EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000003869-57-02/F Helsinki, 8 October 2013

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

For potassium fluoride, CAS No 7789-23-3 (EC No 232-151-5), 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 (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration dossier for potassium fluoride, CAS No 7789-23-3 (EC No 232-151-5) submitted by [redacted] (Registrant).

This decision is based on the registration dossier as submitted with submission number [redacted] for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates after 01 August 2013, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

The compliance check was initiated on 23 August 2012.

On 14 May 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. That draft decision was based on submission number [redacted].

By 13 June 2013 the Registrant did not provide any comments on the draft decision to ECHA.

On 1 August 2013 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

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), 14 and Annex I of the REACH Regulation, the Registrant shall provide the following information and update the Chemical Safety Report accordingly:

1) A revised hazard assessment, taking into account available information on hazards to humans (Annex I sections 1.0.3. and 1.2.)

2) A revised assessment of occupational exposure to include:

    a) Revision of inhalation exposure estimates to predict more realistic estimates of inhalation exposure using appropriate models (Annex I section 5.2.4 and section 5.2.5);
    b) Revision of dermal exposure estimates to predict more realistic estimates of dermal exposure using appropriate models (Annex I section 5.2.4 and section 5.2.5);
    c) Inclusion of a consideration of the impact of inadvertent ingestion on combined exposure because of the specific toxicological profile of inorganic fluoride substances (Annex I section 5.2.4.);
    d) Specification of appropriate risk management measures and operational conditions, to include where necessary proposals for biological monitoring in order to ensure control of risks to health (Annex I section 5.1.1.).

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 **8 October 2014.**

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 for the purpose of registration within the applicable tonnage band of 1000 tonnes or more per year in accordance with **Article 6 and 11(2)** of the REACH Regulation, does not comply with the requirements of Articles **10(b) and 14 or 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.

Missing information related to Chemical Safety Report (CSR)

Annex I sets out the general provisions for assessing substances and preparing chemical safety reports (CSR).

General considerations relating to the toxicity of the substance

Occupational exposure to potassium fluoride has to be considered in the context of its specific toxicity and taking account of the existing background intake of fluoride from other sources. Fluoride exposure from all sources leads to accumulation and long term production of fluorapatite in the bones, causing increase in bone density with resultant skeletal fluorosis. The EFSA Journal (2005) 192, 1-65 provides an "*Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the Tolerable Upper Intake Level of Fluoride*", hereinafter referred to as the "EFSA report", which has relevance. Non-occupational exposure by oral ingestion of fluoride is by water,

food (including fluoridated salt available in Austria, Belgium, Czech Republic, France, Germany, Spain and Switzerland), cosmetic dental products and fluoride supplements. Fluoride intake from food is generally low except when food is prepared with fluoridated water. Exceptions are tea which can contain considerable amounts of fluoride (0.34-5.2 mg/L) (Schmidt and Funke, 1984; Wei *et al.*, 1989; Chan and Koh, 1996), dependent on type, brewing and fluoride content of water. Some brands of instant teas were reported to be another significant source of fluoride intake (up to 6.5 mg/L when prepared with distilled water) (Whyte *et al.*, 2005).

Water sources may contain fluoride ion and in some parts of Europe fluoride is still added to drinking water supplies to seek to reduce the incidence of dental caries. Fluoride concentrations below 1 mg/L are typical though they may be as high as 1.5 mg/L in some parts of the EU. Mineral water sources may also contain fluoride ion and concentrations as high as 5 mg/L have been documented. Uptake of fluoride will then depend on fluid consumption from a range of sources. The margin is small between concentrations of fluoride that deliver what are considered beneficial effects in the treatment of dental caries, and the levels that may cause detrimental effects through long term incorporation into the skeleton.

The EFSA report states *"Numerous epidemiological data support a linear relationship between fluoride intake and bone fluoride content and between bone fluoride content and both incidence and severity of skeletal fluorosis. In the few cases of clinical skeletal fluorosis in which the fluoride intake could be estimated it ranged from 15 to 20 mg/day and the period of exposure was over 20 years. A more precise threshold dose for fluoride causing skeletal fluorosis can not be defined."*

The EFSA report proposes that a tolerable upper intake level of 7 mg/day fluoride is appropriate. *"The epidemiological data with an observed significantly increased risk for fractures at all sites associated with a long-term total daily intake of fluoride of 14 mg/day are considered as supportive evidence. An intake of 0.12 mg fluoride/kg body weight/day converts on a body weight basis (60 kg) into an UL of 7 mg/day for adults."*

The specific toxicity of fluoride compounds is well documented in the literature and potential effects on the human skeleton have been studied in the context of fluoride in urine and daily intake of fluoride ion.

1) Revised hazard assessment, taking into account available information on hazard to humans (Annex I sections 1.0.3. and 1.2.)

In accordance with Annex I section 1.2 and Annex I section 1.0.3. Step 2, hazard assessment includes the evaluation of human information. Every effect for which information is available shall be recorded under the relevant section of the Chemical Safety Report (Annex I Section 1.0.4.). However, human information is currently missing from the dossier even though a large body of published work exists and several reviews of the impact of fluoride on human health have been conducted, for example the above mentioned EFSA Report. Although much of the literature relates to dietary intake of fluoride, it is nonetheless relevant to include in the chemical safety assessment for this substance due to the long term cumulative effects and the need to determine the margin between beneficial and detrimental effect. Occupational sources are additional to absorption of fluoride from other sources e.g. dietary intake and understanding of both is required to allow a full risk characterisation for workers.

Consequently the Registrant is required to revise the human health hazard assessment part of the CSR taking into account available human health hazard information in accordance with Annex I Section 1.0.3. of the REACH Regulation.

2) A revised assessment of occupational exposure (Annex I, sections 5.2.4. and 5.2.5.)

According to Annex I section 5.2.4. the Registrant is required to address each relevant route of human exposure (inhalation, oral, dermal and combined through all relevant routes and sources of exposure). In particular the exposure estimation shall take account of the likely routes of exposure and potential for absorption in humans. This is of particular relevance for the substance potassium fluoride as elaborated below.

a) Inhalation exposure estimates (Annex I sections 5.2.4, 5.2.5 and 5.1.1.)

In accordance with Annex I section 5.2.5. appropriate models can be used for the estimation of exposure levels. The Registrant has reported modelled estimates of exposure using the ECETOC TRA worker model for manufacturing and subsequent downstream user operations. However, the model has been used inappropriately. Specifically, The ECETOC TRA model is not intended to be used for vapour release from inorganic solids and cannot be used to estimate exposures from solutions of inorganic substances in water. Additionally, ECETOC Technical Report No 93 (p 42) states the model "*does not accommodate forms of exposure not adequately addressed by the EASE model, i.e. mists and process fumes.*"

Therefore, the exposure assessment shall be revised taking into account appropriate models for inhalation estimation. Furthermore, the risk management measures resulting from the use of such an appropriate model are to be adequately defined for all relevant scenarios for this substance.

b) Dermal exposure estimates (Annex I section 5.2.4 and section 5.2.5)

Regarding dermal exposure, the ECETOC TRA model has been used inappropriately to deliver estimates, and particularly through the use of the local exhaust ventilation (LEV) exposure modifier, which is advised against in ECHA Guidance on information requirements and chemical safety assessment, Chapter R.14: Occupational exposure estimation, page 21, May 2010. The inappropriate use the ECETOC TRA with the LEV modifier is particularly relevant for the registered substance given the fact that it is a non-volatile inorganic salt. The modelled estimates from the ECETOC TRA are unreliable with respect to potential for dermal exposure, especially when the LEV exposure modifier is included and leads to a failure to recognise significant potential for contamination and the potential for systemic absorption that may arise subsequently, especially via inadvertent ingestion. As a consequence of the use of inappropriate modelling the proposed risk management measures are poorly aligned with the real risks arising in the workplace from the use of this registered substance. Although ECETOC TRA may be used without the LEV exposure modifier other modelling approaches (RISKOFDERM, BEAT) may also be used for estimating potential dermal exposure, and subsequent actual dermal challenge, and offer a better basis for developing more-appropriate risk management measures for managing local and systemic effects.

Therefore, the exposure assessment shall be revised taking into account appropriate models for dermal estimation. Furthermore, the risk management measures resulting from the use of such an appropriate model are to be adequately defined for all relevant scenarios for this substance.

c) Oral exposure estimates (Annex I section 5.2.4.)

Although generally not possible to determine the overall contribution of the oral route for most substances, it is suspected it may play a major role in some tasks, especially those where inhalation exposure is low and systemic exposure via the dermal route is not anticipated.

Many exposure scenarios are presented for the registered substance in the CSR in addition to manufacturing, where relevant inhalation and dermal exposure followed by inadvertent ingestion may occur, including:

- Manufacture of chemicals in an industrial setting (solid up to 100% KF);
- Formulation of fluxing products (solid 100%, and liquid, up to [redacted]% KF);
- Use of fluxing products (liquid or paste, up to [redacted]% KF);
- Formulation of surface treatment products (solid 100%, and liquid, up to [redacted] % KF)
- Use of surface treatment products (liquid or pasty mixture up to [redacted]% KF)
- Manufacture of frits (solid mixture up to 100% KF)

Evidence for the significance of the oral route in such circumstances is provided in several published sources, (*Karita et al. Possible oral lead intake via contaminated facial skin. Sci Total Environ 1997;199:125-31; McDevitt J, Lees P. Exposure of hospital pharmacists and nurses to antineoplastic agents. J OccupMed 1993;35:57-60.; Ho S, Ng T. An evaluation of the significance of mouth and hand contamination for lead absorption in lead-acid battery workers. Int Arch Occup Environ Health 1993;64:439-443.*). This is not specific to fluoride but demonstrates the potential importance of the route for a range of substances used in a variety of ways.

The Registrant has dismissed ingestion exposure as "*not relevant*" in the CSR and in this context it is a missing element in the assessment. However, though it cannot be reliably measured as an external exposure quantity, inadvertent ingestion is, potentially, a significant part of the combined exposures, especially for downstream users where tasks (defined by PROCs) may result in dermal contamination and subsequent transfer to the peri-oral region (UK Health and Safety Executive research report RR 551 "*Inadvertent ingestion exposure in the workplace, 2007*").

Consequently, the Registrant is required to revise the exposure assessment taking into account inadvertent ingestion exposure and its potential impact on combined exposure levels.

d) Risk management measures and operational conditions (Annex I section 5.1.1.)

The success of the risk management measures for the registered substance are best assessed through the use of biological monitoring (integrating the internal exposure resulting from all external exposure routes) as a supplementary risk management measure. Annex I Section 5.2.4. requires ingestion to be assessed. ECHA Guidance on information requirements and chemical safety assessment, Chapter R.14: Occupational exposure estimation, page 3 states, " *... the potential for exposure via ingestion should be kept in mind when considering uncertainties in the exposure assessment as a whole. There are no accepted methods for quantifying exposure by ingestion as such.*" and " *.. consider biological monitoring where all routes of uptake are integrated and accounted for.*"

Annex II section 8.2.1. prescribes the information that needs to be taken into account by employers in carrying out an assessment of risk to health and safety of workers. More specifically, the information provided on exposure controls must be sufficient to enable an employer to carry out an assessment of risk. Consequently, an accurate understanding of the operational conditions and risk management measures needs to be presented in the CSR if this information is to be reliable and sufficient to alert downstream users to the measures they need to take to comply with their obligations under REACH and other legislation. Annex II section 8.1., states a requirement to "*Specify currently applicable specific control parameters including occupational exposure limit values and/or biological limit values.*"

ECHA notes that biomonitoring is already proposed by the Registrant as a risk management measure during the manufacturing phase of the registered compound – but not for downstream users. In comparison to manufacture, many similar processes (as described by PROCs) occur within the exposure scenarios developed for downstream users where either the solid substance or concentrated solutions are handled. For downstream users dermal contamination may lead to transfer to the peri-oral region and inadvertent ingestion cannot be excluded as a potential route of exposure (UK Health and Safety Executive research report RR 551 "*Inadvertent ingestion exposure in the workplace, 2007*"). Biomonitoring methods for systemic fluoride in urine are well-developed and can be used to demonstrate whether exposures are close to anticipated background levels. Significantly raised levels of fluoride in urine will indicate, for downstream users, the need to assess operational conditions and ensure the adequacy of risk management measures for all routes of exposure.

Consequently the CSR is requested to be revised to reflect, where appropriate, the combined nature of exposure and address the ingestion route as part of that combined assessment together with the dermal and inhalation routes and the resultant risk characterisation, risk management measures and operational conditions that are required for downstream users to ensure safe use. Risk management measures proposed in the chemical safety assessment and CSR should reflect the information to be relayed to downstream users.

IV. 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 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.

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