

Committee for Risk Assessment
RAC

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/F

Adopted
31 May 2013

31 May 2013

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OPINION OF THE COMMITTEE FOR RISK ASSESSMENT ON A DOSSIER PROPOSING HARMONISED CLASSIFICATION AND LABELLING AT EU LEVEL

In accordance with Article 37 (4) of (EC) No 1272/2008, the Classification, Labelling and Packaging (CLP) Regulation, the Committee for Risk Assessment (RAC) has adopted an opinion on the proposal for harmonised classification and labelling (CLH) of:

Chemical name: nitric acid

EC number: 231-714-2

CAS number: 7697-37-2

The proposal was submitted by the **Germany** and received by the RAC on **21 June 2012**.

In this opinion, all classifications are given firstly in the form of CLP hazard classes and/or categories, the majority of which are consistent with the Globally Harmonised System (GHS) and secondly, according to the notation of 67/548/EEC, the Dangerous Substances Directive (DSD).

PROCESS FOR ADOPTION OF THE OPINION

Germany has submitted a CLH dossier containing a proposal together with the justification and background information documented in a CLH report. The CLH report was made publicly available in accordance with the requirements of the CLP Regulation at:

<http://echa.europa.eu/harmonised-classification-and-labelling-consultation> on 21 June 2011. Concerned parties and Member State Competent Authorities (MSCA) were invited to submit comments and contributions by **6 August 2012**.

ADOPTION OF THE OPINION OF THE RAC

Rapporteur, appointed by the RAC: **Bogusław Barański**

Co-rapporteur, appointed by the RAC: **Lina Dunauskiene**

The opinion takes into account the comments provided by MSCAs and concerned parties in accordance with Article 37(4) of the CLP Regulation.

The RAC opinion on the proposed harmonised classification and labelling was reached on **31 May 2013** and the comments received are compiled in Annex 2.

The RAC Opinion was adopted by **consensus**.

OPINION OF THE RAC

The RAC adopted the opinion that **nitric acid** should be classified and labelled as follows:

Classification & Labelling in accordance with CLP

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	007-004-00-1	nitric acid ... %	231-714-2	7697-37-2	Ox. Liq. 3 Skin Corr. 1A	H272 H314	GHS03 GHS05 Dgr	H272 H314		Skin Corr. 1A; H314: C ≥ 20 % Skin Corr. 1B; H314: 5 % ≤ C < 20 % Ox. Liq. 3; H272: C ≥ 65 %	B
Dossier submitter's proposal	007-004-00-1	nitric acid ... %	231-714-2	7697-37-2	Ox. Liq. 2 Acute Tox. 1	H272 H330	GHS06	H272 H330	EUH071	Ox. Liq. 2; H272: C ≥ 99 % Ox. Liq. 3; H272: 99 % > C ≥ 65 %	
RAC opinion	007-004-00-1	nitric acid ... %	231-714-2	7697-37-2	Ox. Liq. 2 Acute Tox. 1	H272 H330	GHS06	H272 H330	EUH071	Ox. Liq. 2; H272: C ≥ 99 % Ox. Liq. 3; H272: 99 % > C ≥ 65 %	
Resulting Annex VI entry if agreed by COM	007-004-00-1	nitric acid ... %	231-714-2	7697-37-2	Ox. Liq. 2 Acute Tox. 1 Skin Corr. 1A	H272 H330 H314	GHS03 GHS06 GHS05 Dgr	H272 H314 H330	EUH071	Skin Corr. 1A; H314: C ≥ 20 % Skin Corr. 1B; H314: 5 % ≤ C < 20 % Ox. Liq. 2; H272: C ≥ 99 % Ox. Liq. 3; H272: 99 % > C ≥ 65 %	B

Classification and labelling in accordance to DSD

	Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
Current Annex VI entry	007-004-00-1	nitric acid ... %	231-714-2	7697-37-2	O; R8 C; R35	O; C R: 8-35 S: (1/2-)23-26-36-45	C; R35: C ≥ 20 % C; R34: 5 % ≤ C < 20 % Footnote O; R8: C ≥ 70 %	B
Dossier submitte rs proposal	007-004-00-1	nitric acid ... %	231-714-2	7697-37-2	T+; R26	T+ R: 26	O; R8: C ≥ 65 %	
RAC opinion	007-004-00-1	nitric acid ... %	231-714-2	7697-37-2	T+; R26	T+ R: 26 S: (1/2-)26-28-36/37/39-45-63	O; R8: C ≥ 65 %	
Resultin g Annex VI entry if agreed by COM	007-004-00-1	nitric acid ... %	231-714-2	7697-37-2	O; R8 C; R35 T+; R26	O; T+ R: 8-26-35 S: (1/2-)26-28-36/37/39-45-63	O; R8: C ≥ 65 % C; R35: C ≥ 20 %; C; R34: 5 % ≤ C < 20 %	B

SCIENTIFIC GROUNDS FOR THE OPINION

RAC general comment

The dossier submitter proposes to supplement the current classification of nitric acid by adding acute toxicity (via inhalation) Category 1 as a new classification with the supplemental hazard information statement EUH071 (corrosive to the respiratory tract) and by changing the current classification for concentrated nitric acid (C ≥ 99 %) from Oxidising liquid Category 3 to Oxidising liquid Category 2.

RAC evaluation of physical hazards

Summary of the Dossier submitter's proposal

Explosive properties:

Testing can be waived based on consideration of the chemical structure in accordance with REACH Column 2 of Annex VII, section 7.11: the classification procedure need not be applied because there are no chemical groups present in the molecule which are associated with explosive properties. No classification for explosivity is proposed.

Flammability – flash point:

The study (EU Method A.9) does not need to be conducted because the substance is inorganic and nitric acid is non-combustible.

Flammability in contact with water and pyrophoricity

EU Method A.12 and A.13 can be omitted based on a consideration of the chemical structure and experience and use. No classification for flammability is proposed.

Oxidising properties:

In a standard study for determination of oxidising properties of nitric acid performed according to test method O.2 (UN-test O.2; UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fifth Revised Edition, 2009) nitric acid (C ≥ 99 %) produced the results summarised in the table below:

Method	Results	Remarks	Reference
UN-test O.2 Test for oxidising liquids	The mean pressure rise time for a 1 : 1 ratio of nitric acid (> 99 %) and cellulose is 320.6 ms and therefore the criteria for Category 2 are met ($R_3^* \leq t \leq R_2^{**}$).	HNO ₃ , C > 99 %	BAM 2.23 (2011); BAM Test report, May 06, 2011 (BAM Code 2.23/080411/01)

R₃* - the mean pressure rise time of a 1:1 mixture, by mass, of 50 % perchloric acid and cellulose; R₃= 45.6 ms
R₂** - the mean pressure rise time of a 1:1 mixture, by mass, of 40 % aqueous sodium chlorate solution and cellulose; R₂ = 1013 ms

The mean pressure rise time for a 1:1 mixture, by mass, of nitric acid (C > 99 %) and cellulose is **320.6** ms, which is longer than that for a 1:1 mixture, by mass, of 50% perchloric acid and cellulose (45.6 ms – upper limit for Category 1), but shorter than the mean pressure rise time for a 1:1 mixture, by mass, of 40 % aqueous sodium chlorate solution and cellulose (1013 ms), which is the upper limit for Category 2.

Nitric acid is currently classified and labelled as an Oxidising liquid in Category 3 (Ox. Liq. 3 - H272; May intensify fire; oxidiser) with an SCL of C ≥ 65 % according to CLP. Based on the results of the above test, the dossier submitter proposed to upgrade the classification to = Ox. Liq. 2 - H272 (May intensify fire; oxidiser) according to CLP criteria. The following SCLs are proposed: Ox. Liq. 3 - H272: 99 % > C ≥ 65 % and Ox. Liq. 2 - H272: C ≥ 99 %.

According to the DSD criteria, nitric acid is currently classified as oxidising (O; R8: Contact with combustible material may cause fire) with an SCL of C ≥ 70 %. Based on the results of tests and

taking into consideration the comments received during public consultation that a 1:1 mixture of 65 % aqueous nitric acid with cellulose is given as a reference mixture in the CLP criteria for Category 3 for oxidising liquids, and in the criteria for packing group III in UN-test method O.2, the dossier submitter proposes to classify nitric acid as O; R8 (Contact with combustible material may cause fire) with an SCL of $C \geq 65 \%$.

Metal corrosion

The dossier submitter noted that in the available registration dossiers (e.g. that of the lead registrant), nitric acid is classified and labelled for physico-chemical properties as corrosive to metals: Met. Corr. 1 - H290 (May be corrosive to metals), with SCLs of $C \geq 20 \%$, but the dossier submitter did not include this as a proposed harmonised classification in the CLH report. The reason given for not including this physico-chemical property is the lack of test results which could be compared with the classification criteria.

Comments received during public consultation

Two MSCAs supported the classification of nitric acid as Ox. Liq. 2 - H272, i.e. as proposed by the dossier submitter.

One manufacturer noted the co-existence of two concentration threshold values for oxidising liquids (CLP annex VI, Part 3, table 3.1 vs. table 3.2) and suggested that the threshold concentration for the classification as oxidising liquid be harmonised to 65 % HNO₃. The dossier submitter agreed with this suggestion for a consistent threshold for classification as oxidizing liquid under both CLP and DSD.

One REACH consortium and one trade association proposed the following classification and SCLs:
 $C \geq 70 \%$: Ox. Liq. 2 - H272;
 $65 \% \leq C < 70 \%$: Ox. Liq. 3 - H272

RAC Assessment and comparison with the classification criteria

Oxidising properties:

The mean pressure rise time (t) of a 1:1 mixture, by mass, of nitric acid ($C > 99 \%$) and cellulose is **320.6** ms, which is longer than that of a 1:1 mixture, by mass, of 50 % perchloric acid and cellulose (45.6 ms (R₃) – the lower limit for Category 1), but shorter than 1013 ms, the mean pressure rise time (R₂) of a 1:1 mixture, by mass, of 40 % aqueous sodium chlorate solution and cellulose (the lower limit for Category 2 and upper limit of Category 3).

Thus, the mean pressure rise time observed in the UN-test O.2 for a mixture of nitric acid ($C > 99 \%$) and cellulose is within a range of values for Category 2 (i.e. between 45.6 ms and 1013 ms).

When comparing with the DSD criteria, based on results of the UN-test O.2 and taking into account that a 1:1 mixture of 65 % aqueous nitric acid with cellulose is given as a reference mixture in CLP criteria for Category 3 for oxidising liquids and in criteria for packing group III in UN-test O.2, nitric acid should be classified as oxidising materials with O; R8 (Contact with combustible material may cause fire) with an SCL of $C \geq 65 \%$.

In conclusion, the RAC agrees with the proposal of the dossier submitter that nitric acid $C \geq 99 \%$ should be classified in Category 2 for oxidising liquids (Ox. Liq. 2 - H272: May intensify fire; oxidiser) and nitric acid $99 \% > C \geq 65 \%$ in Category 3 for oxidising liquids (Ox. Liq. 3 - H272) according to CLP, and as O; R8 (Contact with combustible material may cause fire) with an SCL of $C \geq 65 \%$ according to DSD.

Metal corrosion

The dossier submitter did not include a proposal for classification in this hazard class in the CLH report and no results of the metal corrosion test listed in the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria were found in either the CLH report or in the registration dossiers. Therefore, RAC could not conclude on a classification.

RAC evaluation of acute toxicity

Summary of the Dossier submitter's proposal

Acute oral toxicity

No data on the oral acute toxicity of nitric acid was presented by the dossier submitter in the CLH dossier and no classification for oral acute toxicity was proposed.

Acute dermal toxicity

No data on the dermal acute toxicity of nitric acid was presented by the dossier submitter in the CLH dossier and no classification for dermal acute toxicity was proposed.

Acute inhalation toxicity

Acute inhalation toxicity, human study

In numerous human case reports, acute lethality and other severe acute toxic effects have been described following accidental exposure to fumes, vapours or gases originating from nitric acid solutions. Exposure durations were recorded in some case reports, but actual exposure concentrations were in most cases not given.

After single or relatively short exposures to nitric acid, lethality has been caused in humans due to acute pulmonary oedema. In humans, severe effects and/or lethality occurred after a latency period of 3 to 30 hours after exposure. Inhalation of gases and vapours originating from nitric acid can be extremely dangerous since there is no violent respiratory reflex, serving as a protective mechanism, as is observed with e.g. chlorine and ammonia. Thus, inhalation of nitric acid fumes at potentially fatal concentrations may initially remain undetected by the affected person (Hardy and Hamilton, 1974, cited in Durant *et al.* 1991).

During the public consultation, in response to some comments from industry stakeholders, the dossier submitter provided information that when HNO₃, as an ingredient in cleaning products, comes in contact with other materials (metal) or substances (e.g. alkaline ingredients from other cleaning agents) the release of nitrous gases, especially NO₂, is expected. There are many case reports from the poison information centers in Germany providing evidence of severe health damages after use (and presumably misuse) of descaling products containing 20-30% of HNO₃ (between 1999 and 2010). In 23.7% of all cases the symptoms were caused by inhalation.

Acute inhalation toxicity, animal studies

The acute lethal effects of different nitric acids were reported by Gray *et al.* (1954, in NIOSH 1976). So-called 'red fuming nitric acid' (RFNA, containing 8-17 % nitrogen dioxide), 'white fuming nitric acid' (WFNA, containing 0.1-0.4 % nitrogen dioxide), and nitrogen dioxide (NO₂) were examined by inhalation in male albino rats. The test atmospheres for RFNA and WFNA were characterised as a vapour. Deaths occurred by acute pulmonary oedema. The terms "white fuming" and "red fuming" are applied to differentiate between two concentrations of fuming nitric acid. White fuming nitric acid (WFNA) contains about 97.5 % nitric acid by weight, while red fuming nitric acid (RFNA) contains 82.4 - 85.4 %. The percentages of dissolved NO₂ content in WFNA and RFNA are about 0.5 and 14 %, respectively. In practice, HNO₃ is usually found in conjunction with NO₂ (ACGIH 1991). The dossier submitter calculated LC₅₀-values of 77.5 ppm/4h (0.20 mg/l/4h) for RFNA and 83.5 ppm/4h (0.22 mg/l/4h) for WFNA. The 4-hour values were derived from the 0.5-hour LC₅₀-values for RFNA (310 ppm) and for WFNA (334 ppm) as calculated by NIOSH (1976) based on results of Gray *et al.* (1954).

For direct comparison with the classification criteria, conversion of the 0.5-hour exposure values into a 4-hour testing exposure period was carried out in two steps. The 1-hour exposure value was derived by dividing by 2. Because the test atmosphere for RFNA and WFNA was characterised as a vapour, the values for a 1 hour exposure were thereafter divided by a factor of 2 for gases and vapours (according to the CLP Regulation), which amounts to 77.5 ppm/4h for RFNA and 83.5 ppm for WFNA.

Nitric acid can decompose to nitrogen dioxide (NO₂), nitric oxide (NO), nitrous oxide (N₂O), and nitrous anhydride (N₂O₃). The most important decomposition product of nitric acid is nitrogen dioxide. Nitrogen dioxide is highly toxic, and inhalation of nitrogen dioxide may result in fatality. The acute toxic effects from nitric acid fumes are caused by a mixture of nitric acid vapour and oxides of nitrogen, mainly NO₂ and NO. Therefore, acute toxic inhalation effects of nitric acid in humans cannot be isolated from those of its reaction products, since contact with air immediately liberates oxides of nitrogen.

The other acute inhalation toxicity studies, using rabbits and cats, reviewed in the BD supported the high toxicity of nitric acid fumes; however, they did not enable an LC₅₀ value to be established.

According to the dossier submitter, HNO₃ meets the CLP criteria for classification and labelling as Acute Tox. 1 – H330 with the supplemental hazard information statement EUH071 (Corrosive to the respiratory tract) as well as the DSD criteria for classification as T⁺; R26 (Very toxic by inhalation).

Comments received during public consultation

Nine comments on the classification proposal for acute inhalation toxicity were received during public consultation.

Two comments were received from MSCAs supporting classification of nitric acid as proposed by the dossier submitter, i.e. Acute Tox. 1 - H330 and the additional hazard statement EUH071 (Corrosive to the respiratory tract).

One of these MSCAs agreed that action at community level is justified for the acute inhalation toxicity of nitric acid because it is considered a High Production Volume 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 the respiratory tract as target organ. Therefore, a harmonised classification for acute inhalation toxicity to protect human health is justified. 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 bw (the minimum lethal dose reported for humans could be used as equivalent ATE, and the resulting classification would be Category 4).

Seven comments were received from industry:

One manufacturer noted that at higher concentrations of nitric acid, the effects of the nitric acid itself and its precursors or decomposition products cannot be clearly differentiated in studies using fuming acid. Therefore, the effects of nitric acid at lower concentrations in more diluted aqueous solutions and HNO₃ partial pressure should be considered. This manufacturer does not, however, recommend HNO₃ for consumer use.

The dossier submitter clarified in its response, that even using the low partial vapour pressure of 0.336 hpa for the calculation (provided by Fertilizers Europe, France, based on the same parameters as those used in the calculations in BfR Opinion No. 041/2010, except for partial vapour pressure; see RCOM) of the concentration of nitric acid in a bathroom cleaned with a cleaning product containing nitric acid at a concentration of approximately 30%, the resulting nitric acid concentration in the cleaned bathroom is still very high, ca. 8mg/m³. The dossier submitter also noted that even at a low concentration in the cleaning products (20 -30%), nitric acid poses a risk for acute inhalation poisoning in humans. Out of 134 reported cases with health effects attributed to nitric acid reported to BfR, by the poison treatment and information centres in Germany (BfR Opinion No 041/2010), in almost one quarter (23.7%) the symptoms were caused by the inhalation of ingredients in the cleaning products. Therefore, these data support a view of high inhalation toxicity of nitric acid even at lower concentrations in aqueous solutions. The dossier submitter further noted that contact of aqueous solution of nitric acid (as in the cleaning products) with calcium carbonate deposits, metals or ingredients of other cleaning products may release toxic nitrous gases.

One REACH consortium and two national trade associations emphasized that the nitric acid in the REACH registration dossier submitted by the former does not have any consumer use. In

reference to the REACH regulation, it means that the consumer use of nitric acid is not authorised in Europe since 1 December 2010.

According to one trade association, there are two different types of nitric acids with different toxicities, and they can be distinguished by concentration ranges: the 'aqueous nitric acid' (up to 68%) and the 'smoking nitric acid' (higher than 68%). Smoking nitric acid is only obtainable by bubbling NO_x 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 NO_x gases released by concentrated acid. The acute toxicity Category 1 classification for inhalation should therefore only apply to aqueous solutions with nitric acid content greater than 70%, while for nitric acid containing aqueous solutions with concentrations lower than 70%, classification for acute toxicity Category 4 should be applied. They also expressed a view that it is safer to highlight the corrosive risk rather than using the acute toxicity Category 4 classification, because this classification is more restrictive in terms of risk management measures.

The dossier submitter disagreed with the above proposal for the classification of nitric acid based on specific concentrations above or below 70 %, since many cases of nitric acid poisoning were observed following the use of a detergent called 'POR ÇÖZ' (produced in or imported from Turkey) containing only 25 % nitric acid, which was far below the concentration limits of C <70 % proposed by the above trade association.

According to the guidance on the application of CLP criteria, SCLs are not applicable for acute toxicity classifications according to CLP. Classification of mixtures is based on ingredients in the mixture (using the 'additivity formula'). In addition, inhalation of gases and vapours originating from nitric acid do not induce a violent respiratory reflex, which serves as a protective mechanism, as occurs with e.g. chlorine and ammonia. Thus, inhalation of nitric acid fumes at potentially fatal concentrations may go undetected by the affected person. This health hazard is not covered by the existing Annex VI entry where nitric acid has a harmonised classification as Skin Corr. 1A – H314.

The same national trade associations questioned the validity of the Gray *et al.* study (1954) used for calculating the LC₅₀/4h for nitric acid, and suggested using the study of du Pont de Nemours and Company (1987) for this purpose, which was performed with a 70.7% nitric acid aqueous solution and provided data for calculating a 4-hour LC₅₀ of 1562.5 mg/m³. In line with this suggestion, the aforementioned manufacturer stated that although the aerosol criteria were not fully met in the du Pont study, one could estimate that concentrations around 70% nitric acid and the given 1-hour value of 2500 ppm, would correspond to an aerosol value of about 1,6 mg/l/4h. The mortality observed was attributed to corrosive effects. From aerosol exposure, the inhalation toxicity of 70% nitric acid would lead to classification as acute toxicity Category 4. They further stated that lower concentrations cannot have a higher classification than acute inhalation toxicity Category 4, and that therefore, separate, concentration dependent entries in Annex VI of the CLP are needed.

In its response, the dossier submitter pointed out that 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 phases. Thus, it was not possible to perform an exact conversion of the 1-hour exposure value into a 4-hour value. Although the studies by Gray *et al.* (1954) were conducted decades before standard test guidelines were adopted, these studies were considered sufficiently reliable to propose classification of nitric acid as acutely toxic by the inhalation route. The LC₅₀-values for RFNA and WFNA 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/4h was derived, and the corresponding value for WFNA was 0.22 mg/l/4h.

Assessment and comparison with the classification criteria

Comparison with the criteria

The studies by Gray *et al.* (1954) were conducted decades before standard test guidelines were adopted. However, the studies were considered sufficiently reliable to propose classification of nitric acid as acutely toxic by the inhalation route of exposure, in particular since the high inhalation toxicity of nitric acid is supported by data in humans showing severe effects and lethality after single exposure or severe effects in animals exposed from 35 minutes to 315 minutes to fumes at concentrations of 15.3 ppm to 336.5 ppm from heated concentrated nitric acid (see further review in the BD).

The study by du Pont (1987) in which rats were exposed for 1 hour to an aerosol of 70.76 % aqueous solution of nitric acid at concentrations of 260 – 3100 ppm was not considered appropriate for the determination of LC₅₀ of gases and vapours emitted by nitric acid. The nitric acid was airborne as particles and aerosol samples were taken using a gravimetric filter sample but at the highest concentrations, the nitric acid content was not measured. Thus, the respirable concentrations of nitric acid in this study are uncertain.

The case studies of humans accidentally exposed to nitric acid can be taken as supportive evidence of the high acute inhalation toxicity of nitric acid.

Table: Overview on cases of accidental exposed humans to nitric acid solutions

Nitric solutions	Accidental exposed humans	References
20-30 %	134 cases, 23.7% identified as due to inhalation	BfR Opinion No. 041/2010, 06 September 2010
34 %	1 plant guard (lethality)	Rossano (1945)
38 %	8 / 20 firemen (lethality)	Hall and Cooper (1905)
60 %	1 truck driver (lethality)	Schmid (1974, 1974a)
60 %	1 man (lethality)	Bur <i>et al.</i> (1997)
68 %	3 men (lethality)	Hajela <i>et al.</i> (1990)

Cases of human poisoning were observed at nitric acid concentrations of 20% and above. No data are available to predict whether mixtures containing 20% nitric acid represent the lowest concentrations resulting in adverse acute effects. Exposure of volunteers to nitric acid fumes showed an absence of symptoms at the low concentration of 0.0042 mg/l (Sackner and Ford, 1981). There are no data on toxic effects resulting from acute inhalation exposures between this NOAEC and nitric acid at concentrations of 20%.

According to the Guidance on the Application of CLP criteria (version 3.0, November 2012, point 3.1.2.5), SCLs are not applicable for acute toxicity classifications according to CLP. Instead, the relative potency of substances in a mixture, taking into account the 'additivity formula' (section 3.1.3.6.1 of Annex I of CLP regulation) should be used to decide on classification of the aqueous solution of nitric acid with a low concentration of the acid.

Taking into account the data submitted in the CLH dossier and the arguments provided by the dossier submitter, as well as data and arguments provided during public consultation, the RAC is of the opinion that classification with Acute Tox. 1 – H330 (inhalation) with the supplemental hazard information EUH071 (Corrosive to the respiratory tract; CLP) and T⁺; R26 (DSD) is warranted for nitric acid. The classification is based on the lowest derived LC₅₀-value of 77.5 ppm/4h (0.20 mg/l/4h) for gases and vapours released from liquid RFNA in the rat (Gray *et al.* 1954; NIOSH 1976, and the dossier submitters calculations, see the BD) (Acute Tox. 1 – H330, vapours ATE ≤ 0.5 mg/l/4h; T⁺; R26: LC₅₀, vapours ≤0.5 mg/l/4h).

ANNEXES:

- Annex 1 Background document gives the detailed scientific grounds for the opinion. It is based on the CLH report prepared by the dossier submitter; the evaluation performed by RAC is contained in RAC boxes.
- Annex 2 Comments received on the CLH report, response to comments provided by the dossier submitter and RAC (excl. confidential information)