

## ORIGINAL ARTICLE

# Contact allergy to rubber accelerators remains prevalent: retrospective results from a tertiary clinic suggesting an association with facial dermatitis

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## Abstract

**Introduction** Chemicals used for the manufacturing of rubber are known causes of allergic contact dermatitis on the hands. Recent European studies have suggested a decrease in thiuram contact allergy. Moreover, while an association with hand dermatitis is well established, we have recently observed several clinical cases with allergic facial dermatitis to rubber.

**Objectives** To evaluate temporal trends of contact allergy to rubber accelerators from the European baseline series in a tertiary patch test clinic in Denmark, and examine associations with anatomical locations of dermatitis.

**Methods** Patch test and clinical data collected in a Danish tertiary dermatology clinic in Gentofte, Herlev, Copenhagen between 1 January 2005 and 31 December 2014 were analysed. The following rubber accelerators or mixtures in petrolatum from the European baseline patch test series were included: thiuram mix 1.0%, mercaptobenzothiazole 2.0% and mercapto mix 1.0%.

**Results** The overall prevalence of contact allergy to rubber accelerators was 3.1% with no significant change during the study period ( $P_{\text{trend}} = 0.667$ ). Contact allergy to thiuram mix was the most prevalent and was significantly associated with occupational contact dermatitis, hand dermatitis, age >40 years and facial dermatitis in adjusted binary logistic regression analysis. Current clinical relevance of contact allergy to thiuram mix was 59.3%. Patients with contact allergy to mercapto mix and mercaptobenzothiazole had a concomitant reaction to thiuram mix in 35.2% (19/54) and 35.4% (17/48) of the cases respectively.

**Conclusion** Contact allergy to rubber accelerators remains prevalent. Clinicians should be aware of the hitherto unexplored clinical association with facial dermatitis.

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## Conflicts of Interest

All authors declare no conflicts of interests.

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## Introduction

While alterations in the production of protective rubber gloves have decreased the risk of immediate type allergic reactions to latex proteins, glove manufacturers add allergenic rubber accelerators to speed up vulcanization.<sup>1,2</sup> Common rubber accelerators include thiurams, carbamates and mercaptobenzothiazoles and these can all result in delayed type allergic reactions

manifesting as allergic contact dermatitis. The following rubber contact allergens or mixtures in petrolatum are currently recommended in the European baseline patch test series: thiuram mix 1.0%, mercaptobenzothiazole 2.0%, and mercapto mix 2.0%.<sup>3</sup> However, the European Surveillance System on Contact Allergies (ESSCA) recently recommended inclusion of carba mix in the baseline series as an increasing trend of contact sensitization to

carba mix has been observed.<sup>1,4</sup> This comprehensive retrospective observational multicentre study of patch test results from 53 departments in 12 European countries further showed that the prevalence of contact allergy to rubber accelerators ranged between 1.7% and 2.4% across European countries, but notably that the prevalence of contact allergy to thiuram mix had significantly decreased between 2009 and 2012.<sup>2</sup>

A former Danish study from our department showed that the prevalence of positive patch test reactions to thiuram mix significantly decreased from approximately 4% in 1995 to 2% in 2004.<sup>5</sup> This change was ascribed to a general substitution at the time to less allergenic rubber accelerators such as carbamates. Moreover, mandatory leaching, that is, 'washing out' latex proteins from rubber protective gloves during production, primarily was introduced to prevent consumers from being excessively exposed to latex proteins, might at the same time have decreased the overall content of rubber accelerators in rubber protective gloves.

While hand eczema and occupational contact dermatitis are known to be associated with contact allergy to rubber accelerators, we have made the clinical observation that facial dermatitis is surprisingly frequent in patients with rubber allergy and often caused by rubber contamination. Thus, we recently published clinical cases of reluctant facial dermatitis caused by indirect or airborne exposure to rubber accelerators.<sup>6–8</sup> In this study, we investigated the temporal development of contact allergy to thiuram mix, mercapto mix and mercaptobenzothiazole in Herlev-Gentofte Hospital, Denmark between 1 January 2005 and 31 December 2014 and identified high-risk occupations for contact allergy to thiuram mix. Finally, we explored whether rubber allergy was associated with facial dermatitis.

## Methods and materials

A retrospective observational study of consecutively patch tested dermatitis patients treated at a university hospital in Copenhagen, Denmark, between 1 January 2005 and 31 December 2014 was performed. All patients ( $n = 7997$ ) underwent routine patch testing with the following rubber accelerators: thiuram mix 1% in pet., mercapto mix 1% in pet. and mercaptobenzothiazole 2% in pet.

In the database, the following data were available: age, test year, the MOALHFA-index (Male, Occupational contact dermatitis, Atopic dermatitis, Hand dermatitis, Leg dermatitis, Facial dermatitis and Age >40 years), outcome of patch testing. Clinical relevance was defined as 'current', 'previous' or 'unknown'. Importantly, no specific link between the contact allergy and the location of the dermatitis can be made on the individual patient in the database. For example, a patient could have facial dermatitis due to atopic dermatitis and contact dermatitis on the hands due to thiuram allergy.

Patch testing was done with Finn Chambers® (8 mm; Smartpractice, Phoenix, AZ, USA) on Scanpor tape®

(Norgesplaster A/S, Alpharma, Vennesla, Norway). The patch tests were applied to the upper back and occluded for 48 h. Readings were performed on D2, D3/D4 and D7 according to ESCD recommendations.<sup>3</sup> A reaction of 1+, 2+, 3+ were considered to be positive. Irritant, doubtful and negative test reactions were interpreted as negative. In the case of subsequent patch testing, data obtained from the first visit were used in the analysis.

All patients in the database were given an occupational code according to the Danish International System of Standard Classification of Occupations (DISCO-88). These DISCO-88 codes were aggregated to an occupational system on the basis of well-known subgroups.<sup>9</sup>

## Statistical analyses

All data were analysed with SPSS™ (SPSS™ Statistics, Chicago, IL, USA; IBM PASW Statistics) for Windows™, edition 20.0. Univariate associations were expressed as crude odds ratios (OR) with 95% confidence intervals (CIs). The Pearson  $\chi^2$ , and Fischer's exact test when expected  $n < 5$ , were used to determine whether there was a significant difference for categorical variables. The Mann–Whitney  $U$ -test was applied for analysis of differences between the median age of males with thiuram mix contact allergy and females with thiuram mix contact allergy. Adjusted ORs with 95% CIs were calculated by binary logistic regression models where contact allergy to thiuram mix acted as the dependent variable and the MOALHFA-index as explanatory variables. The temporal trend of contact allergy to accelerators (a positive patch test reaction to either thiuram mix, mercaptobenzothiazole or mercapto mix) was expressed as % ( $n$ /total) with 95% CIs. High-risk occupations were estimated by parametric tests and univariate analysis due to moderate sample sizes in the explanatory variables.

## Results

The overall prevalence of contact allergy to at least one rubber accelerator from the baseline series was 3.1% (250/7,997). The prevalence of contact allergy to at least one rubber accelerator remained stable between 2.4% in 2005 and 3.0% in 2014 with no significant change over time ( $P_{\text{trend}} = 0.667$ ) (Fig. 1). Stratification by sex showed that the overall prevalence of contact allergy to rubber accelerators was 2.9% for males and 3.3% for females respectively. The median age in men with contact allergy to rubber accelerators was significantly lower than in women (44 vs. 52 years,  $P = 0.006$ ).

### Thiuram mix

The overall prevalence of contact allergy to thiuram mix was 2.7%, whereas the annual prevalence ranged between 1.8% and 3.3% with no significant trend over time ( $P_{\text{trend}} = 0.532$ ) (Fig. 2). The prevalence of contact allergy to thiuram mix in males ranged between 1.0% in 2005 and 2.8% in 2014, also with

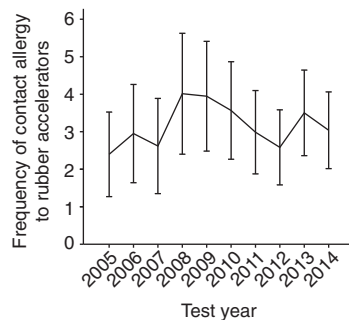


**Figure 1** The prevalence of contact allergy to rubber accelerators\* between 1 January 2005 and 31 December 2014 in a cohort of dermatitis patients from Denmark ( $n = 7997$ ). Estimates are shown with 95% confidence intervals. A test for trend was non-significant ( $P_{\text{trend}} = 0.667$ ). \*Rubber accelerators included ( $n = 250$ ): thiuram mix, mercaptobenzothiazole and mercapto mix.

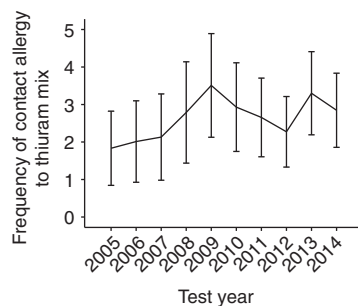


**Figure 2** The prevalence of contact allergy to thiuram mix between 1 January 2005 and 31 December 2014 in a cohort of dermatitis patients ( $n_{\text{total}} = 7997$ ). Estimates are shown with 95% confidence intervals. A test for trend was non-significant ( $P_{\text{trend}} = 0.532$ ).  $n = 212$ .

no significant change over time ( $P_{\text{trend}} = 0.421$ ). In females, the prevalence was 3.3% in 2005 and 3.2% in 2014 with no significant change over time ( $P_{\text{trend}} = 0.931$ ). Contact allergy to thiuram mix was significantly associated with occupational contact dermatitis (OR 2.66; 95% CI 1.91–3.69), hand dermatitis (OR 2.52; 95% CI 1.79–3.56), facial dermatitis (OR 1.72; 95% CI 1.24–2.39) and age >40 years (OR 1.83; 95% CI 1.32–2.53) in adjusted binary logistic regression analyses (Table 1). Present and past clinical relevance of a positive patch test reaction to thiuram mix was 59.3% (126/212) and 38.7% (82/212) respectively. We found no significant association between atopic dermatitis and contact allergy to thiuram mix (OR 0.89; 95% CI 0.61–1.30). Further stratification for doubtful test reactions, +1, +2 and +3 positive patch test reactions revealed no association between having atopic dermatitis and contact allergy to thiuram mix. Stratification of patients with facial dermatitis showed that

2.9% (59/2004) had contact allergy to thiuram mix, and 45.8% (27/59) had current clinical relevance. Further stratification of patients with contact allergy to thiuram mix ( $n = 212$ ) and current relevance (126/212) showed that 21.4% (27/126) of these patients had facial dermatitis. No adjusted analysis was applied on cases within these stratifications due to more moderate sample sizes.

### Mercapto mix and mercaptobenzothiazole

Only unadjusted analyses were applied on cases of contact allergy to mercapto mix and mercaptobenzothiazole due to a moderate sample size of positive test reactions (0.6% and 0.7% respectively). These showed that occupational contact dermatitis, hand dermatitis and leg dermatitis were significantly associated with contact allergy to mercapto mix and mercaptobenzothiazole (Table 1). There was, however, no significant association with facial dermatitis (Table 1). The clinical relevance of mercapto mix and mercaptobenzothiazole was 46.3% (25/54) and 45.8% (22/48) respectively.

### Concomitant reactions

A Venn diagram shows concomitant patch test reactions to the three rubber accelerators (Fig. 3). Patients with a positive patch test reaction to mercapto mix and mercaptobenzothiazole had a concomitant reaction to thiuram mix in 35.2% (19/54) and 35.4% (17/48) of the cases, respectively. In patients with positive patch test reactions to thiuram mix only, 11.3% (24/212) had concomitant reactions to mercapto mix and/or mercaptobenzothiazole. Concomitant reactions between mercapto mix ( $n = 54$ ) and mercaptobenzothiazole ( $n = 48$ ) exist as a total of 39 patients reacted to both.

### Occupational classification

Table 2 shows positive patch test reactions to thiuram mix stratified by occupation. Work within the healthcare, cleaning and food service industry sector were significantly associated with a positive patch test reaction to thiuram mix. Office work and 'others' were, separately, negatively associated with having a positive patch test reaction. Facial dermatitis was frequent in healthcare workers with contact allergy to thiuram mix, as 26.0% (13/50) of the personnel in the healthcare sector with contact allergy to thiuram mix had facial dermatitis.

## Discussion

### Main findings

This retrospective observational study showed that the overall prevalence of contact allergy to rubber accelerators remained high with apparently no trend towards a decrease. Contact allergy to thiuram mix was associated not only with hand dermatitis, occupational contact dermatitis, and age >40 years, but importantly also with facial dermatitis. Work within the

**Table 1** Baseline characteristics according to MOAHLFA-index for thiuram mix, mercaptobenzothiazole and mercapto mix

|                                    | Thiuram mix               |                                                             |          | Mercaptobenzothiazole     |                                                                      |           | Mercapto mix              |                                                              |           |
|------------------------------------|---------------------------|-------------------------------------------------------------|----------|---------------------------|----------------------------------------------------------------------|-----------|---------------------------|--------------------------------------------------------------|-----------|
|                                    | Frequency, %<br>(n/total) | Adjusted<br>odds ratio<br>(95%<br>confidence<br>intervals)* | P-value* | Frequency,<br>% (n/total) | Unadjusted<br>(crude) odds<br>ratio (95%<br>confidence<br>intervals) | P-value** | Frequency, %<br>(n/total) | Unadjusted<br>odds ratio<br>(95%<br>confidence<br>intervals) | P-value** |
| Male                               | 27.8 (59/212)             | 0.69<br>(0.50–0.94)                                         | 0.019    | 43.8 (21/48)              | 1.59<br>(0.90–2.82)                                                  | 0.108     | 40.7 (22/54)              | 1.41<br>(0.82–2.43)                                          | 0.213     |
| Occupational<br>contact dermatitis | 45.8 (97/212)             | 2.66<br>(1.91–3.69)                                         | <0.001   | 37.5 (18/48)              | 2.31<br>(1.29–4.16)                                                  | 0.004     | 33.3 (18/54)              | 1.94<br>(1.10–3.42)                                          | 0.020     |
| Atopic dermatitis                  | 17.5 (37/212)             | 0.89<br>(0.61–1.30)                                         | 0.539    | 20.8 (10/48)              | 1.16<br>(0.58–2.33)                                                  | 0.68      | 14.8 (8/54)               | 0.77<br>(0.36–1.63)                                          | 0.488     |
| Hand dermatitis                    | 66.0 (140/212)            | 2.52<br>(1.79–3.56)                                         | <0.001   | 68.8 (33/48)              | 3.44<br>(1.87–6.35)                                                  | <0.001    | 59.3 (32/54)              | 2.29<br>(1.33–3.94)                                          | 0.002     |
| Leg dermatitis                     | 4.7 (10/212)              | 1.84<br>(0.95–3.57)                                         | 0.073    | 10.4 (4/48)               | 3.05<br>(1.20–7.77)                                                  | 0.032***  | 9.3 (5/54)                | 2.67<br>(1.06–6.76)                                          | 0.049***  |
| Face dermatitis                    | 27.8 (59/212)             | 1.72<br>(1.24–2.39)                                         | <0.001   | 20.8 (10/48)              | 0.78<br>(0.39–1.58)                                                  | 0.492     | 22.2 (12/54)              | 0.85<br>(0.45–1.62)                                          | 0.617     |
| Age >40                            | 72.2 (153/212)            | 1.83<br>(1.32–2.53)                                         | <0.001   | 75 (36/48)                | 1.62<br>(0.84–3.12)                                                  | 0.145     | 74.1 (40/54)              | 1.54<br>(0.84–2.83)                                          | 0.163     |

\*A binary logistic regression was only applied on contact allergy to thiuram mix as dependent variable.

\*\*Chi square test (and Fischer exact test when expected number <5, \*\*\*) and unadjusted odds ratio was used to test for univariate association for mercaptobenzothiazole and mercapto mix contact allergy due to a more moderate sample size.

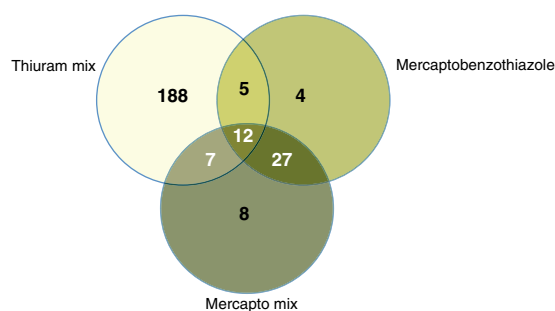


**Figure 3** Venn diagram of observed positive patch test reactions to thiuram mix ( $n = 212$ ), mercaptobenzothiazole ( $n = 48$ ) and mercapto mix ( $n = 54$ ). All patients were patch tested positive to the selected rubber accelerators in the time period between 2005 and 2014.

healthcare, cleaning and food service industry was significantly associated with contact allergy to thiuram mix.

### Interpretation

Our analyses showed that thiuram mix contact allergy was significantly associated with facial dermatitis supporting the findings from three recent case reports from our department.<sup>6–8</sup> The lack of association with mercaptobenzothiazole and mercapto mix could be explained by the low number of positive test reactions, or the less reactivity of mercaptobenzothiazole (EC3-value of 9.7%) in comparison to, for example, dipentamethylenethiuram disulfide or tetramethylthiuram disulfide (EC3-value of

5.2%).<sup>10,11</sup> All patients were extensively patch tested, and all cases underwent stepwise exposure assessment of allergens in the domestic and work environment.

It is important to underscore that our analyses showed that patients with contact allergy to thiuram mix had a higher prevalence of facial dermatitis when compared to patients without thiuram allergy, but that it does not necessarily reflect causation. The found statistical association between contact allergy to thiuram mix and facial dermatitis should therefore be interpreted with caution. However, the recent case reports from our department and our presented results do emphasize that it is important to at least consider indirect exposure to rubber accelerators or even airborne exposure to rubber accelerators when managing a patient with facial dermatitis and rubber allergy.

Patients with contact allergy to rubber accelerators could potentially benefit from mandatory ingredient labelling of rubber protective gloves since these patients thereby easily could avoid re-exposure to the ascertained rubber accelerator.<sup>12</sup> Contact allergy to rubber chemicals has previously also been associated with foot dermatitis probably due to shoe exposure.<sup>13,14</sup> We showed that a positive patch test reaction to mercaptobenzothiazole and mercapto mix was significantly associated with leg dermatitis; a category that also covers foot dermatitis in our clinic.<sup>4</sup>

Our overall prevalence estimate of contact allergy to thiuram mix is in accordance with other recent European and American studies.<sup>1,4,15</sup> However, we could not confirm the recently observed decreasing prevalence rates that have been reported from several European countries and the United States.<sup>1,4,15</sup> Further, we showed that the current clinical relevance of contact

**Table 2** Positive patch test reactions to thiuram mix stratified for occupation. All occupations are listed with frequency of positive patch test reactions to thiuram mix

| Occupation                          | Positive patch test reaction to thiuram mix, % (n) ( <i>n</i> <sub>total</sub> = 212) | No positive patch test reaction to thiuram mix, % (n) ( <i>n</i> <sub>total</sub> = 7757) | P-value | Unadjusted odds ratio (95% confidence interval) |
|-------------------------------------|---------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|---------|-------------------------------------------------|
| Office worker                       | 15.4 (32)                                                                             | 21.3 (1621)                                                                               | 0.04    | 0.67 (0.46–0.98)                                |
| Engineer                            | 0.5 (1)                                                                               | 0.8 (61)                                                                                  | ns      | –                                               |
| Agricultural worker                 | 0.5 (1)                                                                               | 1.2 (88)                                                                                  | ns      | –                                               |
| Healthcare worker                   | 24.0 (50)                                                                             | 13.6 (1040)                                                                               | <0.001  | 2.00 (1.44–2.76)                                |
| Teacher                             | 2.4 (5)                                                                               | 2.4 (182)                                                                                 | ns      | –                                               |
| Technician                          | 2.4 (5)                                                                               | 2.0 (155)                                                                                 | ns      | –                                               |
| Worker in transport sector          | 1.0 (2)                                                                               | 1.8 (135)                                                                                 | ns      | –                                               |
| Others                              | 30.3 (63)                                                                             | 40.6 (3095)                                                                               | 0.003   | 0.64 (0.47–0.86)                                |
| Constructioner                      | 0.5 (1)                                                                               | 0.9 (69)                                                                                  | ns      | –                                               |
| Tile setters/Terazzo worker         | 1.0 (2)                                                                               | 0.3 (26)                                                                                  | ns      | –                                               |
| Electrician                         | 0.0 (0)                                                                               | 0.7 (57)                                                                                  | ns      | –                                               |
| Painter                             | 0.5 (1)                                                                               | 0.9 (69)                                                                                  | ns      | –                                               |
| Worker in metal processing industry | 1.0 (2)                                                                               | 1.5 (109)                                                                                 | ns      | –                                               |
| Mechanic                            | 1.4 (3)                                                                               | 1.2 (91)                                                                                  | ns      | –                                               |
| Machine operators                   | 0.5 (1)                                                                               | 0.9 (70)                                                                                  | ns      | –                                               |
| Worker in food industry             | 8.7 (18)                                                                              | 3.9 (295)                                                                                 | <0.001  | 2.35 (1.43–3.86)                                |
| Cleaner                             | 6.7 (14)                                                                              | 2.8 (211)                                                                                 | <0.001  | 2.53 (1.45–4.42)                                |
| Cosmetologist                       | 0.5 (1)                                                                               | 0.3 (22)                                                                                  | ns      | –                                               |
| Hairdresser                         | 2.9 (6)                                                                               | 3.0 (229)                                                                                 | ns      | –                                               |
| Unknown                             | 1.9 (4)                                                                               | 1.7 (132)                                                                                 | ns      | –                                               |

P-value >0.05. If expected value <5 Fischer's exact test was used.

ns, not significant.

allergy to thiuram mix was relatively high (~60%) and stable across the test period (not shown).

The use of rubber accelerators in rubber protective gloves has not been fully investigated, and many conclusions in the literature regarding the use of rubber accelerators in rubber protective gloves are based on unofficial statements by the industry.<sup>5</sup> While no specific regulation imposes limits on the amount of rubber accelerators in protective gloves, these can be labelled 'Communauté Européenne' (CE), a mandatory conformity marking for certain products, for example, medical devices used to signify that the product follows European legislation.<sup>16</sup> The CE-mark can only be assigned rubber protective gloves if the product adequately protects against cross contamination with respect to the purpose of the glove (surgical vs. examination and procedure gloves), force at break etc. It is, however, important to impose further and more far-reaching European regulations on the content of rubber accelerators in rubber protective gloves. Within the EU, glove manufacturers might to some extent hold the same (unregulated) standards, for example, in matters of adding carbamates instead of thiurams during the vulcanization process or *vice versa*.

It was recently discussed if carba mix again should be included in the European baseline series, as an increasing trend of contact allergy to carba mix has been observed in Europe.<sup>1,4</sup> It has normally been thought that carba mix could be excluded

from the European baseline series as dithiocarbamates constitute a redox pair with thiurams. Thiuram mix is therefore considered a patch test marker for thiuram-carbamate sensitization. Thus, we do not present data for carba mix and carbamates, as these mostly are included in the more specific rubber patch test series in European countries and Denmark. Further, there are ongoing discussions on test concentrations and diagnostic performance of the carba mix.<sup>4</sup>

Uter *et al.*<sup>17</sup> have previously shown that healthcare workers, cleaners and workers in the food service industry are at risk for developing contact allergy to thiuram mix. Other observational studies focusing on contact dermatitis in healthcare workers, cleaners or workers in the food industry have likewise shown that contact allergy to thiuram mix is more frequent in these occupational groups,<sup>18–22</sup> allegedly due to an excessive use of rubber protective gloves, where 'appropriate' skin protection are necessary.<sup>18–22</sup>

Conclusively, rubber accelerators remain important skin sensitizers that may be relevant contact allergens in patients with facial dermatitis. Employers, merchants and employees with contact allergy to rubber accelerators would greatly benefit from a future mandatory ingredient labelling of rubber protective gloves. Experimental analyses of rubber protective gloves and the vulcanization process are, however, still warranted.

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