

The Director General

Maisons-Alfort, 26 October 2017

OPINION

of the French Agency for Food, Environmental and Occupational Health & Safety

on the risk assessment of occupational exposure to products used for nail care and decoration

ANSES undertakes independent and pluralistic scientific expert assessments.

ANSES's public health mission involves ensuring environmental, occupational and food safety as well as assessing the potential health risks they may entail.

It also contributes to the protection of the health and welfare of animals, the protection of plant health and the evaluation of the nutritional characteristics of food.

It provides the competent authorities with the necessary information concerning these risks as well as the requisite expertise and technical support for drafting legislative and statutory provisions and implementing risk management strategies (Article L.1313-1 of the French Public Health Code).

Its opinions are published on its website.

This opinion is a translation of the original French version. In the event of any discrepancy or ambiguity the French language text dated 26 October 2017 shall prevail.

On 23 May 2014, ANSES received a formal request from the French Health Products Safety Agency (ANSM) to conduct the following expert appraisal on the risk assessment of occupational exposure to products used for nail care and decoration.

1. BACKGROUND AND PURPOSE OF THE REQUEST

The expert appraisal work on substances classified as category 2 reprotoxic substances¹ and/or endocrine disruptors (EDs), performed by ANSES following a formal request from the Directorate General for Health (DGS) in 2009, included toluene. A health risk assessment for this substance was therefore conducted by ANSES and published in May 2014. However, it did not include an expert appraisal of the risks associated with the possible presence of toluene in cosmetics, as this question does not fall within ANSES's scope. Nevertheless, the report produced by ANSES highlighted the use of toluene as an additive in cosmetics, mainly in nail varnish.

In 2009, at the request of the DGS, the ANSM had also assessed the health risk associated with the use of toluene in cosmetics, particularly in nail varnish, for end users (consumers), without however taking into account the occupational risk.

These assessments then led to the question being raised of the potential health risks for workers carrying out nail care and decoration activities. In addition, other substances used by these workers, such as acrylic compounds or glues, for example, may also be of concern.

¹ According to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (the CLP Regulation)

The ANSM therefore made a formal request to ANSES on 23 May 2014 to assess the health risks related to occupational exposure to the products used for nail care and decoration.

This request did not include any assessment of the health risks to workers with regard to cosmetics other than those used for nails, or any assessment of the health risks to consumers related to the products used in nail cosmetics.

2. ORGANISATION OF THE EXPERT APPRAISAL

The expert appraisal was carried out in accordance with French Standard NF X 50-110 "Quality in Expert Appraisals – General Requirements of Competence for Expert Appraisals (May 2003)".

It falls within the scope of the Expert Committee (CES) on "Assessment of chemical risks of consumer items and products" (CES CONSO). ANSES entrusted the expert appraisal to several rapporteurs from the CES CONSO (2014-2017 mandate) and the CES "Assessment of the risks related to air environments" (CES AIR) (2014-2017 mandate). The methodological and scientific aspects of the work were presented at nine sessions of the CES CONSO (2014-2017 mandate) between 3 July 2014 and 6 July 2017, and three sessions of the CES AIR (2014-2017 mandate) between 18 September 2014 and 11 May 2017. The work was also presented to the "Data Analysis Methodology and Strategy" working group of the National Network for Monitoring and Prevention of Occupational Diseases (RNV3P) on 23 July 2015, and to the working group of the Toxicovigilance Coordination Committee (CCTV) on 27 April 2015 and 17 March 2016. The work was adopted by the CES CONSO (2014-2017 mandate) at its meeting on 6 July 2017.

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).

The expert appraisal work consisted in:

- describing the nail care and decoration occupations and activities;
- describing the diseases associated with the occupations, and the products and substances called into question;
- describing dermal and atmospheric exposures to the products and substances;
- identifying the substances found in the composition of the products and in the workplace air, and prioritising the identified substances on the basis of the hazard (for more detail on the prioritisation method followed, refer to Annex 1 of this opinion);
- assessing the order of magnitude of the atmospheric concentrations of the substances found in the workplace air and comparing them with the occupational exposure limit values or other reference values;
- issuing recommendations concerning the substances and products used, the means of prevention and protection, training and information for workers, medical monitoring, research orientations to improve knowledge, and more broadly, the chemical safety of cosmetics and occupational exposure assessment in the cosmetics sector.

Data collection:

Data were collected using various means: analysis and synthesis of the scientific literature, hearings and consultations with stakeholders, extraction and exploitation of databases, questionnaire surveys and measurement campaigns.

Hearings took place with the following stakeholders over the period 2015-2016:

- representatives of professional federations or associations:
 - the French National Confederation of Beauty Institutes (CNAIB)
 - the French Federation of Beauty Companies (FEBEA)
 - the International Federation of Professional Education in Perfumery and Beauty Cosmetics (FIEPPEC)
 - the Association of Small and Medium Enterprises in the Cosmetics Sector (COSMED)
 - the French Union of Nail Prosthetists (SNSO)
- the Ile-de-France Regional Directorate for Enterprises, Competition Policy, Consumer Affairs Labour and Employment (DIRECCTE)
- three physicians:
 - Dr Marie-Noëlle Crépy, Dermatologist at the Occupational Disease Consultation Centre (CCPP) of the Hôtel-Dieu in Paris
 - Dr Lynda Bensefa-Colas, Epidemiologist at the CCPP of the Hôtel-Dieu in Paris
 - Dr Vincent Bonneterre, University Professor - Hospital Practitioner at the Grenoble Alpes University Hospital Centre (CHU)

Several consumer associations were contacted and consulted in order to obtain information on any studies conducted on the products used in nail care and decoration activities.

An international consultation was carried out with several institutes, associations, professional federations, agencies, or national authorities in the areas of health and/or occupational safety (Europe and North America).

Data was extracted and processed from several databases: the INRS's² COLCHIC database (database for occupational exposure to chemicals), the French database on products and compositions (BNPC) of the poison control centres' information system, and the European Commission's Cosmetic Ingredients Database (COSING). These data were exploited to identify the substances present in the composition of the products used by these workers and emitted into workplace air.

A tripartite research and development agreement (CRD) was entered into between ANSES, the Métropole Nord Occupational Health Unit and the INRS in order to conduct atmospheric sampling campaigns to identify the (semi)volatile organic compounds or (s)VOCs, present in workplace ambient air and measure the order of magnitude of (s)VOCs and respirable particle concentrations.

This CRD also included a questionnaire survey of nail technicians in order to characterise the study population and their working practices.

Several occupational disease surveillance networks were questioned, including the RNV3P, the Dermato-Allergology Vigilance Network (REVIDAL-GERDA), The UK Health and Occupation

² The French National Research and Safety Institute for the Prevention of Occupational Accidents and Diseases

Research Network (THOR) and the German network of the *Berufsgenossenschaft für Gesundheitsdienst und Wohlfahrtspflege* (BGW). They contributed to the description of the diseases associated with the nail care and decoration occupations and the identification of the products and substances called into question.

An analysis and synthesis of the scientific literature helped describe the diseases associated with the nail care and decoration occupations, identify the products and substances implicated, and describe the dermal and atmospheric exposures to the products and substances. Studies published up to May 2017 were identified with a query on the PubMed® search engine and using the bibliographic reference lists of the studies identified with this query ("snowballing" technique). This corpus of studies published in peer-reviewed journals was supplemented by studies from the grey literature and books identified with the Google® search engine.

An extraction of statistical data from the National Health Insurance Fund for Salaried Workers (CNAMTS) provided indications such as the number of reported occupational diseases or the number of cases of temporary work disability.

Scope of the expert appraisal work:

- workers that may carry out nail care and decoration activities, namely nail prosthetists or stylists and beauticians-manicurists;
- the products and substances used and applied during nail care and decoration activities;
- the following nail care and decoration activities: application and removal of prosthetic nails and classic or semi-permanent varnish.

Description of the nail care and decoration activities:

- Application and removal of classic varnish: a manicure first involves removal of the previous varnish, if necessary, then filing of the nails and care of the cuticles. An exfoliating scrub may be applied, and the hands may be massaged and moisturised. This is followed by polishing of the nails and application of multiple layers of varnish (base-coat, varnish, fixer or top-coat) and air drying. Varnish is taken off with nail-varnish remover.
- Application and removal of semi-permanent varnish: the application procedure is identical to that of classic varnish. The semi-permanent varnish is typically presented in the form of a methacrylic gel that is polymerised under a UV lamp. Semi-permanent varnish is removed either by soaking the nails in acetone, or with acetone-soaked cotton pads held in place on each nail. Sanding may also be carried out.
- Application and removal of prosthetic nails – several techniques are available:
 - *the resin technique* generally involves manufacturing an artificial nail by moulding it over the natural nail. A powdered pre-polymer mixed with a liquid containing methacrylic monomers is applied with a brush. It forms a resin that polymerises and hardens in the air (self-hardening resin). Lastly, the professional files and polishes the nails and may apply a varnish or other personalised "nail art" decoration. The resin is removed either by soaking the nails in acetone, or with acetone-soaked cotton pads held in place on each nail;
 - *the gel technique* typically involves several successive applications of a methacrylic gel that polymerises and hardens after each exposure under the lamp for 2 to 3 minutes. As with the resin technique, the professional then files and polishes the nails and may apply a varnish or other "nail art" decoration. Removal requires the gel to be filed off;
 - *the capsule technique*, consisting in applying preformed capsules to the nail, and *the glass fibre or silk technique*, consisting in gluing small pieces of glass fibre or silk fabric directly

onto the nail or onto a capsule, may be used but are far less widespread. As with the resin and gel techniques, the professional then applies a varnish or other "nail art" decoration.

3. ANALYSIS AND CONCLUSIONS OF THE CES CONSO (2014-2017 MANDATE)

In view of all the information and data collected and processed in the expert appraisal report (ANSES, 2017), the CES CONSO (2014-2017 mandate) decided to group together its conclusion according to the major themes addressed.

With regard to the workers carrying out nail care and decoration activities

- Nail care and decoration activities are carried out by nail prosthetists and also by beauticians. However, not all beauticians carry out nail care and decoration activities.
- A total of 4739 nail prosthetists were identified as registered in France with the Chamber of Trades as of 30 January 2015. Nevertheless, it is difficult to estimate the exact number of practising workers, as this activity is growing strongly.
- These workers may have the status of employee or be self-employed, working in dedicated premises or at their customers' homes.
- This predominantly female population encompasses every age group, with the majority being between 18 and 35 years of age. Field visits identified workers who sometimes do not have a good command of French, which could affect their understanding of the prevention messages.
- No diploma courses are required to exercise this profession in France, but most of the workers interviewed stated that they had followed training in the application of prosthetic nails. This training has highly variable modules and durations that are not harmonised. According to the responses to the questionnaire developed in the framework of the CRD, it seems that around half of the workers have already been made aware of the health risks related to their activity.
- These workers are required to perform various types of nail care and decoration activities, including application of classic or semi-permanent varnish, manicures, application of prosthetic nails using different techniques (gel or resin), and decoration of natural or artificial nails known as "nail art" or nail styling.
- The workers are mainly supplied by distributors but also purchase their products from central purchasing bodies, on the Internet, at trade fairs, or even in pharmacies, etc.
- Nail care and decoration establishments are generally small in size, often with no more than five people.
- The visits to the establishments and the hearings revealed the lack of personal and collective protective equipment. It should also be noted that some of these workers carry out their activities from home or at their customers' homes, making it even more complicated/difficult to install collective protective equipment such as ventilated tables.

With regard to the substances

- Six hundred and ninety-six substances were identified in the composition of the products used or in the workplace air, illustrating the issue of worker exposure to multiple chemical pollutants.
- These substances were prioritised and ranked into three classes on the basis of their human health hazard classification or their inclusion on a list of endocrine disruptors (EDs)³:
 - Sixty substances are in the highest hazard class (classified as CMR, sensitiser and/or included on an ED list), including around fifteen (meth)acrylates, phthalates, parabens, ketones, aldehydes, alkanes, aromatic alcohols, siloxanes, chlorine derivatives, aromatic amines, benzene derivatives, terpenes, inorganic compounds, peroxides, phosphorus derivatives, amides, derivatives of acids, and resins.
 - Among these substances found to be of very high concern, it should be noted that two substances, dibutyl phthalate and n-hexane, are prohibited in cosmetics according to Regulation (EC) No 1223/2009.
 - Ninety other substances were considered to be of concern, including some twenty aliphatic and alicyclic hydrocarbons, alcohols, benzene derivatives, ketones, etc.
 - The other substances are not classified and were deemed to be of less concern.
- Not all the identified substances currently have a harmonised classification (CLP) with regard to sensitisation. This is the case, for example, with ethyl-2-cyanoacrylate, reported by the interviewed physicians as causing dermal sensitisation and also mentioned in the occupational diseases table No 66 of the French general regime (RG66) of occupational diseases, on occupational rhinitis and asthma.
- Toluene is prohibited in cosmetics except for nail products. However, the CES questions its technical value in these products, particularly since formulations are available that do not contain toluene.

With regard to occupational exposure

- The products used in nail cosmetics and mainly implicated in exposures are products for shaping artificial nails (gel, resin) containing (meth)acrylic monomers that are potentially sensitising, irritant and neurotoxic. The solvents and thinners used may have similar properties. Some products contain substances with reprotoxic properties, such as toluene and dibutyl phthalate, and substances with known, possible or suspected carcinogenicity, such as formaldehyde, benzoyl peroxide and titanium dioxide.
- The concentrations of volatile or semi-volatile organic compounds (VOCs or sVOCs) measured in the air at the work station are low compared to those generally measured on industrial sites and are far lower for each substance than the values of the French occupational exposure limits (OELs). Nevertheless, many (s)VOCs may be present

³ Classification of the BKH (http://ec.europa.eu/environment/chemicals/endocrine/strategy/chemical_substances_en.htm) and http://ec.europa.eu/environment/chemicals/endocrine/strategy/chemical_substances_en.htm); Classification of the DHI (http://ec.europa.eu/environment/chemicals/endocrine/pdf/final_report_2007.pdf); Classification of the IEPA (<http://iledi.org/ppa/docs/00/00/00/01/01/82/EndocrineDisruptorsStrategy.pdf>); Sin List (<http://sinlist.chemsec.org/>); US EPA-EDSP (<http://www.epa.gov/ingredients-used-pesticide-products/endocrine-disruptor-screening-program-tier-1-assessments>); TEDX list (<http://endocrinedisruption.org/endocrine-disruption/tedx-list-of-potential-endocrine-disruptors/chemicalsearch>); <http://endocrinedisruption.org/endocrine-disruption/tedx-list-of-potential-endocrine-disruptors/overview>

simultaneously, causing multi-pollutant exposure of workers to low concentrations of individual chemical agents whose effects are unknown. Up to 42 (s)VOCs have been identified on a single work premises. The concentrations of total VOCs and toluene measured are high compared to those measured in housing and in outdoor air.

- For all chemical substances measured more than 10 times in the workplace air of the investigated sites and in the absence of an OEL, the CES relied on different types of toxicity reference values established by different organisations. The levels were observed to have been exceeded for acetaldehyde (present in most of the situations investigated), as well as for acetone, and ethyl and methyl methacrylates.
- The different techniques implemented - gel, capsule or resin - have an impact on the nature and level of emissions. The "gel" technique seems to emit far fewer (meth)acrylates (e.g. ethyl methacrylate (EMA) and methyl methacrylate (MMA)) than the "resin" technique.
- Nail technicians are also exposed to particles from the sanding of nails and resins. This dust has not been characterised in detail, particularly in terms of its chemical content and particle size.
- The protective measures for preventing chemical risk, including general ventilation, localised ventilation such as ventilated² tables, and the wearing of gloves and dust masks, seem to be rarely used by nail technicians. This is all the more critical given that the working premises are usually small in size, less than 30 m², with the minimum area reported as 5 m², which favours the concentration of pollutants in the air of the room if it is insufficiently ventilated.
- Ventilation effectiveness varies according to the ventilation systems used. Among the possible systems, the most efficient and most suited to the activity seems to be a localised suction system such as a ventilated table connected to a filtration system. A survey showed that none of the nail prosthetists used a filtration system.
- Surgical masks may help prevent the transmission of germs but provide no protection from vapours and little or no protection from fine particulate matter. Dust masks are effective at preventing the inhalation of fine particulate matter emitted in particular during sanding operations. If effective ventilation is installed in the working environment, it does not seem necessary to wear a cartridge filter mask.
- It is difficult for nail technicians to protect themselves by wearing gloves during nail care and decoration operations. Some types of gloves, such as nitrile gloves, seem able to reduce the dermal exposure of workers to methacrylates alone, but the concomitant handling of solvents or removers such as acetone degrades these materials, thus reducing their effectiveness.

With regard to occupational diseases

- Surveillance data on occupational diseases in France

- For nail care and decoration workers in particular, surveillance data on occupational diseases are limited, with the numbers of cases probably underestimated, mainly for the following reasons:
 - nail care and decoration involve many self-employed workers and employees of VSEs, populations that rarely receive medical monitoring as part of their job,
 - there is no specific activity coding for nail care and decoration, manicure and pedicure, or the application of prosthetic nails in the nomenclatures of occupational activities.

- The groups of occupational diseases most frequently diagnosed in these workers are:
 - skin disorders, mainly including allergic contact dermatitis (ACD),
 - disorders of the respiratory tract and ENT, mainly including asthma,
 - headaches,
 - musculo-skeletal disorders, mainly including those linked to prolonged and frequent sitting postures and repetitive movements of the hand, wrist or forearm.
- In more than half of the cases, the diagnosed disease was attributed to exposure to the family of (meth)acrylates.
- The health professionals interviewed indicated that they used the occupational diseases table No 82 (RG82) "Disorders caused by methyl methacrylate" for cases concerning exposure to (meth)acrylates other than MMA. This raises the question whether to expand the RG82 table to include disorders caused by all (meth)acrylates.

- Data from the scientific literature on occupational diseases

- To our knowledge, there have been no prospective longitudinal epidemiological studies (prospective cohort studies) among nail care and decoration workers.

General state of health

- Nail technicians declare themselves to be in good health less frequently than female office workers according to a case-control study.
- According to a cross-sectional survey, it seems that the frequency of nail technicians reporting a poor general state of health is higher among those applying nail cosmetics containing (meth)acrylates.
- According to a cross-sectional study, the risk of occurrence of reported symptoms (including headache, irritation of the skin, nose and eyes, cough and respiratory disorders) is higher among the nail technicians most exposed to VOCs.

Skin diseases

- The risk of allergic contact dermatitis (ACD) associated with the exposure of these workers to nail cosmetics, in particular those containing (meth)acrylates, is well established. The ACDs caused by (meth)acrylates can be severe and imply an inability to work as a nail prosthetist or apply semi-permanent varnish.
- Several studies, particularly in Great Britain, have shown an increase in recent years in the number of cases of ACD due to (meth)acrylic monomers, related to their growing use in the application of artificial nails, in nail technicians as well as consumers.
- ACDs due to (meth)acrylates from nail cosmetics are among the most frequent ACDs due to cosmetics. A retrospective analysis in Portugal for the 2012-2014 period showed that (meth)acrylates were the main cause of the ACDs diagnosed in nail technicians, all occupational sectors combined.
- Non-polymerised acrylic products are the most allergenic, compared to finished polymerised products, which have low allergenicity or are non-allergenic. Nevertheless, some products may be incompletely polymerised and then release monomers. Artificial nails made from a mixture of liquid monomer and powdered (meth)acrylate polymer ("resin" technique) are the most allergenic. Compared to the "resin" technique, the preferentially used gels and varnishes which are photopolymerisable reduce the risk of exposure to allergenic (meth)acrylic monomers (e.g. 2-HEMA, 2-HMPA)⁴ but severe cases of contact allergy indicate that they are not without risk, including for non-professional consumers. All

⁴ 2-HEMA: 2-hydroxyethyl methacrylate; 2-HMPA: 2-hydroxypropyl methacrylate

these types of products are now available for non-professional consumers, for example in the form of kits that can be purchased via the Internet. Nail cosmetics are a source of exposure to (meth)acrylates, which contributes to the risk of sensitisation of individuals.

- The acrylates and methacrylates most frequently implicated in cases of ACD diagnosed in nail technicians (greater numbers of cases and highest prevalence of positive patch tests) are 2-HEMA, 2-HEA, 2-HMPA, EGDMA, EA and EMA⁵. Many cross-reactions are observed between acrylates and methacrylates. Clinical case studies indicate that cyanoacrylate glues can also be responsible for ACDs.
- Other skin disorders, such as irritant contact dermatitis, have been documented among nail care and decoration workers using nail cosmetics containing (meth)acrylates, cyanoacrylate glues, thinners and solvents. Skin burns are also possible when mishandling potentially caustic products such as acid liquid "primers".
- The incidence of skin infections is higher in these occupations.

Respiratory and ENT diseases

- Studies, including one using bronchial challenge tests, indicate an increased risk of asthma among workers applying artificial nails. An association has been shown between the duration of contact with acrylic nail cosmetic products in nail technicians and an increase in respiratory tract inflammation, as well as impairment of respiratory function. While the adverse effects of MMA on respiratory health are well described, the fact that other (meth)acrylates may produce the same types of effects cannot be ruled out. Cases of occupational asthma related to cyanoacrylate glues have also been reported.
- Cross-sectional studies indicate an increased risk of self-reported respiratory and ENT symptoms among nail technicians compared to office workers: rhinitis, eye irritation, throat irritation, cough, respiratory irritation, dyspnea and wheezing.
- More rarely, cases of hypersensitivity pneumonitis that can include extrinsic allergic alveolitis, sometimes associated with a short bout of high fever, have been observed in nail prosthetists and were attributed to the toxic impact of methacrylic monomers used with the "resin" technique. Rare cases of pulmonary sarcoidosis have also been reported and were attributed to inhaled (meth)acrylates and fine particulate matter.
- Several studies have shown that the respiratory disorders improved or disappeared outside the work environment.

Neurological effects

- Cross-sectional studies, including two case-control studies, indicate an increased risk of headaches among nail technicians. According to one study, these are mainly tension headaches in people working with the "resin" technique using (meth)acrylates. The headaches were frequently the reason for stopping the "resin" technique. Two other case-control studies did not observe any association between this occupation and the headaches.
- Case-control studies also indicate an increased risk of certain neurological disorders, including impaired cognitive performance, concentration difficulties, and impaired olfactory performance. These disorders are typical of exposure to solvents in other occupational environments.

⁵ 2-HEA: 2-hydroxyethyl acrylate; EGDMA: ethylene-glycol dimethacrylate; EA: ethyl acrylate; EMA: ethyl methacrylate

Adverse effects on reproduction and development

- Indications of an increased risk of adverse pregnancy outcomes and maternal complications associated with nail care and decoration activities are weak and rely primarily on a retrospective study based on registers and an older case-control study. They require additional research.

Cancer

- There is no indication of any increased risk of cancer associated with nail care and decoration activities. A single retrospective study based on registers examined the risk of cancer specifically from manicures and did not show any significant association with cancer.

Other diseases

- Two studies mentioned possible links between nail care and decoration activities and certain autoimmune diseases.
- The risk of musculoskeletal disorders is higher for these occupations and mainly concerns prolonged/frequent sitting postures and repetitive movements of the hand, wrist or forearm.
- Visual fatigue is also mentioned by nail technicians.

With regard to the chemical safety of cosmetic ingredients and the occupational exposure assessment

- Employers in France are subject to the requirement to search for alternatives to CMR agents, as set out in the general principles of prevention in Article L.4121-2 of the Labour Code, and reinforced by Article R. 4412-66 transposing the substitution requirement established by European Directive 2004/37/EC by extending it at French national level to reprotoxic agents. An industrial product with a formaldehyde content greater than 0.1% would be classified as a carcinogen, whereas conversely a cosmetic product with the same content would not, as it is not subject to the classification and labelling requirements laid down by the CLP Regulation.
- The "Cosmetics" Regulation (EC) No 1223/2009 stipulates that products must be without risk to the end user; the latter is defined in the regulation as a consumer or professional using the cosmetic product. Moreover, the Cosmetics Regulation prohibits the presence of CMR substances in cosmetics, except subject to a number of conditions, including a favourable opinion of the Scientific Committee on Consumer Safety (SCCS) of the European Commission's Directorate General for Health.
- Certain CMR substances have received a favourable opinion from the SCCS, such as formaldehyde, for example, which is currently authorised in nail products at concentrations of up to 5%. The use of this substance in hardeners for nails was recently the subject of a re-assessment by the SCCS, which issued a favourable opinion up to a maximum content of 2.2%. So far, the European Commission has not updated Annex III of the Cosmetics Regulation to take this opinion into account.
- Occupational exposure is not currently taken into account in the framework of the chemical safety assessments for cosmetics carried out by the SCCS. For example, the SCCS assessment conducted on formaldehyde in hardeners for nails on 16 December 2014 did not take occupational exposure into account. However, it should be remembered that the company placing the cosmetic on the market is required to carry out an assessment of the risks to end users including workers.

- Compliance with the OELs for substances identified as respiratory sensitisers does not guarantee protection for workers with regard to sensitisation and respiratory allergy, because OELs are not generally established on these effects and it is rarely possible to derive OELs because a threshold below which no sensitising effect is observed cannot be determined.

Recommendations of the CES

With regard to the chemical substances emitted by or contained in the products used by nail technicians

The CES recommends:

- Rapidly eliminating the use of polymerisable (meth)acrylic monomers at the work station (semi-permanent varnish, "resin" technique, gel technique), given:
 - the toxic and, among others, sensitising properties of (meth)acrylic monomers, with several of them being classified as skin sensitisers according to the CLP Regulation (Skin Sens. 1);
 - the risks highlighted in the scientific literature related to their uses in nail cosmetics, in particular the risks of sensitisation and skin allergy;
 - the increases reported in recent years in some European countries in the number of cases of ACD due to (meth)acrylic monomers, related to their growing use in the application of artificial nails, in both nail technicians and consumers;
 - the protective measures such as ventilation, wearing gloves, and masks for protection against dust, which rarely seem to be used by nail technicians.
- Substituting acetaldehyde by another less hazardous substance, due to its C1B classification adopted by the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) in 2016, and the measured exposures.
- Encouraging the elimination of toluene from nail cosmetics, given:
 - the toxic and reprotoxic properties of toluene, which was classified as toxic for reproduction according to the CLP Regulation (R2);
 - the fact that nail varnishes without toluene have been identified.
- Adding ethyl-2-cyanoacrylate (CAS No 7085-85-0) to ANSES's work programme for identified substances, in order to submit a dossier for harmonised classification at European level, as this substance does not currently have any harmonised classification for the sensitisation aspects.

Moreover, the CES reiterates that with regard to occupational exposure in France, in addition to the R1B classification of formaldehyde or of mixtures required to be classified in application of the CLP Regulation, work involving formaldehyde exposure is classified as carcinogenic⁶ and is therefore subject to the substitution requirement under the Labour Code.

With regard to the chemical safety of cosmetic products and occupational exposure assessment

The CES recommends:

- Systematically taking into account an assessment of the risks for workers in the framework of the chemical safety assessments for cosmetic ingredients carried out by the SCCS, in particular for ingredients reserved for professional use;

⁶ Order of 13 July 2006 amending the Order of 5 January 1993 listing carcinogenic chemical substances, preparations and processes within the meaning of the second paragraph of Article R.231-56 of the Labour Code

- Ensuring that the risk assessments for workers are actually available when checks on the companies responsible for placing the cosmetics on the market are carried out by the competent authorities;
- Drafting a methodological guidance document equivalent to that of the SCCS⁷ for assessing exposure and the risks for workers exposed to cosmetics.

With regard to the means of prevention and protection to be implemented

The CES recommends:

- Installing ventilated tables:
 - extraction as close as possible to the emission sources via the ventilated tables, in order to effectively capture the vapours and dust. They should be positioned to take account of the directions of emission of the sanding dust, with sufficient air speeds at the collection grid, and the venting of filtering discharge to the outdoors whenever possible;
 - regular replacement of the active carbon filters in the ventilated tables, in accordance with the manufacturers' recommendations.
- Wearing a dust/gas/vapour mask with an A1P2 filter, or failing this a P2 type dust mask, in particular when applying/removing prosthetic nails and sanding natural or artificial nails, in the absence of effective ventilation at the work station (e.g. ventilated tables);
- Wearing nitrile gloves to apply prosthetic nails, and changing them at least for each operation or whenever they become torn or holed, to reduce dermal exposure to (meth)acrylates;
- Taking the ergonomic aspects into account in the design and layout of work stations;
- Storing new products in a dedicated enclosed area that is separate from meal areas;
- Disposing of all waste in a bin with a self-closing lid;
- Washing hands before and after each customer and before and after meals (this is already stipulated by the Labour Code), and cleaning the equipment and work station before and after each customer;
- Clearly labelling and identifying the contents of repackaged products;
- Implementing a recovery procedure for the product(s) in the event of spillage;
- Eliminating the use by the general public of polymerisation devices for manufacturing prosthetic nails and applying semi-permanent varnish;
- Encouraging the placing on the market of "no-touch" products/techniques, like those already used in industry and by dental prosthetists.

The CES suggests relying on the existing guides drafted by the NIOSH⁸ and the US EPA⁹ in order to transcribe the key points in the form of brochures for workers, like the one provided jointly by the RSI¹⁰, Grenoble University Hospital, the CNAMTS, the RNV3P and the University Joseph Fourier.

⁷ The SCCS notes of guidance for the testing of cosmetic ingredients and their safety evaluation – 9th Revision – 29 September 2015

⁸ An Evaluation of Local Exhaust Ventilation Systems for Controlling Hazardous Exposures in Nail Salons – Department of Health and Human Services – CDC – NIOSH – September 2012

⁹ Protecting the Health of Nail Salon Workers – US EPA – March 2007

¹⁰ Social security scheme for self-employed workers

With regard to the training and information of nail technicians

The CES recommends:

- Making it mandatory for any person required to apply prosthetic nails to follow harmonised diploma courses, including a module on occupational risk prevention and good working practices;
- Producing multilingual tools providing information on occupational risks and making them available to nail technicians;
- Ensuring that any product sheet available on the Internet includes a section on good practices for use, in addition to the technical descriptions of the product.

With regard to the medical monitoring of nail technicians

The CES recommends extending the RG82 occupational diseases table entitled "Disorders caused by methyl methacrylate" to include all methacrylates.

With regard to research orientations for improving knowledge

The CES recommends:

- Improving knowledge on the effects and exposure, particularly regarding inhaled particles during sanding and filing operations;
- Improving knowledge on the occupational diseases and associated exposure of nail technicians, by setting up a prospective longitudinal study to assess, among other things, the effects on sensitisation and reproduction and development. In addition, some results from the literature seem to call for further studies to better characterise the risk, for example on a possible link with autoimmune diseases;
- Taking the sensitising effects into account when developing OELs for substances classified as Category 1 respiratory or skin sensitisers according to the CLP Regulation.

4. AGENCY CONCLUSIONS AND RECOMMENDATIONS

The French Agency for Food, Environmental and Occupational Health & Safety endorses the conclusions and recommendations of its CES.

In addition, the French Agency for Food, Environmental and Occupational Health & Safety wishes to raise awareness among the different stakeholders identified in this study as able to help improve prevention of the risks to workers exposed to the products used in nail care and decoration activities. To this end, it recommends in particular:

To companies marketing cosmetics intended for nail care and decoration activities

- In the short/ medium-term, implementing the development and/or replacement of products intended for nail care and decoration activities so as to eliminate exposure to the sources of various hazardous chemical agents, in particular polymerisable (meth)acrylic monomers, toluene, acetaldehyde, etc.; then, developing "no-touch" products/techniques, in cases where substitution of the hazardous agent may not be technically possible;

- Providing the nail technicians with the necessary information contained in the chemical safety reports of the cosmetics these companies produce, to enable the nail technicians to establish their "single document on occupational risk assessment" (DUER) on a well-informed basis;
- Supplementing any product sheet presenting the technical descriptions of the product available, including on the Internet, with a section on good practices for use.

To workers carrying out nail care and decoration activities

- Strengthening the implementation of the general principles of preventive measures applicable regarding chemical risk, in order to minimise the risk of exposure to hazardous chemical agents:
 - by designing and organising suitable working methods;
 - by substituting, as a priority, the chemicals used in the composition of cosmetics intended for nail care and decoration activities that are classified Category 1A and 1B carcinogenic, mutagenic and toxic to reproduction according to the CLP Regulation;
 - by replacing the use of hazardous products by non-hazardous or less hazardous products, for example, by eliminating the use of products leading to exposure to (meth)acrylic monomers ("resin" technique, "gel" technique, semi-permanent varnish);
 - by setting up protective equipment such as ventilated tables;
 - by making suitable personal protective equipment available to avoid exposure to the chemicals found in the products used and particularly with a view to protecting the skin and eyes; for example: wearing and frequently replacing nitrile gloves when using products involving exposure to (meth)acrylic monomers ("resin" technique, "gel" technique, semi-permanent varnish); in the absence of effective ventilation at the work station (e.g. suction tables), wearing a dust/gas/vapour mask with an A1P2 filter, or failing this a P2 type dust mask, when applying or removing prosthetic nails and sanding artificial or natural nails;
 - by implementing provisions ensuring safety during the handling, storage and transport of chemical agents and waste containing such agents (storage in dedicated premises, disposal of waste in a bin, labelling and identification of repackaged products, etc.);
 - by implementing appropriate hygiene rules such as washing hands before and after each customer and before and after each meal, as well as cleaning the equipment and work station before and after each customer;
- Obtaining supplies preferentially from companies marketing/distributing products for which safety data and practices to be complied with during use are available.

To the public authorities

- Rapidly sending this opinion to the SCCS with a view to conducting a European assessment of the safety of nail cosmetics containing (meth)acrylic monomers for consumers and workers;
- Implementing measures to ensure that:
 - the assessment of the risks to workers is systematically taken into account in the framework of the chemical safety assessments for cosmetic ingredients carried out by the SCCS; to this effect, drafting a methodological guide equivalent to that of the SCCS¹¹ for assessing exposure and the risks for workers exposed to cosmetics would be welcome;
 - the assessments of the risks for workers are actually available during the controls carried out on the companies responsible for placing the products on the market;
 - the best possible risk management measures are implemented rapidly to avoid the allergic contact dermatitis associated with the use of polymerisable (meth)acrylic monomers, both for workers and consumers.
- Making it mandatory for any person required to apply prosthetic nails to follow harmonised diploma courses, including a module on occupational risk prevention and good working practices;
- Revising the RG82 occupational diseases table entitled "Disorders caused by methyl methacrylate" in order to extend it if possible to include all methacrylates;
- Adding ethyl-2-cyanoacrylate to the work programme for identified substances, in order to submit a dossier for harmonised classification at European level, as this substance does not currently have any harmonised classification for the sensitisation aspects;
- Taking the sensitising effects into account when developing OELs for substances classified as Category 1 respiratory or skin sensitisers according to the CLP Regulation.

To research and prevention institutions and organisations

- Improving knowledge on effects and exposure, especially regarding inhaled particles during sanding and filing, and in particular on the toxicity of these particles when these operations are performed on artificial nails made from (meth)acrylates;
- Improving knowledge on the state of health of nail technicians and how it evolves, regarding among other things the risks of sensitisation, allergic contact dermatitis, asthma, adverse outcomes in terms of reproduction and development, neurological disorders, autoimmune diseases and even cancer;
- Developing and disseminating multilingual tools that provide information on prevention of the risks incurred by nail technicians, relying in particular on existing documents.

Dr Roger GENET

¹¹ The SCCS notes of guidance for the testing of cosmetic ingredients and their safety evaluation – 9th Revision – 29 September 2015

KEYWORDS

Nail; nail prosthesis; manicure; meth(acrylate); varnish/polish; resin; gel; metrology; occupational hygiene

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ANSES (2017) *Evaluation des risques des professionnels exposés aux produits utilisés dans les activités de soin et de décoration de l'ongle* [Assessment of the risks for professionals exposed to products used in nail care and decoration activities]. Collective expert appraisal report of the French Agency for Food, Environmental and Occupational Health & Safety, July 2017.
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ANNEX 1: METHOD USED FOR CHEMICAL SUBSTANCES PRIORITISATION FOR THE EXPERT APPRAISAL

Six hundred and ninety-six substances were identified in the composition of the products used or in the workplace air.

A method for prioritising substances based on the **hazard criterion was used to identify the substances posing a risk, dividing them into three groups.**

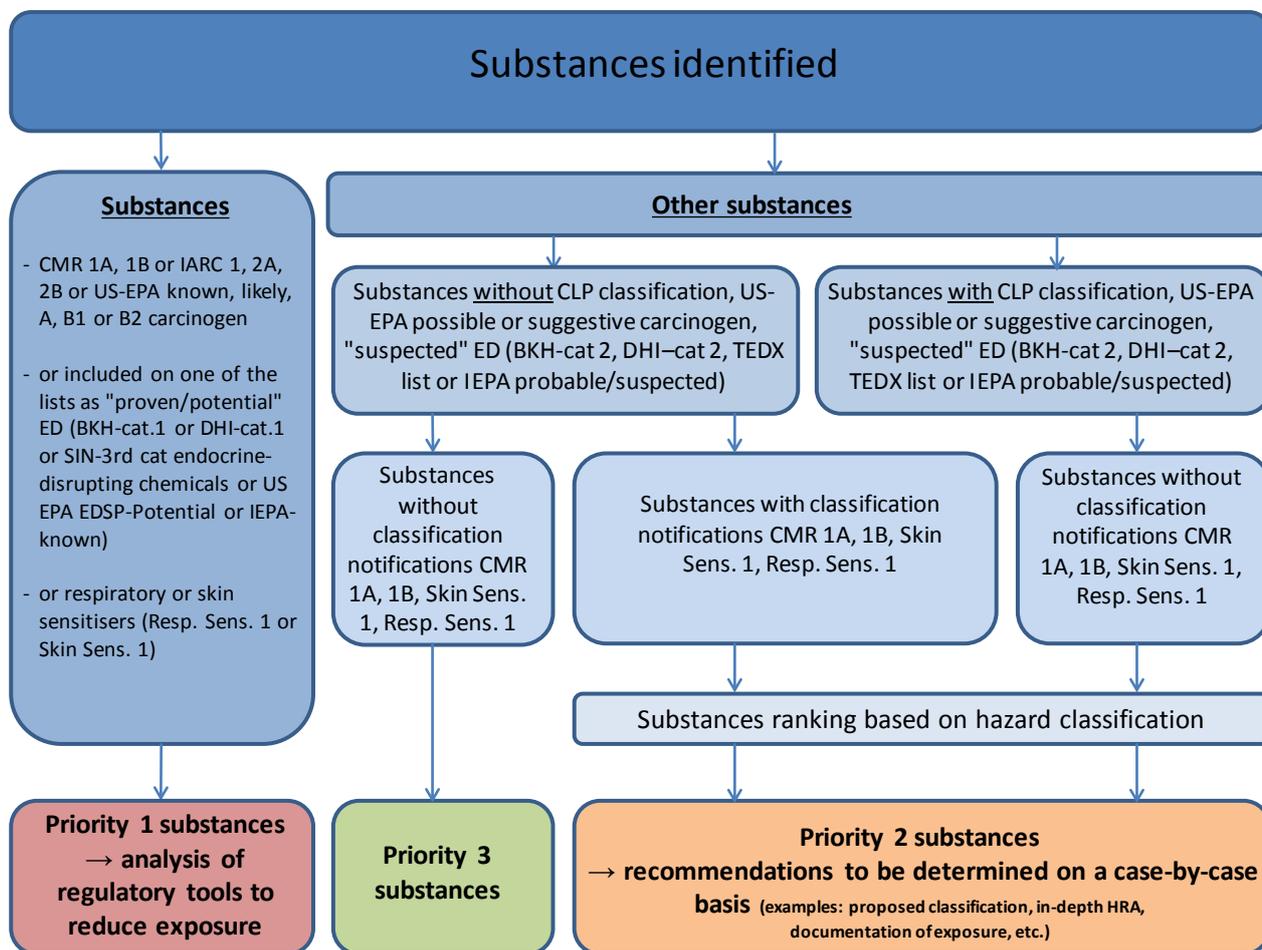
It should be noted that there were insufficient exposure data available to perform a risk assessment. In the absence of sufficiently representative exposure data for all the identified substances and of specific tonnage data on the substances identified for the nail care and decoration activities, the substances were prioritised only on the basis of the hazard.

The harmonised classification for each substance was used when available. Otherwise, the method used the classification notifications according to the Regulation on classification, labelling and packaging of substances and mixtures (CLP)¹², the classification of the International Agency for Research on Cancer (IARC), or the classification of the US EPA. It was also specified for each substance whether it was included on non-regulatory lists of potential endocrine-disrupting substances proposed by European or international organisations¹³ (see Figure 1).

¹² Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP).

¹³ These are the lists of the BKH or the DHI, the Sin List, in the "Endocrine Disruptors Screening Program Tier 1 Assessments" of the US EPA, in the "Endocrine Disruptors Strategy" report of the Illinois Environmental Protection Agency (IEPA), or on the TEDX List as endocrine disruptors. These are lists used by the teams working on endocrine disruptors at ANSES.

Diagram 1: Chemical substances prioritisation method based on hazard classification



All the substances in priority group 1 were considered in the analysis of the results.

The substances in priority group 2 were ranked. This consisted in assigning a score to each one. This score was calculated according to the method of Lithner et al. (2011) as amended (the initial Lithner et al. 2011 method involved assigning a score relying only on the harmonised CLP classification). For the purposes of this request, it was decided to also incorporate the US EPA's carcinogenicity classifications into the score calculation (except those classifications used for priority group 1) and a given substance's inclusion on one of the lists as a "suspected" endocrine disruptor, for which a score was assigned.

The substances in priority group 3 did not undergo any additional processing or specific analysis.

Substances in priority group 1

60 substances were identified in priority group 1, 17 of which were from detections in workplace air. These substances included around fifteen (meth)acrylates, phthalates, parabens, ketones, aldehydes, alkanes, aromatic alcohols, siloxanes, chlorine derivatives, aromatic amines, benzene derivatives, terpenes, inorganic compounds, peroxides, phosphorus derivatives, amides, derivatives of acids, and resins. Among the substances in priority group 1:

- 15 are classified as carcinogens (according to the CLP Regulation, the US EPA or the IARC);
- 1 is classified as mutagens according to the CLP Regulation;
- 2 are classified as toxic for reproduction according to the CLP Regulation;
- 18 substances are included on lists of potential ED substances;
- 30 substances are classified as skin sensitisers (mostly acrylates and methacrylates);
- 2 are classified as respiratory sensitisers.

Substances in priority group 2

Ninety-four substances were identified in group 2, including some twenty aliphatic and alicyclic hydrocarbons, alcohols, benzene derivatives, acids, ketones, etc.

Among these 94 substances, four have a hazard score > 400 ¹⁴, an arbitrary threshold chosen in order to present here only the substances with the highest hazard score. The hazard scores of the other 90 substances were between 10 and 150. Among the substances with a score > 100 , 33 were from detections in workplace air.

Substances in priority group 3

The 542 remaining substances were classified in priority group 3. These chemical substances have no hazard criteria justifying their inclusion in priority groups 1 and 2. Nevertheless, it should be noted that no exhaustive literature searches on the hazards of these substances were carried out, and the fact that these substances belong to group 3 does not mean that they are not hazardous to human health. Among these 542 substances, 91 were detected in workplace air. It should be noted that several (meth)acrylates were identified in group 3 despite having classification notifications, mainly as skin sensitisers. The relevance of these notifications was not investigated.

All the detailed results of the prioritisation method are available in the expert appraisal report.

For all the substances detected more than 10 times in workplace air, and which are found in the COLCHIC database and in the CRD measurement campaign, the decision was made to:

- identify the number of concentration values above the French or European regulatory 8h-OELs (those in the COLCHIC database);
- calculate the order of magnitude of the ratios between the concentration values and the French or European regulatory 8h-OELs (those identified in the CRD measurement campaign).

For all the substances detected in workplace air, it was decided to carry out the same work considering other reference values (RVs) for chronic inhalation exposure selected from among the OELs (excluding French or European regulatory OELs), toxicity reference values (TRVs) adjusted for an occupational population, and Derived No-Effect Levels (DNELs) for workers or adjusted for an occupational population and developed by ECHA's Risk Assessment Committee. This enabled substances with no French or European regulatory 8h-OEL to be compared with an RV. For all the substances, this work made it possible to consider RVs protecting from reversible or more

¹⁴ By decreasing hazard score, these substances are crotonaldehyde, acrolein, methanol and toluene.

sensitive effects that are not necessarily taken into account when establishing OELs, as OELs are management values for the monitoring of occupational exposure.

The comparison of the emission data from COLCHIC and the CRD measurement campaign with the reference values highlighted four chemical substances - ethyl methacrylate, methyl methacrylate, acetone and acetaldehyde - whose concentration values and order of magnitude, as measured in the COLCHIC database and in the CRD, were lower than the regulatory OELs but higher than the selected RVs.

It is important to emphasise that, despite efforts to harmonise the methods for developing OELs, TRVs or DNELs, these reference values were developed according to often disparate methods by various organisations and expert appraisal groups on different dates. This causes a consistency bias between the substances and the different types of reference values, a bias that is inherent to the traditional Quantitative Health Risk Assessment (QHRA) approach. It explains why some substances (e.g. acetone) have lower RVs than those of more problematic substances (e.g. methanol).

The work carried out also highlighted the multitude of substances to which workers are exposed. To clarify this multi-pollutant chemical exposure, two exploratory approaches were considered:

- Calculating six indicators from the data obtained from the CRD measurement campaign:
 - total VOC concentration per beauty salon investigated
 - number of VOCs detected per beauty salon investigated
 - sum of the ratios of the order of magnitude of the concentration values to the 8h-OELs calculated for each chemical substance, per beauty salon
 - sum of the ratios of the order of magnitude of the concentration values to the RVs calculated for each chemical substance, per beauty salon
 - maximum of the ratios of the order of magnitude of the concentration values to the 8h-OELs calculated for each chemical substance detected, per beauty salon
 - maximum of the ratios of the order of magnitude of the concentration values to the RVs calculated for each chemical substance detected, per beauty salon
- Using MiXie, a simple and easy-to-use tool that uses measurement data to assess whether or not chemical substances have additive potential and to situate the cumulative exposure levels relative to the Occupational Exposure Limits (OELs).

As a result, no correlation could be established between the number of VOCs and the concentration of total VOCs in the beauty salons visited. This approach however highlighted the significant influence of acetaldehyde on the indicator values per salon.

Cumulative exposure levels calculated with the MiXie tool fell between 10 and 22% for the eye and upper respiratory tract disorder classes of health effects.