

REACH Authorisation process Nickel and Nickel compounds

February 2011

1. Introduction:

1.1. Authorisation

The REACH Regulation has introduced a new approach to chemicals management within the EU which is already having a significant impact on businesses as they prepare to meet the regulatory deadlines for registration of their important substances. Equally, the Regulation is being deployed to restrict the uses of certain substances and also list for possible Authorisation a range of substances which, by virtue of the criteria set out in Article 57 of REACH, are deemed to be Substances of Very High Concern (SVHCs).

The approach of the regulators (European Chemicals Agency - ECHA and the competent authorities of the Member States) to the REACH listing and Authorisation requirements of REACH has been marked thus far by caution as they explore ways to list and propose for Authorisation on the basis of sound scientific evidence and data. However, they are under considerable pressure from Non-Governmental Organisations (NGOs) and the European Parliament to list more quickly and to develop a large "Candidate List" of substances so as to "drive substitution of hazardous substances". The Commission and ECHA have responded to this pressure with a commitment to have 135 substances on the "Candidate List" for possible Authorisation by the end of 2012.

To achieve this target, it appears that there is an increasing focus on targeting CMR¹ 1A, 1B substances rather than the implied focus of REACH on PBT² and vPvB³ substances due to the relative ease of listing of CMR 1A and 1B in dossier development terms over PBT and vPvB substances. Indeed, 76% of the current "Candidate List" is now composed of CMR 1A and 1B substances (http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp).

All metals and metal compounds are covered by the REACH Regulation. With respect to listing and Authorisation, all metals and metal compounds which are considered as being "Substances of Very High Concern" (SVHC) can be proposed by Member State authorities for inclusion into the "Candidate List" and a following Authorisation. Some 50% of the "Candidate List" comprises metal compounds.

1.2. Status of the Registration of nickel and nickel compounds

The Nickel REACH Consortia, managed by the Nickel Institute, prepared the registration dossiers of nickel metal and twelve nickel compounds (see Annex I). They were successfully registered by December 2010. Overall some 36 nickel containing substances have been registered (see Annex I) by December 2010 including several multi-constituents substances (MCS).

¹ CMR: Carcinogen Mutagens Reprotox

² PBT: Persistent, Bio-accumulative and Toxic.

³ vPvB: very Persistent very Bio-accumulative

1.3. The 1st ATP⁴ to the CLP Regulation and registration of nickel compounds

According to the 1st ATP⁵ to the Classification Labelling and Packaging Regulation (CLP), some 118 nickel compounds should have been registered by the 2010 registration deadline (all of them are CMR 1A and 1B). In fact, at this time, only 22 of the nickel substances listed in the 1st ATP have been registered. This suggests the remaining substances are: i) not on the market at all in the EU; ii) will not be supplied into the European market; or iii) have been withdrawn altogether.

2. Nickel and nickel compounds - Authorisation

As mentioned above, *circa* 100 nickel compounds are classified as CMR 1A and 1B under the 1st ATP of the new CLP Regulation and thus meet one of the criteria for consideration as SVHC.

Already, various NGOs, ETUC⁶, and end use sectors have developed or are developing “lists” of substances of concern based on known or implied hazard classifications – in effect anticipating the official Authorisation process. We would like to draw your attention to the current status of these different co-existing lists: those generated under the legal framework of REACH (“Candidate List” and the Annex XIV) and those drafted by NGOs and DUs sectors.

2.1. “Candidate List” and Annex XIV or “Priority List”

Only nickel compounds corresponding to the criteria of SVHC could be listed on the “Candidate List”. Nickel metal’s current hazard classification does not meet the criteria for consideration as an SVHC and therefore it cannot be listed on the “Candidate List” and is not liable for Authorisation.

With respect to nickel compounds, although they do meet the CMR 1A and 1B criterion, **none of them has been listed on the “Candidate List”** and therefore, *de facto*, none of them are included in Annex XIV. The latter means that so far no use of nickel compounds needs to seek for an Authorisation.

Nevertheless, due to the classification of some nickel compounds, there is a high risk that some of them will be selected by a Member State. Therefore, the Nickel Institute is closely monitoring the situation and developments and is responding to the Authorisation challenge through several initiatives intended to ensure an effective and efficient response and also to make downstream use sectors more aware of the implications of REACH Authorisation for their businesses.

2.2. NGOs and DUs lists

The Nickel Institute is aware that the REACH Authorisation process and the development of the “Candidate List” of SVHC step in particular have spawned parallel efforts by different groups (for example the ETUC or NGO SIN⁷ lists) and also downstream use and end use sectors. These lists are based entirely on hazard characteristics of substances (including non-CMR classification). They do not take account of exposure, current risk management nor the fact that in many industrial situations where they are used, the substances are regulated by existing EU legislation.

⁴ 1st ATP: First Adaptation to Technical Progress

⁵ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:235:0001:0439:en:PDF>

⁶ ETUC: European Trade Union Confederation

⁷ SIN: Substitute It Now

Nickel substances including nickel metal are often included in these lists. However, it is important to remember that only the “Candidate List” has any legal or regulatory significance. Further, being placed on the “Candidate List” under the REACH Regulation is neither a ban nor a restriction. The placing on the “Candidate List” of a substance is designed as a first step in subjecting that substance to robust and detailed scientific evaluation of risk and the definition, eventually, of a basis for its continued use (Authorisation) or substitution if suitable and technically feasible alternatives to that substance exist.

The ETUC and SIN lists are currently not consistent with respect to nickel substances on the EU market. Several substances on these lists are not available on the EU market and have not been registered by December 2010. For example, the SIN list includes 127 nickel containing substances. In fact only 19 from them have been registered. This means that most of the listed nickel compounds are not placed on the EU market.

[3. Nickel Institute and Nickel REACH Consortia - Responding to REACH Authorisation](#)

Given the high probability of key nickel compounds being listed on the “Candidate List”, the Nickel Institute has drawn up a response plan which is designed to ensure that there is an orderly and engaged response to any proposed listing of a nickel substance or group of nickel substances.

Several activities are also ongoing on Socio-Economic Analysis. A scoping study has been finalized end of 2010 and case studies on critical nickel compounds are currently underway.

The Nickel Institute via the Nickel REACH Consortia is working closely with key downstream user sectors since the REACH Authorisation process is a critical issue for the entire supply chain. Ongoing dialogue and activities are taking place in collaboration with important sectors such as surface treatment, aerospace and batteries sectors.

[4. Further information](#)

For further information on how the Nickel Institute is responding to the REACH Authorisation process, please contact: France Capon (fcapon@nickelinstitute.org)

For further information on the status of nickel and nickel substances registered under REACH please go to: www.nickelconsortia.org

Disclaimer: The information contained in this paper is intended for information only and whilst the information is provided in utmost good faith and has been based on the best information currently available, is to be relied upon at the user's own risk. No representations or warranties are made with regards to its completeness or accuracy and no liability will be accepted by Nickel Institute nor any company participating in Nickel Institute or Nickel REACH Consortia for damages of any nature whatsoever resulting from the use of or reliance on the information. This document does not necessarily represent the views of any company participating in Nickel Institute or Nickel REACH Consortia.

Annex I:

Full	Indicates registration under REACH Article 10 as a full dossier					
OSII	Indicates registration under REACH Article 17 as an on-site isolated intermediate (OSII)					
TII	Indicates registration under REACH Article 18 as a transported isolated intermediate (TII)					
'Yes'	Indicates the substance registration under REACH is complete					
'In Process'	Indicates a dossier on the substance has been successfully submitted to ECHA and is being processed, i.e. the completeness check is pending (and could potentially be unsuccessful)					
				Registered As:		
EC No.	CAS RN	Ist ATP	Substance Name	Full	OSII	TII
206-761-7	373-02-4	Y	nickel di(acetate)	Yes	-	-
208-933-7	547-67-1	Y	nickel oxalate	-	Yes	Yes
215-215-7	1313-99-1	Y	nickel monoxide	Yes	In process	Yes
222-102-6	3349-08-4	Y	nickel(2+) propionate	-	Yes	-
224-699-9	4454-16-4	Y	nickel bis(2-ethylhexanoate)	Yes	-	Yes
227-873-2	6018-92-4	N	trinickel dicitrate	-	-	Yes
231-111-4	7440-02-0	Y	nickel	Yes	-	-
231-743-0	7718-54-9	Y	nickel dichloride	Yes	-	-
232-104-9	7786-81-4	Y	nickel sulphate	Yes	-	Yes
232-353-3	8007-18-9	N	antimony nickel titanium oxide yellow	Yes	-	-
233-071-3	10028-18-9	Y	nickel difluoride	Yes	-	-
234-454-8	12004-35-2	Y	dialuminium nickel tetraoxide	-	-	Yes
234-829-6	12035-72-2	Y	trinickel disulphide	Yes	Yes	Yes
235-008-5	12054-48-7	Y	nickel dihydroxide	Yes	Yes	Yes
235-715-9	12607-70-4	Y	[carbonato(2-)]tetrahydroxytrinickel	Yes	Yes	Yes
236-068-5	13138-45-9	Y	nickel dinitrate	Yes	Yes	-
237-396-1	13770-89-3	Y	nickel bis(sulphamidate)	Yes	-	-
238-032-4	14177-51-6	Y	nickel tungsten tetraoxide	-	-	Yes
238-034-5	14177-55-0	Y	molybdenum nickel tetraoxide	Yes	-	In process
240-841-2	16812-54-7	Y	nickel sulphide	Yes	Yes	Yes
242-522-3	18718-11-1	Y	nickel bis(dihydrogen phosphate)	Yes	-	-
242-533-3	18721-51-2	Y	nickel(2+) hydrogen citrate	-	-	Yes
245-119-0	22605-92-1	Y	citric acid, nickel salt	-	-	Yes
273-729-7	69012-29-9	N	Slags, ferronickel-manufg.	Yes	-	-
273-749-6	69012-50-6	Y	Matte, nickel	-	-	Yes
308-765-5	98246-91-4	N	Speiss, lead, nickel-contg.	-	-	Yes
310-050-8	102110-49-6	N	Residues, copper-iron-lead-nickel matte, sulfuric acid-insol.	-	-	Yes
909-803-9		N	Reaction mass of aluminium fluoride and aluminium oxide and chromium (III) oxide and nickel dichloride	-	Yes	-
909-880-9		N	Reaction mass of diiron trioxide and divanadium pentaoxide and nickel monoxide	-	-	Yes
910-417-8		N	Reaction mass of nickel monoxide and silicon dioxide	-	-	Yes
910-663-6		N	Reaction mass of cobalt sulphide and nickel sulphide and trinickel disulphide	-	-	Yes
914-309-1		N	Reaction mass of aluminium fluoride and chromium trifluoride and nickel difluoride	Yes	-	-
927-629-1		N	Residue, Nickel matte leaching (Nickel Ash)+C770	-	-	Yes
930-649-3		N	Residue, Nickel sulphide leaching	-	Yes	-
931-258-0		N	Dipropandioic acid nickel salt	-	-	Yes
931-895-4		N	Reaction product of soluble nickel salt, cobalt salt, manganese salt with alkalines	-	-	Yes
Red			Substances registered by Ni REACH Consortia			