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-0000002560-82-03/A2

Adopted

31 May 2013

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

ECHA has compiled the comments received via the internet that refer to several hazard classes and entered them under each of the relevant categories/headings as comprehensively as possible. Please note that some of the comments might occur under several headings, when splitting the information provided is not reasonable.

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
30/07/2012	Germany	BASF SE	Company-Manufacturer	1

Comment received

At higher concentrations of nitric acid the effects of the acid HNO3 and NO2 as its precursor or its decomposition product cannot be clearly separated in the studies with fuming acids.
The effect of concentration and HNO3 partial pressures should also be considered for more dilute aqueous solutions.

Using the MEASE tool for calculating workers' exposure for the registration dossier of the FARM consortium, it could be predicted that for concentrations below 75% no particular respiratory protection would be needed, except for industrial spraying (PROC7).

We do not recommend HNO3 for consumer use and do not understand the vapour pressure of 89.6 hPa for the 30% HNO3 used in the ConsExpo calculation of BfR.
Taking data from Perry's Chemical Engineers' Handbook we have at 105°C a HNO3 partial pressure of 7.9 mmHg (10.5 hPa) in 30% HNO3.

BASF SE and affiliates registered HNO3 with the FARM consortium (Fertilizers and Related Materials REACH Consortium). Lead company for HNO3 was GPN.

Dossier Submitter's Response

Due to long-time research on the physical and chemical characteristics of nitric acid and countless projects on the subject, different statements regarding the vapour pressure of 30% HNO_3 and the partial pressure of HNO_3 can be found in the respective scientific literature.

Even using the partial vapour pressure of 0.336 hpa (cited by FARM without giving the source) in a model calculation with RIVMs ConsExpo Vs. 4.1 (2008) based on the same parameters as given in the BfR Report, show that the conclusions in this report are justified. The herewith estimated indoor-concentration for practically applied amounts of the cleaning agent is still about 8 mg/m³, which is clearly above recommended OELs. The German short-term OEL (for an exposure time of 15 min.) is about 1 ppm or 2.6 mg/m³ and the exposure limit (TWA) of the National Institute for Occupational Safety and Health (NIOSH) is 2 ppm or 5mg/m³.

In this context it should be noted that the parameters used for the calculations in the BfR Report do not reflect the worst-case scenario. Considering more stringent parameters (e.g. smaller room volume, larger amounts of the applied product, larger surface area) certainly result in higher values for the expected indoor air concentration. In the BfR Report a specific exposure situation was examined, such as applying a cleaning agent in a thin layer on a large area in a small bathroom with a low air-exchange rate. Since such products were also used to remove calcium carbonate deposits from surfaces, it needs to be considered that HNO_3 remains longer on the surface. When HNO_3 as ingredient in such products comes in contact with other materials (metal) or substances (e.g. basic ingredients from other cleaning agents), the release of nitrous gases is expected. Among these, especially NO_2 should be considered here, which is classified as Carc. Cat 3B by the German MAK-Commission.

The conclusion of the BfR is further supported by the many case reports of the poison information centres in Germany which document severe health damages after uses (and supposedly misuse) of descaling products containing 20-30% of HNO_3 between 1999 and 2010. In 23.7% of all cases the symptoms were caused by inhalation.

Consequently, we sustain our position that in cleaning agents containing 20-30% of nitric acid which are for sale to consumers constitute a disproportionally high health risk for consumers. Risk at inhalation is caused by the toxic effects of nitric acid and nitrous gases resulting from reactions with other substances. The comments by FARM and others also indicate that this view is supported by the fertilizer industry which regards the use of HNO_3 in consumer products as not to be recommended for sale to consumers.

RAC's response

Inhalation exposure to nitric acid due to its natural content of nitrous oxides and high reactivity will always be combined with nitrous oxides, mostly nitrogen dioxide. Assessment of the acute inhalation toxicity for classification purposes should be done for concentrated nitric acids and then for diluted aqueous solution calculated according to additivity principles (Section 3.1.3.6.1, Annex I, CLP).

Date	Country	Organisation	Type of Organisation	Comment number
03/08/2012	Sweden		MSCA	2

Comment received

SE supports classification of nitric acid (Cas No 7697-37-2) as specified in the proposal (Ox. Liq. 2 – H272; Acute Tox. 1 – H330, EUH071).

Dossier Submitter's Response

Thank you for the support.
It should be also added to the specific concentration limit (SCL) for the entry in annex VI: Ox. Liq. 2, H272: C ≥ 99 %

RAC's response

Agree with comment

Date	Country	Organisation	Type of Organisation	Comment

				number
03/08/2012	France	FARM REACH CONSORTIUM	Industry or trade association	3

Comment received

There is a proposal of harmonized classification of nitric acid as Acute Toxicity Category 1 for inhalation from Germany. This proposal follows up on an opinion BfR Opinion related to health risks of nitric acid contained in home cleaning products (BfR Opinion N°041/2010) and on a study with concentrated nitric acids containing various portions of NO2: (White Fuming NA 0,1-0,4% NO2 and Red Fuming NA 8-17% NO2).

FARM Consortium would like to highlight that:

1) In 2010, the nitric acid REACH dossier registered by members does not contain any consumer use. In reference to REACH regulation, it means that consumer use are not authorised since the 1st December 2010 in Europe.
This position may not be restrictive enough since products destined for the general public are still imported into Europe (e.g. cleaning products with a nitric acid content of more than 20%).
FARM Consortium recommends adding a restriction in the annex XVII of the REACH regulation 1907/2006, prohibiting the sale of nitric acid solutions containing more than 20% nitric acid to consumers.
Furthermore, the argument on vapor pressure developed by BfR in the report is wrong. Indeed, the HNO3 vapor pressure values used have been overestimated by a factor 270 times, therefore lead to wrong conclusions (more details are given attached).

2) There are two different type nitric acids which influence the toxicity, distinguishable with concentration ranges. On the one hand there is aqueous nitric acid (up to 68%) and on the other hand there is the smoking nitric acid (higher than 68%). Smoking acid nitric is only obtainable by bubbling of NOx into aqueous HNO3 (impossible to obtain by distillation as the 68% acid is an azeotropic mixture). Due to this chemical difference, these products have different acute toxicity profiles.
In the study of Gray et al., 1954, the acute toxicity observed with concentrated nitric acid (higher than 70%) is due to the inhalation of toxic NOx gases released by concentrated acid. The Acute Toxicity Category 1 for inhalation should therefore only apply to aqueous solution with nitric acid content higher than 70%.
A classification as acute toxicity category 4 could be used nitric acid with concentration lower than 70%. **However, it is safer to highlight the corrosive risk rather than use acute toxicity category 4 classifications.** Indeed, the corrosive risks are more restrictive in terms of risk management measures (more details are given attached).

3) Therefore FARM Consortium proposes the following toxicological classification:

Specific Conc. Limits
C ≥ 70% :
Ox. Liq. 3; H272
Skin Corr. 1A; H314; H290 ; EUH071
Acute. Tox 1 ; H330
65≤C<70%
Ox. Liq. 3; H272
Skin Corr. 1A; H314; H290 ; EUH071

20≤C<65%
Skin Corr. 1A; H314; H290 ; EUH071

5≤C<20% Skin Corr. 1B; H314 ; H290

ECHA comment: The attachment document no.1 "FARM position Nitric acid CLP Final 2012 07 31.doc" was submitted separately.

Dossier Submitter's Response

To 1)

In order to protect the general public against products containing HNO_3 it must be examined which measures are suitable for their implementation in the medium term. The classification "acutely toxic" of Category 1 for inhalation of nitric acid is one of further measures for precaution of consumers. As soon as the recommendation to classify nitric acid as "acutely toxic" of Category 1 will be accepted and comes into force on the European level, stricter safety requirements for the packaging such as child-resistant fastenings and tactile warnings will apply to aqueous mixtures which contain 1.0 % nitric acid or more. In addition, restrictions will apply to the trade of consumer products containing nitric acid such as a self-service ban for consumers and a host of duties and requirements for those putting nitric acid into circulation. The recommendation of a restriction in accordance with Article 68 of the REACH regulation (EC) 1907/2006A for the sale of nitric acid-containing consumer products may be a further measure in response to consumer protection which must be examined.

Regarding the vapour pressure in the BfR-Report:
Due to long-time research on the physical and chemical characteristics of nitric acid and countless projects on the subject, different statements regarding the vapour pressure of 30% HNO_3 and the partial pressure of HNO_3 can be found in the respective scientific literature

Even using the partial vapour pressure of 0.336 hpa (cited by FARM without giving the source) in a model calculation with RIVMs ConsExpo Vs. 4.1 (2008) based on the same parameters as given in the BfR Report, show that the conclusions in this report are justified. The herewith estimated indoor-concentration for practically applied amounts of the cleaning agent is still about 8 mg/m³, which is clearly above recommended OELs. The German short-term OEL (for an exposure time of 15 min.) is about 1 ppm or 2.6 mg/m³ and the exposure limit (TWA) of the National Institute for Occupational Safety and Health (NIOSH) is 2 ppm or 5mg/m³.

In this context it should be noted that the parameters used for the calculations in the BfR Report do not reflect the worst-case scenario. Considering more stringent parameters (e.g. smaller room volume, larger amounts of the applied product, larger surface area) certainly result in higher values for the expected indoor air concentration. In the BfR Report a specific exposure situation was examined, such as applying a cleaning agent in a thin layer on a large area in a small bathroom with a low air-exchange rate. Since such products were also used to remove calcium carbonate deposits from surfaces, it needs to be considered that HNO_3 remains longer on the surface. When HNO_3 as ingredient in such products comes in contact with other materials (metal) or substances (e.g. basic ingredients from other cleaning agents), the release of nitrous gases is expected. Among these, especially NO_2 should be considered here, which is classified as Carc. Cat 3B by the German MAK-Commission.

The conclusion of the BfR is further supported by the many case reports of the poison information centres in Germany which document severe health damages after uses (and supposedly misuse) of descaling products containing 20-30% of HNO_3 between 1999 and 2010. In 23.7% of all cases the symptoms were caused by inhalation.

Consequently, we sustain our position that cleaning agents containing 20-30% of nitric acid which are for sale to consumers constitute a disproportionally high health risk for consumers. Risk at inhalation is caused by the toxic effects of nitric acid and nitrous gases resulting from reactions with other substances. The comments by FARM and others also indicate that this view is supported by the fertilizer industry which regards the use of HNO_3 in consumer products as not to be recommended for sale to consumers.

<u>To 2)</u>
The FARM REACH Consortium proposal for classification of nitric acid solutions for acute inhalation toxicity is based on the HNO_3 content: C ≥70 %: Acute Tox. 1; H330; C <70 %: Acute Tox. 4; H332. It was further recommended that the classification as acute toxicity category 4 for nitric acid lower than 70 % should not be used due to the more restrictive management measures regarding classification as corrosive.

We disagree to the proposal for classification of nitric acid based on specific concentrations above or below 70% HNO3 contents.

Reason: The proposal for supplement of classification and labelling of nitric acid for acute inhalation toxicity in accordance with CLP Regulation or Directive 67/548/EEC is based on many cases of poisoning following the use of the detergent 'POR ÇÖZ' (produced in or imported from Turkey) which contained 25 % nitric acid which was far below of the proposed concentration limits for classification as Acute Tox. 4; H332, for C <70 % by the FARM REACH Consortium.
Inhalation of nitric acid fumes/vapours and the nitrous gases released from nitric acid poses a serious health risk. This is shown by cases reported by physicians and by case reports of the German poison control centres. Between 1999 and 2010 severe health damages by the handling of specific nitric acid-containing cleaning products in the home were documented by the poison treatment and information centres in Germany. In 23.7 % of all reported cases the symptoms were caused by inhalation. Therefore, the detrimental health effects of nitric acid when inhaled were assessed. It was shown that even after short-term inhalation nitric acid is equally toxic to humans and animals. If detergents containing nitric acid are used, life-threatening concentrations of nitric acid fumes/vapours and nitrous gases (e.g. NO_2) can be formed in the indoor air, especially if nitric acid comes into contact with metals or organic materials. In the respiratory tract, inhalation of these gas / fume mixtures can cause irritation of the mucous membranes, bronchial catarrh, pneumonia and can, within a typical latency period of 3 to 30 hours, lead to a pulmonary oedema and hence even death. Roughly 30 cases were reported, where in some cases severe damage was caused to the health of people as a result of inhaling fumes or vapours following household use of products containing nitric acid in contents.
In the existing regulation for nitric acid, only the corrosive effects on the skin and eyes have been taken into account, but not the effects following inhalation. Nitric acid can be extremely dangerous even after short-term inhalation due to rapid and progressive acute pulmonary oedema. In addition, inhalation of gases and vapours originating from nitric acid do not set up a violent respiratory reflex, as occurs with chlorine and ammonia, which serves as a warning property. Thus, inhalation of nitric acid fumes at potentially fatal concentrations may go undetected by the affected person. These health hazards are not covered by the existing legal classification of nitric acid in Annex VI for its corrosive reactions as Skin Corr. 1A – H314. In particular, skin corrosion is usually characterised by local effects on the skin, namely, visible necrosis through the epidermis and into the dermis, following the application for up to 4 hours. Therefore protective measures are imperative due to the toxic properties of nitric acid outlined and of nitrous gases released from it.

To 3)
A modification for classification of nitric acid based on the proposed specific concentration limits by the FARM REACH Consortium is not accepted. Since nitric acid meets the criteria for classification and labelling as Acute Tox. 1; H330. We sustain the opinion that consumer products that contain nitric acid at or above a generic cut-off value of 1.0 % constitute a disproportionally high health risk for humans.
Further we would like to suggest that according to the guideline to CLP Regulation specific concentration limits (SCL) are not applicable for acute toxicity classification. Classification of mixtures is based on ingredients of the mixture (additivity formula). For this reason SCLs for acute toxicity will not appear in CLP Annex VI, Table 3.1 or in the classification and labelling inventory.

In addition it should be mentioned that the classification Ox. Liq. 2, H272: C ≥ 99 % has to be added.
In the current CLH proposal the classification and labelling of nitric acid regarding the hazard class corrosive to metals is not included. Therefore, we ask the FARM REACH Consortium to provide test results, so that the SCL for the proposed classification as Met. Corr. 1, H290 can be agreed.

To "Attachment from FARM REACH Consortium, comments on reference studies")

Study by Du Pont (1987):
In the study performed by Du Pont (1987) the 1-hour LC50 value for nitric acid (approx. 71 % aqueous solution) for male and female rats combined was derived at 2500 ppm. However, the test atmosphere was not well-defined at this concentration. The aerosol content was not measured but estimated by the authors to be approximately 100 %. It was assumed that the test atmosphere presented itself as a mixture of liquid, gaseous and vapour phase. Thus, it was not possible to perform an exact conversion of the one hour exposure value into a 4 hour testing exposure. Therefore it was concluded that this LC50 value is not suitable for classification since the test

atmosphere for nitric acid at 2500 ppm was not well-defined and because at this concentration rats were exposed to an atmosphere containing only 59 % respirable particles with a MMAD of 6.5 µm, which exceeded the guidance value of 1-4 µm for an aerosol. Based only on these data no conclusion on classification of nitric acid could be deduced.

Studies by Gray et al. (1954):
It is right that the majority of the data on toxicology to nitric acid originates from outdated and/or inadequate studies which were conducted before international guidelines were developed. There have been only a few toxicological studies of nitric acid, which exists in ambient air generally as a highly water-soluble vapour, suitable for deduction of reliable LC50 values. Since inhalation exposure to nitric acid involves exposure to nitric acid as well as to nitrogen oxides, in particular NO_2, results from acute animal experiments with nitrogen dioxide are also presented. The synopsis of all available data from experimental animals studies has shown that although the studies by Gray et al. (1954) were conducted decades before standard test guidelines were adopted the studies were considered sufficiently reliable to propose classification of nitric acid as acutely toxic by the inhalation route of exposure. The LC50 values for RFNA (red fuming nitric acid, containing 8-17 % nitrogen dioxide) and WFNA (white fuming nitric acid, containing 0.1-0.4 % nitrogen dioxide) were deduced by using the algorithms recommended in OECD GD No. 39 on acute inhalation toxicity testing (2009). For RFNA a LC50 value of 0.20 mg/L/4hr was derived and for WFNA of 0.22 mg/L/4hr. According to CLP Regulation nitric acid has to be classified as Acute Tox. 1; H330 (Annex I, Part 3, 3.1 Acute toxicity, Category 1, vapours: ATE ≤ 0.5 mg/L/4h), and based on the criteria of Directive 67/548/EEC (Dangerous Substances Directive, DSD; Annex VI: LC50, vapours: ≤ 0.5 mg/L/4hr) nitric acid is classified and labelled as T+ (Very toxic); R26.

The classification proposal of nitric acid as acute toxic by inhalation is not only based on animal data. The evidence for acute inhalation toxicity of nitric acid was also obtained from human experience (e.g. data from accident database and experimental studies). No apparent species differences in the toxic response to acute inhalation exposure to HNO_3 could be noted. After a single exposure or relatively brief exposure to nitric acid lethality in animals and humans occurred due to rapid and progressive acute pulmonary oedema. In humans lethality has been observed after a latency period of 3 to 30 hours.

RAC's response

It is not appropriate to treat the fuming nitric acids and aqueous solutions of nitric acid as different substances requiring different classification depending on concentration of nitric acid. The CLP regulation impose the use of the relative potency of substance taking into account the additivity formula (Section 3.1.3.6.1, Annex I, CLP) to set classification for acute inhalation toxicity of the aqueous solution of nitric acid with low concentration of the acid. RAC gives support to the justification provided by the dossier submitter.

Date	Country	Organisation	Type of Organisation	Comment number
03/08/2012	Belgium	Fertilizers Europe	Industry or trade association	4

Comment received

A harmonized classification of nitric acid as Acute Toxicity Category 1 for inhalation is proposed. It is based on health risks of nitric acid containing home cleaning products (BfR Opinion N°041/2010) and on a study (Gray) with concentrated nitric acids containing various portions of NO2: (White Fuming NA 0,1-0,4% NO2 and Red Fuming NA 8-17% NO2).

Fertilizer Europe would like to highlight that:

1) The REACH dossier prepared by its members in 2010 does not describe any consumer use. This means implicitly that consumer uses should be forbidden within Europe since the 1st December 2010.
However this may not be restrictive enough since products destined for the consumer market/general public are still allowed to be imported into Europe (e.g. cleaning products with a Nitric acid content of more than 20%). of Fertilizers Europe therefore recommends adding a restriction in the annex XVII of the REACh regulation 1907/2006, prohibiting the sale of nitric acid solutions containing more than 20% nitric acid to consumers.
Furthermore, the justification given in the BfR report is completely erroneous. The HNO3 vapour

pressure value has been overestimated by a factor 270 times and leads to wrong conclusions (details re provided below).

2) When speaking about nitric acid toxicity two different concentration ranges have to be clearly differentiated: the aqueous nitric acid (up to 68%) and the smoking nitric acid only obtainable by bubbling NOx into aqueous HNO3 (impossible to obtain by distillation as the 68% acid is an azeotropic mixture). Due to this chemical difference these entities have different acute toxicity profiles.
The acute toxicity observed in the study of Gray et al., with concentrated nitric acid (higher than 70%), is due to the inhalation of toxic NOx gases released by such concentrated acid. The Acute Toxicity Category 1 for inhalation should therefore only apply to aqueous solution with nitric acid content higher than 70%.
In the case of nitric acid with concentration lower than 70% an acute toxicity category 4 could be used. However, it is safer to highlight the corrosive risk rather than use acute toxicity category 4 classification. Indeed, the corrosive risks are more restrictive in terms of risk management measures (more details are given below).

Therefore Fertilizers Europe proposes the following toxicological classification:

Specific Conc. Limits
C ≥ 70% Ox. Liq. 3; H272
Skin Corr. 1A; H314; H290; EUH071
Ac. Tox. 1; H330
65≤C≤70% Ox. Liq. 3; H272
Skin Corr. 1A; H314; H290 ; EUH071
20≤C<65% :Skin Corr. 1A; H314; H290 ; EUH071
5≤C<20% : Skin Corr. 1B; H314 ; H290

Dossier Submitter's Response

Please see response to Comment No. 3 of the FARM REACH Consortium.

RAC's response

Please see response to Comment No. 3 of the FARM REACH Consortium

CARCINOGENICITY – no comment received
MUTAGENICITY – no comment received
TOXICITY TO REPRODUCTION – no comment received
RESPIRATORY SENSITISATION – no comment received

OTHER HAZARDS AND ENDPOINTS

Acute toxicity

Date	Country	Organisation	Type of Organisation	Comment number
26/07/2012	France		MSCA	5

Comment received

We agree with the classification proposal (Acute Tox. 1 - H330; EUH071: Corrosive to the respiratory tract).

Dossier Submitter's Response

Thank you for the support.

RAC's response

Agree with comment.

Date	Country	Organisation	Type of Organisation	Comment number
30/07/2012	Germany	BASF SE	Company-Manufacturer	6

Comment received

Though the aerosol criteria are not fully met in the du Pont study, one could estimate that at

concentrations around 70% HNO3 and the given 1-hour value of 2500 ppm this would correspond to an aerosol value of about 1,6 mg/L/4h. The mortality observed is attributed to corrosive effects.
From aerosol exposure, the inhalation toxicity of 70% HNO3 could be classified under acute tox. cat 4 (inhalative-aerosol).
Lower concentrations cannot have a higher classification than acute tox. inhalative cat 4.
This would be the case when applying CLP (derived from a LC50=0.2 mg/L for fuming HNO3) or DPD (using for HNO3: T+; R 26).
Therefore, we need separate concentration-dependent entries in annex VI of the CLP Regulation.

Dossier Submitter's Response

In the study performed by Du Pont (1987) the 1-hour LC50 value for nitric acid (approx. 71 % aqueous solution) for male and female rats combined was derived at 2500 ppm. However, the test atmosphere was not well-defined at this concentration. The aerosol content was not measured but estimated by the authors to be approximately 100 %. It was assumed that the test atmosphere presented itself as a mixture of liquid, gaseous and vapour phase. Thus, it was not possible to perform an exact conversion of the one hour exposure value into a 4 hour testing exposure. Therefore it was concluded that this LC50 value is not suitable for classification since the test atmosphere for nitric acid at 2500 ppm was not well-defined and because at this concentration rats were exposed to an atmosphere containing only 59 % respirable particles with a MMAD of 6.5 µm, which exceeded the guidance value of 1-4 µm for an aerosol. Based only on these data no conclusion on classification of nitric acid could be deduced.

The proposal for supplement of classification and labelling of nitric acid for acute inhalation toxicity in accordance with CLP Regulation or Directive 67/548/EEC is based on many cases of poisoning following the use of the detergent 'POR ÇÖZ' (produced in or imported from Turkey) which contained 25 % nitric acid which was far below of the proposed concentration limits for classification as Acute Tox. 4; H332, for C <70 % by the BASF SE.
Inhalation of nitric acid fumes/vapours and the nitrous gases released from nitric acid poses a serious health risk. This is shown by cases reported by physicians and by case reports of the German poison control centres. Between 1999 and 2010 severe health damages by the handling of specific nitric acid-containing cleaning products in the home were documented by the poison treatment and information centres in Germany. In 23.7 % of all reported cases the symptoms were caused by inhalation. Therefore, the detrimental health effects of nitric acid when inhaled were assessed. It was shown that even after short-term inhalation nitric acid is equally toxic to humans and animals. If detergents containing nitric acid are used, life-threatening concentrations of nitric acid fumes/vapours and nitrous gases (e.g. NO_2) can be formed in the indoor air, especially if nitric acid comes into contact with metals or organic materials. In the respiratory tract, inhalation of these gas / fume mixtures can cause irritation of the mucous membranes, bronchial catarrh, pneumonia and can, within a typical latency period of 3 to 30 hours, lead to a pulmonary oedema and hence even death. Roughly 30 cases were reported, where in some cases severe damage was caused to the health of people as a result of inhaling fumes or vapours following household use of products containing nitric acid in contents.
In the existing regulation for nitric acid, only the corrosive effects on the skin and eyes have been taken into account, but not the effects following inhalation. Nitric acid can be extremely dangerous even after short-term inhalation due to rapid and progressive acute pulmonary oedema. In addition, inhalation of gases and vapours originating from nitric acid do not set up a violent respiratory reflex, as occurs with chlorine and ammonia, which serves as a warning property. Thus, inhalation of nitric acid fumes at potentially fatal concentrations may go undetected by the affected person. These health hazards are not covered by the existing legal classification of nitric acid in Annex VI for its corrosive reactions as Skin Corr. 1A – H314. In particular, skin corrosion is usually characterised by local effects on the skin, namely, visible necrosis through the epidermis and into the dermis, following the application for up to 4 hours. Therefore protective measures are imperative due to the toxic properties of nitric acid outlined and of nitrous gases released from it.

A modification for classification of nitric acid based on the proposed specific concentration limits by the BASF SE is not accepted. Since nitric acid meets the criteria for classification and labelling as Acute Tox. 1; H330. We are keeping on the opinion that consumer products that contain nitric acid at or above a generic cut-off value of 1.0 % constitute a disproportionally high health risk for humans.

Further we would like to suggest that according to the guideline to CLP Regulation specific concentration limits are not applicable for acute toxicity classification. Classification of mixtures is based on ingredients of the mixture (additivity formula). For this reason SCLs for acute toxicity will not appear in CLP Annex VI, Table 3.1 or in the classification and labelling inventory.

RAC's response

Classification of 70% HNO3 into Acute Tox. 4 (inhalation of aerosol) is not sufficiently justified due to weakness of the du Pont study, and against cases of inhalation poisonings of humans using diluted solutions of nitric acid.

Date	Country	Organisation	Type of Organisation	Comment number
03/08/2012	Sweden		MSCA	7

Comment received

Acute toxicity:
SE agrees that action at community level is motivated for the acute inhalation toxicity of nitric acid because it is considered a HPV chemical, and in addition it poses a high health risk to consumers. According to the C&L inventory the majority of notifiers do not self-classify for acute inhalation toxicity or for STOT-SE with respiratory tract as target organ. Therefore, a harmonised classification for acute inhalation toxicity to protect human health is justified.
Based on the information from case reports notified to the German Federal Institute for Risk Assessment and data from Poison Treatment and Information Centres the MSCA could also consider evaluating the toxicity of oral exposure (59.1% of cases) and consider harmonising classification of oral acute toxicity. No self-classification of acute oral toxicity is notified in the C&L inventory and according to BfR Opinion No 041/2010, the lowest fatal dose of oral exposure for humans is 430 mg/kg body weight (minimum lethal dose reported for humans could be used as equivalent ATE, and the resulting classification would be in Category 4).

Dossier Submitter's Response

Thank you for the support to the proposed classification of nitric acid for the acute inhalation toxicity.

The presented CLH report proposes classification of HNO_3 only for acute inhalation toxicity. The acute toxicity of HNO_3 by the oral route of exposure is not described and discussed in the presented CLH report. The recommendation of harmonising classification of oral acute toxicity may be considered. However, the data of nitric acid-induced acute oral toxicity should be examined in a separate procedure.

RAC's response

Agree with justification of a need for classification of inhalation toxicity of nitric acid at the European wide level

Date	Country	Organisation	Type of Organisation	Comment number
03/08/2012	France	Fertilizers Europe	Industry or trade association	8

Comment received

ECHA comment: The comment below was copied from the attachment no. 1 part ***2- Any other hazard classes or endpoints: Acute toxicity****: "FARM position Nitric acid CLP Final 2012 07 31.doc" (****FARM REACH Consortium Position on public consultation by ECHA on the proposal for harmonised Classification & Labelling (CLH) of Nitric acid)***

The conclusion of the CLH report indicates that "the nitric acid should be classified in acute hazard category 1 for inhalation exposure and labelled with signal word "Danger" and hazard statement H330 (Fatal if inhaled). In addition to classification for acute inhalation toxicity nitric acid has to be supplementary labelled with EUH071 (Corrosive to the respiratory tract)" (chapter 4.2.5).

Comments on reference studies:
The classification of nitric acid as Acute Tox. 1 – H330 proposed, is obtained by using LC50 values from a study by Gray et al. 1954. This study used white fuming (WFNA – 97,5 wt% nitric acid) and red fuming nitric acid (RFNA – 82.4 – 85.4 wt% nitric acid).

- This study was rated with Klimisch 3 – not reliable – by the REACH Registration Consortium due to the following reasons:
  - The study did not follow any guideline.
  - Details on materials/methods and results were limited.
  - Dose levels of the two different fuming nitric acids were not given.
  - Results for the LD50 values were only given for the value of NO_2 and not nitric acid.
  - Using a study conducted with exposure to WFNA / RFNA is difficult in terms of extrapolation to lower concentration and different exposure times. Especially 2 things need to be considered:
    - The inhalation LC50 retrieved for WFNA / RFNA cannot be extrapolated to a nitric acid solution
    - The inhalation LC50 cannot be calculated proportionally from 30 minutes to 4 hours (Haber's rule is not valid).

Comments on reference study from BfR Opinion N°041/2010:
It appears that there is a serious error in the BfR report. The calculation model is based on a vapor pressure of 89,6 hPa (or 89,6 mbar) for HNO3 from a 30% solution. It seems that the authors have used the total vapor pressure at a temperature of 50°C (cleaning at 50 °C).

A 30% HNO3 solution has a total vapor pressure of about 90 hPa but the real HNO3 partial vapor pressure is only 0,336 hPa, thus **270 times lowe**r. As a result of this wrong calculation the conclusions of the study are irrelevant.

Comments from the Chemical Safety Report of Nitric acid :

According to the REACH Regulation, an acute toxicity test does not generally need to be conducted if the substance is classified as corrosive to the skin (column 2 adaptations, Annex VIII, section 8.5).
However, an acute toxicity study conducted with methods similar to OECD
Guideline 403 (Acute Inhalation Toxicity) was performed with a 70,7 % nitric acid aqueous
solution (E.I. du Pont de Nemours and Company, Inc., 1987). Groups of 5 male and 5 female
rats were each exposed for 1-hour by nose-only inhalation to an atmosphere of nitric acid in air at concentrations ranging from 260 - 3100 ppm. Following exposure, rats were weighed and observed for 14 days of recovery. A gross pathological examination was performed on all animals at the time of death or after 14 day recovery period.
Clinical signs and gross lesions of external tissues were observed in most rats which were indicative of the test substance's corrosive nature. However, no significant gross lesions indicative of systemic toxicity or cause of death were observed. The combined 1-hour LC50 for the male and female rats was determined to be 2500 ppm (6250 mg/m3). Based on the 1-hour LC50, a 4 -hour LC50 would be expected to be 1562.5 mg/m3.
Two additional nitric acid studies and one nitrogen dioxide study were available. However, none of the studies followed a guideline and were deemed unreliable.

Justification for classification or non-classification
Inhalation - Acute inhalation toxicity study of sufficient quality and tested in accordance with standard methodology showed that the acute inhalation 4 -hr LC50 was 1562.5 mg/m3.
However, clinical signs and gross lesions of external tissues in most rats were indicative of the test substance's corrosive nature, and no systemic toxicity was observed. Based on this, it is sufficient evidence to conclude that nitric acid is a corrosive substance and not an acute inhalation hazard.

Comment on the wrong justification for the need of this action (acc. to section 3 of the CLH report)

Background: Acute Toxicity is none of the hazards which are subject to a harmonized classification according to CLP Article 36 (1): Therefore, in case other hazard classes are subject to a harmonization, a justification is needed according to CLP Article 36 (3):

"*3. Where a substance fulfils the criteria for other hazard classes or differentiations than those referred to in paragraph 1 and does not fall under paragraph 2, a harmonised classification and labelling in accordance with Article 37 may also be added to Annex VI on a case-by-case basis, if justification is provided demonstrating the need for such action at Community level*."

The serious health damages caused by accidents with specific nitric acid-containing cleaning products cannot be avoided with a harmonized classification as Acute Tox. 1. The addressed measures to restrict the placing of the market of nitric acid-containing consumer products are ineffective as follows:

- Correct classification and labelling as Acute Tox 1, even with a pictogram "skull and crossbones" alone is no restriction of supply to the general public in the EU, but only in some countries due to additional national restrictions for placing on the market. In the view of the Authorities, Acute Tox 1 should serve as a prerequisite for applying constraints on sale for consumer products. However, additional national adaptations of the legislations are needed, where not already in place (CLH Report, page 15: "This could then lead to constraints on sale (e.g. in self-service) for consumer products that contain nitric acid ...."). Therefore, to regulate the selling of nitric acid containing consumer products by inclusion in Annex XVII would be a more effective way, as Annex XVII is immediately and directly implemented in every EU member state.
- Child-resistant closures: The current classification as corrosive is sufficient to require child resistant closures if supplied to the general public. Furthermore, not only children, but also adults were among the accident victims.

Conclusion of FARM Consortium:

Reference to the previous comments, FARM Consortium suggests that the Gray study be applied to concentrated nitric acid (higher than 70%), due to the specific production process and the release of NOx. The risk of inhalation of corrosive vapors depends on the vapor pressure and it varies greatly on the concentration of nitric acid. For nitric acid 100%, as shown in the proposal for harmonisation, the vapor pressure is 64 hPa at 20ºC, however for nitric acid 60% the vapor pressure falls to 1.25 hPa at 20ºC, more than 50 times lower.
The Acute Toxicity Category 1 for inhalation only applies for nitric acid content higher than 70%.
For aqueous nitric acid with concentration lower than 70%, as mentioned in the REACH Dossier, it is safer to alert on the corrosive risk category 1 rather than on acute toxicity category 4 classification. Indeed, the corrosive risks are more restrictive in terms of risk management measures. Workers have to protect themselves independently of the exposure time and level.
Finally, FARM Consortium suggests adding a restriction in the annex XVII of the REACH regulation 1907/2006, prohibiting the sale of nitric acid solutions containing more than 20% nitric acid to consumers.

FARM Consortium proposes the following toxicological classification:

Specific Conc. Limits	C ≥ 70%	Ox. Liq. 3; H272 Skin Corr. 1A; H314; H290 ; EUH071 Acute. Tox 1 ; H330
	65≤C<70%	Ox. Liq. 3; H272 Skin Corr. 1A; H314; H290 ; EUH071
	20≤C<65%	Skin Corr. 1A; H314; H290 ; EUH071
	5≤C<20%	Skin Corr. 1B; H314 ; H290

The FARM REACH Consortium is managed by REACH Centrum, based in Brussels.

Further details can be obtained from the FARM Consortium web site:

http://www.reachcentrum.eu/en/consortiumslt/consortia-under-reach/farm-reach-consortium.aspx

ECHA comment: End of attachment no. 1.

Dossier Submitter's Response

To "Comments on reference studies"

Study by Du Pont (1987):
In the study performed by Du Pont (1987) the 1-hour LC50 value for nitric acid (approx. 71 % aqueous solution) for male and female rats combined was derived at 2500 ppm. However, the test atmosphere was not well-defined at this concentration. The aerosol content was not measured but estimated by the authors to be approximately 100 %. It was assumed that the test atmosphere presented itself as a mixture of liquid, gaseous and vapour phase. Thus, it was not possible to perform an exact conversion of the one hour exposure value into a 4 hour testing exposure. Therefore it was concluded that this LC50 value is not suitable for classification since the test atmosphere for nitric acid at 2500 ppm was not well-defined and because at this concentration rats were exposed to an atmosphere containing only 59 % respirable particles with a MMAD of 6.5 µm, which exceeded the guidance value of 1-4 µm for an aerosol. Based only on these data no conclusion on classification of nitric acid could be deduced.

Studies by Gray et al. (1954):
It is right that the majority of the data on toxicology to nitric acid originates from outdated and/or inadequate studies which were conducted before international guidelines were developed. There have been only a few toxicological studies of nitric acid, which exists in ambient air generally as a highly water-soluble vapour, suitable for deduction of reliable LC50 values. Since inhalation exposure to nitric acid involves exposure to nitric acid as well as to nitrogen oxides, in particular NO_2, results from acute animal experiments with nitrogen dioxide are also presented. The synopsis of all available data from experimental animals studies has shown that although the studies by Gray et al. (1954) were conducted decades before standard test guidelines were adopted the studies were considered sufficient reliable to propose classification of nitric acid as acutely toxic by the inhalation route of exposure. The LC50 values for RFNA (red fuming nitric acid, containing 8-17 % nitrogen dioxide) and WFNA (white fuming nitric acid, containing 0.1-0.4 % nitrogen dioxide) were deduced by using the algorithms recommended in OECD GD No. 39 on acute inhalation toxicity testing (2009). For RFNA a LC50 value of 0.20 mg/L/4hr was derived and for WFNA of 0.22 mg/L/4hr. According to CLP Regulation nitric acid has to be classified as Acute Tox. 1; H330 (Annex I, Part 3, 3.1 Acute toxicity, Category 1, vapours: ATE ≤ 0.5 mg/L/4h), and based on the criteria of Directive 67/548/EEC (Dangerous Substances Directive, DSD; Annex VI: LC50, vapours: ≤ 0.5 mg/L/4hr) nitric acid is classified and labelled as T+ (Very toxic); R26.

The classification proposal of nitric acid as acute toxic by inhalation is not only based on animal data. The evidence for acute inhalation toxicity of nitric acid was also obtained from human experience (e.g. data from accident database and experimental studies). No apparent species differences in the toxic response to acute inhalation exposure to HNO_3 could be noted. After a single exposure or relatively brief exposure to nitric acid lethality in animals and humans occurred due to rapid and progressive acute pulmonary oedema. In humans lethality has been observed after a latency period of 3 to 30 hours.

<u>To "Comment on the wrong justification for the need of this action (acc. to section 3 of the CLH report)")</u>
In order to protect the general public against products containing HNO_3 it must be examined which measures are suitable for their implementation in the medium term. The classification "acutely toxic" of Category 1 for inhalation of nitric acid is one of further measures for precaution of consumers. As soon as the recommendation to classify nitric acid as "acutely toxic" of Category 1 will be accepted and comes into force on the European level, stricter safety requirements for the packaging such as child-resistant fastenings and tactile warnings will apply to aqueous mixtures which contain 1.0 % nitric acid or more. In addition, restrictions will apply to the trade of consumer products containing nitric acid such as a self-service ban for consumers and a host of duties and requirements for those putting nitric acid into circulation. The recommendation of a restriction in accordance with Article 68 of the REACH regulation (EC) 1907/2006A for the sale of nitric acid-containing consumer products may be a further measure in response to consumer protection which must be examined.

<u>To "Conclusion of the Fertilizers Europe / FARM Consortium for classification of nitric acid")</u>

The Fertilizers Europe / FARM Consortium proposal for classification of nitric acid solutions for acute inhalation toxicity is based on the HNO_3 content: C ≥70 %: Acute Tox. 1; H330; C <70 %: Acute Tox. 4; H332. It was further recommended that the classification as acute toxicity category 4 for

nitric acid lower than 70 % should not be used due to the more restrictive management measures regarding classification as corrosive.

We disagree to the proposal for classification of nitric acid based on specific concentrations above or below 70% HNO3 contents.

Reason: The proposal for supplement of classification and labelling of nitric acid for acute inhalation toxicity in accordance with CLP Regulation or Directive 67/548/EEC is based on many cases of poisoning following the use of the detergent 'POR ÇÖZ' (produced in or imported from Turkey) which contained 25 % nitric acid which was far below of the proposed concentration limits for classification as Acute Tox. 4; H332, for C <70 % by the Fertilizers Europe / FARM Consortium.
Inhalation of nitric acid fumes/vapours and the nitrous gases released from nitric acid poses a serious health risk. This is shown by cases reported by physicians and by case reports of the German poison control centres. Between 1999 and 2010 severe health damages by the handling of specific nitric acid-containing cleaning products in the home were documented by the poison treatment and information centres in Germany. In 23.7 % of all reported cases the symptoms were caused by inhalation. Therefore, the detrimental health effects of nitric acid when inhaled were assessed. It was shown that even after short-term inhalation nitric acid is equally toxic to humans and animals. If detergents containing nitric acid are used, life-threatening concentrations of nitric acid fumes/vapours and nitrous gases (e.g. NO_2) can be formed in the indoor air, especially if nitric acid comes into contact with metals or organic materials. In the respiratory tract, inhalation of these gas / fume mixtures can cause irritation of the mucous membranes, bronchial catarrh, pneumonia and can, within a typical latency period of 3 to 30 hours, lead to a pulmonary oedema and hence even death. Roughly 30 cases were reported, where in some cases severe damage was caused to the health of people as a result of inhaling fumes or vapours following household use of products containing nitric acid in contents.
In the existing regulation for nitric acid, only the corrosive effects on the skin and eyes have been taken into account, but not the effects following inhalation. Nitric acid can be extremely dangerous even after short-term inhalation due to rapid and progressive acute pulmonary oedema. In addition, inhalation of gases and vapours originating from nitric acid do not set up a violent respiratory reflex, as occurs with chlorine and ammonia, which serves as a warning property. Thus, inhalation of nitric acid fumes at potentially fatal concentrations may go undetected by the affected person. These health hazards are not covered by the existing legal classification of nitric acid in Annex VI for its corrosive reactions as Skin Corr. 1A – H314. In particular, skin corrosion is usually characterised by local effects on the skin, namely, visible necrosis through the epidermis and into the dermis, following the application for up to 4 hours. Therefore protective measures are imperative due to the toxic properties of nitric acid outlined and of nitrous gases released from it.

A modification for classification of nitric acid based on the proposed specific concentration limits by the Fertilizers Europe / FARM Consortium is not accepted. Since nitric acid meets the criteria for classification and labelling as Acute Tox. 1; H330. We are keeping on the opinion that consumer products that contain nitric acid at or above a generic cut-off value of 1.0 % constitute a disproportionally high health risk for humans.

Further we would like to suggest that according to the guideline to CLP Regulation specific concentration limits are not applicable for acute toxicity classification. Classification of mixtures is based on ingredients of the mixture (additivity formula). For this reason SCLs for acute toxicity will not appear in CLP Annex VI, Table 3.1 or in the classification and labelling inventory.

In addition it should be mentioned that the classification Ox. Liq. 2, H272: C ≥ 99 % has to be added.
In the current CLH proposal the classification and labelling of nitric acid regarding the hazard class corrosive to metals is not included. Therefore, we ask the FARM REACH Consortium to provide test results, so that the SCL for the proposed classification as Met. Corr. 1, H290 can be agreed.

Regarding the vapour pressure and the BfR-Report:
Cf. response to Comments No. 1 and 3

RAC's response

It is not appropriate to use the high LC_{50}/4hr in rats, derived from the results of the du Pont study, (1987) for classification purposes since the concentration was not measured but only assumed, and these results are not compatible with observation of human cases of acute inhalation poisoning symptoms and with results of other animal studies (Gray *et al*., 1954)

Date	Country	Organisation	Type of Organisation	Comment number
03/08/2012	Belgium	Fertilizers Europe	Industry or trade association	9

Comment received

ECHA comment: The comment below was copied from the attachment no.2 part ***2- Any other hazard classes or endpoints: Acute toxicity****: "Fertilizers Europe position Nitric acid final 2012 08 01.pdf", item* ***2- Any other hazard classes or endpoints: Acute toxicity****:*

The conclusion (chapter 4.2.5) of the CLH report indicates that "the nitric acid should be classified in acute hazard category 1 for inhalation exposure and labelled with signal word "Danger" and hazard statement H330 (Fatal if inhaled). In addition to classification for acute inhalation toxicity nitric acid has to be supplementary labelled with EUH 071 (Corrosive to the respiratory tract)".

Comments on reference study from Gray et al:
In the CLH Report, a study by Gray et al., 1954 was used to retrieve LC50 values and consequently propose a classification of nitric acid as Acute Tox. 1 – H330. This study used white fuming (WFNA – 97,5 wt% nitric acid) and red fuming nitric acid (RFNA – 82.4 – 85.4 wt% nitric acid).

- This study was rated with Klimisch 3 – not reliable – by the REACH Registration Consortium due to the following reasons:
  - The study did not follow any guidelines.
  - Details on materials/methods and results were limited.
  - Dose levels of the two different fuming nitric acids were not given.
  - Results for the LD50 values were only given for the value of NO_2 and not nitric acid.

- It is not possible to extrapolate to low concentrations and different exposure times a study conducted with exposure to WFNA / RFNA. Especially 2 things need to be considered:
  - The inhalation LC50 retrieved for WFNA / RFNA cannot be extrapolated to a nitric acid solution
  - The inhalation LC50 cannot be calculated proportionally from 30 minutes to 4 hours. (Habers rule is not valid).

Comments on reference study from BfR:
It appears that there is a serious error in the BfR report. The calculation model is based on a vapour pressure of 89,6 hPa (or 89,6 mbar) for HNO3 from a 30% solution. It seems that the authors have used the total vapor pressure at a temperature of 50 °C (cleaning at 50 °C).
A 30% HNO3 solution has a total vapour pressure of about 90 hPa but the real HNO3 partial vapour pressure is only 0,336 hPa, thus **270 times lower**.
Needless to say, as a result of this wrong calculation the conclusions of the study are completely irrelevant.

Comments from the Chemical Safety Report of Nitric acid :
According to the REACH Regulation, an acute toxicity test does not generally need to be conducted if the substance is classified as corrosive to the skin (column 2, Annex VIII, section 8.5).
However, an acute toxicity study conducted with methods similar to OECD Guideline 403 (Acute Inhalation Toxicity) was performed with a 70.7 % nitric acid aqueous solution (E.I. du Pont de Nemours and Company, Inc., 1987). Groups of 5 male and 5 female rats were each expose for 1-hour by nose-only inhalation to an atmosphere of nitric acid in air at concentrations ranging from 260 -3100 ppm. Following exposure, rats were weighed and observed for 14 days of recovery. A gross pathological examination was performed on all animals at the time of death or after 14 day recovery period.
Clinical signs and gross lesions of external tissues were observed in most rats which were indicative of the test substance's corrosive nature. However, no significant gross lesions indicative of systemic toxicity or cause of death were observed. The combined 1-hour LC50 for the male and female rats was determined to be 2500 ppm (6250 mg/m^3). Based on the 1-hour LC50, a 4-hour LC50 would be

expected to be 1562.5 mg/m^3.
Two additional nitric acid studies and one nitrogen dioxide study were available. However, none of the studies followed a guideline and were deemed unreliable.

Justification for classification or non-classification
Inhalation - Acute inhalation toxicity study of sufficient quality and tested in accordance with standard methodology showed that the acute inhalation 4 -hr LC50 was 1562.5 mg/m^3.
However, clinical signs and gross lesions of external tissues in most rats were indicative of the test substance's corrosive nature, and no systemic toxicity was observed. Based on this, it is sufficient evidence to conclude that nitric acid is a corrosive substance and not an acute inhalation hazard.

Comment on the wrong justification for the need of this action (acc. to section 3 of the CLH report)

Background: Acute Toxicity is none of the hazards which are subject to a harmonized classification according to CLP Article 36 (1). Therefore, in case other hazard classes are subject to a harmonization, a justification is needed according to CLP Article 36 (3):

3. Where a substance fulfils the criteria for other hazard classes or differentiations than those referred to in paragraph 1 and does not fall under paragraph 2, a harmonised classification and labelling in accordance with Article 37 may also be added to Annex VI on a case-by-case basis, if justification is provided demonstrating the need for such action at Community level.

The serious health damages caused by accidents with specific nitric acid-containing cleaning products cannot be avoided with a harmonized classification as Acute Tox 1. The addresses measures to restrict the placing of the market of nitric acid-containing consumer products are ineffective as follows:

- Correct classification and labelling as Acute Tox 1, even with a pictogram "skull and crossbones" alone is no restriction of supply to the general public in the EU, but only in some countries due to additional national restrictions for placing on the market. In the view of the Authorities, Acute Tox 1 should serve as a prerequisite for applying constraints on sale for consumer products. However, additional national adaptations of the legislations are needed, where not already in place (CLH Report, page 15: "This could then lead to constraints on sale (e.g. in self-service) for consumer products that contain nitric acid ...."). Therefore, to regulate the selling of nitric acid containing consumer products by inclusion in Annex XVII would be a more effective way, as Annex XVII is immediately and directly implemented in every EU member state.

Child-resistant closures: The current classification as corrosive is sufficient to require child resistant closures if supplied to the general public. Furthermore, not only children, but also adults were among the accident victims.

Conclusion of Fertilizers Europe:

Based on the previous comments and remarks, Fertilizers Europe suggests that the Gray studies apply to concentrated nitric acid (higher than 70%), due to the specific production process and the release of NOx . The risk of inhalation of corrosive vapors is closely related to the vapor pressure and it varies greatly depending on the concentration of nitric acid. For nitric acid 100%, as shown in the proposal for harmonization, the vapor pressure is 64 hPa at 20°C, however for nitric acid 60% the vapor pressure falls to 1.25 hPa at 20°C, more than 50 times lower.
The Acute Toxicity Category 1 for inhalation only applies for Nitric acid content higher than 70%.
In the case of the lower concentrated nitric acid, as mentioned in the Reach Dossier, it is safer to highlight the corrosive risk rather than an acute toxicity category 4 classification. Indeed, the corrosive risks are more restrictive in terms of risk management measures. Workers have to protect themselves independently of the exposure time and level.

Fertilizer Europe proposes the following toxicological classification:

Specific Conc. Limits	C ≥ 70%	Ox. Liq. 3; H272 Skin Corr. 1A; H314; H290 ; EUH071 Ac. Tox 1 ; H330
	65≤C≤70%	Ox. Liq. 3; H272 Skin Corr. 1A; H314; H290 ; EUH071
	20≤C<65%	Skin Corr. 1A; H314; H290 ; EUH071
	5≤C<20%	Skin Corr. 1B; H314 ; H290

ECHA comment: End of attachment no. 2.

Dossier Submitter's Response

Please see response to comment No. 8.

RAC's response

Please see response to comment No. 8.

Physical hazard

Date	Country	Organisation	Type of Organisation	Comment number
26/07/2012	France		MSCA	10

Comment received

• Physical hazards: section 3: classification for physic-chemical properties (p20)

According to UN Test O.2 and CLP regulation (1272/2008):
Cat 1: 1/1 perchloric acid 50% / cellulose: mean pressure rise time: 121 s
Cat 2: 1/1 sodium chlorate 40% / cellulose: mean pressure rise time: 2555 s
Cat 3: 1/1 nitric acid 65% / cellulose: mean pressure rise time: 4767 s
Therefore, if the mean pressure rise time for 1/1 nitric acid >99% /cellulose is really 320,6 ms (as indicated in the CLH report) and not 320,6 s, then the classification should be Ox Liq Cat 1. If 320,6 ms is only a syntax mistake then we agree with Cat. 2.

Dossier Submitter's Response

We suspect a misunderstanding due to an error in the UN Manual of Tests and Criteria:
The above referred values by France MSCA for the mean pressure rise time are taken from the Fourth revised edition of the UN Manual of Tests and Criteria. The Unit in ms was corrected for the mean pressure rise time in table of sub-section 34.4.2.5 by the Fifth revised edition of the UN Manual of Tests and Criteria (2009). However, the cited values are mean values from inter-laboratory comparative trials and are not applicable for classification. Therefore, only measured values for pressure rise time have to be used, as described in the test report.
The mean pressure rise time of 320.6 ms, tested in the 1:1 mixture of nitric acid (C ≥ 99%) and cellulose, is correct. The evaluation of the test results showed that the classification criteria as Ox. Liq. 2 is fulfilled.

RAC's response

The opinion of the Dossier Submitter is justified.

Date	Country	Organisation	Type of Organisation	Comment number
30/07/2012	Germany	BASF SE	Company-Manufacturer	11

Comment received

The co-existence of two concentration threshold values for oxidizing liquids (CLP annex VI, Part 3, table 3.1 vs. table 3.2) caused some irritation among users.
We suggest to harmonize before 2015 the threshold concentration for the classification as oxidizing liquid to 65% HNO3, following the transport regulations.

Dossier Submitter's Response

We agree with the suggestion of BASF SE to harmonize the threshold concentration for the classification as oxidizing liquid to 65% HNO3.

RAC's response

Agree with comment.

REFERENCES: None

ATTACHMENTS RECEIVED: 2

1. FARM position Nitric acid CLP Final 2012 07 31.doc (**FARM REACH Consortium Position on public consultation by ECHA on the proposal for harmonised Classification & Labelling (CLH) of Nitric acid).** Submitted by France/ FARM REACH CONSORTIUM / Industry or trade association. Part of attachment(General comments) is identical to the text in the table. Other part of attachment (2. Acute toxicity) was copied in the table.

2. Fertilizers Europe position Nitric acid final 2012 08 01.pdf (**Fertilizers Europe Position on public consultation by ECHA on the proposal for harmonised Classification & Labelling (CLH) of Nitric acid 2012 -08 -01)**). Submitted by Belgium/ Fertilizers Europe/ Industry or trade association. Part of attachment(General comments) is identical to the text in the table. Other part of attachment (2. Acute toxicity) was copied in the table.