

1,2-Benzisothiazolin-3-one in disposable polyvinyl chloride gloves for medical use

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Background: Benzisothiazolinone is used as a slimicide in the manufacture of disposable powder-free polyvinyl chloride (PVC) gloves. We recently reported 6 patients from dentistry and health care probably sensitized to benzisothiazolinone in PVC gloves.

Objective: The study aimed to investigate how widely disposable PVC gloves for medical use on the Finnish market in 2006 contain benzisothiazolinone and to report new cases from 2 clinics in Helsinki.

Methods: 31 brands of disposable PVC gloves were analysed for their benzisothiazolinone content. We looked through the patient material of Helsinki University Central Hospital to find benzisothiazolinone allergic patients. We also described 3 previously unpublished benzisothiazolinone allergic patients from Finnish Institute of Occupational Health.

Results: 9 (30%) of the 31 glove brands contained 3–26 p.p.m. benzisothiazolinone. From the 2 clinics, we found 5 new benzisothiazolinone allergic patients who had used PVC gloves containing benzisothiazolinone. In addition, 3 patients had used disposable PVC gloves whose benzisothiazolinone content remained unknown.

Conclusions: In Finland, benzisothiazolinone in powder-free PVC gloves has caused a small epidemic of allergic contact dermatitis in dental personnel and other health care workers. 1/3 of the disposable PVC gloves contained some benzisothiazolinone. A concentration of 20 p.p.m. benzisothiazolinone in a glove seems to be enough for sensitization.

Key words: biocide; CAS 2634-33-5; contact allergy; dental nurses; dentists; health care; occupational.
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Accepted for publication 26 July 2007

Background

Benzisothiazolinone (1,2-Benzisothiazolin-3-one, BIT, CAS 2634-33-5) is an antimicrobial agent that is used in industry as a preservative in water-based technochemical products (1, 2). Several cases of occupational allergic contact dermatitis from BIT containing biocides have been reported in industrial laboratory work (3–6) and in the manufacture of paints (5, 7, 8) and varnishes (5, 9). Other several times reported sources of sensitization include the use of metalworking fluids (10–12), paints (13, 14), and wallpaper paste (14, 15).

Allergic contact dermatitis from plastic gloves is rare compared with sensitization by rubber gloves. Most of the reported cases have been caused by polyvinyl chloride (PVC, vinyl) gloves. In past examinations of contact allergy to PVC gloves, several cases of bisphenol A allergy (16, 17), and individual cases caused by an organic pigment (18) and adipic polyester (19) have been reported. Some reusable PVC gloves contain formaldehyde and may aggravate or cause formaldehyde contact allergy (20).

At the Finnish Institute of Occupational Health (FIOH), we recently reported 6 BIT allergic

patients with hand dermatitis and using PVC gloves, which in chemical analysis were found to contain 9–31 p.p.m. BIT (21). BIT is used as a slimeicide in the production of disposable PVC gloves. We wanted to investigate the occurrence of BIT in disposable PVC gloves for medical use in the Finnish market. We also wanted to analyse BIT allergic patients at a clinic of general dermatology, the Skin and Allergy Hospital of Helsinki University Central Hospital (HUCH), and to report previously unpublished patients (No. 1–3 in Table 1) who have been investigated at FIOH after the 1st report.

Methods

We described the patch test methods at FIOH in the first report (21). In HUCH, BIT was tested in the antimicrobial series and in the series of oils

and cutting fluids at the concentration of 0.05% in Petrolatum (Chemotechnique Diagnostics[®], Vellinge, Sweden). Glove material was tested 'as is' without any chamber under Scanpore[®] tape moistened with a drop of acetone.

We scanned the skin test files at HUCH from January 2000 to April 2006 for allergic reactions to BIT (+/++/+++). We checked the clinical records of BIT allergic patients for test reactions to other isothiazolinones, occupation, symptoms, exposure, and diagnosis. We also located the same data on our 3 latest, previously unreported patients investigated at FIOH in 2006 and 2007.

The Finnish sales representatives of disposable PVC examination gloves were asked to provide us samples of their gloves. The study included 31 different brands of gloves (Table 2), which covered more than 90% of the Finnish market volume of these products in spring 2006.

Table 1. Patients with BIT contact allergy and hand dermatitis who had used PVC gloves at work, year of investigation, occupation, patch test reactions to BIT (0.05% in petrolatum) and PVC glove material, duration of hand dermatitis, and clinical diagnosis

Patient number	Year of investigation	Occupation	Patch test reaction to BIT	Patch test reaction to PVC glove material	Duration of hand dermatitis	Diagnosis
New patient at FIOH investigated after the first report (21)						
1	2006	Dental nurse	++	Dermagrip PVC glove ^a moistened with water ++, moistened with acetone ++	15 years	Atopic dermatitis, OACD from BIT in Dermagrip PVC gloves
2	2007	Assistant nurse	++	Medi-Point PVC glove ^b moistened with water?+, moistened with acetone – Everguard latex glove – contained 6.8 p.p.m. BIT)	1 year	OACD from BIT in Medi-Point PVC gloves
3	2007	Dentist	++	Dermagrip PVC glove ^a moistened with water?+, moistened with acetone?+	4 years	OACD from BIT in Dermagrip PVC gloves
HUCH patients: patients who had used BIT containing PVC glove brands						
4	2006	Physical therapist	++	Medi-Point PVC glove ^b ?+	21 years	OACD from BIT in Medi-Point PVC gloves
5	2004	Dental nurse	+	Dermagrip PVC glove ^a –	7 years	OACD from bis-GMA
Patients who had used disposable PVC gloves the BIT content of which is unknown						
6	2004	Dentist	+	Sensicare PVC glove ^c +	1 year	OACD from PVC gloves
7	2003	Dentist	+	Sensicare non-latex PVC gloves ^c –	1 year	OACD from thiurams in rubber gloves
8	2001	Dental nurse	+	PVC glove ^c + (brand not mentioned)	12 years	OACD from PVC gloves
Patients who had used household or unknown type of PVC gloves						
9	2006	Waitress	+	PVC glove ^c – (brand or type not mentioned)	10 years	—
10	2005	Kitchen worker	++	Star household-type PVC glove ^d	1 year	Atopic dermatitis
11	2004	Cleaner	+	Gloves ^c NT (previously used household-type PVC gloves) ^c	9 years	OACD from thiurams in rubber gloves

BIT, 1,2-benzisothiazolin-3-one; OACD, occupational allergic contact dermatitis; FIOH, Finnish Institute of Occupational Health; HUCH, Helsinki University Central Hospital; bis-GMA, 2,2-bis(4-(2-hydroxy-3-methacryloxypropoxy)phenyl)propane; NT, not tested; PVC, polyvinyl chloride.

^aIn 2 previous analyses glove batches contained 9 and 22 p.p.m. BIT.

^bIn a previous analysis contained 31 p.p.m. BIT.

^cBIT content not analysed.

^dDid not contain BIT in chemical analysis in 2006 (24).

Table 2. Analysed disposable PVC gloves for medical use, and benzisothiazolinone content. The results are based on the analysis of only 1 batch of each brand

Glove brand	Product batch code when available	BIT content (p.p.m.)	BIT content, % (weight)
‘High-BIT’ (≥ 20 p.p.m.)			
Dermagrip, powder-free	LOT VD-0508165-3	26	0.0026
Evercare Soft, powder-free	LOT 0506211	22	0.0022
Evercare Gold, powder-free	LOT 0508187	20	0.0020
Evercare Flex, powder-free	LOT 0507124	20	0.0020
‘Intermediate-BIT’ (6–19 p.p.m.)			
SC Value PF, powder-free	LOT 0506106-5202	16	0.0016
Medi-Point, powder-free	LOT 0507004	9	0.00091
‘Low-BIT’ (2–5 p.p.m.)			
TT Clear PF, powder-free	LOT 0504157-0302	5	0.00049
Top Glove – Guard-perfect, powder-free	LOT AF051220	4	0.00038
Arista, powder-free	LOT 05071863	3	0.00033
No BIT (< 2 p.p.m.)			
Sensisafe, powder-free ^a		< 2	$< 0.0002^b$
Famoflex 91, powder-free		< 2	< 0.0002
Famoflex 94, powdered		< 2	< 0.0002
Famomed 99, powder-free		< 2	< 0.0002
Vinyl exam Gloves Medi-Point, powdered	LOT 0409197	< 2	< 0.0002
Top Glove – Guard-classic, lightly powdered	LOT AF050515	< 2	< 0.0002
Sempercure vinyl, powdered	LOT 03200505750017	< 2	< 0.0002
Sempercure vinyl, powder-free	LOT 09200507040153	< 2	< 0.0002
Sempercure Synstretch, powder-free	LOT 11200507200007	< 2	< 0.0002
TopDent, powdered	LOT D05141	< 2	< 0.0002
TT Clear PF, powdered	LOT 0508078-0203	< 2	< 0.0002
SC Value, powdered	LOT 0503080-5102	< 2	< 0.0002
Saila, powdered	LOT 050223	< 2	< 0.0002
Saila, powder-free	LOT 051205	< 2	< 0.0002
Saila, powdered blue	LOT 051010	< 2	< 0.0002
Arista, powdered	LOT 040553	< 2	< 0.0002
Kielo, powder-free		< 2	< 0.0002
Synsation vinyl, powdered	LOT 05112907DF	< 2	< 0.0002
Synsation PF vinyl, powder-free	LOT 05123040DF	< 2	< 0.0002
Evercare Soft, powdered	LOT 0508104	< 2	< 0.0002
Evercare, powder-free	LOT 0512028	< 2	< 0.0002
Evercare Soft, powder and phthalate free	LOT 0900143-2	< 2	< 0.0002

^aThe glove batch was somewhat outdated.

^bContains BIT more than the detection limit but less than the limit of quantification.

Chemical analysis of BIT

The concentrations of BIT in the PVC gloves were analysed by high performance liquid chromatography with a ultra violet detector at 230 nm. Mass spectrometry confirmed the detection. Accurately weighed slices taken from the palm or the back of glove (100 mg and 200 mg) were extracted with 5 ml of a mixture of water and methanol (3:1) overnight at room temperature. The liquid chromatography column was a reversed phase C18 column (Waters Symmetry Shield, 3.5 μ m particles, 150 mm $\times$ 2 mm). The mobile phase was methanol and water (32:68) with 2 mM of ammonium acetate, the flow rate was 0.2 ml/min. The repeatability of the method expressed as relative standard deviation of 6 replicates was 6% at the 20 p.p.m. level. The overall uncertainty of the method was 40% (at 95% confidence level) for a concentration level of about 20 p.p.m. (weight). The recovery of

BIT was 99% at the 20 p.p.m. level. The limit of quantification was 2 p.p.m.

Results

The 3 most recent previously unpublished patients from FIOH are presented in Table 1 (No. 1–3). We did not analyse their gloves as we had analysed the same brands before (21).

In HUCH, a total of 5450 patients were tested with BIT (0.05% pet.), and 16 (0.003%) of them had allergic reactions to BIT. In Table 1, we present 8 of the 16 patients who had hand dermatitis and who had used PVC gloves at work (Nos. 4–11) and whose sensitization thus possibly derived from PVC gloves. The remaining 8 patients had not used PVC gloves at work, only 2 of them had hand dermatitis, and none of them worked in dentistry or health care. They were thus unlikely to

have been sensitized to BIT through PVC gloves, and other exposure to BIT could also not be identified in this group.

None of the 16 BIT allergic patients in HUCH or 3 patients in FIOH had patch test reactions to the mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one (CMI/MI, Kathon CG[®]) or to 2-*N*-octyl-4-isothiazolin-3-one.

We analysed BIT in 31 brands of disposable PVC gloves for medical use, which cover at least 80% of the Finnish market for these gloves. The results of the analyses appear in Table 2. Based on the results, we divided the BIT containing gloves into 3 groups labelled 'High-BIT' with a concentration of ≥ 20 p.p.m., 'Intermediate-BIT' with 6–19 p.p.m. and 'Low-BIT' with 2–5 p.p.m.

Discussion

In the present market survey, most of the PVC gloves did not contain BIT. The BIT containing gloves were exclusively powder-free, and none of the 10 powdered brands analysed contained BIT. This is in accordance with the information we received from a manufacturer that BIT is used as a slimicide in the manufacture of powder-free PVC gloves. However, there were also many powder-free gloves that did not contain BIT.

In 2002 at FIOH, we noticed allergic reactions to BIT and PVC gloves in an assistant nurse, and in chemical analysis we could show BIT in the glove material (21). Later we investigated 3 similar patients from dental care. By analysing the gloves of 3 BIT allergic patients, we found 3 brands of disposable PVC gloves that contained BIT 9–31 p.p.m. (21). Consulting the records at FIOH, we found 2 'historical cases' from our files: dental workers with BIT allergy and hand dermatitis, who had used some of these BIT containing brands (21). All of the 3 patients whose gloves were analysed had used a brand that contained at least 20 p.p.m. BIT (a 'High-BIT' glove). Thus, the concentration of 20 p.p.m. seems to be sufficient for sensitization. The border between 'Low-BIT' and 'Intermediate-BIT' was chosen arbitrarily. Because the number of diagnosed patients is still small, it is impossible to say if the lower concentrations can induce or elicit contact allergy. The previously known 'High-BIT' brands have now been analysed for 2 or 3 times including the results of the market survey: there were differences between the batches, but in every analysis they have contained at least 9 p.p.m. ('intermediate') BIT. In the present market survey, there were 4 'High-BIT' gloves: 2 of them, Evercare Soft and Dermagrip, we already knew from our clinical cases, and the remaining

gloves, Evercare Flex and Evercare Gold, were marketed by the same company as Evercare Soft. Thus, the market survey did not show any new companies promoting 'high-BIT' gloves: this finding strengthened our conception that the gloves had truly sensitized our patients.

While FIOH is a special clinic of occupational dermatology with highly selected patient material, HUCH's Skin and Allergy Hospital is a clinic of general dermatology. In HUCH the relative number of BIT allergic patients was only a fragment of that of FIOH, which is in accordance with the occupational nature of the allergen. Besides possible exposure to BIT in PVC gloves, no other source of sensitization was found in the patients at HUCH. 5 of the patients, all from dentistry or health care, had used disposable PVC gloves, and in 2 of them, the use of BIT containing brands could be confirmed. In the remaining 3 cases the BIT content of the gloves remained unknown. In HUCH there were no classic BIT allergies from laboratory work, paints, and paint manufacturing or metalworking fluids, but 1 in 4 of the BIT allergic patients were dental workers. Among the patients in our previous report from FIOH, the over-representation of dental workers was even more obvious: among the 11 BIT allergic patients investigated since 2001 there were 4 dentists and 2 dental nurses (54%) (21). In the 2 clinics, we have so far found a total of 11 patients (4 dental nurses, 4 dentists, 2 assistant nurses, and 1 physiotherapist) with BIT allergy who have had exacerbations of their hand dermatitis while using 1 of the glove brands labelled 'High-BIT'. It should be borne in mind, however, that it is a small epidemic in a country with 5 million inhabitants.

The sensitization to BIT from PVC gloves seems to affect mostly dental personnel and to a minor extent other health care workers. The epidemic did not appear until this millennium (21). For fear of human immunodeficiency virus infection dental personnel started to use natural rubber latex gloves, and this led to an epidemic of immediate-type natural rubber contact allergy in the 1980s and 1990s (22). Instead of rubber gloves, many of them then began to use PVC gloves, and in Finland the market for these gloves has expanded considerably during the recent years. In 2002 according to the Finnish Register of Occupational Diseases, there were no new cases of immediate natural rubber allergy in dentists or dental nurses. Dental workers seem to be especially vulnerable to protective glove allergy, possibly because they use protective gloves most of their working day. In addition to the constant use of occlusive gloves, dental workers are also exposed to other factors that irritate the skin such

as frequent hand washing and the use of disinfectants. Defective skin barrier because of irritation or pre-existing eczema and the occlusive effect of the gloves probably enhance percutaneous penetration of allergens and increase the risk of sensitization to glove allergens. Most of our patients have had a relatively long history of hand dermatitis, and it is possible that the sensitization to BIT in the gloves requires pre-existing dermatitis, such as atopic dermatitis or irritant contact dermatitis.

The BIT containing PVC gloves do not always induce allergic reactions: 3 of our 11 cases have had allergic reactions to the glove material (or an ultrasound extract of the glove), 4 have had doubtful reactions and 4 have been totally negative. This distribution is not surprising when the BIT concentrations in the gloves (9–31 p.p.m.) have been more than 10 times lower than the patch test concentration of BIT (500 p.p.m.).

Many of our BIT allergic patients have been able to continue their work after changing to nitrile gloves, which are recommended in dental work because of their lower permeability to sensitizing methacrylates (23). We have analysed 2 brands of nitrile gloves for BIT: the first 1 was negative when the detection limit was 2 p.p.m. (21) and the 2nd 1 contained 1.3 p.p.m. (detection limit 1 p.p.m.). Concentrations below 2 p.p.m. are probably too low to cause sensitization or elicitation of allergic contact dermatitis. According to the present market survey, powdered PVC gloves are safe for BIT allergic patients, and there were several powder-free PVC gloves that did not contain BIT. We have also analysed 2 brands of household-type PVC gloves but found no BIT (24). Regarding natural rubber gloves, BIT may occur in their manufacture or in their glove powder (25, 26), but there are no case reports of BIT allergy from natural rubber gloves. Patient No. 2 (Table 1) first changed her PVC gloves to powder-free Everguard natural rubber latex gloves, but after 1 month she had an exacerbation of her hand dermatitis and consequently she changed to nitrile gloves. We analysed her Everguard latex gloves, although they were negative on patch testing, and found that they contained 6.8 p.p.m. BIT. The concentration was low, but we cannot exclude the possibility that the exacerbation was because of the small amount of BIT in the latex glove. We have now established the presence of BIT in latex gloves, which must derive from their manufacturing process because they were powder-free. A need for a new market survey on latex gloves arouse with the finding. We should also analyse a larger number of nitrile gloves to assess their safety for BIT allergic patients.

Although European Union regulations require labelling of the responsible manufacturer, the

name was given in only 3 packages. Even a special inquiry to the Finnish representatives of the gloves did not yield the information of all of the gloves. Nevertheless, most of them, if not all, are manufactured in the Far East, and the problem of BIT sensitization from the gloves might be global. We recommend that the possibility of BIT allergy should always be considered when investigating hand dermatitis patients using powder-free PVC gloves. Dental personnel and health care workers are not possibly always tested with BIT because it is included in the commercial patch test series of industrial biocides and metalworking fluids but not e.g. in dental materials, preservatives or cosmetics series. It would be helpful, if the manufacturers of protective gloves would declare all the antimicrobial agents used in the manufacturing process, including those of the raw materials, even if the final concentration in the glove is low.

In conclusion, BIT in powder-free disposable PVC gloves has caused a small epidemic of contact dermatitis in Finland affecting dental personnel and other health care workers. In a marker survey of disposable PVC gloves for medical use, 30% of the 31 brands analysed contained some BIT. A concentration of 20 p.p.m. BIT in the glove seems to be enough to sensitize patients who already have hand dermatitis.

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