



PREPARATION MANUAL FOR PLASTIC PROCESSORS

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INSTRUCTIONS FOR COLLECTING DATA TO PREPARE THE IMPLEMENTATION OF REACH

This document aims to give you an idea of what REACH will mean for your company. The first thing you will have to do is to collect basic data (usually existing in your company), and put them together in this form. **These data will always remain in your company and nobody will retrieve or consult them.** The following exercise is only intended as a means of discovering where you stand in terms of REACH.

The form to be completed is an Excel spreadsheet in which you store the information required. In most cases, a list of relevant possibilities is provided. For each column you receive an indication as to what is expected from you as well as further explanations. You will also find some references to the related articles or annexes of the Regulation and you will be informed, as far as possible, about the possible impact of your input.

This document is based on the Council Common Position for the REACH Regulation of 12 June 2006 approved by the Council on 27 June 2006. It is obvious that the text will be further modified before EIF in 2007. It is nevertheless useful to do this exercise now instead of postponing it until the final version is released. This effort will have to be made anyway, regardless of any future modifications. Implementing REACH will require a large amount of preparatory work to be done by the industry as a whole. This should happen as soon as possible. Furthermore, this will give you the opportunity to further assess new proposals or amendments to the current proposal and thus will allow you to already pinpoint some possible problems. Once approved, this Regulation will directly enter into force in the whole European Community.

Take into account that your supplier has to do this exercise as well, for the substances that he buys and manufactures. He will probably not be able to come with a direct answer to some of your questions. Save therefore all your questions for the end.

You must complete one spreadsheet per legal entity within your company.

The spreadsheet also includes two empty columns for you to store any additional data that you deem relevant in your particular case.

Your comments and suggestions for improvement are always welcome. If you experience problems filling out this form, please do not hesitate to contact:

- The **EuPC Helpdesk**: Song-Lâ Ophaso (reach@eupc.org) or
- **Fedichem**: Erwin Annys (eannys@fedichem.be) for the French and Dutch versions.

PLASTIC PROCESSORS' PREPARATORY INVENTORY OF SUBSTANCES AND PREPARATIONS FOR REACH

This sheet is intended for anyone who purchases substances or preparations both from within and from outside the EU.

Note that if you are the importer of a substance or preparation into the EU you have obligations under REACH as if you were the manufacturer of that substance or preparation.

Cell A: Product

What: This is the name of the substance/preparation, its trade name or trivial name, in other words the name used within the company (e.g. ESBO for epoxydised soy bean oil, MEK for methylethylketon, etc.).

Cell B: SDS

What: This is the Safety Data Sheet that must be supplied to the professional user in any case if the substance or preparation is classified as dangerous (and in some other particular conditions). The SDS must be compiled in accordance with Directive 2001/58/EC, as it must be indicated on the sheet itself. After Entry Into Force (EIF) of the REACH Regulation the SDS must be prepared according to Annex II.

Where: This sheet shall be supplied to the professional user by the person (manufacturer, importer or distributor) responsible for placing a chemical substance or preparation on the market.

Why: This enables you to check whether you comply with the Directive. The SDS also allows you to see whether you know the composition of the substance or preparation (strictly speaking, the sheet must only indicate the hazardous substances) and mentions the intended uses.

Cell C: Substance/Preparation:

What: Is this a substance or a preparation? Article 3, §1 and 2, provides the following definitions:

- ‘Substance’: a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;
- ‘Preparation’: a mixture or solution composed of two or more substances.

Where: The answer to the above question is provided by the SDS, which contains the necessary information in order for you to make out whether it is a substance or a preparation. In the event of impurities being mentioned or if no safety data sheet being required, you will probably find more details on the technical data sheet.

Why: REACH deals with the registration of substances, which implies that some of the following columns are less important as far as preparations are concerned.

→ **Consequences:** Beware of preparations you are buying directly from a non-EU manufacturer. They may contain substances that are not registered in the EU.

Cell D: Composition of the preparation

What: Is the composition known? Do you know the components (name and/or CAS and/or EINECS/ELINCS numbers)? It is important to know the quantity of each substance, if it is used in several preparations, and if it is originated from outside the EU.

Where: You may find the data of interest in the safety data sheet or in the technical information given by your supplier.

Why: If you import preparations from outside the EU, you should know their components and check whether all components are registered. If you buy preparations in the EU, knowing their composition allows you to see whether there is any substance subject to authorisation in it.

Cell E: Chemical Name

What: This is the exact chemical name as given in the IUPAC (International Union of Pure and Applied Chemistry) nomenclature. Such name does not exist for preparations, except for a number of specific cases. As regards preparations, you should write “does not apply”.

Where: This name is indicated on the SDS.

Why: The chemical name according to the IUPAC nomenclature is required for the registration of substances.

Cell F: CAS Number

What: This is the Chemical Abstract Service number, i.e. a single number allocated to a substance that allows you to obtain a vast amount of information on this substance, within the framework of the largest and most used database in the world, including all substances mentioned in the scientific literature since 1957.

You can often find the CAS number on the SDS.

The website of the European Chemicals Bureau (ECB) offers you the possibility to link the name of the substance with the CAS and EINECS numbers:

<http://ecb.jrc.it/esis/esis.php?PGM=ein&DEPUIS=autre>

You can search by the chemical name or by one of the two numbers in order to find the other one. You must, however, know the name in English, French, Spanish or German.

Cell G: EINECS/ELINCS Numbers

What: EINECS stands for European INventory of Existing Commercial chemical Substances. This is a list of all substances placed on the European market between 1 January 1971 and 1 January 1981, which are called phase-in substances. Article 23 informs when the phase-in substance has to be registered according to annual tonnage. EINECS numbers begin with a 2 or 3.

ELINCS stands for European List of Notified Chemical Substances. This is a list of the new chemical substances (described by Directives 79/831/EC and 92/32/EC), i.e. substances to which the Regulation shall directly apply.

Where: The EINECS/ELINCS number can sometimes be found on the SDS.

The website of the ECB offers you the possibility to link the name of the substance with the CAS and EINECS numbers:

<http://ecb.jrc.it/esis/esis.php?PGM=ein&DEPUIIS=autre>

Cell H: Identified use

What: Define the use(s) of the substance/preparation. You should list the uses in the most general terms. If you have a non-standard use this should certainly be specified.

Why: Under REACH your use(s) of the substance/preparation must be covered by your supplier in his Chemical Safety Report (CSR). If it is not the case, you must make your use(s) known to your supplier in writing as soon as the pre-registration phase of REACH starts (between 12 and 18 months after the EIF of REACH). If for confidentiality reasons (see cell I below) you do not wish to identify your use, you will have to perform the Chemical Safety Assessment (CSA) yourself, consign it in a CSR, and notify the Chemical Agency.

→ **Consequence:** If you specify a non-standard use you should be prepared to provide your supplier with all necessary information for him to prepare an Exposure Scenario (ES).

Cell I: Confidentiality

What: Do you want to keep the use of the substance/preparation confidential and not to share it with your supplier and therefore his customers?

Why: If so, do you accordingly choose to be responsible for the CSA?

→ **Consequence:** You will have to perform the CSA yourself, consign it in a CSR, and notify the Chemical Agency.

Cell J: Alternatives

What: Are there any alternatives available on the European market or outside the EU? An alternative can be:

- **Another substance:** If the substance is subject to authorisation, can another substance be used within the specific product or process that is not subject to authorisation?
- **Another process** in which the substance is no longer needed.

Why: It is necessary to know whether there are products or processes using substances and/or preparations that are not subject to authorisation because the risk of a negative impact, possibly the disappearance from the market, is higher when a product is subject to authorisation.

→ **Consequence:** The lack of alternatives and the resulting disappearance from the market will pose the problem of replacement.

Cell K: Critical

What: Is this a key component – from a technical or economic point of view – which can hardly, if at all, be replaced? If there are no alternatives, the substance must be considered as critical.

Why: Critical substances should receive due attention as a matter of priority because possible restrictions or disappearance from the market jeopardise the survival of your product.

Cell L: Annual Tonnage

What: What quantity do you use per year, per legal entity?

Why: Thresholds for preparing a CSR are 10 tonnes in case of registration and 1 tonne if the use is not supported by the supplier.

Cell M: Suppliers

What: Who are your suppliers? You can provide a list, give your suppliers' number or refer to any other document.

Why: The REACH approach focuses on increasing the communication between suppliers and customers. The exchange of information, in particular about the use of the substance/preparation, is essential.

Cell N: EU sourcing

What: Do you buy these substances and/or preparations directly from a supplier within or outside the EU or both?

Why: You will be subject to registration if you buy directly outside the EU. Besides, non-EU suppliers cannot register themselves and may fail to provide the necessary information about the uses of the substance/preparation.

→ **Consequence:** The non-EU manufacturer has the possibility to appoint an 'only representative' to perform the registration in his place. If he has not done so, you are considered as the importer and as a result, you must take care of the registration yourself.

Cell O: Subject to Authorisation

What: Article 56 provides that following substances can be included in Annex XIV, the list of substances falling under authorisation:

- Carcinogenic category 1 and 2;
- Mutagenic category 1 and 2;
- Toxic for reproduction category 1 and 2;
- Persistent, bio accumulative and toxic;
- Very persistent and very bio accumulative;
- Having endocrine disrupting properties.

Where: The first three categories are the CMRs (Carcinogenic and Mutagenic for Reproduction), which are already mentioned on the SDS. For the other three categories your supplier will be able to provide you with the exact classification after his own registration and evaluation. These substances will be subject to the authorisation procedure.

Why: The purpose of REACH is to ensure that the risks posed by these substances of very high concern are adequately controlled. These substances can however only be used after a complex authorisation procedure.

Reference: Please refer to Articles 56 and 65.

→**Consequence:** If a substance is not authorized, it will disappear from the market. If it is authorized, it may be subject to restrictions.

As a downstream user, you have to notify the European Chemicals Agency of your use of such substance under the authorised conditions (Article 65).

Cell P: Comments

What: Please feel free to write any relevant comment.

LIST OF ACRONYMS

Acronym	Definition
CAS	Chemical Abstract Service
CMR	Carcinogenic and Mutagenic for Reproduction
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
ECB	European Chemical Bureau
EIF	Entry Into Force
EINECS	European INventory of Existing Commercial chemical Substances
ELINCS	European List of Notified Chemical Substances
ES	Exposure Scenario
IUPAC	International Union of Pure and Applied Chemistry
SDS	Safety Data Sheet