COLLECTIVE EXPERT APPRAISAL: SUMMARY AND CONCLUSIONS

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

Assessment of the health effects and methods for the measurement of exposure levels in workplace atmospheres for

decamethylcyclopentasiloxane, CAS No. 541-02-6

This document summarises the work of the Expert Committee on “health reference values”, “characterisation of substance hazards and toxicity reference values”, “expert appraisal for recommending occupational exposure limits for chemical agents” (OEL Committee) and the Working group on metrology.

Presentation of the issue

On 3 February 2012, ANSES received a formal request from the French Directorate General for Labour to conduct the scientific expert appraisal work required for setting occupational exposure limits for decamethylcyclopentasiloxane (D5).

France does not currently have any occupational exposure limits for D5.

The Directorate General for Labour asked ANSES to assess this substance and propose occupational exposure limits based on health considerations for D5.

Scientific background

The French system for establishing OEL values has three clearly distinct phases:

- independent scientific expert appraisal (the only phase entrusted to the Agency);
- 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 implementation timetable, depending on any technical and economic feasibility problems.

The organisation of the scientific expertise phase required for the establishment of Occupational Exposure Limits (OELs) 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.

Occupational exposure limits, as proposed by the Expert 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 expert's Committee based on information available from epidemiological, clinical, animal toxicology studies, etc. Identifying concentrations that are safe for human health generally requires adjustment factors to be applied to the values identified directly by the studies. These factors take into account a number of uncertainties inherent in 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 value (8h-OEL): this corresponds to the limit of the time-weighted average (TWA) of the atmospheric concentration of a chemical in the worker's breathing zone, over the course of an 8-hour shift. In the current state of scientific knowledge (in toxicology, medicine, epidemiology, etc.), the 8h-OEL is designed to protect workers exposed regularly and for the duration of their working lives 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 atmospheric concentration of a chemical in the workers' 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 atmospheric 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-OEL 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 the OELs, the OEL Committee assesses the need to assign a "skin" notation, when significant penetration through the skin has been identified (ANSES, 2017). 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 the atmospheric limit levels, yet can potentially cause health effects even when the atmospheric levels are respected.

The Committee also assesses whether or not it is necessary to assign a "noise" notation, indicating a risk of hearing impairment in the event of co-exposure to noise and the substance below the recommended exposure limits, to enable preventionists to implement appropriate measures (collective, individual and medical);

The Committee also evaluates the applicable reference methods measuring exposure levels in workplace atmospheres. 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). The Agency also mandated the Committee on “Characterisation of substances hazards and toxicity reference values” (Substances Committee) for the health assessment effects and the Working Group on Metrology to assess the methods for measuring atmospheric concentrations in the workplace.

The methodological and scientific aspects of the expert appraisal work were regularly submitted to the Committee.

The report produced takes into account the comments and additional information provided by the members of the Committee.

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

Prevention of risks of conflicts of interest

ANSES analyses the links of interest declared by the experts prior to their appointment and throughout the work, in order to avoid potential conflicts of interest with regard to the matters dealt with as part of the expert appraisal.

The experts’ declarations of interests are made public *via* the ANSES website (www.anses.fr).

Description of the method

For the assessment of health effects:

A summary report was prepared by ANSES and submitted to the substances and OEL Committees, which commented on and added to it.

The summary report was based on bibliographic information taking into account the scientific literature that had been published on this substance up to 2016. The literature search was undertaken in the following databases: Medline, Toxline, HSDB, ToxNet (CCRIS, GENE-TOX, IRIS), ScienceDirect, Scopus and ECHA. The available reports were also consulted, including that

of the SCCS[1] of 2015 ("Opinion on decamethylcyclopentasiloxane (cyclopentasiloxane, D5) in cosmetic products").

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

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

The summary report presents the various protocols for measuring D5 in workplace atmospheres, which were identified and grouped according to the methods used. 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 (ANSES, 2017).

A list of the main sources consulted is detailed in the methodology report (ANSES, 2014).

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 sufficiently clear);
- 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 the various validation data and the technical feasibility, in order to recommend the most suitable method(s) for measuring concentrations for comparison with OELs.

The report, as well as the summary and conclusions of the collective expert appraisal, were adopted by the Expert Committee on expert appraisal for recommending occupational exposure limits for chemical agents on 15 May 2017.

This collective expert appraisal work and the summary report were submitted to public consultation from 22/11/2017 to 22/01/2018. The people or organizations that contributed to the public consultation are listed in appendix 2 of the report (only available in French). The comments received were reviewed by the Committee on Health Reference Values (term of office 2017-2020) who finally adopted this version on the 03/05/2018.

Results of the collective expert appraisal on health effects

Regarding the references for D5, various data mentioned in this document can be found in the Opinion of the Scientific Committee on Consumer Safety on D5 (SCCS, 2015) and on the website of the European Chemicals Agency (ECHA) (public registration data), and refer to unpublished studies.

Toxicokinetics data

[1] SCCS: Scientific Committee on Consumer Safety

Absorption

Absorption by inhalation is low, at around 14% in humans (ECHA, 2015; SCCS, 2015) and 1% to 2% in animals (Tobin *et al.*, 2008).

Considering the uses of D5, oral exposure in humans is *a priori* unlikely. In animals, it was shown that the oral absorption of D5 depended on the vehicle used: it ranged from 10% to 25% when D5 was delivered neat or diluted in corn oil or simethicone fluid (ECHA, 2015; SCCS, 2015).

Lastly, dermal absorption of D5 is low; it ranged from 0.02% to 1.5% depending on the study (in humans, *in vivo*, or *in vitro*) (ECHA, 2015; SCCS, 2015). The Canadian authorities chose the value of 0.17% dermal resorption, based on the publication by Jovanovic *et al*., 2008 (Health Canada, 2008). The SCCS decided to refer to an *in vitro* study in human skin, selecting a resorption value of 0.06% after correction (SCCS, 2015).

Distribution

Following a study by inhalation in rats, it was observed that D5 was rapidly distributed throughout the body with a similar profile for both sexes. The maximum concentration in most tissues was found in the first three hours following exposure, except in adipose tissue, where the concentration remained fairly stable in the 168 hours following exposure (Tobin *et al*., 2008).

In an unpublished study, an x-ray of the whole body was undertaken in rats exposed to radiolabelled D5 administered in corn oil. It showed that radioactivity was present in the whole body and distributed to major organs such as bone marrow, liver, kidneys, and adipose tissue (ECHA, 2015; SCCS, 2015).

After dermal exposure to radiolabelled D5 in rats, no radioactivity was found in the blood of the animals, and only trace levels of radioactivity were found in certain tissues (ECHA, 2015; SCCS, 2015).

Metabolism

Following a study by inhalation, two major metabolites, methylsilanetriol and dimethylsilanediol, and five minor metabolites were identified in the urine of the tested animals, whereas D5 itself was not detected. In faeces, two compounds were observed: D5 and a substance putatively identified as hydroxylated D5 (Tobin *et al*., 2008).

Metabolism appeared similar after oral exposure, with all of the radioactivity found in the urine attributed to polar metabolites and the majority of the radioactivity in faeces attributed to D5 (ECHA, 2015; SCCS, 2015).

The nature of the identified metabolites, and especially of methylsilanetriol, suggested that demethylation is involved in the metabolism of D5 (Varaprath *et al*., 2003).

Excretion

In humans, plasma concentrations of D5 peak immediately following an exposure to 10 ppm (52 ng/g of plasma) and return to a basal level within 24 hours. In addition, more than 75% of D5 is eliminated within six hours, indicating rapid excretion of the compound (ECHA, 2015; SCCS, 2015).

It would seem that in animals, following exposure by inhalation, D5 is excreted primarily in exhaled air. Excretion of the compound would then be similar in urine and faeces. The majority of radioactivity was eliminated within 24 hours of exposure. No significant difference was identified

between males and females, or depending on the type of exposure (single, repeated, etc.) (Tobin *et al*., 2008; ECHA, 2015; SCCS, 2015).

In a study on ingestion by rats (ECHA, 2015; SCCS, 2015), the majority of the administered radioactivity was excreted in faeces, irrespective of the vehicle used and the sex of the animal (>80% of the administered dose). The other main routes of elimination are urine and exhaled air, which account for more than 4% and 10% of the administered dose, respectively.

Given the very low levels of absorption, excretion is difficult to estimate for the dermal route, in both humans and animals.

Toxicity data

Acute toxicity

Data in humans

Volunteers exposed to 10 ppm of D5 for one hour showed no symptoms (ECHA, 2015; SCCS, 2015).

Data in animals

D5 has a very low level of toxicity following acute exposure, regardless of the route. Of the eight available studies, apart from a study by inhalation determining an LC_{50} of 8670 $mg.m^{-3}$ (after 4-hour exposure of rats to concentrations of 4620 to 15,370 $mg.m^{-3}$), no other studies have shown mortality in animals, even at very high concentrations (ECHA, 2015; SCCS, 2015).

Irritation and sensitisation

No data are available to assess D5's potential for respiratory irritation or sensitisation, in either humans or animals.

Data in humans

A Human Repeated Insult Patch Test (HRIPT) showed that D5 is not a skin irritant or sensitiser in humans (ECHA, 2015; SCCS, 2015).

Data in animals

D5 showed no potential for skin irritation or sensitisation in the various tests undertaken. However, with two slightly positive Draize tests (of four undertaken), it would seem to be a mild eye irritant.

Subchronic and chronic toxicity

Data in humans

There are currently no data on the long-term effects of D5 in humans.

Data in animals

- Hepatic effects

Effects on the liver were the most commonly observed effects in the panel of studies undertaken on D5. Indeed, all of the repeated toxicity studies (by oral route and by inhalation) observed at least an increase in liver weight. This increase in liver weight was associated with a doubling of γ-

GT in females in the study on subchronic exposure by inhalation in rats undertaken by Burns-Naas *et al.* (1998b).

- Respiratory effects

Various respiratory effects have been observed.

Pulmonary vascular mineralisation was observed from 30 ppm in a two-generation study conducted in rats (Siddiqui *et al.*, 2007) but was not dose related. It is likely that this phenomenon referred to as mineralisation was actually calcification.

Still in the two-generation study by Siddiqui *et al.* (2007), a statistically significant increase in the incidence of minimal alveolar histiocytosis in F0 and F1 females was observed at 160 ppm.

Lastly, pulmonary inflammation was also a constant effect reported in the available studies on repeated toxicity by inhalation for D5, with in particular an accumulation of alveolar macrophages. This effect has mainly been observed at high doses (from 160 ppm), except in the subchronic study by Burns-Naas *et al*. (1998b).

Genotoxicity

D5 showed no genotoxic potential in the various *in vitro* (Ames test, mammalian chromosome aberration test, mammalian cell gene mutation test) and *in vivo* (mammalian erythrocyte micronucleus test, unscheduled DNA synthesis test) studies undertaken (ECHA, 2015; SCCS, 2015).

Carcinogenicity

Data in humans

There are no data available on carcinogenicity in humans.

Data in animals

Regarding carcinogenicity, uterine endometrial adenocarcinomas were observed in the chronic toxicity study which exposed rats by inhalation to 0, 10, 40 and 160 ppm. Despite statistical significance at the highest dose, no dose-response relationship was found, meaning that this effect could not be attributed to exposure to D5. In addition, the mechanism of action was not fully elucidated. It may have been an effect related to the ageing of the rats, especially considering the incidence rate for the historical controls (Jean *et al.*, 2016).

Toxicity to reproduction and development

Data in humans

There are no data available on the effects on development or reproduction in humans.

Data in animals

Only one two-generation study is available for D5. Rats were exposed to 30, 70 and 160 ppm. No toxic potential for reproduction and development was observed (Siddiqui *et al.*, 2007).

Establishment of OELs

Several effects were observed in repeated-exposure animal studies undertaken with D5:

Hepatic toxicity: According to the US EPA (2002), a doubling of γ-GT as observed in the study on subchronic exposure by inhalation in rats undertaken by Burns-Naas *et al.* (1998b) is sufficiently indicative of a compound's toxicity to the liver. However, the non-reproducibility of this increase in γ-GT and the fact that this increase was not combined with other changes in biochemical or histopathological parameters in the same study suggest an adaptive effect of the liver, not toxicity.

Pulmonary vascular mineralisation: Considering the limited information available about this effect as described in the study by Siddiqui *et al.* (2007), as well as the lack of a dose-response relationship, it cannot be used as a criterion for the assessment of toxicity.

Alveolar histiocytosis: Alveolar histiocytosis is an infiltration of the pulmonary tissue by monocyte-macrophage lineage cells. In animals, according to Élies (2009 thesis), it was reported in carcinogenesis studies in which C57BL/6 mice were the models used. According to Boorman (1990) and Mohr (1992), histiocytosis was found in Fischer rats in chronic studies. In general, the aetiology of histiocytosis was not specified. Based on the limited information available about this effect as described in the study, including the lack of a dose-response relationship, it cannot be used as a criterion for the assessment of toxicity.

Pulmonary inflammation: Despite the preponderance of this effect, dose-response relationships were difficult to establish in the available studies. Inflammatory effects were primarily observed at high doses, for which the animals were not exposed to vapours only but also to aerosols. It is thus possible that this inflammation was a physiological response of the body to the entrance of a foreign substance and was therefore not specific to D5. Only one study, by Burns-Naas *et al.* (1998b), reported an increase in this inflammatory phenomenon at concentrations at which D5 was still in vapour form, but did not include an analysis to assess the statistical significance of the results. Therefore, this effect cannot be used as a criterion for the assessment of toxicity.

15min-STEL

The analysis of all the available studies on D5 shows that none of the assessed effects are easy to use. It appears that D5 is a substance with low toxicity. Effects are mainly observed from the vapour/aerosol limit concentration, i.e. from 160 ppm (according to the values mentioned by the authors in the various studies on the substance). Given the nature of these effects (pulmonary inflammation in particular), they seem related to the presence of liquid particles.

Therefore, the Committee chose to base the 15min-STEL for D5 on the concentration from which particles were observed in the studies undertaken, i.e. **2500 mg.m^{-3}**. In light of the physico-chemical nature of the choice of this point of departure, no adjustment factors are necessary.

The Committee recommends a 15min-STEL of 2500 mg.m^{-3}.

8h-OEL

Given the lack of relevant systemic effects for exposure by inhalation and the nature of the point of departure chosen for the 15min-STEL (irritating effect associated with the vapour/aerosol phase change), an 8h-OEL is not considered necessary for this compound.

"Skin" notation

Since the dermal absorption of D5 appears to be very low (ranging from 0.02% to 1.5% depending on the study) and in the absence of additional quantitative data, a “skin” notation does not appear necessary for D5.

"Noise" notation

None of the available studies suggest an ototoxic effect of D5. Accordingly, the "noise" notation is not assigned.

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

Assessment of the measurement methods for D5 in workplace atmospheres

Two methods for measuring D5 in workplace atmospheres were identified and analysed (see Table 1).

Table 1: Methods for measuring D5 in workplace atmospheres

Method		Protocol	Category
No.	Description	Workplace atmospheres	Regulatory 15min-STEL and monitoring short-term exposure
1	Active sampling on a tube containing Amberlite XAD-2 resin Solvent desorption, analysis by gas chromatography with flame ionisation detection	NF ISO 16200-1 (2001) NF X43-267 (2014) Métropol M19 (2007)	3
2	Passive sampling on an SKC 575-001 disc badge, activated charcoal, solvent desorption, analysis by gas chromatography with flame ionisation detection	ISO 16200-2 (2000)	3

Additional validation data on Method 2 were found in the validation report for the SKC sampler published on the manufacturer's website and were assessed (SKC 2014).

Data on each method's range of validity and limit of quantification with regard to the 15min-STEL are presented in the following figure:

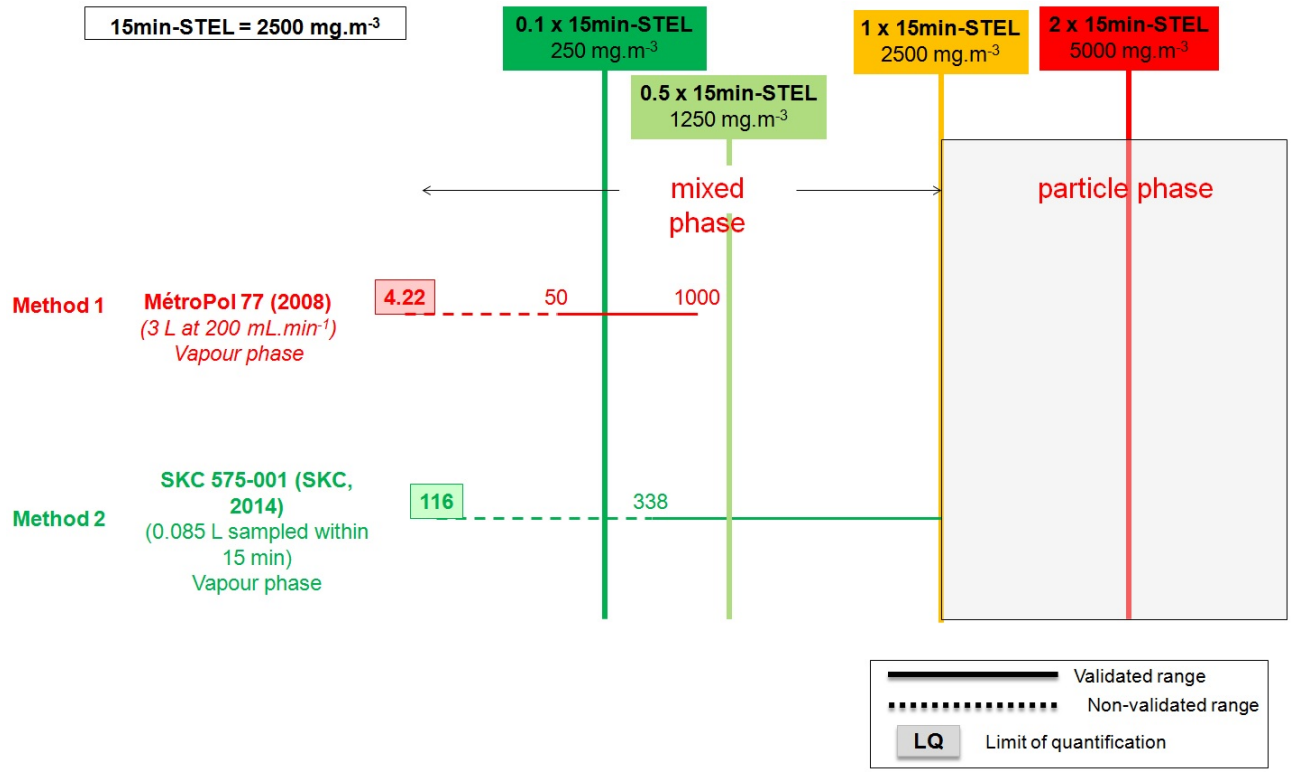

Figure 1: Range of validity and limit of quantification of the two methods compared to the range from 0.1 to 2 times the 15min-STEL proposed by the Committee.

Exposure to the particle phase is preponderant due to the low volatility of D5 at ambient temperature, its various uses in formulations of oils, detergents, anti-foaming agents and waterproofing agents, and the use of certain processes such as nebulisation.

In addition, the 15min-STEL corresponds to the saturation vapour pressure of D5 at 20°C and 1013 hPa, i.e. 2500 $mg.m^{-3}$. From this concentration, the atmosphere becomes laden with particles from the condensation of D5.

In this context, and given the physico-chemical properties of D5, the sampling system must be suited to the joint collection of vapours and particles (inhalable fraction) of D5.

The two identified methods apply only to the gas form of the pollutant and cannot be used to assess the potential presence of D5 in a mixed phase.

Moreover, there are no available data on the expanded uncertainty of Method 1. No additional publications or reports were found providing information about these missing criteria for Method 1.

The two methods are therefore classified in Category 3 for control of the recommended 15min-STEL and the monitoring of short-term exposure.

Conclusions and recommendations

The two identified and analysed methods are classified in Category 3 as they cannot be used to assess exposure to D5 in the form of a mixed phase and do not meet the requirements of the NF EN 482 Standard for monitoring the 15min-STEL.

Conclusions of the collective expert appraisal

Based on the data currently available for D5, the Committee recommends setting a 15min-STEL of 2500 $mg.m^{-3}$ but no 8h-OEL.

The Committee does not recommend a "skin" notation.

The Committee does not recommend a "noise" notation.

Regarding the methods for measuring D5 in workplace atmospheres, neither of the analysed methods can be recommended for monitoring the 15min-STEL. The Committee recommends developing and validating a measurement method that can jointly sample the inhalable fraction and vapours of the substance for comparison with the proposed 15min-STEL[2].

[2] It should be noted that a measurement method of D5 present as a mixture of airborne particles and vapour is currently being developed and validated by INRS (French National Research and Safety Institute for the Prevention of Occupational Accidents and Diseases).

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