SCHÖNHEITSPFLEGE"
KOMPETENZPARTNER IM IKW

Data Sources for the Safety Assessment of Cosmetic Products in the EU

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Background

This contribution is to provide an overview of the data sources which can be used for the toxicological review of cosmetic ingredients and finished products.

The information presented below constitutes an overview which can provide assistance. The original texts of the respective regulations are legally binding for the statutory provisions. The mentioned literature sources have been compiled to the best of our knowledge. IKW cannot accept any responsibility for the updatedness and completeness of the texts since the legal situation and scientific findings are constantly developing further. It is the responsibility of the safety assessor to obtain comprehensive and updated information about the assessment of the safety of the cosmetic products and their ingredients to be evaluated.

Some of the data sources mentioned here also provide information on efficacy or environmental data. The primary goal of this document is, however, a compilation of data sources for the assessment of the safety of cosmetic products for human health in the EU in accordance with Article 10 of the EC Cosmetic Products Regulation [CPR, Regulation (EC) No 1223/2009].

1. General legal bases and requirements in respect of safety assessment

Please refer to the document "General information for manufacturers and distributors of cosmetic products in Germany" on the website of IKW, which is permanently updated.

Please also note the specific Information on the EC Cosmetic Products Regulation [CPR, Regulation (EC) No 1223/2009] on the IKW website.

Further information and guidelines on the CPR can be accessed via the Cosmetics Europe website.

Particularly regarding the safety assessment of cosmetic products you may find a comprehensive compilation of relevant sources at www.safetyassessor.info/information.

2. European chemicals legislation

The REACH Regulation [Regulation (EC) No 1907/2006] was published in the Official Journal of the EU on 30 December 2006 (L 396); the correction of spelling mistakes was published in the Official Journal of the EU on 29 May 2007 (L 136). It governs the **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals (REACH) on the European market as such and as components of products such as cosmetic products.

The corrected REACH Regulation can be retrieved here on the internet or via www.reach-clp-biozid-helpdesk.de/en/. IKW has compiled a short instruction (in German) including the most important aspects of REACH from the cosmetics industry's point of view.

Substance safety reports in accordance with the REACH Regulation must only take into account environmental risks for ingredients of cosmetic products but not risks for human health which result from the end uses of cosmetic products (Article 14, Clause 5, Letter b), since their safety for human health is governed by the provisions of the CPR.

The CLP Regulation (**C**lassification, **L**abelling and **P**ackaging) is a European Union regulation from 2008 which aligns the EU system of classification, labelling and packaging of chemical substances and mixtures to the Globally Harmonised System (GHS). The CLP Regulation can also be retrieved via www.reach-clp-biozid-helpdesk.de/en/.

3. Sources for toxicological data

Identification of the substance to be considered
Prior to the search for data a clear identification of the substance and / or substance mixtures (eg plant extract) is required. Essential data for identification purposes include

- The INCI designation (CosIng database or ICID),
- The precise chemical designation,
- The CAS number,
- The EU number (EINECS/ELINCS).

The commercial designation for raw materials is, however, only conditionally helpful (eg for an exchange of information with the corresponding raw material producer). If a substance is expressly regulated by cosmetics law, the corresponding reference must likewise be precisely identified (Annex X, No. y).

Regulated versus unregulated substances
In the annexes of the CPR many substances are regulated in view of their use in cosmetic products (banned and/or restricted or expressly approved for certain fields of application). For other substances, which are not explicitly regulated by cosmetics law, the basic requirement of Article 3 applies, according to which any product made available on the market must be safe for human health. Corresponding evidence must be compiled in the product information file of the respective product, ie in particular in the safety report.

Data from the raw material manufacturer

As a primary source for substance data, the raw material manufacturer and/or supplier should be consulted who can, as a rule, make available data for those applications and concentrations that he recommends. In this connection it must be taken into account that the raw material manufacturer can of course only make available data for his own substances in each case. A substance with the same name but from different manufacturers can have a different toxicological profile due to different production processes. In the event of positive list substances, ie colouring agents, preservatives and UV filters, it can as a rule be assumed that the substances have been tested by the public authorities and can be considered as safe for the described uses and the approved maximum concentration. Here, too, it is recommended to carry out an orienting review of the specifications in order to ensure that these substances have the standard market quality. The unequivocal chemical identity and defined composition are in most cases the basis for the preceding evaluation of the substance by the competent scientific advisory body of the European Commission (currently the SCCS, Scientific Committee on Consumer Safety, previously the SCCP, SCCNFP or SCC) and the subsequent legal provisions.

Data sources from public authorities or official organisations

For cosmetic products, communications should primarily be taken into account from authorities which are competent for consumer protection. In Germany these are BfR (Federal Institute for Risk Assessment), an advisory institution of the Ministry of Food and Agriculture (BMEL) and its risk management authority, the Federal Agency for Consumer Protection and Food Safety (BVL). Official publications by these authorities include in Germany the Federal Law Gazette *Bundesgesetzblatt*, the Federal Gazette *Bundesanzeiger*, the Journal for Consumer Protection and Food Safety of BVL or the Federal Health Gazette or the websites. The Federal Health Gazette occasionally publishes individual regulations governing substances as was in the past the case for instance for the contamination of surfactants with the banned dioxane, recommended maximum values for plants or plant ingredients or substances of animal origin (propolis) or, for instance, on limit values for formaldehyde, for heavy metals in cosmetic agents or in toothpaste. Other interesting sources for substance evaluations are on a national public authority level for instance the website of BfArM (Federal Institute for Drugs and Medical Devices), the UBA (Umweltbundesamt, Federal Agency for the Environment) the Federal Agency for Occupational Safety and Health (BAuA, legal texts on chemicals law and the commercial handling of substances or preparations) and the *Berufsgenossenschaften* (Employers' Liability Insurance Association), eg for workplace issues of the Institute for Occupational Safety and Health (IFA) of the Statutory German Accident Insurance.

Examples of consumer protection authorities of other EU member states: RIVM (NL), ANSM (FR).

On a European level the SCCS (Scientific Committee on Consumer Safety) acts as a scientific advisory body of the European Commission. Other relevant sources are the opinions of the former scientific advisory bodies (in particular SCCP and SCCNFP). Opinions of SCCS on a substance lead as a rule to a corresponding regulation on the substance at issue in cosmetics law.

Concerning legislation, the Official Journal of the European Union is the legally binding publication platform. The European Commission has published a lot of information on the internet on the legal regulation and safety of cosmetic products. Concerning many scientific issues, the EU bodies – the Commission as well as their Scientific Committees – organise public internet consultations. SCCS, in particular, makes even its opinions available to public comments in most cases. The CosIng Database not only includes the INCI designations of cosmetic ingredients but also contains partly more extensive references to the regulatory status of a substance or existing assessments by the mentioned scientific committees.

Raw material data from the dangerous substances law

Furthermore, the legally anchored raw material data have to be taken into account, as they are included in the German dangerous substances regulation and/or in European chemicals law. Cosmetic products are exempt from the classification and labelling under the dangerous substances law and/or the CLP Regulation (see below). Nonetheless the corresponding provisions on dangerous substances should be known for a substance assessment in order to take these data into due account at a safety assessment for a cosmetic product. In this connection it needs to be considered that provisions under dangerous substances law are, as a matter of principle, laid down on the basis of a potential danger at the workplace but the actual risk in connection with an application in end consumer products is not taken into account [eg the concentration in the product, such as exposure route (orally, dermally, inhalational) or the frequency and duration of applications]. This risk is as a rule much lower for products used in households such as cosmetic products, as the formal classification of an individual ingredient suggests under dangerous substances law. As a rule, the safety data sheet of a raw material provides the corresponding information.

On the website of the JRC (Joint Research Centre of the EU) a lot of information can be retrieved on the current and future dangerous substances law. The responsibility for chemicals law has been allocated on the EU level under the REACH Regulation to the European Chemicals Agency which is in charge of the implementation of the REACH Regulation 1907/2006, the CLP Regulation 1272/2008 (Classification and Labelling) as well as their legislative updates, intented upcoming issues and explanatory documents. The CLP Regulation is particularly relevant for the identification of existing and upcoming CMR-classifications. Upcoming CMR-classifications can be of direct impact, if the relevant substance is used as cosmetic ingredient.

Scientific assessments on issues relating to chemicals law are carried out by SCHEER (Scientific Committee on Health, Environmental and Emerging Risks) of the European Commission or its predecessor body CSTEE (Scientific Committee on Toxicity, Ecotoxicity and the Environment). These assessments are as a rule integrated into future chemicals law. Interdisciplinary issues, such as biological safety or nanotechnology, have been covered formerly by the EU advisory body SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks).

Further data and information on substances and certain issues

The European Food Safety Authority (EFSA) advises frequently on ingredients of foods which can also be relevant for cosmetic products.

RAPEX Notifications (Notifications under the EU Rapid Alert System for Dangerous Products) should likewise be taken into account in order to avoid known errors from being repeated. In the same way as RAPEX Notifications, information disclosed by investigations offices can help to avoid known errors. At present many annual reports of the investigation offices are freely available on the internet.

We list below, by way of example, some websites of German investigation offices which currently make available their annual reports on the internet free of charge (mostly available in German only):

- Bavarian Regional Office for Health and Food Safety
- Chemical and Veterinary Investigation Office Karlsruhe
- Chemical and Veterinary Investigation Office Freiburg
- Chemical and Veterinary Investigation Office Ostwestfalen-Lippe (CVUA-OWL)
- Chemical and Veterinary Investigation Office Rhein-Ruhr-Wupper (CVUA-RRW)
- Chemical and Veterinary Investigation Office Westfalen
- Regional Investigation Office Rheinland-Pfalz
- Lower Saxony Regional Office for Consumer Protection and Food Safety

Some Swiss investigation offices (cantonal laboratories) are likewise making available their investigation reports on the internet. Detailed investigation reports on cosmetic products are made available by the Cantonal Laboratory Basle City, as well as the Cantonal Laboratory Basle Countryside. On the homepage of the Cantonal Laboratory Zurich the summary annual reports can be downloaded. The other Swiss cantonal laboratories are likewise present on the internet.

Non-regulatory national/European information and data sources

In many cases a well thought-through search in the standard search engines (eg Google / selection of appropriate interlinking of keywords) provides already orienting results, whereby a discerning safety assessor can distinguish between relevant and serious sources and sources of a low scientific quality. In search engines one frequently finds already many of the above-mentioned official sources as well as the expert information referred to below.

On the national level, the following data sources can, for instance, be mentioned for Germany: Publications of the Federal Environmental Agency / Advisory body for existing substances, a body which had the mission – until 2007 – to review substances which were already on the market at the introduction of the Chemicals Act in 1980 in terms of safety and environmental compatibility. An overview of the reports with a reference to a commercial sourcing platform can be found under the link https://www.gdch.de/publikationen/weitere-publikationen.html. Both on a national level and on

an international level, substance reports can be inspected or acquired under the ICCA programme (International Council of Chemical Associations).

The annually updated MAK and BAT value list (available through the publisher John Wiley & Sons) applies, more specifically, to occupational safety in handling the corresponding substances. In many cases supplementary detailed reports can be obtained on the individual substances. The two sources are also available online – partly on a fee basis.

The Publications of the Council of Europe, eg on plants, the series of directories "Plants in Cosmetics", Volume 1-3 and the publication "Active Ingredients Used in Cosmetics" are relevant in Europe but not legally binding.

ECETOC reports can be obtained from the European Centre for Ecotoxicology and Toxicology of Chemicals in Brussels. In this connection special reference is made to the JACC reports including, for instance, a report on hydrogen peroxide. BIBRA, a British organisation, also makes available reports on chemical base materials.

HERA (Human and Environmental Risk Assessment) is an approach by AISE (International Association for Soaps, Detergents and Maintenance Products). Substance reports, more particularly on important ingredients for detergents and cleaning agents, are available here. Some of these substances (eg certain surfactants) are also relevant for cosmetic products.

IVDK – German Information Network of Dermatological Hospitals – collects information from the networked hospitals about cases of allergy and covers them in corresponding publications.

The Toxicology Forum is a scientific series of events which occasionally also raises and covers topical issues.

For perfumes, a process has been established according to which a perfume manufacturer makes available a corresponding Perfume Certificate (including a safety assessment) for the desired application. In the event of special interest or specific issues, a comprehensive search can be carried out on the pages of the International Fragrance Association (IFRA). The self-regulation strategy of this industry is, for instance, published in the so-called IFRA Code of Practice, which defines, amongst others, standards for individual fragrances.

Official sources on an international Level

On an international level publications by the World Health Organisation (WHO) or by JECFA (Joint FAO/WHO Expert Committee on Food Additives), the advisory body of the WHO for food additives, have to be mentioned. Another relevant institution on an international level is the OECD, which publishes both test methods and toxicological reports on individual substances (in particular on so-called HPV Substances - HPV = High Production Volume, substances which are used in high volumes).

SIDS Reports on HPV Substances (SIDS: Chemicals Screening Information Datasets) are likewise available on the internet.

Another institution of WHO is IARC (International Agency for Research on Cancer) which makes substance monographs available.

Furthermore, publications from the USA can be useful sources of information. In this connection reference is made, more particularly, to the CIR reports (Cosmetic Ingredient Review), which are elaborated with the participation of the US Personal Care Product Council (PCPC). Further sources for toxicological data in the USA can be: FDA (Food and Drug Administration), EPA (Environmental Protection Agency), NTP (National Toxicology Program).

4. Literature

Examples for Standard Reference Publications

- Fiedler: Lexikon der Hilfsstoffe für Pharmazie, Kosmetik und angrenzende Gebiete (Encyclopedia of Excipients for Pharmaceuticals, Cosmetics and Related Areas)
- Römpp Chemie Lexikon/Römpp Online
- Merck Index
- Hagers Enzyklopädie der Arzneistoffe und Drogen
- Martindale: The complete drug reference
- BLUE LIST Cosmetic Ingredients

Scientific journals

The following journals include sometimes articles on cosmetic products or substances which can be used as raw materials in cosmetic products. They can be obtained through the respective publishing house, bookshops or libraries; some have an internet presence under the name of the respective magazine.

- Bundesgesundheitsblatt – Gesundheitsforschung – Gesundheitsschutz
- Food and Chemical Toxicology
- Journal für Verbraucherschutz und Lebensmittelsicherheit des BVL
- Mutation Research
- Regulatory Toxicology and Pharmacology
- Reproductive Toxicology
- Birth Defects Research Part A: Clinical and Molecular Teratology – formerly: Teratology
- Toxicology and Applied Pharmacology
- Cosmetics & Toiletries

- Parfümerie und Kosmetik (publication stopped) – today: COSSMA
- SOFW Journal

- Further information and literature – selected special interest publications

Further Literature and Sources of Information

- Website of Cosmetics Europe (previously Colipa), Sections Publications/Guidelines/ Recommendations
- German Society for Scientific and Applied Cosmetology (DGK)
- kosmet (database of the International Scientific Federation of Scientific Cosmetic Chemists, IFSCC)

Scientific publications (individual magazine articles) can be obtained, if required, through different services, eg the aforementioned kosmet database, from the publisher itself or the document delivery service Subito.

Data Quality

The quality of data from toxicological studies or publications is essential for an assessment of their validity. Basic and currently broadly accepted statements and quality criteria were published in a paper by Klimisch et al: *H.-J. Klimisch, M. Andreae and U. Tillmann: A Systematic Approach for Evaluating the Quality of Experimental Toxicological and Ecotoxicological Data; Regulatory Toxicology and Pharmacology, 25 (1997), 1-5*.

Online Research

As far as online research by electronic means is concerned, there are two possibilities (sources):

Commercial services in online databases such as DIMDI, STN, RTECS, PubMed and others. This requires a certain expert knowledge and participation in training, since specific query routines have to be observed to obtain all information. Partly a free of charge preliminary research is possible but further access to the documents found may then be subject to fees.

Research on cosmetics and chemicals safety without prior fee-based registration. Many different sources can be mentioned which can be subdivided, for instance, as follows:

- Meta data sources on chemical safety, such as from certain universities
- News pages on the safety of cosmetic products or their ingredients which have partly already been described, eg BfR, BMEL, IKW, Cosmetics Europe, SCCS, EU Commission, CIR, FDA etc.
- TOXNET (Toxicology Data Network – Databases on toxicology, hazardous chemicals, environmental health, and toxic releases), also covers some other databases
- RTECS (Registry of Toxic Effects of Chemical Substances)
- Scientific journals such as Nature, Science, Bild der Wissenschaft etc.
- Free text search in search engines such as Google etc.

Warning on wrong Internet information

Please note: The internet is a system in which everybody can publicly circulate without any filter (eg by a responsible and competent publisher) any information. This has the adverse effect that occasionally negative internet publications appear on some substances with wrong (pseudo) information. Unfortunately this negative and wrong information is taken up by the public at large with great interest and continues to be circulated so that the manufacturers of cosmetic products receive permanently a lot of unfounded enquiries eg allegedly carcinogenic sodium lauryl sulphate or the alleged induction of breast cancer by aluminium compounds in antiperspirants. These accusations are identified by companies, expert scientists and the competent authorities immediately as untenable but can only be corrected with a high expenditure in terms of time and staffing – if at all.

Particularly striking fake information on the internet or chain letters are disclosed as fakes on websites such as the "Hoax info pages" of TU Berlin or on the website "Urban Legends".

See also "Assessments of cosmetic ingredients by apps and online portals".