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Helsinki, 14 November 2019

Substance name: N-1-naphthylaniline
EC number: 201-983-0
CAS number: 90-30-2
Date of latest submission(s) considered: 7 August 2018
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)[1] of N-1-naphthylaniline (Registrant(s))

DECISION ON SUBSTANCE EVALUATION

Based on Article 46(3) of the REACH Regulation (Regulation (EC) No 1907/2006), ECHA requests you to submit the following information on N-1-naphthylaniline:

Skin absorption: In vitro method (Test method EU B.45; OECD TG 428) with specifications and with additional modifications as specified in Appendix 1, in particular:

- **The study shall be performed using well characterised viable human skin from appropriate locations of the human body, an appropriate solvent and doses which are representative of relevant human exposure situations.**
- **The study shall be designed such that a minimum of 8 skin samples from at least four donors can be evaluated.**
- **The study shall be in line with the Scientific Committee on Consumer Safety (SCCS) basic criteria for the in vitro assessment of dermal absorption of cosmetic ingredients (SCCS, 2010), which are specified in Appendix 1.**

Deadline to submit the requested information

You have to provide an update of the registration dossier(s) containing the requested information, including robust study summaries and, where relevant, an update of the chemical safety report by **16 November 2020**. In addition to the robust study summaries, you shall submit the full study report for the information request by the same deadline by attaching it to the relevant endpoint study record in IUCLID, because a robust study

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

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summary alone might not sufficiently reflect the additional specifications and modifications requested in this study.

The deadline takes into account the time that you may need to agree on which of the registrant(s) will perform the required tests (3 months is allocated for this).

The reasons of this decision and any further test specifications of the requirements 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.

Based on Article 53 of the REACH Regulation, you are requested to inform ECHA who will carry out the study on behalf of all registrant(s) within 90 days. Instructions on how to do this are provided in Appendix 3.

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[2] by Christel Schilliger-Musset, Director of Hazard Assessment

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

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Appendix 1: Reasons

Based on the evaluation of all relevant information submitted on N-1-naphthylaniline ("NPNA") 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 health.

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.

During the initial evaluation of the registration dossier, human health concerns regarding neurotoxicity and haemotoxicity, as well as developmental toxicity were identified. In a first decision[3] ECHA accordingly requested a combined neurotoxicity and subchronic oral repeated dose toxicity study in rat (OECD TGs 424 and 408), as well as a prenatal developmental toxicity study in rat or rabbits, oral route (OECD TG 414). In the course of the subsequent evaluation based on this new information, the concerns on neurotoxicity and reproductive toxicity could not be substantiated. However, the haematotoxic properties after (repeated) exposure to NPNA were again confirmed by the provided subchronic repeated dose toxicity study.

In the first decision, ECHA also requested information on the exposure assessment for workers, as well as missing information for consumer uses as consumer applications were listed in technical data sheets and product registers for the substance. This request included the corresponding exposure scenarios and risk characterisations for consumers. You provided information about the article service life (rubber products) for consumers and for use scenarios relevant for workers after receiving the decision.

The new information was assessed in the follow-up evaluation period by the evaluating MSCA. Based on the exposure assessment of the new uses, there is a potential risk for workers and consumers during the handling of NPNA or articles/preparations containing NPNA which requires further clarification. With regard to the use of NPNA by workers there is a range of scenarios at risk which occur during the formulation of NPNA preparations.

Therefore, in the course of the subsequent evaluation of the new information provided by you, a concern regarding dermal exposure of consumers and workers was identified, as calculation of risk characterisation ratios (RCRs) yielded values > 1 for some of the considered dermal exposure scenarios.

1. **Skin absorption: In vitro method (Test method EU B.45; OECD TG 428) with specifications and additional modifications**

[3] "DECISION ON SUBSTANCE EVALUATION PURSUANT TO ARTICLE 46(1) OF REGULATION (EC) NO 1907/ 2006 For N-1-naphthylanhline, CAS No 90-30-2 (EC No 201-983-0)" https://echa.europa.eu/documents/10162/20c7df64-d64f-4e21-8916-9dc084848dcc

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The concern(s) identified

NPNA is considered a moderate skin sensitiser according to Table R.8-24 in ECHA Guidance on Information requirements and chemical safety assessment (Chapter R.8, version 2.1, November 2012). Consequently, it has to be classified as "skin sensitising Cat. 1 B (H317: May cause an allergic skin reaction)" in accordance with Annex VI of Regulation (EC) 1272/2008. Most, but not all of the C&L notifiers self-classified the substance appropriately. Therefore, dermal exposure to NPNA should be minimised or even prevented.

With regard to skin sensitising effects, you stated in your registration dossier(s) that "the general population does not come into contact with the test article itself. The exposure is limited to rubber articles that contain the test article at very low concentration and with low release. Therefore, the risk is considered to be negligible." ECHA cannot support the conclusion that the risk can be considered negligible, as RCR values >1 for dermal exposure scenarios were calculated by the evaluating MSCA and a threshold value for skin sensitising effects cannot be established based on the available information (ECHA, 2012). Thus, a risk for skin sensitising effects after (repeated) dermal exposure of consumers and workers cannot be excluded based on the available information. Hence, exposure of the general population and workers to NPNA should be minimised. For further refinement of risk assessment, additional information is considered necessary.

Regarding systemic effects (haemotoxicity), long-term (>15 days per year) and infrequent (<15 days per year) DNELs were derived by the evaluating MSCA based on the results of the provided subchronic and subacute repeated dose toxicity studies, respectively. You have received information on the DNELs derived by the evaluating MSCA during an informal communication. It is to be noted that the DNELs calculated by the evaluating MSCA differ from the DNELs you derived in your registration dossier(s), as differing dose descriptor starting points (NOAEL vs. LOAEL) were used and no DNELs for infrequent exposure were derived by you.

The evaluating MSCA considers the lowest tested dose of 5 mg/kg bw/day in the subchronic repeated dose study recently provided by you ([redacted], 2016) as a LOAEL instead of a NOAEL as proposed by you, because at this level haemotoxicity was observed. At this test dose significantly increased bilirubin levels in plasma of exposed animals, extramedullary haematopoiesis and pigment storage in spleen, as well as bilirubin in urine were observed. Moreover, applying a linear mixed model approach ('sex' as random factor) a significant increase in spleen weight was observed at 5 mg/kg bw/d, as well ($p = 0.034$). All findings are indicative of a haemolytic anemia. In addition, the observed effects are clearly dose-dependent starting at the lowest tested dose of 5 mg/kg bw/day. Consequently and according to ECHA Guidance on Information requirements and chemical safety assessment (Chapter R.8, version 2.1, November 2012) (ECHA, 2012), DNEL derivation has to allow for an additional assessment factor of 3 to account for the conversion from LOAEL to NOAEL, eventually yielding lower long-term DNEL values than calculated by you.

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In addition and according to Section 15.2.3 "Frequency of use and duration of exposure " in ECHA Guidance on Information requirements and chemical safety assessment (Chapter R.15, version 3.0, July 2016), DNELs for infrequent exposure can be calculated for consumer risk assessment, if the frequency of consumer exposure is <15 days/year (by default: 24 h/day) (ECHA, 2016). The derived DNELs for infrequent use are, thus, markedly higher than those for long-term systemic effects. Although several tools foresee the possibility of averaging out infrequent exposure over a year, "this practise is strongly discouraged" in ECHA Guidance on Information requirements and chemical safety assessment (Chapter R.8, version 2.1, November 2012) (ECHA, 2012), because a scientific reasoning is lacking (see also R.15.2.3 Approaches to adjustment for duration and frequency of exposure; ECHA (2016)). Hence, infrequent DNELs were derived based on the NOAEL of 5 mg/kg bw/day (haemotoxicity) from the available subacute repeated dose study ([redacted], 2002).

Based on the available data it is unreasonable to decide on the leading health effect for dermal exposure scenarios, as – besides sensitising effects – systemic effects (specifically haemotoxicity) are to be expected as well at rather low concentrations, particularly depending on the percentage of dermal absorption and penetration of NPNA.

No specific information on dermal absorption and penetration of NPNA was provided in your registration dossiers and in further informal communications with you. For derivation of respective dermal DNELs, you stated in the dossier(s) that "the test article is expected to penetrate the skin", wherefore "an absorption ratio of 100% is assumed as worst case scenario". However, upon assessment of this information, the evaluating MSCA identified that the dermal absorption value used by you for dermal DNEL derivation was not set to 100%, but rather to 100% of the oral absorption. As oral absorption is estimated to be 50% based on the information available in your dossiers, dermal absorption in fact was also set to 50%. Likewise, for deriving the respective dermal DNELs for systemic effects, dermal absorption was assumed to be equal to oral absorption by the evaluating MSCA, because in general, dermal absorption is not expected to be higher than oral absorption (ECHA (2012), Section R.8.4.2). Hence as in your calculations, a value of 50% was used for dermal absorption as well when deriving the respective dermal DNELs.

According to Table R.7.12-3 in ECHA Guidance on Information requirements and chemical safety assessment (Chapter R.7c, version 3.0, July 2017) (ECHA, 2017), dermal absorption is influenced by many factors, including the physico-chemical properties of the substance. The "Guidance Document on Dermal Absorption" by the European Commission (EC - Health & Consumer DG 2004) further reports that for substances with a log Pow <-1 or >4 and a molecular weight >500 g/mol a default value of 10% could be assumed for dermal absorption. The log Pow of NPNA is 4.28 and, thus, close to the limit value for the default assumption. The molecular weight of NPNA, however, is <500 g/mol (219.3 g/mol). This means that the necessary assumption criteria for using a default value of 10% for dermal absorption of NPNA are not met. Nevertheless, the specific physico-chemical properties of NPNA indicate that dermal absorption of this substance might be significantly lower than 50% (e.g. a molecular weight > 100 g/mol [219.3 g/mol], water solubility between 1 and 100 mg/L [3 mg/L at 20 °C, pH > 7.9 - < 8] and a partition coefficient Log Kow > 4 [4.28]). As no substance specific data is currently available, the

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assumption that dermal absorption of NPNA is <50%, therefore, needs further supporting evidence. As long as no substance-specific data on dermal absorption of NPNA is available, dermal absorption has to be considered equal to oral absorption (=50%) when deriving systemic DNELs, which might be regarded as a conservative approach.

The dermal worker exposure estimate provided by you was calculated with EasyTRA 4.1.0. In some instances, the exposure values have been calculated with the RiskofDerm v2.1 model. For dermal exposure, the substance concentrations in preparations have been modified using a linear approach.

The dermal consumer exposure was calculated by the evaluating MSCA in line with ECHA Guidance on Information requirements and chemical safety assessment (Chapter R.15, version 3.0, July 2016) by using the ECETOC TRA consumer tool. The calculations were shared with you informally during the evaluation process. The model is based on the assumption that the total substance in a layer on the exposed skin with a thickness of 0.001 cm (for rubber articles) and the same substance concentration as in the product determines the external exposure (ECHA, 2016). Frequent contact with the palm of one hand (e.g. when touching a tank hose) and infrequent contact with the palm of both hands and forearms (e.g. when changing tyres) was assumed to be realistic. The dermal dose is proportional to the affected skin area and the mean number of events per day (one event/day was considered), but does not feature any time dependency. Thus, results of this model can only be compared with 24h-DNELs for infrequent or long-term use depending on the use frequency in the exposure scenario. Further refinement of the exposure assessment or use of a different model is only possible by considering the diffusion respective migration behaviour of NPNA. Therefore, the evaluating MSCA asked you informally about the availability of such information on NPNA in rubber products, which was answered as negative by you. Based on the available data, refinements of the dermal exposure scenarios are not possible.

By using a conservative value for dermal absorption for DNEL derivation and calculating the exposure scenarios as described above, the subsequent risk characterisation resulted in RCR values >1 with respect to systemic toxicity for each dermal exposure scenario that was considered for consumers (RCRs up to >6) and for several dermal exposure scenarios for workers. For workers, the combined RCR calculated by the evaluating MSCA is in the range of 1.05 to 2.70 for 43 out of 68 scenarios based on the chemical safety report provided in the dossier update submitted on 7 August 2018.

Why new information is needed

As safe use of NPNA with respect to systemic effects after dermal exposure could not be established, ECHA considers that further information, specifically an in vitro skin absorption test using human skin samples, is necessary. Results of this study will enable a refined dermal DNEL derivation and, hence, a more realistic risk assessment for NPNA, which could clarify the regulatory relevance of the ascertained high RCR values. The results of the study will ultimately allow to establish if the substance actually and realistically poses a risk to human health or whether the risks can be considered adequately controlled.

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Without substance specific information on dermal absorption such a necessary refinement is not possible and the risks of NPNA to human health have to be considered not controlled.

In the registration dossiers, no information on dermal absorption rates is available, and the dermal absorption is considered equal to oral absorption (=50%) when deriving dermal DNELs. Therefore, the current dermal DNELs might be overestimated due to the default assumption of high percentage of dermal absorption. If the dermal absorption, however, was in fact shown to be significantly lower than the currently used 50%, a more reliable and realistic risk characterisation assessment could be performed, which might result in lower RCRs. However, due to the absence of this key information and in view of an expected significant exposure of consumers and workers, the evaluating MSCA is not able to conclude on risks for consumers and workers after dermal exposure to NPNA.
In view of the above listed limitations of available information, a study is considered necessary as it generates robust and reliable data for adequate DNEL derivation and risk characterisation for the dermal route of human exposure and for determining appropriate potential risk management measures.

What is the possible regulatory outcome

The results of the requested dermal absorption study are considered necessary for an adequate derivation of dermal DNELs for infrequent and long-term exposure. The derivation of more realistic DNELs will allow the evaluating MSCA to refine the subsequent risk characterisation and finally conclude, whether there are realistic risks for consumers and workers after dermal exposure. Currently the DNELs might be overestimated and, thus, may not necessarily reflect realistic conditions due to the high dermal absorption estimated; however without substance specific information on dermal absorption such a necessary refinement is not possible and the risks of NPNA to human health have to be considered not controlled. Hence, clarification of whether there is a realistic risk regarding dermal exposure of consumers and workers is considered essential for ECHA to be able to adequately conclude on appropriate risk management measures to be implemented, e.g. regulatory management option analysis (RMOA), which potentially could lead to a restriction.

Considerations on the test method and testing strategy

The OECD TG 428 study shall be performed using well-described viable human skin from appropriate locations of the human body (preferably hairless skin), an appropriate solvent and doses which are representative of relevant human exposure situations in a manner that at least eight skin samples from at least four donors can be taken for evaluation.

As the guideline OECD TG 428 describe the investigation of dermal absorption from a rather broad and unspecific perspective, the dermal absorption study has to be in line with the Scientific Committee on Consumer Safety (SCCS) basic criteria for the in vitro assessment of dermal absorption of cosmetic ingredients, which addresses in more detail important points to consider in order to obtain scientifically valid results (SCCS, 2010).

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In these relatively complex in vitro studies, there are a number of points that require special attention that shall be considered by you:

1) The design of the diffusion cell (technicalities and choice between static and flow through system).
2) The choice of the receptor fluid (physiological pH, solubility and stability of chemical in receptor fluid should be demonstrated, no interference with skin/membrane integrity, analytical method, etc.).
3) Skin integrity is of key importance and should be verified.
4) Skin temperature has to be ascertained at normal human skin temperature.
5) The test substance has to be rigorously characterised.
6) Dose (several small dosages shall be used) and vehicle (aqueous solution)/formulation should be representative of the in-use conditions.
7) Dose, volume and contact time with the skin have to mimic in-use conditions. The duration has to be at least 24 hours.
8) Regular sampling is required over the whole exposure period.
9) Appropriate analytical techniques should be used. Their validity, sensitivity and detection limits should be documented in the report.
10) The test compound is to be determined in all relevant compartments:
    - product excess on the skin surface (dislodgeable dose),
    - stratum corneum (e.g. adhesive tape strips),
    - living epidermis (without stratum corneum),
    - dermis,
    - receptor fluid.
11) Mass balance analysis and recovery data are to be provided. The overall recovery of test substance (including metabolites) should be within the range of 85 - 115 %.
12) Eight skin samples from at least four donors shall be used. Variability/validity/reproducibility of the method shall be demonstrated and discussed.

The amounts measured in the dermis, epidermis (with stratum corneum) and the receptor fluid will be considered as dermally absorbed and taken into account for further calculations of respective DNELs. You shall submit the full study report for the requested skin absorption study. Considering the complexity of the case as described above, a complete rationale and access to all information available in the full study report (implemented methodological details, raw data collected, interpretations and calculations, consideration of uncertainties, argumentation, etc.) are needed. This will allow the evaluating MSCA to fully assess the provided information, including the statistical analysis, and to efficiently clarify the concern for the dermal exposure of consumers and workers.

Consideration of alternative approaches

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The request for a skin absorption in vitro test (Test method EU B.45; OECD TG 428) is suitable and necessary to obtain information that will allow to clarify whether there is a realistic risk regarding dermal exposure of consumers and workers. More explicitly, there is no equally suitable alternative way available of obtaining this information.

To clarify the potential risk of dermal use of the substance, instead of requesting complex information on each of the numerous uses of the substance and on various article matrices, ECHA considers it less onerous to request information on a single parameter of the substance relevant to consumers and workers, i.e. dermal absorption.

The proposed test is considered the scientifically most appropriate measure as the in-vitro test system most closely emulates the exposure situation for humans and therefore is superior to an in vivo study in animals which would also be less appropriate considering animal welfare.

Consideration of your comments

You are of the opinion that the risk assessment performed by you yields RCRs below 1 for each dermal exposure scenario and therefore is satisfying all ECHA recommendations and following all ECHA guidelines. Thus, you do not agree that there is currently a risk and further experimental data are required. The evaluating MSCA modified the decision to clarify the justification for the request. Even after considering the information in your updated dossier and further informal communication with you, the DNELs derived by you differ from the ones derived by the evaluating MSCA, as differing dose descriptor starting points (NOAEL vs. LOAEL) were used. Further, the evaluating MSCA asked you informally about information on migration and release of NPNA from rubber products, especially from products intended for consumer use and contact, which you did not provide thereafter. Without this information (and without having received further information from you), exposure scenarios can only be calculated as described above.

Applying the DNELs and exposure scenarios calculated by the evaluating MSCA, the risk associated with handling NPNA by both, workers and consumers, has to be considered not adequately controlled (RCRs >1) in some cases. Thus, further experimental data is deemed necessary for refinement of risk assessment to be able to conclude, whether the substance actually and realistically poses a risk to human health or not.

It is acknowledged that the parameter 'dermal absorption' might be currently significantly overestimated in the performed DNEL calculations by you and the evaluating MSCA (i.e. 50 % absorption). However without substance-specific experimental data no refinement of risk assessment of NPNA can be conducted. A realistic and hence potentially lower value for dermal absorption (<50 %) might lead to higher DNEL values and, thus, lower RCRs.

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References

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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 PBT properties and wide dispersive use, N-1-naphthylaniline CAS No 90-30-2 (EC No 201-983-0) was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2012. The updated CoRAP was published on the ECHA website on 29 February 2012. The competent authority of Germany (hereafter called the evaluating MSCA) was appointed to carry out the evaluation.

In accordance with Article 46(1) of the REACH Regulation, a substance evaluation decision was issued on 14 May 2014 requesting further information. You submitted all the requested information on 17 August 2017. The evaluating MSCA carried out the evaluation of the information in your updated registration(s) and other relevant and available information.

In the course of the follow up evaluation, the evaluating MSCA identified additional concerns regarding dermal exposure of consumers and workers and RCRs > 1 for the considered exposure scenarios.

The evaluating MSCA considered that further information was required to clarify the above-mentioned concern. Therefore, it prepared a draft decision under Article 46(3) of the REACH Regulation to request further information. It subsequently submitted the draft decision to ECHA on 14 June 2018.

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. On 7 August 2018 you submitted update(s) of the registration dossier(s).

The evaluating MSCA took the comments from you and the information in the updated registration dossier(s) into account as reflected in the reasons (Appendix 1). The request(s) and the deadline were not amended.

Proposals for amendment by other MSCAs and ECHA and referral to the 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.

As no amendments were proposed, ECHA took the decision according to Articles 52(2) and 51(3) of the REACH Regulation.

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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.

3. In relation to the required experimental study, the sample of the substance to be used ('test material') has to have a composition that is within the specifications of the substance composition that are given by all registrant(s). It is the responsibility of all the registrant(s) to agree on the tested material to be subjected to the test subject to this decision and to document the necessary information on the composition of the test material. The substance identity information of the registered substance and of the sample tested must enable the evaluating MSCA and ECHA to confirm the relevance of the testing for the substance subject to substance evaluation.

4. In relation to the experimental studies the legal text foresees the sharing of information and costs between registrant(s) (Article 53 of the REACH Regulation). You are therefore required to make every effort to reach an agreement regarding each experimental study for every endpoint as to who will carry out the study on behalf of the other registrant(s) and to inform ECHA accordingly within 90 days from the date of this decision under Article 53(1) of the REACH Regulation. This information should be submitted to ECHA using the following form stating the decision number above at: https://comments.echa.europa.eu/comments_cms/SEDraftDecisionComments.aspxF
Further advice can be found at:
http://echa.europa.eu/regulations/reach/registration/data-sharing
If ECHA is not informed of such agreement within 90 days, it will designate one of the registrants to perform the studies on behalf of all of them.