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Cosmetovigilance in the Netherlands 2016–2017

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Cosmetovigilance in the Netherlands 2016–2017

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Colophon

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Synopsis

Cosmetovigilance in the Netherlands 2016–2017

Cosmetics are in principle safe to use. In some cases, however, cosmetic products may lead to undesirable reactions, such as itching and erythema. In 2009, the RIVM set up a monitoring system in which participating dermatologists can register undesirable and allergic reactions caused by cosmetics: Consumer Exposure Skin Effects and Surveillance (CESES). In the period under consideration, as in previous years, undesirable and allergic reactions mainly occurred on the face and hands after using skin/facial care and hair products. Most patients were diagnosed with contact allergy. Again as in previous years, isothiazolinones (preservatives) and fragrances were the ingredients causing most of the allergic reactions.

This report provides an overview of the 90 notifications received within CESES in the period October 2015–October 2017. Dermatologists carry out patch tests and, where necessary, tests on specific ingredients of the associated cosmetic products.

Isothiazolinones are widely recognised as an important cause of contact dermatitis. For this reason, the use of the potent allergen methylchloroisothiazolinone/methylisothiazolinone (MCI/MI) was prohibited in leave-on products in 2015. In rinse-off products it may be used in a concentration up to 0.0015%. The same limitations will start to apply to methylisothiazolinone (MI) in 2018. Only one notified case could be attributed to MCI/MI in the last two years. It is expected that in the course of 2018 the incidence of notifications caused by MI in cosmetics will decline. It is not yet clear what preservative(s) will replace MI, and developments will be closely followed.

Three cases of allergic reactions to (meth)acrylates in nail products were reported. As this is an increase over previous years, this development will be monitored.

To encourage the notification of cases within CESES, support was provided to one of the participating clinics to fill in the questionnaire. Considering the success of this experiment, we will investigate the options to continue this support and extending it to the other clinics. An update of the questionnaire in August 2017 enabled dermatologists to notify reactions to tattoos and tattoo aftercare products. Although these are not cosmetic products, they sometimes contain sensitizing substances and reactions to these products are not yet monitored.

Keywords: cosmetics, undesirable reactions, monitoring, cosmetovigilance, contact allergy

Publiekssamenvatting

Huidklachten door cosmetische producten in Nederland 2016-2017

Cosmetica zijn in principe veilig, maar kunnen soms huidklachten veroorzaken, zoals roodheid en jeuk. Het RIVM beheert sinds 2009 een monitoringssysteem waarin deelnemende dermatologen ongewenste en allergische reacties na gebruik van cosmetica kunnen registreren (CESES, Consumer Exposure Skin Effects and Surveillance). Net als in voorgaande jaren meldden de dermatologen vooral klachten op het gezicht en de handen na gebruik van huid- of gezichtsverzorgingsproducten en haarproducten. De meest gestelde diagnose is contactallergie. Net als in voorgaande perioden veroorzaakten de conserveringsmiddelen isothiazolinonen en geurstoffen de meeste allergische reacties.

Dit blijkt uit een overzicht van de negentig meldingen die binnen CESES tussen oktober 2015 en 2017 zijn afgerond. Om te bepalen welk ingrediënt de klacht veroorzaakt, voeren dermatologen bij deze patiënten een allergieonderzoek uit, indien nodig met specifieke ingrediënten uit het verdachte product.

Isothiazolinonen zijn al lange tijd bekende veroorzakers van contactallergie. Daarom mag het mengsel methylchlorisothiazolinon /methylisothiazolinon (MCI/MI) sinds 2015 alleen nog worden gebruikt in producten die je afspoelt in een lage concentratie (0,0015 procent). Deze beperkingen gaan in 2018 ook gelden voor methylisothiazolinon (MI).

In de afgelopen twee jaar is er maar één klacht gemeld over MCI/MI. Naar verwachting zal ook het aantal klachten door MI verminderen. Wel moet in de gaten worden gehouden of eventuele vervangende conserveringsmiddelen ongewenste reacties veroorzaken.

Er waren drie meldingen van allergische reacties op (meth)acrylaten in nagelproducten. Aangezien dat er meer zijn dan in voorgaande jaren, wordt dit nauwgezet in de gaten gehouden.

Om te stimuleren dat klachten in CESES worden gemeld, is een van de klinieken ondersteund bij het invoeren van de gegevens in de vragenlijst. Onderzocht wordt of deze succesvolle proef ook bij andere centra kan worden uitgevoerd.

In augustus 2017 is er een update van de vragenlijst uitgevoerd waardoor het mogelijk is klachten te melden die door tatoeages en 'nazorproducten' voor tatoeages worden veroorzaakt. Strikt genomen zijn dit geen cosmetische producten, maar ze bevatten soms allergene stoffen en er bestaat nog geen monitoringssysteem voor.

Kernwoorden: cosmetica, huidklachten, monitoring, cosmetovigilance, contactallergie

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Summary

This report summarises the notifications received in the clinical route of the CESES project between October 2015–2017. These notifications from dermatologists describe undesirable reactions attributed to the use of cosmetics under normal, foreseeable, circumstances. Between October 2015 and October 2017, 90 notifications were finalized, of which 89 were also initiated in this period. Erythema, scaling and itching were the most often reported symptoms. As in previous CESES reports, skin and hair products were the most reported product types and most of the reactions reported were on the face and hands.

Patch tests showed that fragrances and isothiazolinones were responsible for the majority of the undesirable reactions (46% and 21% of the cases, respectively).

Isothiazolinones are widely recognised as an important cause of contact dermatitis. The use of methylchloroisothiazolinone/methylisothiazolinone (MCI/MI) in leave-on products was prohibited in 2015. As a result, only one notified case in the last two years could be attributed to MCI/MI; the other fourteen reactions to isothiazolinones were attributed to MI.

Recently, the concentration limit of MI was re-evaluated in the EU and it will be lowered to 0.0015% in 2018. The use of MI in leave-on products will also be prohibited. The expected reduction in the allowed use/concentration of MI should lead to a reduction in allergic reactions to isothiazolinones, but it may lead to an increased use of other preservatives, which may also give rise to contact allergy in humans. Three cases were reported of adverse reactions to (meth)acrylates in nail products. As these substances are under scrutiny at European level, further developments will be closely monitored by the Dutch authorities. In an update of the CESES questionnaire, tattoos were added as a product group. Tattoos are known sometimes to cause (severe) allergic reactions, but there is still much uncertainty regarding the incidence and allergens involved.

To increase the number of notifications, support was provided by RIVM to one of the participating clinics. Considering the success of this experiment, we will try to continue this support and investigate providing similar assistance to the other clinics.

1 Introduction

The Consumer Exposure Skin Effects and Surveillance (CESES) project was initiated by the RIVM in 2009, at the request of the Netherlands Food and Product Safety Authority (NVWA) and the Ministry of Health, Welfare and Sport (VWS). The aim of the project is to monitor undesirable reactions attributed to cosmetics products. These monitoring data are used to gain insight into the incidence and prevalence of undesirable reactions to cosmetics and to assist in the identification of the specific products and product ingredients responsible for these reactions. This knowledge can in turn contribute to the regulation of cosmetics in the EU. A complete overview of the background and goal of the CESES project can be found in previous reports and in a scientific paper (Salverda-Nijhof et al. 2011; De Wit-Bos et al. 2012; Salverda et al. 2013).

This report provides an overview and discussion of the notifications obtained in the period 1 October 2015 – 1 October 2017. With one exception, all the notifications were also initiated in this period. As the public route for complaints on cosmetics is no longer organized by the RIVM but by the NVWA, only dermatologist notifications will be discussed in depth. A short summary of the consumer complaints reported to the NVWA is given in Chapter 2.

The dermatologists who reported undesirable reactions in the past two years are part of six participating dermatological centres. These centres comprise four academic hospitals (Erasmus MC, UMCU, VUMC and UMCG) and two peripheral hospitals (St Antonius Hospital and VieCurie Hospital).

Within the CESES project, an undesirable reaction is defined as any adverse effect attributed to the use of cosmetics under reasonably foreseeable conditions.

Due to increased interest in the incidence and causality of allergic reactions to tattoos, the option to report these reactions was included in the update of the questionnaire in August 2017.

2 Consumer complaints reported to the NVWA

A short summary is provided here of the consumer complaints relating to adverse health effects caused by cosmetics. These complaints were received by the NVWA in 2016 and 2017.

In 2016, fourteen complaints and seven serious undesirable effects (SUEs, defined in the Cosmetics Regulation as 'undesirable effects which result in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death') were registered by the NVWA. In 2017 there were 34 complaints and five SUEs. All SUEs were reported by responsible persons or importers.

Five complaints in 2017 related to products that fall under the directive for medical devices; however, as four of these were toothpastes, they have been reported as cosmetics in the questionnaire. Most toothpastes are cosmetics, with the exception of toothpastes marketed for medicinal use, which can be recognised by a CE mark.

Seven of the twelve SUEs were caused by (oxidative) hair colourants. Symptoms included swelling, blisters, itching and pain on the scalp and face.

Most remarkable was the large number (10) of complaints caused by toothpaste in 2017, seven of which were of the same type and brand. Symptoms included redness and painfulness of the gums and tongue and swelling of the lips. The NVWA is currently seeking to resolve this issue.

The causal agent could be identified in only one case, namely peanut oil in a cream. As the presence of this ingredient was only reported in Latin on the packaging, it was not recognised by a consumer with a peanut allergy.

3 Overview of notifications from dermatologists

A general overview of the notifications by dermatologists finalized in the period October 2015– October 2017 is provided here.

The results are analysed in the following ways:

- A general analysis (Sections 3.1–3.5) of the information provided in all notifications (e.g. occupation, description of the undesirable reaction and product details).
- Results of patch tests with the European Baseline series and of the patch tests on cosmetic products and their batch-specific ingredients (Section 3.6–3.8).

3.1 Number of undesirable reactions

In the period between 1 October 2015 and 1 October 2017, dermatologists finalised 90 case reports of undesirable reactions. Figure 1 shows the number of notifications initiated by dermatologists per month. Only one notification started before October 2015. Particularly remarkable are the high numbers of notifications at the end of 2015 and in the last three months of 2017. The former consisted of notifications from several clinics. The latter can be explained by the additional support provided at the VUMC for the notification of cases.

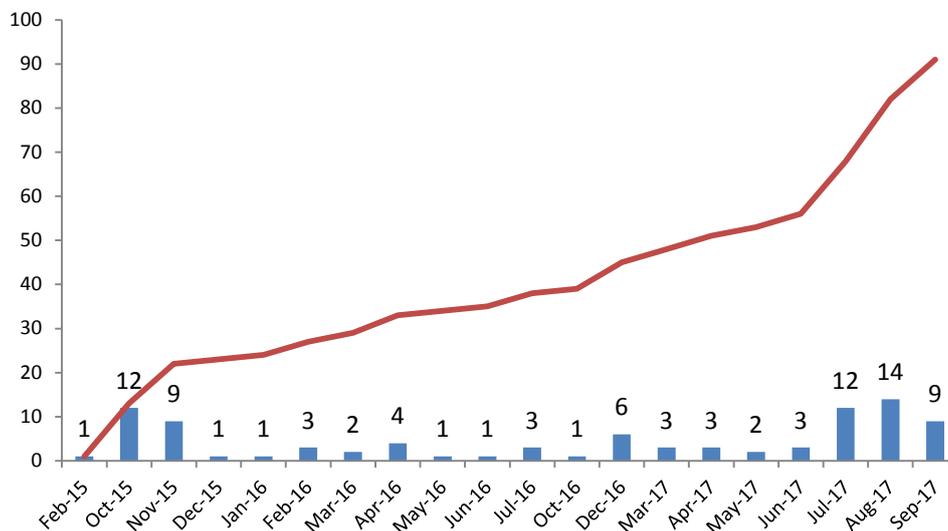


Figure 1: Number of notifications per month and cumulative numbers between 1 October 2015 and 1 October 2017

Figure 2 shows the number of notifications per participating dermatological centre in the reporting period.

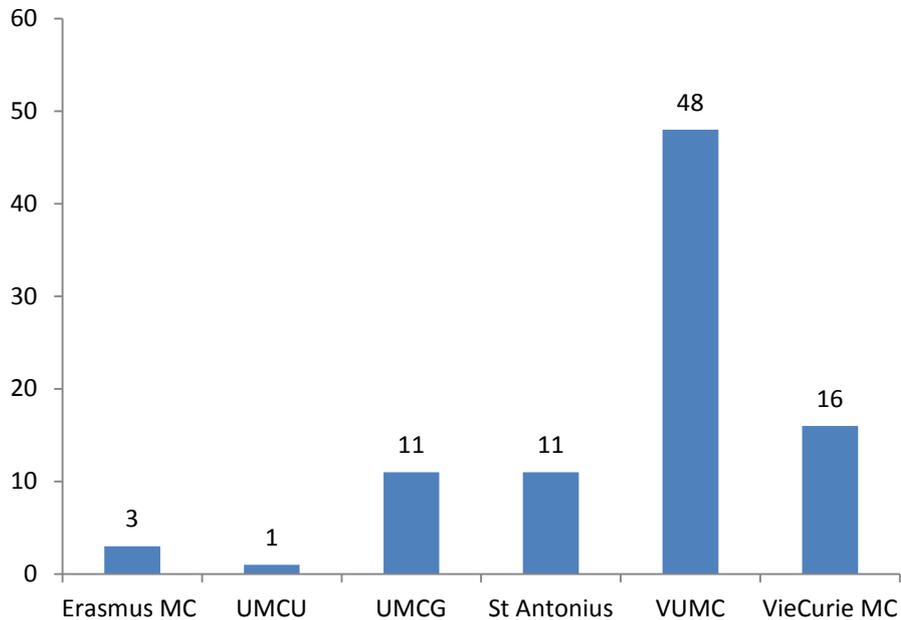


Figure 2: Number of notifications per participating dermatological centre

3.2 Description of the undesirable reactions

The largest number of undesirable reactions occurred on the face (24%, n=45), followed by the hands (18%, n=34), neck (11%, n=21) and arms (10%, n=18) (Figure 3). This distribution is generally similar to earlier reports, although the percentage of reactions reported for eyes and eyelashes is somewhat lower in the present report.

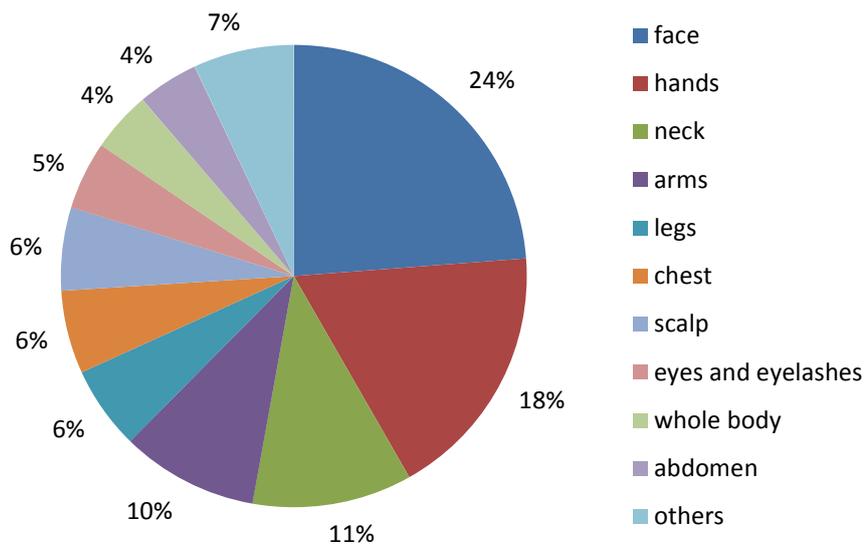


Figure 3: Reported location of undesirable reaction after cosmetics use in % (n=188). The category 'others' includes lips, armpits and back.

The reported symptoms included mainly erythema (27%, n=75), scaling (20%, n=55) and itching (16%, n=44). Oedema (8%, n=22), papules

(10%, n=28) and plaques (7%, n=19) were the next most frequently reported symptoms (Figure 4). A severe reaction was observed in only one case (1%) and concerned pain.

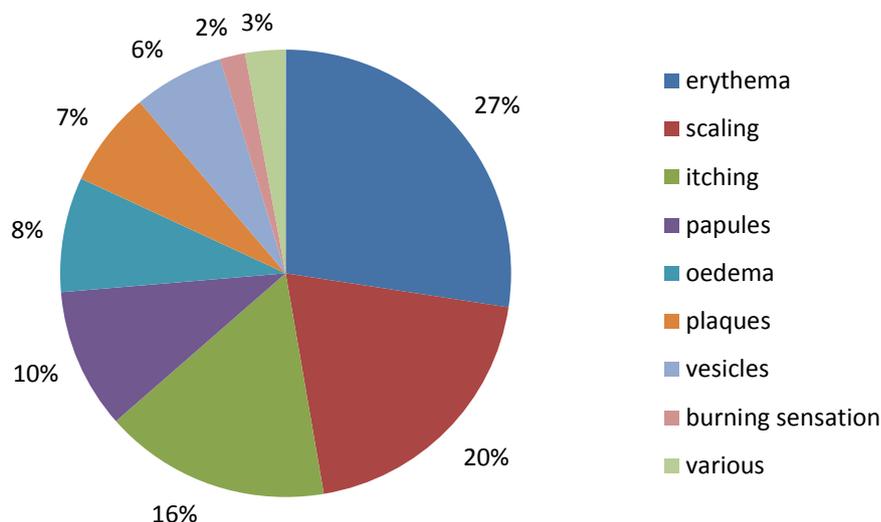


Figure 4: Reported symptoms of undesirable reaction after cosmetics use in % (n=274). The category 'various' includes hypokeratosis.

Most patients (73%, n=59) stated that they did not know when the undesirable reaction had started, and about a quarter of all patients were still suffering from the reaction when they visited the dermatologist. For 17% (n=12) it was not the first time they had had an undesirable reaction to the respective cosmetics product. In these cases, the reaction was either equal in severity (67%) or more severe (33%) in comparison with previous reactions.

3.3 Cosmetic products

For all patients, the dermatologists reported one or more cosmetic products as allegedly responsible for the undesirable reaction. They reported a total of 95 suspected products. The most frequently reported product category was skin products (35%, n=33) followed by hair products (26%, n=24); see Figure 5 for an overview. Make-up was reported 12 times (13%) and bath/shower products 10 times (11%), all other products a maximum of 4 times.

Most of the reported skin products were body lotions and day/night creams, but there were also three reported reactions to massage oils and, unusually, one reaction to neem oil (a vegetable oil pressed from the fruits and seeds of the neem tree (*Azadirachta indica*)). The hair products were mostly shampoos; they also included one styling wax and one hair dye.

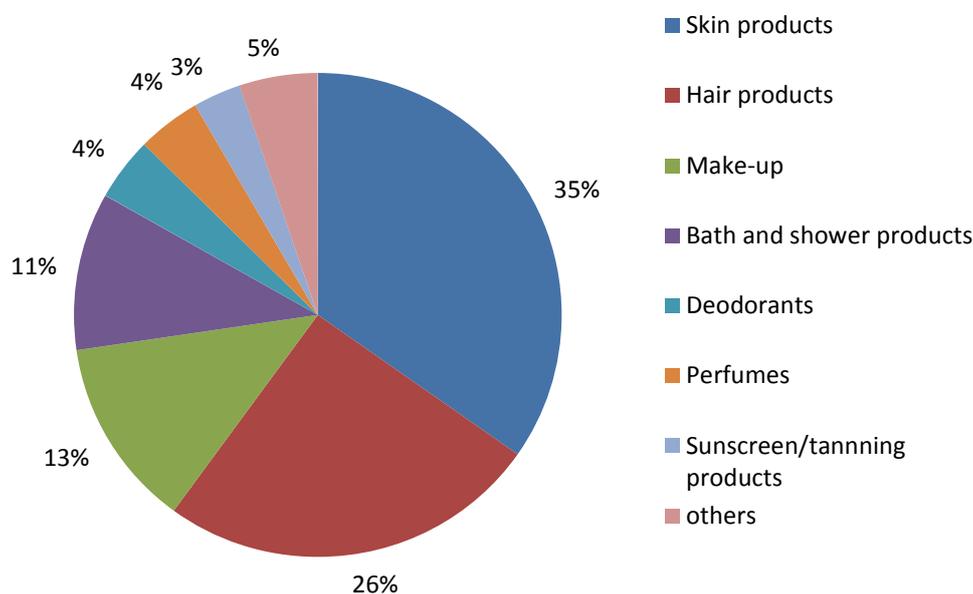


Figure 5: Categories of reported products that probably caused an undesirable reaction in % (n=49). The category 'others' includes shaving products, soaps and mouth care products.

3.4 Factors possibly related to the undesirable reaction

In 8% of the cases (n=7) a causal relationship was reported between the reaction and occupation (three beauty specialist/nail stylists, one cook, one catering assistant, one physician and one surgery assistant) and in seven cases this relationship was possible, but not confirmed. Thirty patients (33%) also suffered from other skin problems than those reported, mostly constitutional eczema, and 45 patients (51%) from an allergy.

3.5 Diagnosis and treatment

The final diagnosis was filled in for 88% of the patients (n=79). Based on the medical history, physical examination and the results of diagnostic patch testing, 84% of these patients (n=66) were diagnosed with one condition, which was allergic contact dermatitis. The other 13 patients were diagnosed with a combination of allergic contact dermatitis and other allergies or skin conditions.

Treatment was described for 88 patients, often consisting of a combination of treatments, including local corticosteroids, avoidance of the allergen, and/or emollients.

3.6 Patch tests

All 90 patients were patch tested with the European baseline series and 98% (n=88) of patients had a positive response to one or more allergens. Positive responses were mainly to MCI/MI and/or MI (27%, n=23, counting patients reacting to both substances as one positive) and fragrance mix I (31%, n=27). Other substances that tested positive relatively often were nickel sulphate (20%, n=18), fragrance mix II (19%, n=17), cocamidopropylbetaine (15%, n=13) and myroxylon pereirae (Peru balsam, 13%, n=11) (see Table 1).

The use of nickel sulphate in cosmetics products is prohibited, meaning that these reactions were likely not the result of using cosmetics. There were also 53 reactions (60%) to a variety of other substances, including dimethylaminopropylamine (DMAPA, n=4), wool-alcohols (n=4), tea tree oil (n=3), geraniol (n=2) and (meth)acrylates (n=3) (see Section 5.1).

Table 1: Patch test results with European baseline series and additional substances in patients seen by participating dermatologists reported in the period 2015–2017 (top 10)

Allergen	% positive
Fragrance mix I	31%
MI and/or MCI/MI (Kathon CG ®)	27%*
Nickel sulphate	20%
Fragrance mix II	19%
Cocamidopropylbetaine (CAPB)	15%
Myroxylon pereirae	13%
Amerchol L 101	9%
Formaldehyde	8%
Benzophenone 4	8%
PPD (Paraphenylenediamine)	8%

* Twelve patients (14%) were sensitised to both MI and MCI/MI, five (6%) to MCI/MI and six (7%) to MI only.

An additional patch test with the batch-specific ingredients of the cosmetics product was performed in two cases. In both cases none of the substances was positive and in one case the reactions to the products were equivocal. Thus, it was not possible to confirm a causal relationship between the product and the reaction.

3.7 Causality assessment

A senior dermatologist assessed the likelihood that an ingredient in the product caused the undesirable effect(s). This assessment was based on the outcomes of the European Baseline patch test series, information on the ingredients of the cosmetic product(s) and, when performed, the patch test with batch-specific ingredients of the cosmetic product. Regarding the outcomes of the European Baseline patch test series, only relevant cosmetic allergens (i.e. allergens used in cosmetics) were taken into account for causality assessment. A causal relationship between the undesirable reaction and the reported cosmetic product could be established for 70 (80%) of the 90 patients. For 43 of the 90 patients (48%) this causality was likely and for 27 patients (30%) very likely. The causality was unlikely or questionable for 20 patients (22%); in these cases it was not possible to determine what ingredient caused the reaction.

In one case the product was not available in Europe and in two cases the product was not a cosmetic but a (hand) disinfectant, and in another it was a medicinal shampoo containing coal tar. These products do not fall within the scope of the CESES.

Table 2 gives an overview of the final diagnosis of the causative agent if the causality of the reaction was likely or very likely. The differences from Table 1 are caused by the absence of the cases with an unlikely/questionable causality and because there are substances that

tested positive in the patch test, but were not present in the cosmetics product that supposedly caused the complaint.

All fragrances have been taken together, as these are not always specified in the ingredients list, which means that it is often unclear exactly which substance is responsible for the reaction. In addition, related fragrances often display cross-sensitisation to each other. Myroxylon pereirae (Peru balsam), tea tree oil and propolis are also indicative for fragrance allergy and have been included in this group.

Table 2: All ingredients for which a causal relationship was reported in the period 2015–2017

Allergen	N positive (out of 70)	% positive
Fragrances*	32	46%
MI	14	20%
Cocamidopropylbetaine (CAPB)	8	11%
PPD	6	9%
(Meth)acrylates	3	4%
Cetyl alcohol	2	3%
MCI/MI (Kathon CG ®)	1	1%
Dimethylaminopropylamine DMAPA)	1	1%
Lanoline	1	1%
Neem oil	1	1%
Iodopropynyl butylcarbamaat	1	1%
Formaldehyde	1	1%
Tocopherol	1	1%

* Including fragrance mix I & II, individual fragrances and fragrance indicators (Myroxylon pereirae (Peru balsam), tea tree oil and propolis)

4 Publications

In the period 2015–2017, three papers were published on interesting case reports resulting from the CESES project.

The first was a case of allergic contact cheilitis probably caused by olaflur, an amine fluoride used in only one brand of toothpaste. This report appears to be the first documenting contact allergy to olaflur specifically. Two cases of allergic reactions to amine fluoride had previously been reported but, in those cases, the exact chemical nature of the amine fluoride remained unclear (De Groot et al. 2017b). The notification on which this publication was based is not included in this report because the case was closed before 1 October 2015.

The second case report (De Groot et al. 2017a; Jagtman et al. 2017a) discussed a case of allergic contact dermatitis caused by neem oil. Neem oil (synonyms: *Melia azadirachta* seed oil [INCI name], nim oil, margosa oil) is a vegetable (fixed) oil obtained from the seed of the neem tree, *Azadirachta indica*, by cold pressing. Contact allergy to neem oil had previously been described in only three patients. The allergen(s) in neem oil is/are unknown.

The third case was a patient with allergic contact dermatitis on the palms of the hands, the forehead and hair margin caused by iodopropynyl butylcarbamate (IPBC) in a hair styling wax. Routine testing in two tertiary referral centres in The Netherlands yielded high prevalence rates of sensitisation (3.9% in the period 2009–2012), but as IPBC often induces false-positive reactions due to irritation, the actual incidence will be lower. Because most reactions caused by IPBC are caused by its use in cosmetics, inclusion of this preservative in a cosmetics series is recommended (Jagtman et al. 2017b).

5 Discussion

5.1 Identification of cosmetic products and product ingredients

Isothiazolinones

The ingredients that caused the most reactions were fragrances and the preservative methylisothiazolinone (MI) and/or its mixture with methylchloroisothiazolinone (MCI/MI). Both fragrances and isothiazolinones have been recognised as potent allergens and were also the primary causative agents in previous years. The total number of positive patch-test reactions to isothiazolinones has been relatively stable at around 30% since 2009.

The high incidence of allergic reactions to MI and/or MCI/MI as indicated by cosmetovigilance data has resulted in a more stringent restriction of these substances. The use of MCI/MI as a preservative in cosmetic products was prohibited in leave-on products in 2015 and the concentration limit in rinse-off products was set at 0.0015%. The same limitations will start to apply to MI in 2018 (for new products from 27 January and for products already on the market from 27 April).

In the last two years about an equal number of patients reacted to MI and MCI/MI in the patch test. In the period 2009–2014, there were about twice as many positive reactions to MCI/MI as to MI (De Wit-Bos et al. 2014). This change is likely the result of the shift in use from MCI/MI to MI in cosmetic products. Only one product still contained MCI/MI in 2015–2017; in the other fourteen cases, MI was probably the cause of the reaction.

It is expected that in the course of 2018 the incidence of notifications caused by MI in cosmetics will decline. It is not yet clear what preservative(s) will replace MI; developments will be closely followed.

Cocamidopropylbetaine

Cocamidopropylbetaine (CAPB) tested positive in 15% of the notifications and for almost all of those (11% of the notifications) a causal relationship was determined. This is consistent with previous years, when the prevalence was 12% (De Wit-Bos et al. 2014; Woutersen and Bakker 2016). CAPB is a relatively mild surfactant that is used in a wide range of shampoos and soaps. Reported use concentrations range from 0.2% to 25%. Its sensitising properties are considered to be related to the presence of impurities DMAPA and the fatty acid amidopropyl dimethylamine (amidoamine). For this reason, the Cosmetic Ingredient Review (CIR) Expert panel concluded that CAPD is safe in cosmetics as long as they are formulated to be non-sensitising, which may be based on a Quantitative Risk Assessment (QRA) for skin sensitisation (Burnett et al. 2012). However, there is no concentration limit for CAPB in cosmetics in Europe, nor specific criteria for its impurities.

(Meth)acrylates

Of particular interest are the reactions to (meth)acrylates. Recently, Sweden raised an alert to the Commission and the Competent Authorities of the Member States because they had noted several severe allergic reactions to (meth)acrylates in gellack (see RAPEX notification A12/1226/14). Gellack is a type of nail product that contains

(meth)acrylate monomers, which are cured under a UV lamp. As (meth)acrylate monomers are sensitizers, exposure of the skin poses a risk of skin sensitization. In response to these concerns, the Scientific Committee for Consumer Safety (SCCS) recently published an opinion on 2-hydroxyethyl methacrylate (HEMA). It was concluded that, as long as contact with the skin is prevented, the use of HEMA in nail systems up to 35% does not pose a risk to the consumer. However, it was also indicated that the risk for professionals will probably be higher and that, considering the increased popularity of these nail systems for use at home, the incidence should be kept under surveillance (SCCS 2017).

In previous CESES reports, (meth)acrylates were not specifically mentioned and the background data show that the incidences were very low, with only two reactions to ethyleneglycoldimethacrylate and one to ethyl acrylate between 2009 and 2014. Thus it is noteworthy that three cases were reported in the last two years. One was a reaction specifically to HEMA in gellack, the other two to a mixture of (meth)acrylates in nail products. Two patients worked as nail stylists, in addition to personally using nail products.

It is still too early to determine whether these incidences are the start of a rising trend, or coincidental. Additional attention should be paid to these substances to determine whether further action is warranted.

5.2 Addition of tattoos and tattoo aftercare products to CESES

In recent years, there has been an increase in the popularity of tattoos and there are indications that they may induce a relatively high number of adverse reactions, including allergic contact dermatitis (Bassi et al. 2014; Brady et al. 2015). Measurements by the NVWA of black tattoo inks shows that these often contain harmful substances, in particular poly-aromatic hydrocarbons (PAHs) and heavy metals (NVWA 2017). Research shows that in particular red inks are relatively often the cause of allergic reactions (Wenzel et al. 2013).

As there is still a high level of uncertainty regarding which substances induce the adverse reactions, it was decided to add tattoos as a product group to the CESES questionnaire, although they are not cosmetic products. In the update of the questionnaire from August 2017, both permanent and temporary tattoos were added as product categories in the questionnaire.

As there were no finalized notifications of reactions to tattoos at 1 October 2017, there are no results in this report. It is expected that these will be discussed in the report over the results of 2018.

5.3 Number of notifications

The number of notifications must be sufficiently high to have the statistical power to detect changes in the incidence of allergic reactions to specific substances. However, the notification of cases is relatively time-consuming, and we see a decline in notifications over the years. To counter this, an experiment was started in 2017 in which support by the RIVM was provided to VUMC. As shown in Figure 1, this resulted in a strong increase in the number of notifications. Considering the success of this experiment, we will consider continuing this support and extending it to the other clinics.

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