



# BMJ Open Protocol for a systematic review on systemic and skin toxicity of important hazardous hair and nail cosmetic ingredients in hairdressers

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## ABSTRACT

**Introduction** Hairdressers constitute a major subgroup in the service sector. They are exposed to various substances hazardous for skin, airways or systemically. Accordingly, skin and other occupational diseases are common. The present systematic review will compile and appraise evidence regarding skin, systemic and airways toxicity of an indicative set of specific, important product ingredients. Additionally, evidence concerning hand eczema morbidity among hairdressers will be reviewed.

**Methods and analysis** Systematic searches will be performed in two electronic literature databases (Medline, Web of Science—Core Collection), the Cochrane register and two collections of toxicological dossiers (Scientific Committee on Consumer Safety of the European Commission and the MAK Commission of the German Research Council). Additional literature sources will be retrieved using hand search of reference lists of included studies and snowballing methods. We will include studies with all types of quantitative study designs, including results from in vitro and in vivo experiments, chemical analysis, epidemiological findings and clinical results. We will assess the risk of bias within studies amalgamating an abbreviated version of the Mixed Methods Appraisal Tool, basic Cochrane criteria and US Environmental Protection Agency assessment factors for scientific information. As we expect large heterogeneity in methods and outcomes, we will conduct a narrative synthesis of results instead of a meta-analysis, except where quantitative pooling is feasible.

**Ethics and dissemination** Ethical approval and patient consent are not required as this is a systematic review based on published studies. The results of this study will be published in international peer-reviewed journals.

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## INTRODUCTION

The hairdressing sector in the European Union (EU) is dominated by small-businesses and micro-businesses with some 400 000 salons employing over 1.5 million workers, which amounts to approx. ten per cent of the total service sector in Europe. In order

## Strengths and limitations of this study

- Exhaustive search for relevant studies in the most relevant databases and through additional literature sources.
- This review is not limited to specific study designs or participant groups.
- Due to expectedly very heterogeneous methods and outcomes, we will have mostly to undertake narrative synthesis instead of meta-analysis.

to ensure good health conditions within the workforce and subsequently avoid a loss of working hours, health and safety are crucial issues. In everyday work, hairdressers are in contact with many hazardous and toxic agents, which entails different occupational health risks such as skin damage, respiratory problems, reproductive disorders, various forms of cancer and so on. Additionally, evidence concerning the morbidity of hand eczema among hairdressers will be reviewed.

Research has shown that up to 70% of hairdressers suffer from work-related skin damage, mostly hand dermatitis, at some point during their career. The most important risk factors for developing occupational skin diseases (OSD) are wet work and occupational contact to irritants, as for example, detergents or hairdressing chemicals, and allergens. In Europe, OSD represent up to 35% of all reported occupational diseases, and the often chronic course causes extensive suffering for the affected workers. The economic burden of OSD in the EU exceeds €5 billion per annum, spent on treatment, compensation and loss of productivity. The chronic course of OSD, mainly irritant and allergic contact dermatitis of the hands, may result in detrimental

socioeconomic consequences, for example, job loss and long-term unemployment.

Other occupational health problems of hairdressers are respiratory disorders related to inhalation exposure to hazardous chemicals from the used products, for example, hair sprays. Aerosols are widely encountered in hairdressing and may reach the lungs, depending on particle size. Bleaches and hair sprays are emphasised by hairdressers as the most irritative substances for airways at their workplace.<sup>1</sup> Ammonia is an irritating chemical present in the air of hairdressing salons during bleaching or perm procedures, often in concentrations exceeding occupational exposure limits, as is formaldehyde during hair straightening procedures.<sup>2–4</sup> According to epidemiological evidence, hairdressers and hairdressing apprentices are prone to irritation of the upper airways, reporting symptoms of watery nose, nasal congestion and cough in higher proportions than control subjects unexposed to chemical irritants.<sup>5 6</sup>

EU cosmetics legislation restricts the use of carcinogenic, mutagenic or toxic for reproduction (CMR) substances. Exceptions to this general rule are possible, subject to the conditions laid down in Article 15 of the Cosmetics Regulation EU 1223/2009. For example, a substance classified in category 2 may be used in cosmetic products where the substance has been evaluated by the Scientific Committee on Consumer Safety (SCCS) and found safe for use in cosmetic products. However, professionals are qualitatively and quantitatively much more exposed to such substances than a typical consumer or client. As one example, hairdressers apply colour about six times a day with their hands—which might already be previously damaged by occupational skin strains—being exposed, sufficiently protected or not by gloves, as opposed to consumers who apply on average once every 4 weeks a permanent colouring, exposing both hands and scalp. The specific professional exposure is normally not assessed in SCCS opinions, even though special aspects may be mentioned and referred to the Risk Assessment Committee. Thus, safety concerns related to occupational exposure remain. Indeed, in a monograph published in 2010, the International Agency for Research on Cancer (IARC) confirmed that the occupational exposure of hairdressers should be considered as probably carcinogenic (IARC group 2A).<sup>7</sup> A new strategy for chemicals are currently being developed in EU ([https://ec.europa.eu/environment/strategy/chemicals-strategy\\_en](https://ec.europa.eu/environment/strategy/chemicals-strategy_en)) making a compilation of evidence especially relevant. Hence, in the context of the project ‘Promoting the autonomous implementation of the European framework agreement on occupational health and safety in the hairdressing sector’, a series of systematic reviews will be performed, the methods of which are described in the present publication.

## METHODS AND ANALYSIS

### Patient and public involvement

Patients and/or the public were not involved in the development of this research project; however, stakeholders

**Table 1** Eligibility criteria following the PECOS scheme, adapted from (University of York 2009)<sup>9</sup>

Criterion	Inclusion	Exclusion
Participants	Hairdressers, patients, cosmetic products	None
Exposure	Exposure to (an) eligible chemical(s)	N/A
Comparator	Clients, consumers, normal population (no, or less, exposure)	N/A
Outcome	Skin toxicity event (contact allergy, irritancy)	N/A
	Systemic toxicity (CMR, ED, respiratory)	N/A
Study design	Experimental studies, for example,	Qualitative studies
	Chemical analyses	
	in vivo toxicological studies	
	in vitro toxicological studies	
	Observational studies, for example,	
	Case-control studies	
	Prospective and retrospective cohort studies	
	(Repeated) cross-sectional studies	
	Case reports, clinical series	

CMR, carcinogenicity/mutagenicity/reproductive toxicity; ED, endocrine disruption; N/A, not applicable.

from the occupational insurance and employers and employees’ associations, respectively, have provided input regarding the scope of substances to assess.

### Design

This study will be a systematic review with primarily narrative data synthesis and will be based on the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) checklist.<sup>8</sup> In the event of protocol amendments, the date of each amendment will be accompanied by a description of the change and the rationale.

### Eligibility criteria

Eligibility criteria for studies to be included in the systematic review are reported following the PECOS (Participants, Exposure, Comparator, Outcome, Study design) scheme adapted from (University of York 2009)<sup>9</sup> table 1.

The scope of the systematic review, while focusing on workers in the hairdressing trade, is not limited to this particular subgroup, that is, clinical studies illustrating exposure to, and morbidity from, chemicals in hair cosmetics in other groups will be considered, too. The focus of this systematic review is on a quantitative assessment of the morbidity in terms of skin toxicity (mostly contact allergy) and systemic toxicity (eg, CMR; see table 1) in humans as well as on in vivo and in vitro results regarding these respective toxicological endpoints. Furthermore, the overall morbidity of hand eczema among hairdressers will be quantified. We will include all types of studies with quantitative empirical data (see

**Table 2** List of most relevant product groups in hairdressing with substances finally included into the systematic review

	Product category	Substance(s)
1	Oxidative hair dyes/colourants	<i>p</i> -Phenylenediamine (PPD; CAS no. 106-50-3) and its salts (CAS no. 624-18-0, 16245-77-5), toluene-2,5-diamine (PTD; CAS no. 95-70-5) and its sulphate (CAS no. 615-50-9), 2-methoxymethyl-PPD (mePPD; CAS no. 337906-36-2)
2	Bleaches	Persulfate salts: ammonium, APS, CAS no. 7727-54-0; potassium, PPS, CAS no. 7727-21-1; sodium, SPS, CAS no. 7775-27-1
3	Perms and relaxing substances	Salts and esters of thioglycolic acid: glyceryl thioglycolate (GMTG; CAS no. 30618-84-9), ammonium thioglycolate (ATG; CAS no. 5421-46-5)
4	Cosmetic glues	2-Hydroxyethyl methacrylate (HEMA; CAS no. 212-782-2), ethyl cyanoacrylate (ECA; CAS no. 7085-85-0)

table 1). Observational studies are likely to be the most important source of information for this review, supplemented by basic research evidence derived from in vivo and in vitro methods.

### Target substances

Following deliberations within the project consortium and following the proposed potentially problematic types of products considered in this project (table 2), a Delphi survey was held shortlisting altogether 33 substances. Feedback was provided by 48 of 121 experts and stakeholders invited (response: 39.7%). After initial candidates had been removed as they were regarded as irrelevant for the purpose, and additional entries had been added, the remaining above-threshold candidates were eventually consented by the research consortium and finally included in the list of substances to be considered, shown in table 2.

### Searches

We will conduct systematic searches using the following electronic databases: Pubmed/Medline and Web of Science–Core Collection (WoS). Additionally, the Cochrane registry, and the archive of scientific opinions of the SCCS of the European Commission and its predecessors will be searched for studies, reviews and opinions (the latter normally concluding on data submitted by industry concerning the safety of a cosmetic ingredient; [https://ec.europa.eu/health/scientific\\_committees/consumer\\_safety\\_en](https://ec.europa.eu/health/scientific_committees/consumer_safety_en), last accessed 10 Feb. 2021). As far as available, dossiers in English language of the German ‘MAK Commission’ on the substances available will be identified and used in the synopsis and discussion of results (<https://onlinelibrary.wiley.com/doi/book/10.1002/3527600418>, last accessed 10 February 2021). All searches will be performed at the very start of the project, by 1 March 2021. Furthermore, we will hand search the bibliographies of all studies identified through the electronic database search and meeting the inclusion criteria. We will also perform forward-snowballing by using the six most important references identified, and check all references citing any of these publications. This citation analysis will be performed based on the WoS database.

Concerning those substances where an abundance of data exists on any one of the toxicological endpoints

which has been summarised adequately in the past, only literature published since then will be searched for. We will use English search terms only. Generally, title, abstract and key words will be the items to be searched.

The searches are composed of the following modules: (i) substance identifiers (“SUB”), (ii) skin toxicity endpoints (“SKIN”) and (iii) systemic/respiratory toxicity endpoints (“SYS”) which are defined below. Moreover, the searches will be split into the following topics, using the same set of substance identifiers as common denominator:

- ▶ “SUB” AND “SKIN”: this, and the following, combination will be used to identify all studies contributing evidence to the endpoints, whether or not related to exposure as hairdresser.
- ▶ “SUB” AND “SYS”: as above.

### SUB

Substance identifiers include all relevant MeSH terms and important synonyms. The latter include the preferred chemical (International Union of Pure and Applied Chemistry) name as well as the International Nomenclature of Cosmetic Ingredients term, along with CAS number and synonyms—but excluding trademarks—identified in the CAS database (SciFinder). The substance identifiers are shown in online supplemental appendix A. In order to increase the sensitivity of the search, at some expense on its specificity, product (group) descriptors are additionally employed in the search for relevant substances, joined by an OR operator, and “hairdress\*” as reference to “hairdressing products”, but also to the job title, as shown below. Pilot searches in Medline of the suggested terms combined with “contact AND dermatitis” (CD) and “contact AND allergy” (CA), respectively, yielded meaningful results; the number of references is indicated in parentheses after each search string:

- ▶ hairdress\* (n=305 along with CD, n=228 with CA, respectively).
- ▶ hair dyeing (n=48 along with CD, n=44 with CA, respectively).
- ▶ hair colouring (n=193 along with CD, n=153 with CA, respectively).
- ▶ permanent wave (n=30 along with CD, n=18 with CA, respectively).

- ▶ acid perm (n=1 along with CD, n=1 with CA, respectively).
- ▶ persulfate\* (n=57 along with CD, n=48 with CA, respectively).
- ▶ persulphate\* (n=15 along with CD, n=10 with CA, respectively).

### SKIN

Endpoint/disease identifiers include the relevant MeSH terms and common medical language synonyms listed below:

Allergens[MeSH] OR Haptens[MeSH] OR agents, contact sensitizing[MeSH] OR allergic OR Dermatitis, Allergic Contact[MeSH] OR Dermatitis, Contact[MeSH] OR contact allergy OR Skin Tests[MeSH] OR Local Lymph Node Assay[MeSH] OR guinea pig maximization test OR Patch Tests[MeSH] OR Skin Irritancy Tests[MeSH] OR contact dermatitis OR contact urticaria OR contact sensitization OR Occupational Diseases[MeSH] OR work related.

### SYS

Endpoint/disease identifiers include the relevant MeSH terms and common medical language synonyms listed below:

Allergens[MeSH] OR Irritants[MeSH] OR allergic OR irritative OR Respiration Disorders[MeSH] OR respiratory OR Inhalation[MeSH] OR Rhinitis[MeSH] OR Asthma OR Neoplasms[MeSH] OR cancer OR Carcinogens[MeSH] OR Biomarkers, Tumor[MeSH] OR Carcinogenicity Tests[MeSH] OR Mutagens[MeSH] OR Mutagenicity Tests[MeSH] OR genotoxicity OR Reproductive Health[MeSH] OR reproductive toxicity OR reprotoxic OR Pregnancy Outcomes[MeSH] OR Pregnancy Complications[MeSH] OR Pregnancy[MeSH] OR Infertility[MeSH] OR Congenital Abnormalities[MeSH] OR birth defect OR congenital malformations OR Abortion, Spontaneous[MeSH] OR Developmental Disabilities[MeSH] OR developmental toxicity OR Menstruation Disturbances[MeSH] OR Spermatogenesis[MeSH] OR Fertility[MESH] OR Fecundability OR Time to pregnancy OR low birth weight OR Endocrine Disruptors[MeSH] OR Endocrine System Diseases[MeSH] OR Toxicity Tests[MeSH] OR Toxicity Tests, Acute[MeSH] OR Toxicity Tests, Subacute[MeSH] OR Toxicity Tests, Chronic[MeSH] OR Toxicity Tests, Subchronic OR dermal absorption OR Occupational Diseases[MeSH] OR work related OR hairdresser\* OR hairdressing.

### Hand eczema

To identify studies concerning the morbidity of hand eczema among hairdressers, the following search, combining free text and MeSH terms will be used:

((Hairdresser\* OR Hairdressing apprentice\*)

AND

("Dermatitis"[MeSH] OR Dermatitis OR "hand eczema" OR "contact allergy" OR "allergic contact dermatitis" OR

"irritant contact dermatitis" OR "occupational dermatitis" OR "skin"[MeSH])

AND

("Morbidity"[MeSH] OR "Risk"[MeSH] OR prevalence OR incidence OR Hazard OR consequences OR severity)).

### Further restraints

Only accepted publications newer than 1999 (ie, 1 January 2000 and following) will be considered in the systematic search and work-up, thereby relying on up-to-date methodological standards and testing guidelines (eg, the degree of patch test standardisation achieved by the millennium; Organisation for Economic Co-operation and Development guidelines for testing of chemicals for sensitisation and CMR). Moreover, it appears important to refer to risk related to current exposures, with at least partially improved cosmetic product safety, for example, regarding permissible use levels of hazardous substances in hair dyes and other safety measures implemented by the EU Cosmetics Regulation (1223/2009/EC) or other pertinent regulations (eg, use of bleach pastes instead of powders reducing airborne exposure to persulfate salts). Notwithstanding, reviews and scientific dossiers (such as from SCCS and predecessors, and the MAK Commission) based on previous literature will be considered in the discussion to achieve a complete appraisal of toxicological effects within scope.

### Data management

For one search query (eg, skin toxicity), the search results will be exported from Medline and WoS in a suitable format and imported into Zotero libraries, documenting the number of references contributed by each export/import set. In the Zotero library, bibliographical duplicates will be identified and the entry including less information (eg, no abstract) be discarded. Each entry will be identified by a unique, human readable ID generated by using the BetterBibtex Plug-in, with manual editing where necessary. The remaining unified library will be exported in RIS format and imported into a new Rayyan project (Rayyan QCRI, <https://rayyan.qcri.org/welcome>, last accessed 21 February 2021) for shared screening by two reviewers for eligibility based on title, key words and abstract. In case of discordant results, the entry will be reviewed by a third experienced reviewer and a final decision be made. Finalisation is expected by 31 March 2021. Reasons for non-inclusion will be documented, and summarised at the end for use in the PRISMA-P flowchart.

### Study selection

The final set of references deemed eligible for full text screening by above-mentioned two reviewers will be exported from Rayyan in Bibtext format for import into the Zotero cloud-based reference database, after the initial set of references has been archived. Zotero offers freely definable 'tags' for entries. These will be used to identify which of the selected substance(s) is/are treated in the

article (see shorthands for substances in [table 2](#)); these tags will be added when scrutinising and extracting the full text articles, again, independently by two reviewers, with a third senior reviewer consensualising divergent results between the two initial reviewers. All decisions and reasons leading to the exclusion of studies at this stage will be documented, providing information on the individual assessments by both initial reviewers and the final decision. At the end of this process, a set of full text articles to be included in the systematic review will be identified.

### Data extraction

Two reviewers will independently extract the data from studies meeting the inclusion criteria using standardised, pre-piloted publication record forms (PRFs). There will be different PRFs, owing to the different methodology and outcomes generated, according to study type. Thereby, one form each will be used for (i) clinical patch test studies, (ii) other observational studies addressing respiratory and systemic diseases, (iii) experimental (in vivo and in vitro) studies and (iv) morbidity of hand eczema. A third senior reviewer will review the extracted data and make final decisions in contradictory cases. The following basic data will be extracted for observational studies: publication ID, year of study execution, country of origin, study design, methods, study setting and population involved, information on basic characteristics of participants (eg, age, gender, ethnicity), number of participants, number of positive outcome(s) and funding source. For experimental studies, publication ID, year of study execution, country of origin, study design, methods, study setting, test system/animals, number of observational units, outcomes (mean and spread) and funding source will be documented. Outcomes will be extracted in subcategories as defined in [box 1](#) to enable meaningful data synthesis and analysis. Finalised PRFs (expected by mid-May 2021) will be preserved and published as supplemental material to the systematic review.

If necessary, outcome information will be approximated from figures in the reports. If more than one publication reports on the same study we will combine information from the publications if they report on different outcomes and use the more comprehensive one(s) if the shorter one(s) do(es) not add any additional information. If any contradictions with regards to content appear between such multiple publications, we will extract the information given in the more recent publication. We will contact study authors by email if important methodological details are missing.

### Risk of bias within included studies and quality of evidence assessment

Suitable criteria for assessing risk of bias and quality of evidence will be applied. Two reviewers will independently appraise studies meeting the inclusion criteria after full text scrutiny without being blinded to the studies. The published Mixed Methods Appraisal Tool will be used on the study level in case of homogeneous methodology, and

## Box 1 Subcategories of outcomes

### Skin toxicity

- ▶ Skin sensitisation/contact allergy in humans (eg, numbers tested, numbers positive, test methods).
- ▶ Skin irritation in humans (eg, exposure conditions leading to irritation).
- ▶ Sensitisation in vivo or in vitro (eg, guideline vs non-guideline method, main read-out such as EC3-value for Local Lymph Node Assay).
- ▶ Irritancy in vivo or in vitro (eg, guideline vs non-guideline method, main read-out).

### Systemic toxicity

- ▶ Carcinogenicity/cancer risk in humans (eg, epidemiological studies on occupational vs consumer exposure).
- ▶ Carcinogenicity in vivo or in vitro (eg, mechanistic studies, tumour promoting activity and frequency of tumour incidence).
- ▶ Mutagenicity in vivo or in vitro (eg, genotoxicity tests, main read-out).
- ▶ Reproductive and developmental toxicity in humans (eg, menstrual disorders, sperm production, pregnancy and birth outcomes).
- ▶ Reproductive and developmental effects in vivo (eg, male and female reproductive effects, developmental and post-natal toxicity).
- ▶ Endocrine disruption in vivo or in vitro (eg, test methods, adverse effects on endocrine relevant endpoints, endocrine/androgen/thyroid/steroidogenesis).

### Respiratory toxicity

- ▶ Airways sensitisation and irritation in humans (eg, inhalatory exposure, inhalatory allergens, respiratory irritants, asthma, rhinitis, occupational diseases) and animal models.

### Hand eczema

- ▶ Hairdresser/hairdressing apprentice.
- ▶ Gender.
- ▶ Morbidity (prevalence, incidence).
- ▶ Debut (onset).
- ▶ Severity/frequency of eruptions.
- ▶ Concomitant atopic dermatitis.
- ▶ Diagnosis (self-reported vs physician diagnosed).

on the outcome level in case of multiple methodologies used in one study.<sup>10</sup> Moreover, information and selection bias will be examined following basic Cochrane collaboration recommendations,<sup>11</sup> and further criteria relating to scientific validity as elaborated by a working group of the US Environmental Protection Agency<sup>12</sup> will be included in the risk of bias assessment tool amalgamated from these three resources.

### Data synthesis and analysis

There will be substantial heterogeneity both in methodologies (even in the subcategories of ‘experimental’ and ‘clinical’ research) and in outcomes. Instead of a meta-analysis, we will primarily conduct a narrative synthesis following guidance from the Centre for Reviews and Dissemination.<sup>9</sup> Summary tables will present the main characteristics of the included studies, their finding as well as their quality rating. Notwithstanding, if for a subset of eligible studies a quantitative summary appears feasible, in view of sufficiently uniform methodology and outcome definition, graphical summaries as Forest plots

with an assessment of heterogeneity ( $I^2$ ) will be presented. In such cases, the strength of cumulative evidence will be assessed using the *Grading of Recommendations Assessment, Development and Evaluation (GRADE)* criteria.<sup>13</sup> Apart from a results presentation evidently stratified for the substances concerned, subgroup analyses or meta regression approaches are not foreseen.

### Ethics and dissemination

Ethical approval and patient consent are not required as this is a systematic review based on published studies. This systematic review has been registered in PROSPERO. The results of this review will be published in international peer-reviewed journals.

### Protocol amendments

This is the initial version of the study protocol. Amendments to the protocol will be filed with PROSPERO and listed in the results publication(s), which will otherwise refer to the present publication.

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**Contributors** WU: conceptualisation, methodology, resources, writing - original draft; JDJ: conceptualisation, methodology, writing - review and editing; MSH: conceptualisation, writing - review and editing; SK: conceptualisation, methodology, writing - review and editing; HFvdM: methodology, writing - review and editing; JM: conceptualisation, methodology, writing - review and editing; RT: conceptualisation, methodology, writing - review; ZB: conceptualisation, methodology, writing - review; CS: conceptualisation, methodology, writing - review; SMJ: conceptualisation, methodology, writing - review and editing, project administration, funding acquisition, guarantor of the review. All authors have read and approved the final submitted version of the manuscript.

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**Disclaimer** Other than being given the opportunity to provide input in the initial Delphi process to identify relevant substances, the sponsor has no role in the development of the protocol, nor in the performance of the systematic review and the publication of its results.

**Competing interests** WU has received a honorarium for a lecture on contact allergy from mixed dermatopharmaceutical sponsors (GEIDAC, Toledo, September 2018) and travel reimbursement for participation in study meetings of the IDEA

project (IFRA). WU is external expert for the SCCS. Other authors: none to declare. Provenance and peer review: not commissioned; externally peer reviewed.

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