

Committee for Risk Assessment  
RAC

Annex 2  
Response to comments document (RCOM)  
to the Opinion proposing harmonised classification and  
labelling at EU level of

Nitric Acid ... %

EC Number: 231-714-2  
CAS Number: 7697-37-2

CLH-O-0000001412-86-210/F

Adopted  
8 June 2018

## COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during public consultation are made available in the table below as submitted through the web form. Any attachments received are referred to in this table and listed underneath, or have been copied directly into the table.

All comments and attachments including confidential information received during the public consultation have been provided in full to the dossier submitter (Member State Competent Authority), the Committees and to the European Commission. Non-confidential attachments that have not been copied into the table directly are published after the public consultation and are also published together with the opinion (after adoption) on ECHA's website. Dossier submitters who are manufacturers, importers or downstream users, will only receive the comments and non-confidential attachments, and not the confidential information received from other parties.

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Substance name: nitric acid ... %

EC number: 231-714-2

CAS number: 7697-37-2

Dossier submitter: Germany

## GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
09.06.2017	Austria	Environment Agency Austria	National Authority	1
Comment received				
I would like to thank Germany for their careful and comprehensively written CLH Report for Nitric acid (< and > 70%). I support the classification proposal.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH Report for Nitric acid comment AT.docx				
Dossier Submitter's Response				
DE would like to thank AT for the support.				
RAC's response				
The support is noted.				

Date	Country	Organisation	Type of Organisation	Comment number
09.06.2017	Belgium	<confidential>	Industry or trade association	2
Comment received				
EDA's Position on Nitric Acid On the CLP report in the context of the public consultation launched by ECHA on the 24 April 2017. Part 1: Comment on the harmonized classification and labelling of nitric acid and more particularly on the Hazard class Acute toxicity and proposed future entry in Annex VI of CLP Regulation The European dairy industry uses nitric acid blends for cleaning purposes, but is only the end user of the chemical, and this is at lower concentrations. The specialists in the manufacture and storage of the raw chemical remain the producers, who are the only people who may come into contact with nitric acid at over 70% concentration.				

Most nitric acid is sold and transported to dairy processing companies by the chemical blending industry, who will mix the nitric acid with other chemicals (for example phosphoric acid) in order to produce a cleaning agent with the best properties to remove the calcium based deposits in milk processing tanks and pipework.

Typically, the acid blends will be transported around 53% v/v concentration, in order to ensure prevention of toxic fume production, but also to maximise the efficiency of transportation. The acid blends are only dangerous to humans at the point of transfer from one storage tank to another. This is the critical risk point.

A reclassification of toxicity in Annex VI will only mean that a lower concentration of acid will be transported to dairy sites. This concentration will still be harmful with direct contact, and the consequence of a significant increase in transportation of acid will be to increase the risk of exposure at the critical risk points – the transfer of the acid from manufacturer's storage tanks to road tanker, and then again on transfer from road tanker to dairy processor storage tanks.

In effect, the proposed change to the legislation will not, in practice, lower the risk of nitric acid, but increase the risk by perhaps three times, as there will be three times as many transfers (producer to road tanker and road tanker to customer) as before.

The European Dairy Association is therefore highlighting the very real and practical danger of reclassifying nitric acid, as opposed to a theoretical situation in a previously unknown occurrence of sudden, massive release of nitric acid (at less than 70% concentration).

Part 2: impact assessment in the dairy sector

### 2.1. Use of nitric acid in dairy installations

Nitric acids are used in cleaning specifically in CIP plants (cleaning in place).

- Against mineral and metallic stains (scale coming from minerals, oxydation, galalith/ erinea/ 'pierre de lait', etc.)
- To act in dissolving these scales and galalith
- With temperatures of mostly 65°C (50°C in manual washing)

The concentration in the tanks, used in the dairy industry, of nitric acids is usually 50%. With special dosage pumps the nitric acid is pumped into CIP tanks where the concentration used in the dairy industry varies between 0.5 and 2%. The dissolution is done with water.

With technical nitric acid of <26% concentration, the volumetric consumption will be up to three times greater. This means that additional costs could arise for inventory management, delivery, storage etc.

A differentiation is necessary for nitric acid used by consumers or for commercial use. For consumers, products must comply with stricter safety requirements than products for commercial use, as there are less regulations on how the chemical is used, and no monitoring of consumer behaviour by the authorities.

For industrial use, production facilities are for the most part permitted, and constantly monitored by both safety and environmental regulatory bodies in European countries. Staff at industrial facilities are also trained in the use and handling of chemicals, whereas the general public as consumers are not.

### 2.2. Practical and social consequences of a possible reclassification

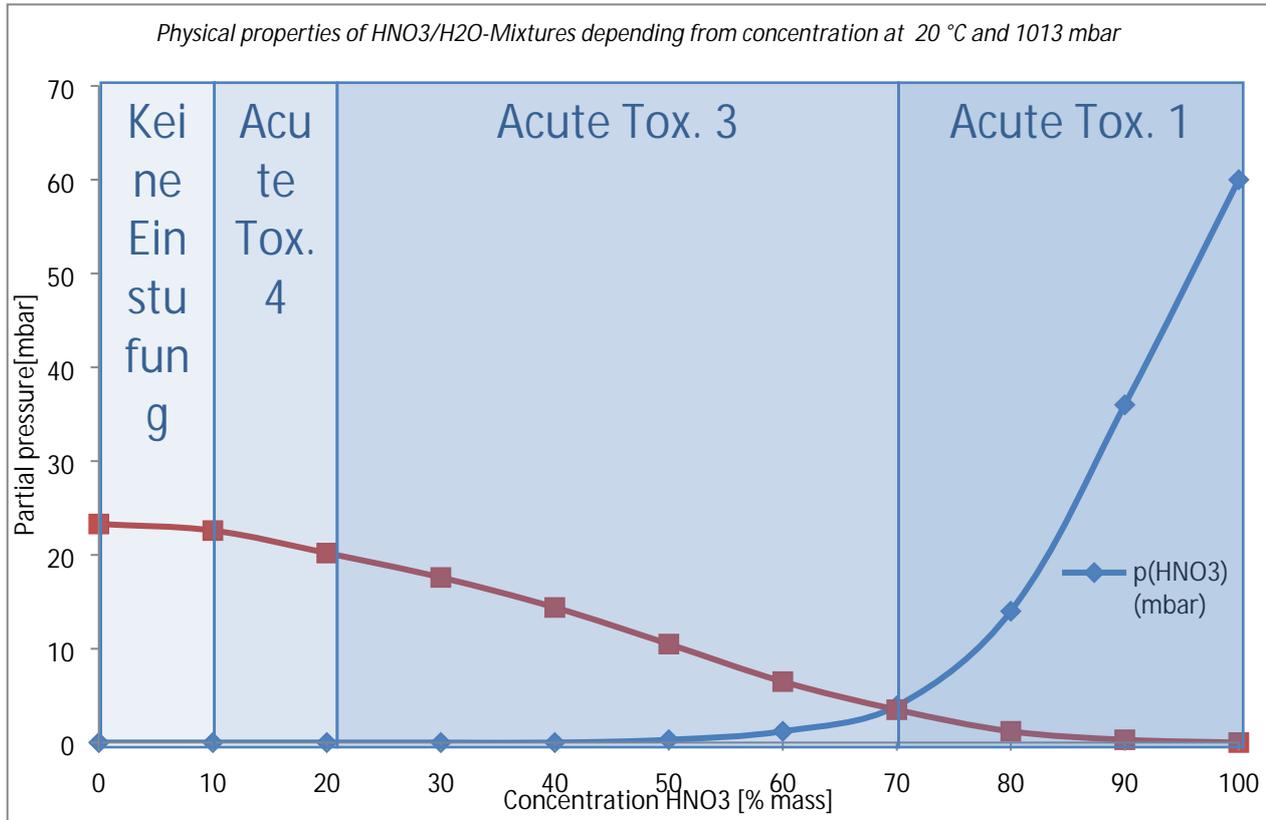
If being re-classified as 'acute toxic' nitric acid it would fall under more restrictive measures – namely the so-called "Seveso III" Directive.

This Directive 2012/18/EU "on the control of major-accident hazards involving dangerous substances" demands very specific measures to be taken by the plants dealing with those

<p>substances. The control measures are heavy and expensive - due to the overall high hazard for substances falling under 'Seveso'. This is unsustainable.</p> <p>A reclassification of toxicity in Annex VI will only mean that a lower concentration of acid will be transported to dairy sites. This concentration will still be harmful with direct contact, and the consequence of a significant increase in transportation of acid will be to increase the risk of exposure at the critical risk points – the transfer of the acid from manufacturer's storage tanks to road tanker, and then again on transfer from road tanker to dairy processor storage tanks.</p> <p>In effect, the proposed change to the legislation will not, in practice, lower the risk of the nitric acid, but increase the risk by perhaps three times, as there will be three times as many transfers (producer to road tanker and road tanker to customer) as before.</p> <p>Today, more than 30 European dairy plants have a storage capacity higher than 50 tons for nitric acid with a concentration between 26 and 65%. Then, Seveso measures and "branding" will also be associated with these installations which are producing food - not chemicals - and it will create a misunderstanding or mistrust among consumers.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2017 06 09 EDA position on nitric acid for ECHA consultation (FD).pdf</p>
<b>Dossier Submitter's Response</b>
<p>From the recent fitness check evaluation of all chemical legislation except REACH it is recognized that generic risk considerations based on classification alone might lead to measures which appear to be disproportionate.</p> <p>However, the problem cannot be solved in the context of the CLP Regulation but needs to be thoroughly considered in the down-stream consequences.</p> <p>Therefore we are aware of the challenges that might be associated with the proposed classification. However, we would like to point out that classification and labelling is dealing with the intrinsic toxic properties of a substance and that considerations on risk are not foreseen in this process.</p> <p>The necessity to classify nitric acid &lt; 70 % for the endpoint acute toxicity is underlined by cases of severe poisonings (including death) following handling of nitric acid at concentrations of 20 % or higher.</p>
<b>RAC's response</b>
<p>Classification and labelling according to CLP is only based on the intrinsic (toxic) properties of substances. Consideration of risk or socio-economic impact is not part of the CLP regulation.</p>

Date	Country	Organisation	Type of Organisation	Comment number
09.06.2017	France	UNIFA	Company-Manufacturer	3
<b>Comment received</b>				
<p>As described in the document attached, the non-linearity of nitric acid vapor pressure, and more particularly below 70%, underlines that the linearity of the CLP additivity formulae is not relevant in the case of nitric acid (substance with an azeotrope at 68%).</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment Nitric acid CLH_UNIFA comments 08062017.pdf</p>				
<b>Dossier Submitter's Response</b>				
<p>We are aware of the non-linear behaviour between the concentration of nitric acid in aqueous solution and in gas phase underlined by the presence of an azeotropic point. This was the reason, why classification of nitric acid (C &gt; 70 %) and nitric acid (C ≤ 70 %) are</p>				

considered separately. The classification proposal is, however, based on the assumption of linearity below and above the azeotropic point, respectively, as can be seen from the figure:



**RAC's response**

RAC supports the approach with two separate entries proposed by the Dossier Submitter (DS) as this seems to be a relevant simplification of the non-linearity. Additional entries would become too complicated, there is no scientific basis for deciding on the levels, and the human cases show that even lethal effects have occurred at concentrations below the threshold proposed for no classification in the comment.

Date	Country	Organisation	Type of Organisation	Comment number
06.06.2017	Belgium	Fertilizers Europe	Industry or trade association	4

**Comment received**

Fertilizers Europe welcomes the CLP report and the proposal on the harmonized classification of nitric acid. The proposal recognizes the need for classifications to be based on the relevant concentrations of the nitric acid. Fertilizers Europe submits supporting physico-chemical data characterizing nitric acid and its solutions in water.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment HNO<sub>3</sub>\_2017.06.06\_I-T\_FE\_ECHA\_submission\_vf (2).doc

### Dossier Submitter's Response

#### Ad: "Executive Summary"

We would like to thank Fertilizers Europe for the support and for the substantial background to the proposal to base the classification of HNO<sub>3</sub>-containing mixtures on partial pressure.

#### Ad Part I a:

As concerns the non-linearity between nitric acid in the gaseous and aqueous phase, the issue has already been considered by suggesting different classification entries for nitric acid ( $C > 70\%$ ) and nitric acid ( $C \leq 70\%$ ). We are aware of the non-linear behaviour between the concentration of nitric acid in aqueous solution and in gas phase underlined by the presence of an azeotropic point. The classification proposal is, however, based on the assumption of linearity below and above the azeotropic point.

#### Ad Part Ib

No accurate LC<sub>50</sub> value for nitric acid 70 % was derived. However, the results of single 4-hour exposure to 2.65 mg/L in conjunction with the observations of severe pain, enduring distress, and suffering of animals enable classification and labelling of the test substance. It is assumed that the real LC<sub>50</sub> value for nitric acid 70 % lies within the range of the cut-off values for classification in the acute inhalation toxicity hazard Category 3 (vapours) according to CLP and which is  $2.0 < ATE \leq 10.0$  mg/L/4hr.

We have sympathy for fertilizers Europe stating "70 % nitric acid solution is the highest concentration of this entry, and as such represents the 100 % case of the entry 'nitric acid  $C \leq 70\%$ ". We agree that the LC<sub>50</sub> used for inhalation does not as such relate to the concentration in the solution from which the substance is vaporized but only to the concentration in the vapour giving the lethal effects. As a consequence the converted acute toxicity point estimate for the ATE value of 3 mg/L/4h could be seen as intrinsic LC<sub>50</sub> value for HNO<sub>3</sub> inhalation from water based systems. This value could then be used as general starting point for ATE calculation concerning mixtures. We would suppose RAC to consider this alternative.

#### Ad Part II

We are also of the opinion that the CLP Regulation uses a simplified method to address the acute inhalation toxicity of diluted mixtures. Even if the vapour pressure, which is not linear to the concentration in the aqueous solution, might be an important driving force for concentrations in the inhalation vapour phase, this phenomenon is not reflected in the CLP-rules for classification. Instead ATE values are used in a pragmatic and generic approach for a rough calculation of a range of toxicity. Therefore the suggestions brought up by Austria concerning the relationship between acute inhalation toxicity and vapour pressure are interesting with respect to modelling inhalation exposure but not relevant for the classification of mixtures. However, considerations in this respect need to be performed in workers risk assessment.

### RAC's response

Ad part Ia – RAC supports the reply provided by the DS.

Ad part Ib – RAC supports the reply provided by the DS. Regarding the ATE, RAC agrees with the comment that a correction of the default ATE is not relevant. RAC has proposed to use the studied concentration as the ATE (i.e. 2.65 mg/L/4h).

Ad Part II – RAC supports the response provided by the DS. See also the response by RAC on comment 3.

## OTHER HAZARDS AND ENDPOINTS – Acute Toxicity

Date	Country	Organisation	Type of Organisation	Comment number
09.06.2017	Austria	Environment Agency Austria	National Authority	5
Comment received				
<p>From the explanation under the heading "Acute inhalation toxicity estimate (ATE inhalation)", on pages 29-31, it appears that the ATE of 3 mg/L/4h should be corrected to 2.1 mg/L/4h. I would ask to explain this with some more words, since the ATE of 3 mg/L/4h is based on an LC50 value for the pure HNO<sub>3</sub>, not a 70% HNO<sub>3</sub> solution. Furthermore it appears clear from the CLH report, that for calculating ATEs for mixtures containing less than 70% HNO<sub>3</sub>, DE suggests to use the formula from CLH regulation, Annex I, Part 3, Point 3.1.3.6.1. or 2.</p> <p>It would be useful to include also considerations, why these formulas should be used in spite of the fact that the relation between aqueous concentration of HNO<sub>3</sub> and its vapour pressure is not linear. For regulation of products it is important to agree on a highest concentration that would not lead to a classification in category 3 (but only 4 or no classification). Eventually the available human data indicating accidents at the low concentrations of 20% could be used to support this?</p> <p>However the following logic should be considered and discussed by RAC: The application of the formula according to CLP Annex I, 3.1.3.6.1 (<math>100/ATE_{mix} = C_i/ATE_i</math>) to calculate the maximum <math>C_i</math> in the solution which would not lead to classification of the mixture for (vapour) inhalation toxicity (<math>100/10 = C_i/3</math>; <math>C_i = 30\%</math>) is scientifically not convincing, since there is no linear relationship between the aqueous concentration of HNO<sub>3</sub> and its vapour pressure. Considering the vapour pressure of HNO<sub>3</sub> at 60% (i.e. 120 Pascal) and 70% (i.e. 390 Pascal) and applying the ideal gas law (vapour pressure [Pa] x molecular weight [g/mol]) / (gas constant R (8,314) x temperature [K] (298)) results in a saturated vapour concentration of 3 mg/L HNO<sub>3</sub> and 9.9 mg/L HNO<sub>3</sub>, respectively. Considering that HNO<sub>3</sub> is classified in category 3 (ATE of 3 mg/L), a concentration in the solution of 60% and higher would result in a saturated vapour concentration leading to lethality. Consequently these mixtures should be classified for category 3.</p> <p>A solution with 50% HNO<sub>3</sub> (i.e. 30 Pascal) would lead to a saturated vapour concentration of 0.76 mg/L. This is 4-fold below the ATE of 3 mg/L for HNO<sub>3</sub>, hence the ATE<sub>mix</sub> for this vapour is 4 fold higher, i.e. 12 mg/L. Consequently a 50% solution should be classified in category 4 (category 4 range: 10-20 mg/L).</p> <p>Following this logic, any solution leading to a saturated vapour concentration from 0.9 mg/L and higher should be classified with acute toxicity category 3 (ATE<sub>mix</sub> &lt; 10mg/L). Any solution leading to a saturated vapour concentration between 0.9 mg/L and 0.45 mg/L should be classified with acute toxicity category 4 (ATE<sub>mix</sub> between 10 mg/L and 20 mg/L).</p> <p>see attachment including this comment and a table with vapour pressures).</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH Report for Nitric acid_comment AT.docx</p>				
Dossier Submitter's Response				
<p>We would like to thank Austria for the interesting proposal considering the vapour pressure of HNO<sub>3</sub> as relevant parameter for the assessment of inhalation toxicity.</p> <p>However, we are of the opinion that the CLP Regulation in general uses a simplified method to address the acute inhalation toxicity of diluted mixtures which does not rely on actual inhalation exposure. Instead a linearized calculation based on the intrinsic ATE value is used for classification giving a rough assessment of the potential inhalation toxicity of a liquid mixture. In doing so classification for inhalation toxicity on purpose</p>				

does not depend on vapour pressure or other parameters relevant for inhalation exposure assessment. Classification will thus be robust whatever exposure might occur.

It has to be kept in mind that different techniques might be used in practice for application of the mixture. This may lead to aerosol generation in addition to vapours which substantially increases the inhalation exposure above the level calculated with saturated vapour pressure. The comments of Austria are therefore highly welcome and will need to be included in calculations concerning risk assessment at the workplace.

#### RAC's response

RAC agrees with the comment regarding not to correct the ATE, but otherwise support the response from the DS when it comes to keeping the CLP system simple and robust. RAC also notes that evidence suggest that it is not only the vapour pressure of nitric acid that determines the hazard, as severe toxic effects in humans have been observed at concentrations where the vapour pressure is low.

Date	Country	Organisation	Type of Organisation	Comment number
09.06.2017	Belgium	<confidential>	Industry or trade association	6

#### Comment received

Please find the EDA's comprehensive position attached below.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2017 06 09 EDA position on nitric acid for ECHA consultation (FD).pdf

#### Dossier Submitter's Response

From the recent fitness check evaluation of all chemical legislation except REACH it is recognized that generic risk considerations based on classification alone might lead to measures which appear to be disproportionate. However, the problem cannot be solved in the context of the CLP Regulation but needs to be thoroughly considered in the downstream consequences.

On that background we are aware of the challenges that might be associated with the proposed classification. However, we would like to point out that classification and labelling is dealing with the intrinsic toxic properties of a substance and that considerations on risk are not foreseen in this process.

The necessity to classify nitric acid  $\leq 70\%$  for the endpoint acute toxicity is underlined by cases of severe poisonings (including death) following handling of nitric acid at concentrations of 20 % or higher.

#### RAC's response

Classification and labelling according to CLP is based on the intrinsic (toxic) properties of substances. Consideration of risk or socio-economic impact is not part of the CLP regulation.

Date	Country	Organisation	Type of Organisation	Comment number
09.06.2017	France	UNIFA	Company-Manufacturer	7

#### Comment received

Taking account of the demonstration attached based on vapor pressure, two other additional entries should be considered for the hazard of acute toxicity by inhalation.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Nitric acid CLH\_UNIFA comments 08062017.pdf

<b>Dossier Submitter's Response</b>				
We welcome the comment provided by UNIFA and would like to address the issues raised by UNIFA as follows:				
1a) The current classification proposal is restricted to nitric acid below 70 % concentration.				
1b) We agree to the argument that the LC <sub>50</sub> used for inhalation does not as such relate to the concentration in the solution from which the substance is vaporised but only to the concentration in the vapour giving the lethal effects(see above). As a consequence the converted acute toxicity point estimate for the ATE value of 3 mg/L/4h could be seen as intrinsic LC <sub>50</sub> value for HNO <sub>3</sub> inhalation from water based systems. This value could then be used as general starting point for ATE calculation concerning mixtures. We would suppose RAC to consider this alternative.				
2) We would like to thank for the interesting proposal considering the vapour pressure of HNO <sub>3</sub> as relevant parameter for the assessment of inhalation toxicity. However, we are of the opinion that the CLP Regulation in general uses a simplified method to address the acute inhalation toxicity of diluted mixtures which does not rely on actual inhalation exposure. Instead a linearized calculation based on the intrinsic ATE value is used for classification giving a rough assessment of the potential inhalation toxicity of a liquid mixture. In doing so classification for inhalation toxicity on purpose does not depend on vapour pressure or other parameters relevant for inhalation exposure assessment. Classification will thus be robust whatever exposure might occur.				
It has to be kept in mind that different techniques might be used in practice for application of the mixture. This may lead to aerosol generation in addition to vapours which substantially increases the inhalation exposure above the level calculated with saturated vapour pressure. The comments are however highly welcome and will need to be included in risk assessment calculations.				
<b>RAC's response</b>				
1a – Noted.				
1b – RAC supports the comment in that a correction of the ATE is not relevant in this case.				
2 – RAC supports the response provided by the DS. See also the RAC response to comment number 3.				
<b>Date</b>	<b>Country</b>	<b>Organisation</b>	<b>Type of Organisation</b>	<b>Comment number</b>
09.06.2017	Belgium	AISE International Association for Soaps, Detergents and Maintenance Products	Industry or trade association	8
<b>Comment received</b>				
Detailed comments on the ATE for Acute toxicity Cat. 3 are provided in the attached paper				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment AISE comments on nitric acid CLH final.docx				
<b>Dossier Submitter's Response</b>				
We would like to thank AISE for the comment. We have sympathy for AISE's disagreement to a virtual ATE value of 2.1 mg/L/4h (see also above). The value is the				

<p>result of an extrapolation from 70 % to 100 %. However, we agree that the LC<sub>50</sub> used for inhalation does not as such relate to the concentration in the solution from which the substance is vaporized but only to the concentration in the vapour giving the lethal effects.</p> <p>As a consequence the converted acute toxicity point estimate for the ATE value of 3 mg/L/4h could be seen as intrinsic LC<sub>50</sub> value for HNO<sub>3</sub> inhalation from water based systems. This value could then be used as general starting point for ATE calculation concerning mixtures. We would suppose RAC to consider this alternative.</p>
RAC's response
RAC is also of the opinion that a correction of the ATE is not relevant in this case. RAC has proposed to use the studied concentration as the ATE (i.e. 2.65 mg/L/4h).

Date	Country	Organisation	Type of Organisation	Comment number
09.06.2017	France		MemberState	9
Comment received				
<p>FR finds regrettable that the study carried out especially to support a lower classification than existing does not conform to guideline with only one concentration tested. In particular, in the description of the study, the choice of the concentration used is not justified (is it the maximum attainable concentration?). Considering the fact that there is only one concentration, it is an important point to clarify.</p> <p>In addition, 4 animals lost their nose tips. Could you please clarify if this state should be considered as a moribund state of the animals? In this case, those animals should have been killed, and considered in the interpretation of the test result in the same way as animals that died on test (OECD guideline).</p>				
Dossier Submitter's Response				
<p>We welcome the comments submitted by France mainly on animal welfare aspects. We are not aware that – comparable to testing proposals under REACH – any discussion addressing the scientific justification (necessity) or animal welfare aspects with respect to this test has been performed for that particular case.</p> <p>The history behind this test is described in section 2.1 of the dossier. In brief, in RAC-24 the proposal to classify nitric acid with Acute Tox. 1; H330 (Fatal if inhaled) with the supplemental hazard information EUH071 (Corrosive to the respiratory tract) had been agreed upon published for its potential inclusion in the 7<sup>th</sup> Adaptation to Technical Progress (ATP). In February 2014, members of industry commented that the toxic effects of nitric acid at lower concentrations in more diluted aqueous solutions (i.e. below the azeotropic point at approximately 70 %) and of pure, highly concentrated acid may be very different. As the result of a dialogue with industry representatives in April 2014, industry volunteered to perform a guideline conforming acute inhalation toxicity study to provide quantitative animal data on the acute inhalation hazard potential of nitric acid, at the azeotropic point (approximately 70 %).</p> <p>According to the sponsor of the test, it was aimed at minimising aerosol while maximising vapour. The concentration tested should therefore be considered as a sort of limit concentration. As such, the sponsor considers the study as being conform to OECD 403, which might be a matter of debate.</p> <p>As described in section 4.2.1.2 of the CLH report, the study is commented as follows: "It is to be expected that this tissue damage has led to severe pain and severe distress</p>				

lasting for the duration of the damage, the ensuing inflammatory process and persists after the local tissue damage has healed. Such persistent pain and distress lead to suffering of animals. There were also some unspecific toxic effects, especially piloerection and yellow-stained fur."

#### RAC's response

RAC initially shared the concern expressed by the French CA, and therefore asked for clarification regarding the symptoms and whether the laboratory had followed the OECD Guidance document on the recognition, assessment, and use of clinical signs as humane endpoints for experimental animals used in safety evaluation (OECD Guidance No. 19, 2000). The laboratory replied that the wording 'loss of the nose tip' is misleading and that they will amend the study report to clarify that the effect was a superficial, small-area tissue damage at the very tip of the nose. They also stated that the clear result of the evaluation of the clinical signs (according to OECD Guidance No. 19, 2000) was that no surviving animal was in a moribund state during the study.

Although it seems that the animals suffered from the exposure, the description of the symptoms is not sufficiently detailed to allow an independent assessment of the findings. RAC therefore accepts the clarification from the study director and accepts that animal welfare considerations have been followed. Thus, based on one dead animal and signs of toxicity in many other animals, RAC supports the proposal from the DS that the LC<sub>50</sub> is likely to be in the range of 2-10 mg/L/4h, and that classification in Category 3 is warranted.

Date	Country	Organisation	Type of Organisation	Comment number
08.06.2017	Germany	BASF SE / E-CMI/Q	Company-Manufacturer	10

#### Comment received

The way to find the classification of nitric acid in concentrations above 70% is not fully understood:

Experiments performed by Gray and coworkers in the 1950ies employed NO<sub>2</sub> gas and vapours emitting NO<sub>2</sub> from Red Fuming Nitric acid or White Fuming Nitric acid. A test atmosphere enriched with NO<sub>2</sub> was obtained by passing a stream of air through glass wool that was rinsed with White or Red Fuming Nitric Acid (1).

Values reported in these studies and adopted by NIOSH refer to NO<sub>2</sub> (2).

The analytical method employed for NO<sub>2</sub> quantification is described to be insensitive towards atmospheric nitric acid and nitrates (3).

The conversion of NO<sub>2</sub> values to nitric acid concentrations remains unclear.

1. Gray, E. Le B., Goldberg, S.B., and Patton, F.M.:

Toxicity of the Oxides of Nitrogen: I.

Introduction and Apparatus, A.M.A. Arch. Indust. Hyg. Occup. Med. 10:409-17, 1954.

2. Gray, E. Le B., Patton, F.M., Goldberg, S.B., and Kaplan, E. :

Toxicity of the Oxides of Nitrogen: II.

Acute Inhalation Toxicity of Nitrogen Dioxide, Red Fuming Nitric Acid, and White Fuming Nitric Acid, A.M.A. Arch. Indust. Hyg. Occup. Med. 10:418-22, 1954.

3. Patty, F.A., and Petty, G.M.: Nitrite Field Method for the Determination of Oxides of Nitrogen (Except N<sub>2</sub>O and N<sub>2</sub>O<sub>5</sub>), J. Indust. Hyg. & Toxicol. 25:361, 1943.

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment HNO3_class_grtr_70.zipx
<b>Dossier Submitter's Response</b>
We would like to point out that classification of nitric acid in concentrations above 70 % has already been discussed; the issue here is classification of nitric acid at concentrations $\leq 70$ %.
<b>RAC's response</b>
The classification of nitric acid at concentrations above 70 % is based on the LC <sub>50</sub> values reported in two rather old acute inhalation studies in rats with exposure to concentrated fuming nitric acid. The reported LC <sub>50</sub> -values support Acute Tox. 1. It is likely that NO <sub>2</sub> emitted from the fuming nitric acid contributes to the toxicity, but Category 1 is justified, has been agreed by RAC previously (at RAC-24) and is now confirmed by RAC.

Date	Country	Organisation	Type of Organisation	Comment number
06.06.2017	Belgium	Fertilizers Europe	Industry or trade association	11
<b>Comment received</b>				
<p>In particular, data is given describing the non-linear relationship between the concentration of nitric acid in solution and its concentration in the corresponding vapor phase. The relevance of this non-linear behavior for the classification based on inhalation toxicity, as measured in the vapor phase, is given. Nitric acid shows a large negative deviation from the ideal (linear) correlation, meaning that at rather high concentrations in solution only a low concentration in the corresponding vapors is found. A diagram is enclosed in the documents attached. An azeotrope (a constant boiling mixture) is formed by nitric acid and water at a concentration of just above 68 %, attesting to the non-linear behavior of nitric acid.</p> <p>These non-linear physico-chemical data underline that for nitric acid, applying additivity formulae, based on a linear correlation between the concentration in the solution and the inhalation dose in the vapor phase (and derived toxicity classification) is not justified. For more detailed information see the attached document.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment HNO3_2017.06.06_I-T_FE_ECHA_submission_vf (2).doc</p>				
<b>Dossier Submitter's Response</b>				
We are aware of the non-linear behaviour between the concentration of nitric acid in aqueous solution and in gas phase underlined by the presence of an azeotropic point. This was the reason, why classification of nitric acid (C > 70%) and nitric acid (C $\leq$ 70 %) are considered separately. The classification proposal is, however, based on the assumption of linearity below and above the azeotropic point, respectively.				
<b>RAC's response</b>				
RAC supports the approach proposed by the DS.				

## PUBLIC ATTACHMENTS

1. CLH Report for Nitric acid\_comment AT.docx [Please refer to comment No. 1, 5]
2. 2017 06 09 EDA position on nitric acid for ECHA consultation (FD).pdf [Please refer to comment No. 2, 6]
3. Nitric acid CLH\_UNIFA comments 08062017.pdf [Please refer to comment No. 3, 7]
4. AISE comments on nitric acid CLH final.docx [Please refer to comment No. 8]
5. HNO3\_2017.06.06\_I-T\_FE\_ECHA\_submission\_vf (2).doc [Please refer to comment No. 4, 11]

CONFIDENTIAL ATTACHMENTS

1. HNO3\_class\_grtr\_70.zipx [Please refer to comment No. 10]