Helsinki, 29 June 2018

Substance name: ethylene dinitrate
EC number: 211-063-0
CAS number: 628-96-6
Date of latest submission(s) considered[1]: 26 June 2017
Decision/annotation number: Please refer to the REACH-IT message which delivered this communication (in format SEV-D-XXXXXXXXXX-XX-XX/F)
Addressee(s): Registrant(s)[2] of ethylene dinitrate

DECISION ON SUBSTANCE EVALUATION

Based on Article 46(1) of the REACH Regulation (Regulation (EC) No 1907/2006), you are requested to submit the following information on the registered substance:

Exposure-related request: Missing scenarios, uses, assessments:

> Reliable information on the risk management measures (RMMs) and Operational Conditions (OCs) adopted in order to prevent exposure of the workers and release to the environment as further elaborated in Appendix 1 (Reasons).

You have to provide an update of the registration dossier(s) containing the requested information and an update of the chemical safety report by **8 July 2019** for the requested information.

The reasons of this decision and any further test specifications are set out in Appendix 1. The procedural history is described in Appendix 2. Further information, observations and technical guidance as appropriate are provided in Appendix 3. Appendix 4 contains a list of registration numbers for the addressees of this decision. This appendix is confidential and not included in the public version of this decision.

[1] This decision is based on the registration dossier(s) on the day until which the evaluating MSCA granted an extension for submitting dossier updates which it would take into consideration.

[2] The terms registrant(s), dossier(s) or registration(s) are used throughout the decision, irrespective of the number of registrants addressed by the decision.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has a suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Authorised[3] by Leena Ylä-Mononen, Director of Evaluation

[3] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons

Based on the evaluation of all relevant information submitted on ethylene dinitrate and other relevant available information, ECHA concludes that further information is required to enable the evaluating Member State competent authority (MSCA) to complete the evaluation of whether the substance constitutes a risk to human and to the environment.

The evaluating MSCA will subsequently review the information submitted by you and evaluate if further information should be requested to clarify the concern for Reproduction/Developmental Toxicity including Endocrine Disrupting-like effects; sensitization; genotoxicity/carcinogenicity; PBT/vPvB; wide dispersive use; high (aggregated) tonnage.

The Lead Registrant updated the dossier on 26 June 2017. In this update the Lead Registrant concludes that there is no release to the environment and no exposure to workers for safety reasons and due to the specific use of the substance. In this case ECHA highlights that the concerns remain not clarified, as specified below.

Once the requested information on exposure is submitted, the evaluating MSCA will assess whether it is demonstrated that there is no release to the environment and no exposure to workers and whether the risk management measures (RMMs) and Operational Conditions (OCs) adopted will be considered sufficient for a safe use of the substance and whether no further requests will be needed. On the other hand, if the provided information on exposure and uses will indicate release to the environment and exposure to workers, the evaluating MSCA will consider preparing a second draft decision to clarify the abovementioned concerns.

1. Exposure-related request

According to the Lead Registrant's IUCLID file, the substance presented an high aggregate tonnage and the uses by professional users described by Environmental Release Category (ERC) 8f: "Wide dispersive outdoor use resulting in inclusion into or onto a matrix", entry 3.5: "life cycle description". Indeed, the wide dispersive use and the high (aggregated) tonnage are the initial grounds for concern to be clarified under substance evaluation for the exposure/risk based concern.

On 26 June 2017, the Lead Registrant updated his own IUCLID file explaining the reference to the ERC 8f in a "General remarks" (entry 3.5.4). In this remark the Lead Registrant stated that there is no appropriate ERC for such a highly explosive substance handled in dedicated cartridges. According to the Lead Registrant, therefore, the ERC 8f describes the usage of the substance formally but not the real exposure and it is misleading because the production site has to fulfil the highest safety standards under strictly controlled conditions, due to the high explosive properties of the substance. In the updated IUCLID file the Lead Registrant confirms that leakage of the substance from the cartridge cannot occur even at intensive contact with water. In addition, following its use as explosive, the substance is completely converted into carbon dioxide, nitric oxides and water. Cartridges not exploding as foreseen will always be brought to explosion for

safety reasons. Thus, no "unexploded cartridges" exist which could accidently lead to a release of the substance to the environment.

The Lead Registrant refers to the application of strictly controlled conditions (SCCs) in the IUCLID file. In this context, it shall be observed that additional information on SCCs can found in the ECHA Guidance on intermediates (and in the ECHA Practical Guide No 16) where a description and explanation of SCCs is provided together with an explanation on how they should be reported and described in a IUCLID dossier.

ECHA acknowledges the new information provided by the Lead Registrant in the "General remarks" section of the updated dossier but open issues related to the exposure assessments in the CSRs still remain. As stated in the ECHA Guidance on IR & CSA, Environmental Exposure Assessment, R.16.1.2 (version 3.0, February 2016), the whole exposure estimation is built upon the definition of the life cycle stages of the substance giving rise to release/exposure (see part D and Chapter R.12) and the identification of the covered uses for each life cycle step. Once this framework has been completed, the proper exposure estimation can start.

ECHA highlights that if in the IUCLID dossier you (the Registrant(s)) declare an ERC 8f (i.e.: "Wide dispersive outdoor use resulting in inclusion into or onto a matrix"), this shall be also addressed in the CSR. Otherwise, if this ERC 8f does not represent the actual use of the substance, the exposure assessment provided in the CSR shall be amended accordingly, as foreseen by REACH Regulation (Annex I, 0.3; 5.0; 5.2.2).

Moreover, in the commenting phase, you (the Lead Registrant) concluded that there is no release to the environment and no exposure to workers for safety reasons and the specific use of the substance.

However, ECHA notes that in the CSRs submitted by the different Registrant(s) of ethylene dinitrate this lack of exposure is not always addressed and properly described. Therefore, you (the Registrant(s)) are requested to provide consistent information regarding the actual identified uses, environmental release and exposure to workers rates in the CSR and IUCLID files; In particular, you (all Registrant(s) of ethylene dinitrate) shall provide a harmonised exposure evaluation in line with the new information provided by the Lead Registrant in the "General remarks" section of the updated dossier of 26 June 2017.

ECHA underlines that you (all Registrant(s) of ethylene dinitrate) are expected to provide a detailed description of uses in the CSR(s), including a description of all conditions of use (RMMs and OCs) for each of the identified uses. This detailed explanation shall contain:

- A description (or flow chart) of the technological lines and processes where the substance is used and processed during its lifecycle, including a description of the specific activities where potential for workers' (including professional users) exposure/emission to environment may arise (including loading and unloading, transfer of substance, maintenance of equipment, sampling etc);

- For each identified use, a description of the technical measures in place to prevent releases to the environment and exposure of the workers/professional users;
  A description of the article/product design (i.e. the cartridge) which would ensure prevention of unintended releases of the substance;
- A description of the procedural and control technologies in place to minimise emission to the environment/exposure to workers/professionals.

Additionally, you (all Registrant(s)) shall ensure that the risk is considered controlled for all compartments in every declared site. According to REACH Regulation (Annex I, 5.1.1, Annex I, 6) the Chemical Safety Reports should be updated refining the exposure assessment for compartments to guarantee that the risk is controlled.

The request is relevant due to insufficient and inconsistent information regarding the ES(s) description and implemented RMMs/OCs by you (all Registrants) for all sites to refine the evaluation and to ensure that the risk is controlled.

ECHA is concerned about the properties of the substance due to specific endpoints, such carcinogenicity and reproduction/developmental toxicity and PBT/vPvB properties. However, if you (all Registrants) can provide reliable information on the absence of human and environmental exposure associated with the use of the substance and the risk management measures (RMMs) and Operational Conditions (OCs) adopted will be considered sufficient for a safe use of the substance, further requests may not be needed. On the other hand, if the provided information on exposure and uses will indicate release to the environment and exposure to workers, the evaluating MSCA will consider preparing a second draft decision to clarify the abovementioned concerns.

Consideration of registrants' comments on the draft decision and PfAs and of the PfAs

One Member States Competent Authority submitted a proposal for amendment (PfA) to the draft decision requesting to identify precisely the substances generated upon explosion (NOx fumes) and to provide an exposure assessment and risk characterization of these substance. The evaluating MSCA considered that, on the basis of available information, the amount of NOx fumes emitted from the mining industry would not significantly affect the environment if compared with emissions from fuels burning. Therefore, the PfA request was not included in the decision.

In your comments on the proposals for amendment, you state that the risk assessment will be revised with regard to the risk management measures and the substance-life cycle as requested, and that any inconsistencies in your exposure assessments will be checked and clarified.

Furthermore, you state that if the evaluation of the information requested in the present decision would lead to requests for experimental studies in a subsequent substance evaluation decision, such experimental studies would not be technically possible due to the extremely high explosive properties of the registered substance.

You also state that the PBT/vPvB assessment substance data were considered and an evaluation was made, highlighting BCF endpoint and read-across arguments.

ECHA acknowledges these comments and will take these into consideration when determining the need for any further for information to clarify the concerns following the evaluation of the information requested in the present decision.

Appendix 2: Procedural history

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to suspected R, suspected sensitiser, potential endocrine disruptor, suspected PBT/vPvB, wide dispersive use, high (aggregated) tonnage, ethylene dinitrate CAS No 628-96-6 (EC No 211-063-0) was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2016. The updated CoRAP was published on the ECHA website on 22 March 2016. The competent authority of Italy (hereafter called the evaluating MSCA) was appointed to carry out the evaluation.

In accordance with Article 45(4) of the REACH Regulation, the evaluating MSCA carried out the evaluation of the above substance based on the information in your registration(s) and other relevant and available information.

In the course of the evaluation, the evaluating MSCA identified additional concerns regarding carcinogenicity.

The evaluating MSCA considered that further information was required to clarify the abovementioned concerns. Therefore, it prepared a draft decision under Article 46(1) of the REACH Regulation to request further information. It subsequently submitted the draft decision to ECHA on 22 March 2017.

The decision making followed the procedure of Articles 50 and 52 of the REACH Regulation as described below.

ECHA notified you of the draft decision and invited you to provide comments.

Registrant(s)' commenting phase

ECHA received comments from you and forwarded them to the evaluating MSCA without delay.
The evaluating MSCA took the comments from you, which were sent within the commenting period, into account and they are reflected in the reasons (Appendix 1). The request(s) and deadline were amended.

Proposals for amendment by other MSCAs and ECHA and referral to Member State Committee

The evaluating MSCA notified the draft decision to the Competent Authorities of the other Member States and ECHA for proposal(s) for amendment.

Subsequently, two Competent Authorities of the Member States and ECHA submitted comments and proposals for amendment to the draft decision. The evaluating MSCA reviewed the proposals for amendment received and, where considered appropriate, the draft decision was amended accordingly.

ECHA referred the draft decision, together with your comments, to the Member State Committee.

ECHA invited you to comment on the proposed amendments.

Your comments on the proposed amendment(s) were taken into account by the Member

State Committee.

MSC agreement seeking stage

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-60 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This decision does not imply that the information provided by you in the registration(s) is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on your dossier(s) at a later stage, nor does it prevent a subsequent decision under the current substance evaluation or a new substance evaluation process once the present substance evaluation has been completed.

2. Failure to comply with the request(s) in this decision, or to otherwise fulfil the information requirement(s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.