~~CONFIDENTIAL~~

European Chemicals Agency

For final decision: CCH-D-0000001692-74-06/F Helsinki, 10 November 2011

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For Lithium Nickel Cobalt Aluminium Oxide ([redacted]), EC Nr. 700-042-6, Registration Number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration dossier for **Lithium Nickel Cobalt Aluminium Oxide** [redacted] EC NR. 700-042-6, submitted by [redacted] (the "Registrant"), latest submission number [redacted] per year.

The compliance check was initiated on 9 July 2010.

On 7 June 2011 ECHA notified the Registrant of its draft decision and invited him pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

By 7 July 2011 the Registrant did not provide to ECHA comments on the draft decision.

On 29 July 2011 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them as pursuant to Article 51(1) of the REACH regulation to submit proposals to amend the draft decision within 30 days. Subsequently, one Competent Authority of the Member States submitted proposals for amendment to the draft decision.

On 31 August 2011 ECHA notified the Registrant of proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments within 30 days of the receipt of the notification.

ECHA reviewed the proposals for amendment received and decided to modify the draft decision accordingly.

On 12 September ECHA referred the draft decision to the Member State Committee.

On 30 September 2011, the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant on the proposals for amendment of the Member State Competent Authority into account.

A unanimous agreement of the Member State Committee on the modified draft decision was reached on 14 October 2011 in a written procedure launched on 3 October 2011.

This compliance check decision does not prevent ECHA to initiate further compliance checks on the present dossier at a later stage.

II. Information required

Pursuant to Articles 41(1)(c), 41(3), 10(b), 14 and Annex I of the REACH Regulation the Registrant shall submit the following information for the registered substance:

1. A full justification on the Derived No-Effect Levels (DNEL(s)) for workers (Articles 10(b) and 14(1), Annex I, Section 1.4.1);
2. Operational conditions and risk management measures in the exposure scenario to reduce or avoid direct and indirect exposure of the different environmental compartments to the registered substance (Articles 10(b) and 14(4), Annex I, Section 5.1.1);
3. Documentation of exposure estimation and risk characterisation for workers, demonstrating that the risk to humans can be considered to be adequately controlled (Articles 10(b) and 14(4), Annex I, Sections 5.2.4, 5.2.5, 6.3 and 6.4) including:
   (a) worker exposure estimation;
   (b) consistent descriptions of operational conditions and risk management measures;
   (c) adequately detailed information on personal protection equipment (PPE);
   (d) worker risk characterisation (demonstrating that the risk to humans can be considered to be adequately controlled); and
4. Refinement of environmental hazard assessment for the aquatic compartment (including sediment) (Articles 10(b), 14(3), Annex I, Section 0.5).

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated IUCLID dossier to ECHA by 10 November 2012.

III. Statement of reasons

Based on the examination of the technical dossier, ECHA concludes that the information therein, submitted by the Registrant for registration of the above mentioned substance in accordance with **Article 6** of the REACH Regulation, does not comply with the requirements of Articles **10, 12 and 14 and with Annex I** thereof. Consequently, the Registrant is requested to submit the information mentioned above that is needed to bring the registration into compliance with the relevant information requirements.

1) A full justification on the Derived No-Effect Levels (DNEL(s)) for workers

According to Articles 10(b) and 14(1) of the REACH Regulation, a chemical safety assessment (CSA) of the substance shall be prepared, which shall identify a Derived No Effect Level (DNEL) as specified in Section 1.4.1 of Annex I of the REACH Regulation. This comprises in particular a full justification on the choice of the information used, the route of exposure (oral, dermal, inhalation) and the duration and frequency of exposure to the substance for which the DNEL is valid. When establishing the DNEL, the following factors shall, inter alia, be taken into account if more than one route of exposure is likely to occur which is the case for the registered substance:

(a) the uncertainty arising, among other factors, from the variability in the experimental information and from intra-and inter-species variation;
(b) the nature and severity of the effect;
(c) the sensitivity of the human (sub)-population to which the quantitative and/or qualitative information on exposure applies.

In the Section 5.11.2 of the chemical safety report (CSR) the Registrant provided dose descriptors per endpoint and derived endpoint-specific DNELs for acute oral toxicity, subacute repeated dose toxicity and reproductive toxicity (fertility impairment and developmental toxicity). For the derivation of the DNELs, the overall assessment factor [redacted] was used.

This overall assessment factor deviates from the commonly agreed assessment factors that are listed in the ECHA Guidance on information requirements and chemical safety assessment (Chapter R.8 on Characterisation of dose [concentration]-response for human health). There it is recommended to apply the following assessment factors:

- interspecies (rat, correction for differences in metabolic rate per body weight): 4
- interspecies (remaining differences): 2.5
- intraspecies (workers): 5
- exposure duration (subacute to chronic): 6

The Registrant did not follow these recommendations and did not provide any justification on the derivation of workers DNEL as required in the Section 1.4.1 of Annex I of the REACH Regulation. Instead, the Registrant applied less protective assessment factors than those recommended by the above mentioned ECHA Guidance. Neither the Registrant applied assessment factors to cover uncertainties due to remaining interspecies differences (4 x 2.5) and exposure duration (6).

The Registrant is therefore requested to provide a full justification on DNEL derivation for workers. If not fully justifiable, the Registrant shall reconsider the derived DNELs for workers and reassess related risks. The chemical safety report (CSR) shall be amended accordingly.

2) Operational conditions and risk management measures in the exposure scenario to reduce or avoid direct and indirect exposure of the different environmental compartments to the registered substance

Annex I, Section 5 of the REACH Regulation requires the Registrant to generate exposure scenarios and exposure estimations for the registered substance. The exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the identified hazards.

Pursuant to Articles 10(b) and 14(4) as well as Annex I, Section 5.1.1 of the REACH Regulation, an exposure scenario includes, when relevant, a description of:

1. the risk management measures to reduce or avoid direct and indirect exposure of humans (including workers and consumers) and the different environmental compartments to the substance;
2. the waste management measures to reduce or avoid exposure of humans and the environment to the substance during waste disposal and/or recycling.

The CSR provided by the Registrant describes predicted releases of the registered substance to the environment and states that no release to the aqueous environment, air and soil as well as sewage treatment plants is anticipated from [redacted] due to employment of stringent engineering controls. The Registrant also states that no release of the substance is anticipated for [redacted] use and that all the waste is to be sent for recycling, but does not describe the operational conditions or the risk management measures to achieve predicted negligible release to the environment.

Therefore, the Registrant is requested to describe operational conditions and risk management measures for all developed environmental exposure scenarios, including waste management measures to reduce or avoid direct and indirect exposure the different environmental compartments to the registered substance and to update the CSR accordingly.

3) Documentation of exposure estimation and risk characterisation for workers

According to Articles 10(b) and 14(4) of the REACH Regulation, an exposure assessment and risk characterization shall be included in the chemical safety assessment if the registered substance meets the criteria for the hazard classes and/or categories specified in Article 58(1) of Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures (CLP Regulation) or is assessed to meet the persistent, bioaccumulative and toxic (PBT) or very persistent or very bioaccumulative (vPvB) criteria according to Annex XIII of the REACH Regulation. The registered substance is self-classified by the Registrant as Skin Corrosive, Category 1B, Eye Irritant, Category 1, and Specific Target Organ Toxicity (STOT) Rep. Exp. 2 in accordance with the CLP Regulation.

According to Annex I, Section 6.3 of the REACH Regulation, the risk characterisation for human health consists of a comparison of the exposure of each human population known to be or likely to be exposed with the appropriate DNEL. According to Annex I, Section 6.4, for any exposure scenario, the risk to humans and the environment can be considered to be adequately controlled, if the estimated exposure levels do not exceed the DNELs.

DN(M)ELs (Derived No-Effect Levels/Derived Minimum Effect Levels)

The Registrant selected non-quantifiable DNELs on irritation/corrosion and derived DNELs for Repeated Dose toxicity and Reproductive toxicity endpoints as the descriptors for the most critical health effects.

The Registrant states that it is not possible to calculate risk characterisation ratios (RCRs) for acute systemic and acute local effects for dermal or inhalation exposure as no DN(M)EL values are applicable for these routes of exposure. ECHA notes that when no DNEL or DMEL can be set, the Registrant shall carry out qualitative risk characterisation including the description of risk management measures as described in the Part E on Risk

Characterisation, Table E.3-1 of ECHA Guidance on information requirements and chemical safety assessment.

Exposure estimation and risk characterisation

In Section 9.1.2 of the CSR the Registrant provides only qualitative exposure estimation by stating that both worker acute and long-term exposure concentrations are negligible: "*Negligible/No exposure is anticipated as appropriate engineering controls and use of PPE will minimise any potential exposure to workers where exposure is possible*" (Section 9.1.2 of the CSR, Tables 26-29).

However, in Section 10 of the CSR on Risk characterisation the Registrant provides the output of the ECETOC TRA software used to calculate the estimated exposure to the workers, applying generic low effects value of [redacted] and [redacted] as reference values for inhalation and dermal exposure. The selection of applied reference generic low effects values has not been justified. The result of ECETOC TRA Table indicates that higher tier/further assessment is required (margins of exposure 0.02 for inhalation and 0.2 for dermal) but the Registrant did not perform further assessment.

ECHA notes that instead of margins of safety, which have been used for chemical risk assessment before the REACH Regulation came into force, risk characterisation ratios (RCRs) have to be provided. The RCRs are missing in the submitted CSR. Therefore, the Registrant did not show that the exposure levels do not exceed the appropriate DNEL(s) as required by the Annex I, Section 6.4 of the REACH Regulation.

In Table 25 of the CSR the Registrant states that "*the effectiveness of containment systems is anticipated to be 90% and that there is a continuous monitoring of the dust level in the production areas*". However, in Table 23 of the CSR it is stated that "*There is no data on room size and ventilation rate. LEV (= local exhaust ventilation) is used to minimise dust concentration in the atmosphere, but the ventilation rate is not known*". Therefore, the CSR statements are inconsistent and the claim for 90% effectiveness of the containment system is not justified. ECHA notes that, according to the Annex I 5.2.5 of the REACH Regulation, where adequately measured representative exposure data are available, special consideration shall be given to them when conducting the exposure assessment.

Table 23 in the CSR includes information on personal protection equipment (PPE). The Registrant recommends wearing protective equipment, gloves and expects their effectiveness to be close to 100%. This expectation is, however, not justified in the registration dossier. For dermal protection, no description is given on the type of the protective glove material or breakthrough time of the glove as required in the Section 8.2 of Annex II of the REACH Regulation.

The Registrant is therefore requested to perform worker exposure assessment and risk characterisation in a way that the risk to humans can be demonstrated to be adequately controlled and to update the CSR accordingly. This includes:

- worker exposure estimation (using modelling and tools as recommended in the Chapter R14 of ECHA Guidance on information requirements and chemical safety assessment);
- providing available monitoring data;
- consistent descriptions of operational conditions and risk management measures;
- adequately detailed information on PPE;

- worker risk characterisation (quantitative for endpoints with DNEL, qualitative for endpoints with no DNEL) demonstrating that the risk to humans can be considered to be adequately controlled.

4) Refinement of environmental hazard assessment for the aquatic compartment (including sediment)

Pursuant to Article 10(b), 14(3) and Annex I, 0.5 of the REACH Regulation, where available and appropriate, an assessment carried out under Community legislation (e.g. risk assessments completed under Regulation (EEC) No 793/93) shall be taken into account in the development of, and reflected in the CSR. Deviations from such assessment shall be justified.

Nickel, one of the components of the registered substance, has been evaluated under risk assessments completed under Regulation (EEC) No 793/93 (report published in 2008[1], referred further as EU RAR (2008)). In the dossier submitted, there is neither reference to the EU RAR (2008) nor any justification for the deviation from this report. This assessment shall be taken into account and reflected in relevant parts of the CSR.

Therefore, the Registrant is requested to refine the environmental hazard assessment for the aquatic compartment (including sediment), and to update the CSR accordingly, or alternatively, to justify fully why the data has not been taken into account.

IV. General requirements for the generation of information and Good Laboratory Practice

ECHA always reminds registrants of the requirements of Article 13(4) of the REACH Regulation that reads:

> "*Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international test standards recognised equivalent by the Commission or the Agency and with the provisions of Directive 86/609/EEC, if applicable.*"

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to the technical progress and use the applicable test methods to generate the information on the endpoints indicated above.

National authorities monitoring good laboratory practice (GLP) maintain lists of test facilities indicating the relevant areas of expertise of each facility.

V. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months

[1] http://esis.jrc.ec.europa.eu/doc/existing-chemicals/risk_assessment/REPORT/nickelreport311.pdf

of receiving notification of this decision. Further information on the appeal procedure can be found on ECHA's internet page at http://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Done at Helsinki,

[redacted]

Jukka Malm
Director of Regulatory Affairs