EUROPEAN TYRE & RUBBER manufacturers' association

# REACH
# Rubber Industry
# Frequently Asked Questions

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This document should not be used as a substitute for the applicable rules as defined in the regulation (CE) N° 1907/2006.

Some answers can also be found in consulting the following documents:

- ECHA FAQ : Frequently asked questions on REACH by Industry
  http://ec.europa.eu/echa/reach/faq_en.html

- DG Environment - European Commission FAQ : Questions and Answer on REACH
  http://ec.europa.eu/environment/chemicals/reach/publications_en.htm

# List of Frequently Asked Questions

# 1 REGISTRATION

## 1.1. A substance not yet registered for use in rubber processing is now used in the rubber manufacturing process. What has to be done at the DU level?

In any case, the registration has to be done by the supplier, while the downstream user will have to provide information on the "new" use the registration has to be extended for.

According to Art. 28 (Paragraph 6), potential registrants who, after 1st December 2008, manufacture/import for the fist time a phase-in substance, if the submission to the agency is in accordance with specific deadlines (See mentioned article for details), they can benefit from the special provisions (Art. 23) as pre-registered substances.

## 1.2. A substance not yet registered for use in rubber industry is now used in the rubber manufacturing process. What has to be done at the supplier's level?

In case the supplier has already registered the substance but the not for a specific use (fodetail see user indictors system described in RIP 3.2-2 ) the registration dossier need to be updated in order to include the new use.

Where the manufacturer, importer or downstream user, is unable to include it as an identified use for reasons of protection of human health or the environment, he shall provide the Agency and the downstream user with the reason(s) for that decision in writing without delay (article 37.3).

## 1.3. What is the implication for a registrant, when the production / import volume of a substance exceeds / falls below the volume threshold as determined by Article 3 No 30, Article 23?

In this case re-registration has to be done with the requirements associated with new volume. It has to be remembered that the registration is dynamic and it will need to be updated in the future if there is a change in any of the following: manner of use of a substance, changes in exposure scenario, new hazard or risk information, volume class or other aspect that may influence the assessment previously determined for the purpose of registration.

The extended deadlines, from which it is possible to benefit in case of pre-registration, will vary according with the new volume.

## 1.4. What happens, when a registrant decides not to register (in 2018 at the latest)?

Substances which are not registered will no longer be available on the EU market ("No data, no market" principle - article 5) so It will not be possible to manufacture or import the substance until the registration will be completed. In particular, according to REACH:

- a substance cannot be put on the market if not registered by its EU manufacturers or importer.
- Import will not be possible, because it is considered as putting on the market per definition.
- Manufacturing for outside EU markets is permitted.

### 1.5. Is the registration number required for all substances produced / imported from Jan.1st 2009 on?

No, the registration number will be available when the individual registration procedure is finalized. At the latest:

- **1st December 2010 if**
  - > 1000 tonne/year or
  - > 100 tonne/year if classified under CHIP (Hazard Information and Packaging for Supply) as very toxic to aquatic organisms
  - > 1 tonne/year if classified under CHIP (Hazard Information and Packaging for Supply) as Cat 1 or 2 CMR
- **1st June 2013 if**
  - >100 tonne/year
- **1st June 2018 if**
  - >1 tonne/year

With the pre-registration the potential registrant gets a pre-registration no. for the substance. DU should ask their suppliers reporting the pre-registration no. to them, because that is the evidence for entering the registration process.

# 2 INFORMATION AND COMMUNICATION

### 2.1. What are the requirements for preparing the SDS?

The Safety Data Sheet has to be provided in case dangerous substances of preparations are placed on the market. Specifically for the rubber industry, this situation correspond to the case in which rubber preparations are shipped to third parties.

Specific indication of the content of the safety Data Sheet are described in Annex II (Guide to the compilation of safety data sheets) of the REACH regulation.

- The SDS will be supplied in the official language of the Member State where the substance or preparation is placed on the market.
- A SDS will be provided free of charge on paper or electronically.

- If a Chemical Safety Assessment (CSA) has been performed for a chemical substance or a preparation, the information in the SDS has to be consistent with the information from the CSA.
- The exposure scenarios relevant to the CSA of the substance or preparation will come in an annex to the SDS together with the uses of the chemical substance or preparation.
- Any downstream user shall include relevant exposure scenarios and other relevant information when preparing its own SDS to make known to its supplier the use of the chemical substance or preparation, so that this information will be used by the supplier to perform a CSA.

## 2.2. What is the DU required to do if he does not want to disclose the information relating to use of a substance(s) to his supplier?

You may be concerned that providing information to suppliers may risk the loss of confidential process information. There are a number of ways to overcome this problem:

- Use a general description of conditions of use and risk management measures in your sector; or
- Prepare an own chemical safety report (Art. 37.4). This requires considerable effort, so it is advisable to contact suppliers at an early stage to determine whether or not it is likely to be necessary.

## 2.3. What level of details do we need to communicate to our suppliers concerning the uses of chemicals?

According to Art. 14 (1907/2006/EC), only for the following substances exposure scenario and risk characterization are required:

- Substances that meet the criteria for classification as dangerous (67/548/EC)
- Substances assessed to be PBT or vPvB

In making a use known, the user shall provide sufficient information to allow the manufacturer, importer or downstream user who has supplied the substance, to prepare an exposure scenario.

If your supplier considers that your information is not sufficient he may not include your use in the registration dossier and therefore he will not be allowed to put the substance on the market for your use.

## 2.4. According to article 33, the producer or importer shall supply appropriate instructions to the recipient of the article": what do we mean by "appropriate

**instructions" (which instructions do we need to communicate to the recipient of the article - examples)?**

According to Art. 33, any supplier of an article (producer, importer, distributor) containing a substance subject to authorization in a concentration above 0,1 % weight by weight (w/w) must provide :

- To the article's end user (industrial or professional user): the sufficient information, available to the supplier, to allow safe use of the article. The minimum information is the name of that substances.
- To the consumer who asks for it: sufficient information, available to the supplier, to allow safe use of the article. The minimum information is the name of that substance. The relevant information shall be provided, free of charge, within 45 days of receipt of the request.

### 2.5. What information do I have to include in the Registration dossier?

The information to be submitted in the Registration dossier, described in detail in Annex VI, includes:

- General registrant information;
- Identification of the substance;
- Information on manufacture and use(s) of the substance(s)
- Classification and labelling;
- Guidance on safe use;
- Information on exposure for substances registered

Other specific information required will depend on the tonnage (see Art. 12 for details).

### 2.6. An accelerator masterbatch manufacturer produce a blend containing accelerator, rubber and a filler. Who has the duty to register, the masterbatch substances supplier or the master batch producer?

The supplier (manufacturer or importer of the chemicals). The registration has to be done by the one who first puts the substance(s) on the market. If masterbatch manufacturers do not produce or import the substances they use, they are considered as downstream users.

## 3 SUBSTANCES, IMPURITIES AND INTERMEDIATES

### 3.1. Can a compound or a substance in a rubber mixture be considered an intermediate (less registration data would be required)?

According to Article 3 (Paragraph 15) Intermediate refers to any substance. Therefore:

- the definition of intermediate applies to substances and not to a compound; and
- in order to be considered an intermediate, the substance has to be manufactured for and consumed in or used for chemical processing in order to be transformed into another substance.

An intermediate of any kind is related to be processed in a facility of the manufacturer with two clearly defined exceptions:

- The substance is always remaining in the manufacturer's responsibility;
- Any substance released from the manufacturer's sphere of responsibility to a third party (put on the market) has to undergo the full registration procedure.

### 3.2. A substance or substances in preparations may be accompanied by impurities. Within the 80%/20% ratio, impurities are not subject to registration. Is that also the case even if the impurity is toxic?

Yes, it is also the case for toxic impurities.

### 3.3. Substances in articles that are intended to be released: Will substances such as anti ageing agents and sun blockers be considered as intended to be released?

Tyres do not contain substances "intended to be released".
In particular, the intention of aging protecting substances, such as antioxidants for instance, may be to migrate to the surface but NOT TO BE RELEASED. This is even more evident if we think that their function will be completely lost in the moment they leave the article (an opposite example is fragrances, which are explicitly added to be released during the service life of articles).

Possible release is different from "intended release". See for instance the case of release of tyre particles during tyre's service life (Page 68 of ECHA guidance, where also additional clarifications may be found):

*"A release is not considered to be an intended release"* if the release *"is an unavoidable side-effect of the functioning of the article. Without the release, the article would not work, but the release is not directly intended. Examples: wear and tear of materials under conditions with high friction, e.g. break linings, tyres."*

### 3.4. Rubber compounds are treated with anti tacking agents, some of which are classified as R50/53. Are the anti tacking materials an ingredient of the compound?

Yes, it is. They need to be registered if they exceed the 1 ton/year threshold.

### 3.5. Does a GRG manufacturers need to register a substance produced during the process (vulcanization for instance)?

No. This substance is not placed on the market.
But it would be opportune to take this topic into account in the CSA of the original substances.

### 3.6. How can I identify substances which may be included in the annex XIV, in particular those likely to be PBT or vPvB?

The criteria used to define which substances will be subject to authorization are clearly defined in article 57 :

- As for CMR 1 & 2, the criteria are established in accordance with the directive CE/67/548) ;
- As for PBT and vPvB substances, the criteria are included in REACH Annex XIII ;
- As for any other substances, there must be scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to CMR 1&2 or PBT, vPvB.

Except for substances already classified (CMR, PBT, vPvB), at the moment it is only possible to determine which substances will be included through examination of the criteria described in Art. 57.

According to Article 58, the Agency shall make its first recommendation of priority substances to be included in Annex XIV by 1 June 2009. The Agency shall make further recommendations at least every second year with a view to including further substances in Annex XIV.

Prior to a decision to include substances in Annex XIV, the Agency shall, taking into account the opinion of the Member State Committee, recommend priority substances to be included specifying for each substance the items set out in paragraph 1. Priority shall normally be given to substances with:

- PBTor vPvB properties; or
- wide dispersive use; or
- high volumes.

### 3.7. How is the term "substance is intended to be released under normal or reasonably foreseeable conditions of use" applied in the case of tyres during use ?

The release requirements relate to substances that are intended to be released during the service life of the articles. A release of substances from articles is intended when:

- the release is essential for the end use of function of the article or vice versa, without the release of the substances, the article would not work sufficiently (e.g.: felt tip pen containing ink)
- the release contributes to a quality or minor function of the article, or, in other words the, release contributes to an "added value" of the article, which is not directly connected to the end use function (e.g.: perfume candle)

A release is not considered to be an intended release in case of release of substances formed during chemical reactions (e.g.: Release of substances from articles catching fire and ozone released from copy machine).

More detailed examples and criteria are available in the guidance RIP 3.8.

**In the case of tyres there are no substances that are "intended to be released."**

### 3.8. How do we consider a substance which appears during a process, for example vulcanisation.

By-products, which are secondary or incidental products arising during a manufacturing process or as a result of a chemical reaction do not need to be registered (Annex V) but they have to be considered in the exposure scenario(s), and thus will be part of the Chemical Safety Assessment/Report (CSA, CSR).

### 3.9. If the rubber mixture is considered dangerous according to 1999/45/CE and so on, does the tyre manufacturer have to supply to every customer the Safety Data sheets of each substance contained in the blend?

No. The DU has to provide a new SDS for the preparation.

The supplier of a substance or preparation must provide the user of the substance or preparation with an SDS in a greater number situations than in the past (article 31):

(a) where a substance or preparation meets the criteria for classification as dangerous in accordance with Directives 67/548/EEC or 1999/45/EC; or

(b) where a substance is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII; or

(c) where a substance is included in the list of substances that are candidates for authorisation.

Safety Data Sheets are not required for dangerous substances in articles because this is covered in article 33.

For more detail and exemptions see Art. 31 and annex II.

### 3.10. For a substance which contains 10 % impurity(ies): do I have a duty to register both substance and impurity/ies?

No, according to RIP 3.10, in order to consider a substance as mono-constituent, it may contain up to 20% (w/w) of impurities.

The guidance for identification and naming of substances under REACH (RIP 3.10) explicitly mentions that:

> *impurities do not contribute to the naming of the substance and need only to be specified by name, CAS-number and EC-number and/or molecular formula.*

Therefore, impurities do not need to be registered, but only mentioned in the substance identification parameters, according to REACH Annex VI item 2 (degree of impurity, nature of impurity, etc…).

### 3.11. Would the Registration for a substance having a 10 % impurity be different from that having a different impurity level?

If the amount of impurity is less than 20% (w/w), the only difference will be in the substance identification parameter (description of the degree of impurities).

Registrants of the same substance with different level of impurities will be part of the same SIEF.

# 4 DOWNSTREAM USERS

### 4.1. What are the new obligations for a downstream users from 1st of June 2008 ?

The most important elements of REACH for DU are set out in Title V of REACH (articles 37-39). (http://ecb.jrc.it/documents/REACH/RIP_FINAL_REPORTS/RIP_3.5_DOWNSTREAM_USERS_REQUIREMENTS/RIP_3.5-2_DOWNSTREAM_USERS_REQUIREMENTS/DU_2_roles_and_obligations.pdf):

1. If you use dangerous substances and preparations, you will still receive **safety data sheets**, which under REACH may have one or more exposure scenarios attached. If you receive an exposure scenario, you must check whether your current use is covered and whether you comply with the conditions described in that exposure scenario.
   If you use a substance or preparation **outside the conditions described in the exposure scenario**, or if your use is not covered by the exposure scenario, you have several options :
   - you may make your use/use conditions known to your supplier so that the supplier can prepare an exposure scenario covering your use conditions
   - you may change your conditions of use so they comply with the supplier's exposure scenario,
   - you may find another supplier who provides an exposure scenario covering your conditions of use,
   - you may prepare your own chemical safety report1 , or
   - you can find an alternative substance, preparation or process and stop using the substance/preparation in question.

2. If you **place dangerous preparations on the market** (formulator) you will still have to provide safety data sheets to your customers. According to Art. 31 of REACH, consolidation or development of exposure scenarios may be required. The exposure scenarios have to cover uses of substances in preparations further down the supply chain and need to be attached to the safety data sheet (article 31 of REACH).

   A SDS has to be provided in any case, when the customer is asking to receive one. Furthermore the SDS has to be provided when shipping to a third party, e.i. any legal entity inside a company.

3. **Communication along the supply chain** on the use of substances and preparations **will significantly increase under REACH**:
   REACH increases the extent of information to be communicated to you by your suppliers to enable you to use chemicals safely. In addition, REACH requires you to communicate new information you may have on hazards and possible inadequacy of recommended risk management measures to your suppliers.
   You may initiate communication upstream and downstream, e.g. when pro-actively identifying your uses to a supplier, or collecting information on customers uses.
   You may also be asked to forward information, e.g. upstream when a customer has new information on substance properties or downstream when registrants seek information on the end-use of their substances.

4. **The use of some substances may be subject to an authorisation** requirement. This will be indicated by your supplier, usually in the safety data sheet. You may use the

substance provided that the use is in accordance with the conditions of an authorisation granted to an actor up his supply chain. If your use is not covered by such an authorisation, and you want to continue this use, you will have to apply for an authorisation for your own use and, if relevant, for your customers" uses (article 56 of REACH).

5. **Some substances may be subject to restrictions** on their use, placing on the market or to bans (article 67 of REACH). Restrictions that were in place under the Marketing & Use Directive (76/769/EEC) are carried over in REACH.

6. If you **produce or import articles** you may have to register substances which are intended to be released from the articles. This is not required if that use of the substance is already covered by another registration. If the article contains above 0.1% (w/w) of certain substances of high concern, you may have to notify the Agency and inform your customers on safe use of the article, depending on the quantity of the substance used and whether exposure can be excluded (article 7 and 33 (1) of REACH). Consumers of articles can also request information about these substances2 (article 33 (2) of REACH).

### 4.2. An accelerator master batch manufacturer produces a blend containing accelerator, rubber and a filler. Summarizing, from the point of view of the masterbatch manufacturer: which are their duties?

The supplier of substances has the duty to register them before placing them on the market. The master batch producers, in case they do not produce the substances themselves, are considered as DU and therefore may be asked to supply their suppliers with information concerning the use of the substances and, if necessary, exposure scenarios.

All details are contained in Articles 37-39. Information needs to be delivered also down the supply chain in order to address risks associate with the use of the master batches.

### 4.3. Reach and Transportation: is going to be applied in rubber blends transportation?

REACH doesn't change the regulation of the transportation. Transport information has to be included in the Safety Data Sheet (heading 14).
Any special precautions which a user needs to be aware of or needs to comply with in connection with transport or conveyance either within or outside his premises have to be indicated. Where relevant, information on the transport classification for each of the modal regulations have to be provided: IMDG (sea), ADR (Council Directive 94/55/EC of 21 November 1994 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road1), RID (Council Directive 96/49/EC of 23 July 1996 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail2), ICAO/IATA (air).

This information might include inter alia:

- UN number,
- class,
- proper shipping name,
- packing group,
- marine pollutant,
- other applicable information.

# 5 EXPOSURE SCENARIO AND CHEMICAL SAFETY ASSESSMENT

## 5.1. CSA for rubber blends. Substance producers ask if they have the duty to carry out the CSA of their substances in the rubber blends and how.

In accordance with Art. 14, a chemical safety assessment shall be performed and a chemical safety report completed for all substances subject to registration in quantities of 10 tonnes or more per year per registrant.

In certain cases, in which the concentration of the substance in the preparation is low, the chemical safety assessment does not need not be performed (for more details see Art. 14(2).

The CSA is a part of the registration procedure, which must be performed by the manufacturer, or the importer of a substance.

If the substance is classified as dangerous or is PBT or vPvB, then an exposure assessment and risk characterization shall be performed to demonstrate that the risks are adequately controlled. This exposure assessment is done using exposure scenarios for each use of the substance and during its entire life cycle.

## 5.2. An accelerator master batch manufacturer produces a blend containing accelerator, rubber and a filler. Are special exposure scenarios for master batches needed?

Exposure scenarios need to be developed according to the particular uses along the entire supply chain.

An exposure scenario is a set of conditions that describe how a substance (as such, in a preparation or in an article) is manufactured or used during its life-cycle and how the manufacturer or importer or downstream user controls or recommends controlling exposure of humans and the environment.

Exposure scenarios must be prepared when a substance is manufactured or imported in quantities of 10 tonnes per year and above and classified as dangerous or as PBT/vPvB (article 14.4).

In addition, all life-cycle stages resulting from the identified uses of the substance shall be covered by the assessment, including for example the ‘use’ of a masterbatch containing the substance as well as the waste stage.

# 6 IMPORT OF ARTICLES AND PREPARATIONS

## 6.1. If I'm importer of articles or preparations, do I have the duty to perform the registration of the substances contained in the article or preparation?

If no only representatives are appointed, the importers of the substance/preparation/ article are responsible for carrying out registration procedures in the following cases:

- they import a substance on its own or in preparation in quantities of 1 tonne and above per year and per importer (article 6) ;
- they import an article **releasing a substance intentionally** (this is not the case for tyres) and the latter is present in the article in quantities of 1 tonne and above per year and per importer (article 7).

A notification may be required according with the following flow chart.
Following a notification, a registration could be asked following a decision of ECHA.