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COLLECTIVE EXPERT APPRAISAL: SUMMARY AND CONCLUSIONS

Regarding the "expert appraisal for recommending occupational exposure limits for chemical agents"

Assessment of health effects and methods for the measurement of exposure levels in workplace atmospheres for potassium hydroxide (CAS No. 1310-58-3)

This document summarises the work of the Expert Committee and working groups on health effects and metrology.

Presentation of the issue

On 12 June 2007, the French Agency for Environmental and Occupational Health Safety (AFSSET), which became ANSES on 1 July 2010, received a formal request from the French Directorate General for Labour to conduct the expert appraisal work required for establishing recommendations on measures to be taken in the event of specific exposure profiles such as those with peaks.

A first report, published in June 2009[1], issued recommendations on measures to be taken in the event of an existing 8h-OELV without short-term exposure limit (STELV).

A second report, published in October 2010[2] addressed the second part of the issue, i.e. substances with a short-term exposure limit (15min-STELV) but no 8h-OELV. Among other things, it recommended studying the 36 French substances existing under French labour regulations with a short-term exposure limit but no 8h-OELV in order to recommend health values from the most recent scientific literature. This report on potassium hydroxide was written in this context.

France currently has an indicative 15-minute exposure limit of 2 $mg.m^{-3}$ for potassium hydroxide. This value was set in the Circular of 13 May 1987 of the Ministry of Labour (not published in the OJ).

Scientific background

The French system for establishing OELVs has three clearly distinct phases:

- independent scientific expert appraisal (the only phase entrusted to ANSES);
- proposal by the Ministry of Labour of a draft regulation for the establishment of limit values, which may be binding or indicative;
- stakeholder consultation during the presentation of the draft regulation to the French Steering Committee on Working Conditions (COCT). The aim of this phase is to discuss the effectiveness of the limit values and if necessary to determine a possible

[1] http://www.anses.fr/ET/DocumentsET/VLEP_Picsdexpo_Avis_0906.pdf
[2] http://www.anses.fr/ET/DocumentsET/10_10_VLEP_Pics_exposition_Avis.pdf

implementation timetable, depending on any technical and economic feasibility issues.

The organisation of the scientific expertise phase required for the establishment of Occupational Exposure Limits (OELVs) was entrusted to AFSSET in the framework of the 2005-2009 Occupational Health Plan (PST) and then to ANSES after AFSSET and AFSSA merged in 2010.

The OELs, as proposed by the Committee on expert appraisal for recommending occupational exposure limits for chemical agents (OEL Committee), are concentration levels of pollutants in workplace atmospheres that should not be exceeded over a determined reference period and below which the risk of impaired health is negligible. Although reversible physiological changes are sometimes tolerated, no organic or functional damage of an irreversible or prolonged nature is accepted at this level of exposure for the large majority of workers. These concentration levels are determined by considering that the exposed population (workers) is one that excludes both children and the elderly.

These concentration levels are determined by the OEL Committee experts based on information available from epidemiological, clinical and animal toxicology studies. Identifying concentrations that are safe for human health generally requires correction factors to be applied to the values identified directly by the studies. These factors take into account a number of uncertainties inherent to the extrapolation process conducted as part of an assessment of the health effects of chemicals on humans.

The Committee recommends the use of three types of values:

- 8-hour occupational exposure limit (8h-OEL): this corresponds to the limit of the time-weighted average (TWA) of the concentration of a chemical in the worker's breathing zone over the course of an 8-hour work shift. In the current state of scientific knowledge (toxicology, medicine, epidemiology, etc.), the 8h-OEL is designed to protect workers exposed regularly and for the duration of their working life from the medium- and long-term health effects of the chemical in question;
- Short-term exposure limit (STEL): this corresponds to the limit of the time-weighted average (TWA) of the concentration of a chemical in the worker's breathing zone over a 15-minute reference period during the peak of exposure, irrespective of its duration. It aims to protect workers from adverse health effects (immediate or short-term toxic effects such as irritation phenomena) due to peaks of exposure;

Ceiling value: this is the limit of the concentration of a chemical in the worker's breathing zone that should not be exceeded at any time during the working period. This value is recommended for substances known to be highly irritating or corrosive or likely to cause serious potentially irreversible effects after a very short period of exposure.These three types of values are expressed:

- either in $mg.m^{-3}$, i.e. in milligrams of chemical per cubic metre of air and in ppm (parts per million), i.e. in cubic centimetres of chemical per cubic metre of air, for gases and vapours;
- or in $mg.m^{-3}$, only for liquid and solid aerosols;
- or in $f.cm^{-3}$, i.e. in fibres per cubic centimetre for fibrous materials.

The 8h-OELV may be exceeded for short periods during the working day provided that:

- the weighted average of values over the entire working day is not exceeded;
- the value of the STEL, when it exists, is not exceeded.

In addition to OELs, the OEL Committee assesses the need to assign a “skin” notation, when significant penetration through the skin is possible (ANSES, 2014). This notation indicates the need to consider the dermal route of exposure in the exposure assessment and, where necessary, to implement appropriate preventive measures (such as wearing protective gloves). Skin penetration of substances is not taken into account when determining atmospheric limit levels, yet can potentially cause health effects even when the atmospheric levels are respected.

The OEL Committee assesses the need to assign an “ototoxic” notation indicating a risk of hearing impairment in the event of co-exposure to noise and the substance below the recommended OELs, to enable preventionists to implement appropriate measures (collective, individual and/or medical) (ANSES, 2014).

The OEL Committee also assesses the applicable reference methods for the measurement of exposure levels in the workplace. The quality of these methods and their applicability to the measurement of exposure levels for comparison with an OEL are assessed, particularly with regards to their compliance with the performance requirements in the NF-EN 482 Standard and their level of validation.

Organisation of the expert appraisal

ANSES entrusted examination of this request to the Expert Committee on expert appraisal for recommending occupational exposure limits for chemical agents (OEL Committee). This body mandated:

- The working group on health effects to conduct the expert appraisal work on health effects;
- The working group on metrology to assess measurement methods in workplace atmospheres.

Six ANSES employees contributed to this work and were responsible for scientific coordination of the different expert groups.

The methodological and scientific aspects of the work of these groups were regularly submitted to the OEL Committee. The final report takes account of all their observations.

This expert appraisal was therefore conducted by groups of experts with complementary skills. It was carried out in accordance with the French Standard NF X 50-110 “Quality in Expertise Activities”.

Preventing risks of conflicts of interest

ANSES analyses interests declared by the experts before they are appointed and throughout their work in order to prevent potential conflicts of interest in relation to the points addressed in expert appraisals.

The experts’ declarations of interests are made public on ANSES's website (www.anses.fr).

Description of the methodology

For the assessment of health effects

A summary report was prepared by the working group on health effects and submitted to the OEL Committee, which commented on it and added to it.

The information in the summary report on the health effects of potassium hydroxide was taken from Medline and Toxline databases queried up to April 2012 and summary documents written by the ACGIH (most recent revision in 2001).

For the assessment of methods for measuring exposure levels in workplace atmospheres

A summary report was prepared by the working group on metrology and submitted to the OEL Committee, which added its own comments.

The summary report presented the various protocols for measuring potassium hydroxide in workplace atmospheres grouped together based on the methods they use. These methods were then assessed and classified based on the performance requirements set out particularly in the French Standard NF EN 482: "Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents" and the decision-making criteria listed in the methodology report.

A list of the main sources consulted is detailed in the methodology report.

These methods were classified as follows:

- Category 1A: the method has been recognised and validated (all of the performance criteria in the NF-EN 482 Standard are met);
- Category 1B: the method has been partially validated (the essential performance criteria in the NF-EN 482 Standard are met);
- Category 2: the method is indicative (essential criteria for validation are not clear enough);
- Category 3: the method is not recommended (essential criteria for validation are lacking or inappropriate).

A detailed comparative study of the methods in Categories 1A, 1B and 2 was conducted with respect to their various validation data and technical feasibility, in order to recommend the most suitable method(s) for measuring concentrations for comparison with OELs.

The collective expert appraisal work and its conclusions and recommendations were adopted on 8 July 2013 by the OEL Committee (term of office 2010-2013)

The collective expert appraisal work and the summary report were submitted to public consultation from 01/10/2014 to 01/12/2014. The people or organizations who contributed to the public consultation are listed in appendix of the report (only available in French). The comments received were reviewed by the OEL Committee (term of office 2014-2017) who adopted this version on 9 March 2015.

Results of the collective expert appraisal on the health effects of potassium hydroxide

Kinetics and metabolism

Potassium hydroxide is corrosive at the contact site and in principle has no systemic toxicity. When in contact with tissues, potassium hydroxide is rapidly converted into its constitutive ions and excreted into urine as K^+ ions and neutralised for HO^- ions. The local caustic effects of potassium hydroxide are due to HO^- ions rather than K^+ ions (OECD, 2001).

General toxicity

Toxicity in humans

No studies on acute exposure through inhalation were identified in the literature.

When in contact with the eyes, mucous membranes and skin, potassium hydroxide causes severe burns (Patnaik, 2007; Kuckelkorn *et al*., 1993; Dick and Ahlers, 1998).

A study undertaken among extraction and grinding workers in potash mines did not find any link to diseases (Waxweiler, 1973).

Pahwa and McDuffie (2009) studied factors that may contribute to increased risk of cancer development in 1434 potash mine workers. After data analysis, the study did not draw any conclusions.

A study on dose-response relationships between exposure to potash, diesel exhaust and nitrogen oxides and lung function was undertaken in two potash mines (Lotz *et al.*, 2008). A sample of 410 miners from mine A and 463 miners from mine B were examined. Seventy five percent of the cohort from mine A and 64% from mine B were examined 5 years later. Exposure levels were measured in operators with various characteristic functions. The study results indicate that exposure to multiple compounds can cause lung function disorders in potash miners exposed over long periods. It should be noted that no precise assessment of potash exposure is available in this study.

Toxicity in animals

No data on the toxicity of KOH by inhalation in animals were found in the scientific literature.

No data on the subchronic or chronic toxicity of KOH by inhalation in animals were found in the scientific literature.

Due to the lack of data on the toxicity of KOH in humans and animals to establish an OEL, studies on similar compounds were taken into account.

Thus, sodium hydroxide, the closest compound in terms of structure and chemical reactivity, completely dissociates in water and biological fluids into Na^+ and OH^- ions. Similarly, potassium hydroxide dissociates into K^+ and OH^- ions. Considering that hydroxide ions are responsible for local caustic effects, data on NaOH are given below.

General toxicity of sodium hydroxide

Fritschi *et al.* (2001) conducted in 1996 a cross-sectional study among 2404 employees in 3 alumina refineries and an alumina shipping port. The aim of this study was to investigate associations between respiratory symptoms, lung function and cumulative exposure to alumina and bauxite dust, as well as recent exposure to caustic mist. The workers were questioned about their jobs (tasks and sub-tasks) and respiratory symptoms related to their work (wheeze, chest tightness, rhinitis) and were given lung-function tests.

For caustic mist, static measurements were taken at the workstation over a 15-min. period in the worker's breathing zone. It should be noted that the tasks performed by the workers involved moving in and out of the sampling regions. Tasks involving peak exposure to caustic mist were classified semi-quantitatively into one of three exposure groups: low (0.05 mg.m^{-3}), medium (0.05 to 1 mg.m^{-3}) or high (>1 mg.m^{-3}).

Each subject was classified according to the highest peak exposure in one of the tasks performed in the job held at the time of the study. The authors specify that the duration and frequency of the exposure peaks were not examined in this study. Only current jobs were considered as the hygienists were not confident they could accurately estimate caustic mist worker's exposure in previous jobs.

In this study, over 40% of the subjects were exposed to caustic mist (the workers in refineries 2 and 3 were more exposed than those in refinery 1). No exposure was recorded for 822 (34%) participants, 160 (6.7%) were exposed to all three contaminants, and 636 (26%) were exposed to only one of the three contaminants. However, the authors do not give any data about the latter group of workers.

The subjects in group 3 (caustic mist exposure >1 mg.m^{-3}) were the only ones who reported respiratory symptoms such as wheeze and rhinitis. An exploration of lung function showed no significant differences between the 3 groups for forced expiratory volume in 1 second (FEV1). However, for the second parameter, forced vital capacity (FVC), it was significantly higher in groups 2 and 3 but this increase could not be linked to any effects.

Despite its many limitations (cross-sectional study, multi-exposure, imprecise exposure measurement, relevant critical effect collected through a questionnaire), this study shows that the production operators in the group with the highest exposure (> 1 mg.m^{-3}) to caustic mist reported significantly more respiratory symptoms such as wheeze and rhinitis but show no modification of lung function.

Establishment of OELs

15-minute short-term exposure limit

Although the toxicological profile for this substance is imperfect and incomplete, it indicates that the critical effect is irritation of the mucous membranes and respiratory tract. This short-term effect and the lack of systemic damage justify establishing only a 15min-STEL for potassium hydroxide.

No relevant data are available in the literature to establish a 15min-STEL for KOH, even when considering similar compounds such as sodium hydroxide. It should be noted that there is a French indicative OEL of 2 mg.m^{-3} (Circular of 13 May 1987) for which no supporting documents were found. The available data that were examined include those of Fritschi *et al*. (2001), which do not confirm or contradict the validity of this 2 mg.m^{-3} value.

8h-OEL

The toxicological profile and review of the literature did not show any long-term effects.

The OEL Committee does not recommend an 8h-OEL for potassium hydroxide.

"Skin" notation

Since the substance does not produce any systemic effects and there are no quantitative data to calculate skin absorption, no skin notation can be assigned for potassium hydroxide.

Conclusion

8h-OEL: not recommended

15min-STEL: cannot be recommended based on scientific data

“Skin” notation: not assigned

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Results of the collective expert appraisal on measurement methods in workplace atmosphere

Assessment of methods for measuring potassium hydroxide in workplace atmosphere

Based on the non-regulatory indicative OEL of 2 mg.m^{-3} established in the Circular of 13 May 1987, four measurement methods were identified and assessed (see Table 1).

For all of these methods, sampling is performed with a sampler of the inhalable fraction equipped with a filter.

Table 1: Summary table of methods for measuring potassium hydroxide in workplace atmospheres

No	Methods	Similar protocols
1	Measurement of hydroxides by potentiometric titration	Protocol 1: Measurement of basic aerosols - MétroPol (Sheet 028 – 2002) Protocol 2: Alkaline dusts - NIOSH Method 7401 (NMAM issue 2 - 1994)
2	Measurement of potassium by flame atomic absorption spectroscopy	Protocol 3: OSHA-ID-121 Method (2002): Metal and metalloid particulates in workplace atmospheres
3	Measurement of potassium by inductively coupled plasma atomic emission spectroscopy (ICP-AES)	Protocol 4: Standard NF ISO 15202: Determination of metals and metalloids in airborne particulate matter by inductively coupled plasma atomic emission spectrometry – Part 1: Sampling (July 2012) Part 2: Sample preparation (March 2012) Part 3: Analysis (December 2005) Protocol 5: Elements by ICP (Nitric/Perchloric Acid Ashing) – NIOSH Method 7300, (NMAM issue 3: 2003) Protocol 6: Elements by ICP (Aqua Regia Ashing) – NIOSH Method 7301 (NMAM issue 1: 2003) Protocol 7: Elements by ICP (Hot Block/HCl/HNO_3 Digestion) – NIOSH Method 7303 (NMAM issue 1: 2003)
4	Measurement of cations by ion chromatography	Protocol 8: Method DFG (E) (2001): Alkali metal hydroxides and alkaline earth hydroxides Protocol 9: PR NF ISO 17091- Determination of lithium hydroxide, sodium hydroxide, potassium hydroxide and calcium dihydroxide - method by ion chromatography. Protocol 10: BGIA 7638 - hydroxides (LiOH, NaOH, KOH, Ca(OH)2)

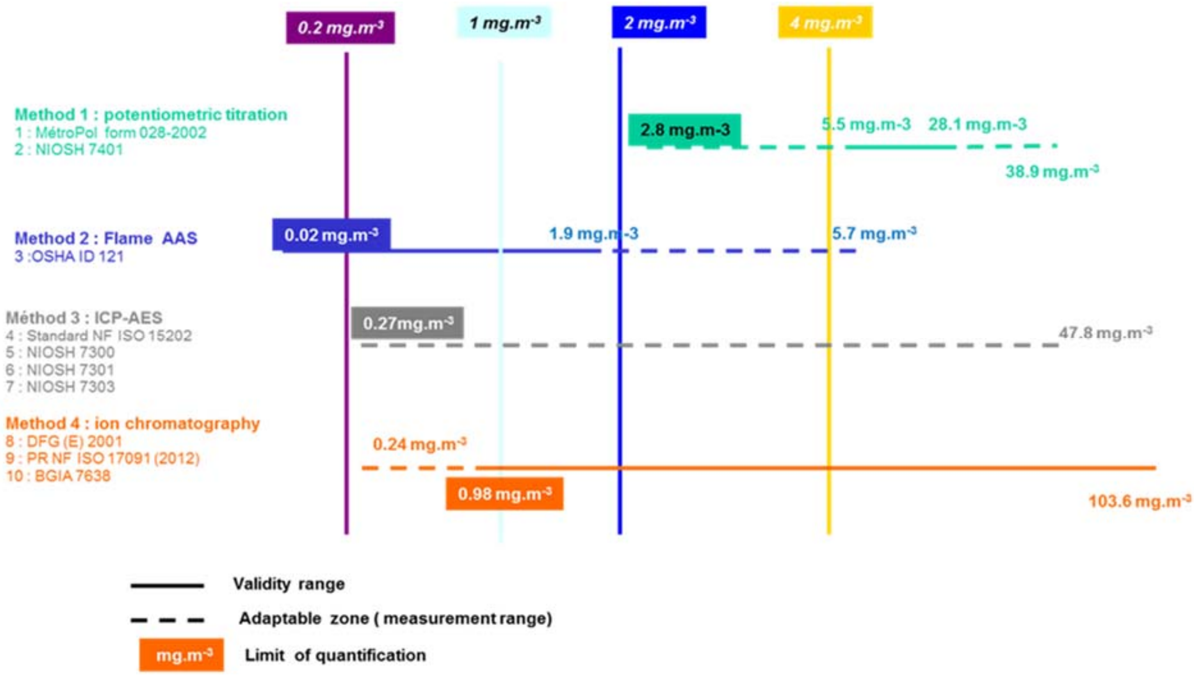

Figure 1: Ranges of validity and limits of quantification for the various compared methods from 0.1 to 2 times the value of 2 mg.m^{-3} for potassium hydroxide (for measurements over 15 min.)

Conclusion and recommendations

Two methods have been classified in category 2:

- Method 2, described in protocol 3 (Method OSHA-ID-121 (2002): Metal and metalloid particulates in workplace atmospheres), involves metals and metalloids and taking an air sample through a filter, which is desorbed in deionised water and then analysed by flame atomic absorption spectrometry.
- Method 4, described in the following protocols: protocol 8: Method DFG (E) (2001): Alkali metal hydroxides and alkaline earth hydroxides; protocol 9: PR NF ISO 17091 - Determination of lithium hydroxide, sodium hydroxide, potassium hydroxide and calcium dihydroxide - method by ion chromatography; and protocol 10: BGIA 7638 - hydroxides (LiOH, NaOH, KOH, Ca(OH)2). This method involves cations and consists in taking a sample of air to be analysed through a filter mounted on a sampler to collect particles of LiOH, NaOH, KOH and $Ca(OH)_2$. This filter is then subject to extraction with water or an acidic eluent, treated by ion chromatography with suppression to separate the elements Li, Na, K and Ca. After this separation, these elements are measured with a conductivity detector.

Two other methods were identified and classified in Category 3, due to incompleteness of data for assessing the method for measuring of potassium:

- Method 1, described in protocol 1 (Measurement of basic aerosols - MétroPol (Sheet 028 – 2002)) and protocol 2 (Alkaline dusts - NIOSH Method 7401 (NMAM issue 2 - 1994),
- Method 3, described in protocol 4: Standard NF ISO 15202: Determination of metals and metalloids in airborne particulate matter by inductively coupled plasma atomic

emission spectrometry; protocol 5: Elements by ICP (Nitric/Perchloric Acid Ashing) – NIOSH Method 7300, (NMAM issue 3: 2003); protocol 6: Elements by ICP (Aqua Regia Ashing) – NIOSH Method 7301, (NMAM issue 1: 2003); and protocol 7: Elements by ICP (Hot Block/HCl/HNO_3 Digestion) – NIOSH Method 7303 (NMAM issue 1:2003)

None of the identified methods perfectly meet the requirements of the NF EN 482 Standard.

Methods 2 and 4 have been classified in Category 2 due to their lack of selectivity. Nonetheless, the available validation data for Method 4 are more complete than the validation data found for Method 2 (primarily analytical).

In the absence of other potassium sources, this method could be used to assess the concentration of potassium hydroxide in a workplace atmosphere for comparison with the non-regulatory 15-min. value of 2 $mg.m^{-3}$ in force since 1987.

The group therefore recommends, for the monitoring and control of the 15-min. value of 2 $mg.m^{-3}$ value, the following indicative method:

Method	Protocols	Category
Sampling the inhalable fraction using a 37mm cassette and a quartz fibre filter - Dissolution in a solution of water or sulphuric acid - Measurement of cations by ion chromatography	**Protocol 8:** Method DFG (E) (2001): Alkali metal hydroxides and alkaline earth hydroxides	2
	Protocol 9: PR NF ISO 17091 - Determination of lithium hydroxide, sodium hydroxide, potassium hydroxide and calcium dihydroxide - method by ion chromatography.	
	Protocol 10: BGIA 7638 - hydroxides (LiOH, NaOH, KOH, $Ca(OH)_2$)	

Conclusions of the collective expert appraisal

Based on the data that are currently available, the OEL Committee:

- does not recommend establishing an 8h-OEL for potassium hydroxide given that no long-term effects have been identified;
- does not recommend a 15min-STEL for potassium hydroxide due to poor bibliographic data available to date to establish a value even when considering those for a similar compound (sodium hydroxide). Therefore, the OEL Committee recommends undertaking experimental studies to establish a 15min-STEL;
- does not recommend a “skin” notation.

Lastly, the OEL committee would like to emphasise that:

- KOH is an irritating and corrosive substance. Thus, while recommending a 15min-STEL appears justified, no relevant data are available in the literature to establish this value, even when considering similar compounds such as NaOH. Given the serious effects associated with exposure to this substance, the OEL Committee recommends taking protective measures to reduce exposure insofar as possible. It should be noted that there is a French indicative OEL of 2 $mg.m^{-3}$ (Circular of 13 May 1987) for which no supporting document was found. The available data that were examined do not anses French agency for food, environmental and occupational health & safety

confirm or contradict the validity of this 2 mg.m^{-3} value. Moreover, the OEL Committee also recommends undertaking additional studies to provide a basis for scientifically sound recommendations;

- of the 4 identified methods for measuring potassium hydroxide in workplace atmospheres that were assessed, none have been fully validated for comparison with the non-regulatory indicative OEL of 2 mg.m^{-3};
- nonetheless, in the absence of other potassium sources, an indicative measurement method for assessing the concentration of potassium hydroxide in an atmosphere for comparison with the value of 2 mg.m^{-3} may be classified in Category 2. This method involves taking a sample of the inhalable fraction using a 37mm cassette and a quartz fibre filter which is then dissolved in a solution of water or sulphuric acid, after which the cations are quantified by ion chromatography.

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AFNOR NF ISO 15202 : Détermination des métaux et métalloïdes dans les particules en suspension dans l'air par spectrométrie d'émission atomique avec plasma à couplage inductif :

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- partie 2 : Préparation des échantillons (mars 2012)
- partie 3 : Analyse (décembre 2005).

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Date summary validated by the OEL Committee: 09 March 2015