draft versions of group restrictions are not visible to all users.</p> <p>The list can be ordered by:</p> <ul style="list-style-type: none"> - group restriction No - type of group restriction - restriction - group restriction specification <p>Clicking on the GR No link will allow you to view all information regarding the group restriction:</p> <ul style="list-style-type: none"> - type of group restriction - the group restriction specification - the substances to which the group restriction is applicable - the version/status of the group restriction

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Webpage and section	Description
Webpage of a group restriction – version	<p>This webpage gives the detailed information about the last version of a particular group restriction.</p> <ul style="list-style-type: none"> - type of group restriction - the group restriction specification - the substances to which the group restriction is applicable - the version/status of the group restriction <p>This version can have the status "draft" or "valid". The status is "draft", when that version of the group restriction is not yet authorised or included in EU legislation. Draft versions of group restrictions are not visible to all users.</p>
Webpage of a group restriction – history	<p>This section lists the history of a particular group restriction: current and previous versions are listed in reverse chronological order. Each time the information on a group restriction change (e.g. the restriction changes, or a substance is added to the group) a new version of the group restriction is created.</p> <p>Clicking on the GR No link will allow you to view the detailed information of that version of the group restriction. The previous versions are not visible to all actors.</p>
Webpage Legislation - Search Criteria	<p>The aim of this section is to provide a reference for existing legislation pertinent to Food Contact Materials. The following filters can be used to limit the results returned by your search:</p> <p>Category</p> <p>A grouping of substances used to classify substances used as Food Contact Materials. There are 17 groups of food contact materials. By selecting a category, you restrict your search action to the EU legislation applicable to that particular category of food contact materials.</p> <p>Legislation type</p> <p>Different legislation types are : Commission Decision, Commission Directive, Commission Regulation, Council Decision, Council Directive and Council Regulation.</p> <p>Legislative reference</p> <p>The Official European Commission Journal reference.</p> <p>Keyword title</p>

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Webpage and section	Description
	<p>A word or phrase from the title of the legislation is being searched.</p> <p>Repealed</p> <p>'Yes' indicates legislation that is no longer in effect because it has been removed or reversed. 'No' therefore assumes that the legislation is still effective.</p>
<p>Webpage Legislation - Search Results</p>	<p>The legislations are automatically ordered by legislative reference. It is also possible to order by Title, O.J.Ref., Publication date and Entry into force date.</p> <p>If you indicate "repealed" as yes, the search result shows the legislation repealed by another one and will be directly displayed next the 'repealing' legislation. In case the resulting list is spread over more than one page, it is possible to navigate to another page by using the select box with the page number or by the links 'next' and 'previous' at the bottom of each page list.</p> <p>Results for searches will return:</p> <p>Legislative Ref. the Legislative reference</p> <p>Title the title of the legislation</p> <p>O.J. Ref. the Official Journal reference</p> <p>Pubi. the date of publication</p> <p>Entry the date of entry into force</p> <p>Category/ies the Category/ies the legislation affects</p> <p>Within the column labelled 'title' a link button provides you with the possibility to review the legislative text in one of a number of typical formats.</p>
<p>Webpage Notes on verification of compliance - Search criteria and results</p>	<p>A note on verification of compliance appears in the part Authorised use of a substance (Webpage of a substance - Section Authorisation of the use of this substance in Food Contact Materials). In the part Authorised use of a substance, the note number refers to the detailed rules applicable for verification of compliance for this substance.</p> <p>This webpage contains the Notes numbers and the detailed rules applicable for verification of compliance for this substance.</p> <p>By means of the field Key word in the search panel, it is possible to search for a particular note.</p>
<p>Webpage Documents - Search Criteria</p>	<p>Different types of documents are available in the database. The results panel retrieves documents based upon the filters added in the search criteria panel.</p>

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Webpage and section	Description
	<p>Δ When no filter is applied, <i>all</i> documents in the database are listed by document type in alphabetical order.</p> <p>Documents can be searched by:</p> <p>Document type Users can choose from a number of options including: EFSA Opinion List, SCF Report, Legislation document, etc.</p> <p>File name Enter a full or partial file name to retrieve a list of matching documents.</p> <p>Version date By using the calendar control, users can pick a date corresponding to the version date (date a document was published)</p> <p>Reference A full or partial reference to the document reference.</p> <p>Keyword additional info Users can enter a word or phrase which could appear in the additional information field for the information held on the document: the reference to the application procedure, additional info on the subject, etc. Clicking on the filename will allow you to open the document. The access to the different types of documents depends on the actor's rights</p>
<p>Webpage Documents - Search Results</p>	<p>It is possible to sort the result by type of document, document reference, file name and version date. If the result of the search action is displayed on several pages, the sorting action is done for the complete list.</p>
<p>Webpage Reports</p>	<p>Reports provide for an effective way to present the data available in the system. Reports contain data extracted from the system following the criteria/filters applied, grouped, ordered and presented in a consistent way.</p> <p>The reports in the database have been grouped together by subject matter to help you find what you are looking for with more ease. In the <i>Get started</i> part on the homepage, you can find a help document explaining the content of the reports.</p>

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	<p>All reports are made available in PDF, Flashpaper, Microsoft Excel and Microsoft Word Formats.</p> <p>To launch a report click on the file format icon from the right hand side of the page which corresponds to the report you require.</p> <p>Depending upon the report you have selected you may or may not then be required to provide additional information (criteria) in order for the report to be created. If this is the case, a pop-up window will be displayed asking you to complete one or more additional fields which help to create the report specified.</p>