

**GUIDANCE ON COMPLETION OF THE IUCLID 5 DOSSIER:
IRON [EINECS number 231-096-4, CAS number 7439-89-6]**

as elemental iron in massive form and in powder form

**SUPPLEMENT TO
GUIDANCE DOCUMENT ON COMPLETION OF CHAPTERS 1 & 3
OF THE IUCLID 5 DOSSIER**

INTRODUCTION

This document is intended to address some issues not covered by our guidance document on elemental iron.

SECTION 3.5: IDENTIFIED USES

Some uses have been left out in the Lead Registrant's dossier. It is therefore the Lead Registrant's intention to update the iron dossier as soon as possible in 2011 at which time section 3.5 will be updated with the addition of these missing uses. In the meantime, we advise member registrants to edit section 3.5 of their own dossiers and add the relevant uses [please advise us of any uses added so that the Lead Registrant can update its dossier accordingly].

SECTION 11: GUIDANCE FOR SAFE USE

The Lead Registrant's dossier does not include Guidance for Safe Use for elemental iron in this section. Our suggestion for manufacturers or importers of alloys [mixtures] and articles containing elemental iron is as follows:

we suggest that you create a new end point for your alloy [mixture] or article in Section 11 and fill it in with your own information for your alloy [mixture] or article - do not tick the box indicating that the LR has submitted GSU. You can include appropriate risk management measures in your CSR part A and submit a separate Part A - there is an ECHA guidance document on this:

http://www.iron-consortium.org/assets/files/ECHA/ECHA%20-%20dsm_19_how_joint_csr_en.pdf

CHEMICAL SAFETY REPORT

Part B of the Chemical Safety Report submitted by the Lead Registrant does not include any manufacturing process information in section 2.1. This issue will be reviewed at the time that the Lead Registrant dossier is updated in 2011. In the meantime, member registrants who are manufacturers should rely on the information provided in section 3.1 of the IUCLID dossier [Technological process] - a new block should be added in which the technological process for manufacture of the alloy [mixture] or article can be described. Importers and Only Representatives do not need to complete section 3.1.

The Lead Registrant submitted a joint Part A of the Chemical Safety Report which does not include Risk Management measures specifically for elemental iron in section 1. Our suggestion is that manufacturers and importers of alloys [mixtures] and articles containing elemental iron create a separate Part A and include their own Risk Management Measures for their alloy [mixture] or article [see preceding section of this document].

For Importers and Only Representatives we suggest the following for Part A of the Chemical Safety Report:

Importers

2: DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED:

As an importer, the registrant declares that the risk management measures referred to in section 1 are implemented during own handling and use of the substance in the EU.

3: DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED:

As an importer, the registrant declares that the risk management measures referred to in section 1 are communicated to customers when they are relevant for their uses.

Only Representatives

2: DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED:

As Only Representative the registrant declares that the Risk Management Measures referred to in section 1 are communicated to the non EU Company that is represented.

3: DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED:

As Only Representative the registrant declares that the Risk Management Measures referred to in section 1 are communicated to all customers, when they are relevant for their uses.

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