

## Who is responsible for the supply of a SDS in case of an OR?

### Introduction:

Article 8 is not very clear with regards to the obligations of an Only Representative (OR) regarding the preparation and provision of Safety Data Sheets. A common understanding of such obligations is necessary.

Cefic understands that this is under legal analysis by the European Commission; however, the recently published guidance on SDS states that the responsibility of preparing the SDS falls on the OR. Cefic would like to bring this issue to the attention of the Forum.

### Explanation:

Both the legal text and the ECHA guidance on registration are not very clear on this topic, hence interpretative tools shall be used. The following questions need to be answered:

- *What is meant by “The OR shall keep available information on the supply of the latest update of the safety data sheet referred to in Article 31”?*
- *Is the OR responsible for compiling a SDS according to Annex II for substances subject to Article 31?*
- *Is the OR part of the supply chain?*
- *Who is accountable for the content of a SDS according to Article 31?*

Cefic has analysed these questions and tried to find a suitable interpretation for companies involved in supply chains with ORs. The conclusions are the following:

- the OR does not have the obligation to provide the SDS, but he shall only keep track of the communication on the supply of the latest update of the SDS
- the OR needs to have a copy of the latest version of the SDS for enforcement purposes and shall also have information when and to whom the SDS was sent
- the importer can be considered as supplier of the substance, which means that he is responsible for providing an SDS to his recipient.
- it is up to the non-EU manufacturer (the legal owner of the substance) to decide by contractual agreement, if he wants to outsource the compilation of the SDS to the OR.
- in case of mixtures the OR cannot be held responsible for the compilation of the SDS for the mixture. The non-EU formulator of mixtures containing multiple substances with different ORs should ensure that he receives the relevant information from the registration dossiers from each OR for each substance included in his mixture. The non-EU formulator should supply the EU REACH compliant SDS for the mixture to the EU importer.
- The non-EU formulator should provide the OR with the evidence- by appropriate action - that the SDS for the mixture was sent to the EU importer.

### Background document:

Cefic position on OR&SDS:



Final Cefic paper on  
ORs and SDS\_280610

