

ORIGINAL ARTICLE

N,N-dimethylacrylamide—A new sensitizer in the FreeStyle Libre glucose sensor

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Background: Isobornyl acrylate (IBOA) has recently been identified as one sensitizer in the FreeStyle Libre glucose sensor. Analyses with gas chromatography-mass spectrometry (GC-MS) have indicated the presence of *N,N*-dimethylacrylamide (DMAA) in the sensor.

Material and methods: Seven patients were referred for patch testing after developing skin reactions when using FreeStyle Libre. All patients were patch tested with IBOA and DMAA. Two patients were tested with adhesive patches that had been removed from the sensors "as is," and two patients were tested with acetone extracts of materials from the sensor. The extracts were analysed with GC-MS.

Results: Six patients reacted to both IBOA and DMAA, and one patient reacted only to DMAA. Positive reactions were also observed in both patients tested with the adhesive patch "as is". One patient reacted to both an extract of the adhesive patch and an extract of the sensor itself. When analysed with GC-MS, IBOA was found in both extracts and DMAA was found in the extract of the sensor.

Conclusion: Both IBOA and DMAA may be present in adhesives used in medical devices such as glucose sensors or insulin pumps, and should be patch tested when suspected contact allergic reactions to these products are investigated.

KEYWORDS

adhesive, allergic contact dermatitis, diabetes mellitus, FreeStyle Libre, gas chromatography-mass spectrometry, glucose sensor, isobornyl acrylate, medical device, *N,N*-dimethylacrylamide

1 | INTRODUCTION

Isobornyl acrylate (IBOA) has recently been identified as a cause of allergic contact dermatitis in diabetics using FreeStyle Libre (Abbott Diabetes Care, Witney, UK), which is a flash glucose sensor applied with an adhesive onto the skin for up to 14 days.¹ The chemical investigations leading to the identification of IBOA were carried out at the Department of Occupational and Environmental Dermatology in Malmö, Sweden. Further analyses with gas chromatography-mass spectrometry (GC-MS) indicated the presence of *N,N*-dimethylacrylamide (DMAA) (CAS no. 2680-03-7) (Figure 1) in the FreeStyle Libre sensor. Therefore, we patch tested this substance in patients with suspected allergic contact dermatitis caused by glucose sensors and/or insulin pumps. In this article, we present seven

patients with a history of skin reactions to FreeStyle Libre who were diagnosed with contact allergy to DMAA. Six of them were also allergic to IBOA.

2 | PATIENTS AND METHODS

2.1 | Patients

2.1.1 | Case 1

Case 1 was an 11-year-old girl with a 1-year history of type 1 diabetes who had used the FreeStyle Libre glucose sensor for 2 months when she developed dermatitis at the application site. Using the sensor at different places did not reduce the problems. The patient's dermatitis

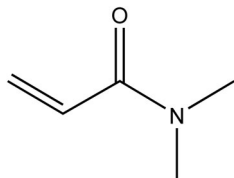


FIGURE 1 Molecular structure of *N,N*-dimethylacrylamide

healed after she ceased using the FreeStyle Libre sensor. Instead, she started using the Dexcom G4 Platinum glucose sensor (Dexcom, San Diego, California), without any skin problems. On examination, sharply demarcated hyperpigmentation was seen at a site of previous FreeStyle Libre application, without any ongoing dermatitis.

2.1.2 | Case 2

A 28-year-old woman with type 1 diabetes of 16 years' duration was referred because of skin problems resulting from the use of FreeStyle Libre. She had used this device for 2.5 years, and had already started to experience irritation underneath the patch after 4 months. For alleviation, she tried to use a hydrocolloid plaster, in which she made a tiny hole for the needle, to be put between the skin and the adhesive patch on the sensor. Four months prior to presentation at the department, her skin problems underneath the patch grew worse, with oozing eczematous lesions. Therefore, she ceased using FreeStyle Libre so that, upon examination, no eczema was seen. Her history also showed the use of sculptured acrylic nails for 4 months with pruritus of the neck on the day after re-sculpturing of the nails.

2.1.3 | Case 3

A 6-year-old girl with type 1 diabetes was referred because of dermatitis at the application site of FreeStyle Libre. She had used this glucose sensor for 2 years, and her skin symptoms started after 6 months. Since then, she has been treated intermittently with a topical class III corticosteroid (mometasone furoate).

2.1.4 | Case 4

An 11-year-old non-atopic girl with type 1 diabetes diagnosed in 2016 was referred because of dermatitis at the application site of FreeStyle Libre. Since 2017, she has been using the insulin pump OmniPod (Insulet Corporation, Billerica, Massachusetts) and the glucose sensor FreeStyle Libre. Both were applied alternatively on the upper arms. She changed the application site of the insulin pump every 3 days, and changed the sensor every 14 days. After 6 months of therapy, she developed itching and eczematous skin lesions corresponding to the application area of FreeStyle Libre. A hydrocortisone butyrate cream led to resolution of the eczema; however, this recurred with further applications of the glucose sensor. At the time of the patch test investigation, she had started to use a hydrocolloid plaster underneath the glucose sensor. The patient continued to use the OmniPod insulin pump as she had never experienced any skin reactions in connection to the pump in spite of its content of IBOA,² probably because of the relatively short duration of application of the device to the skin.

2.1.5 | Case 5

An 11-year-old girl with no previous skin disease or allergy had suffered from type 1 diabetes for 2 years. After she had used FreeStyle Libre for 1 year, she developed a skin reaction situated distinctly under the sensor. She had experienced no skin problems connected with the adhesive of the infusion sets for insulin delivery that she used. She stopped using FreeStyle Libre, and the school nurse applied a topical corticosteroid. After some time, she completely discontinued use of the device, owing to intense itching and recurring eczema regardless of where on the outer aspect of the upper arm she attached the sensor. At presentation, she had ceased using the sensor, but still had dryness and scaling on the outer aspects of the upper arms.

2.1.6 | Case 6

A 52-year-old woman suffering from type 1 diabetes had used FreeStyle Libre for 2 years. After 2 months of use, she developed annular eczematous dermatitis at the glucose sensor site on her arm. She tried to use a thin hydrocolloid dressing between the skin and the sensor, without any beneficial effect. Since then, she has used self-monitoring of blood glycaemia, and her diabetes has again become unstable. She had never been exposed to sculptured acrylic nails.

2.1.7 | Case 7

A 66-year-old man suffering from type 1 diabetes had used FreeStyle Libre for 1 year. After 1 month of use, he developed annular eczematous dermatitis at the glucose sensor application site on his arm. Thereafter, he applied an adhesive barrier wipe (Skin-Tac wipe; Torbot Group, Warwick, New York) between the skin and the sensor, which made it possible for him to continue using the FreeStyle Libre sensor.

2.2 | Patch testing

Cases 1 to 5 were evaluated at the Department of Occupational and Environmental Dermatology, Skåne University Hospital, Malmö, and cases 6 and 7 were evaluated at the Department of Dermatology of the Cliniques universitaires Saint-Luc in Brussels. All commercial patch test preparations were from Chemotechnique Diagnostics (Vellinge, Sweden) in Malmö and/or Trolab (Hermal, Reinbek, Germany) in Brussels. Patch testing was performed with 8-mm Finn Chambers AQUA (SmartPractice, Phoenix, Arizona) in Case 1 and 4, and with 8-mm Finn Chambers (SmartPractice) attached to Scanpor tape (Norgesplaster, Vennesla, Norway) in cases 2 and 3. Cases 5 to 7 were tested with IQ Ultra chambers (Chemotechnique Diagnostics). The tests were occluded on the back for 2 days. Reading of the tests was performed on day (D) 3 and D7 in cases 1 to 5, and on D2 and D4 in cases 6 and 7. The tests were read and scored according to the ICDRG and ESCD criteria.^{3,4}

In Malmö, all patients were tested with an in-house glucose sensor series containing IBOA 0.1% and 0.01% pet. and DMAA 0.1% pet. (both from Sigma-Aldrich, Steinheim, Germany), as well as a number of substances indicated from GC-MS analyses to be present in the FreeStyle Libre sensor, including antioxidants for plastic materials such as butylated hydroxytoluene (BHT) and *p*-tert-butylphenol. Cases 1, 2 and 4 were also tested with the Swedish baseline series. The constituents of sesquiterpene lactone mix (SLM), that is, alantolactone,

costunolide, and dehydrocostus lactone (all from Sigma-Aldrich), were each tested at a concentration of 0.1% (wt/vol) in ethanol in cases 1, 4, and 5. In Brussels, cases 6 and 7 were tested with IBOA 0.1% pet. and with DMAA 0.01% and 0.1% pet. (both from Sigma-Aldrich), and with the European baseline series, and meth(acrylates), plants and plastics/glues series. Both cases were also tested with alantolactone, costunolide, and dehydrocostus lactone (all from Sigma-Aldrich, each tested 0.1% pet.), and with a piece of the adhesive patch from the sensor.

Case 1 was additionally patch tested with 2-ethyl cyanoacrylate and with acetone ultrasonic bath extracts⁵ made from (a) the adhesive patch from the FreeStyle Libre sensor, (b) the Freestyle Libre sensor (with the patch removed), and (c) a Dexcom G4 Platinum sensor. Each extract was concentrated to a volume of 1 mL with a rotary evaporator before being used for patch testing. Two months later, supplementary patch testing with DMAA at 0.032% (wt/vol), 0.010%, 0.0032%, 0.0010%, and 0.00032%, all in acetone, with IQ Ultra chambers was performed. Case 2 was additionally tested with an extended baseline series and an acrylate series containing 2-ethyl cyanoacrylate, and, on D3, also with acrylamide 0.1% (wt/wt) pet. and *N*-methylolacrylamide 0.1% (wt/vol) aq. (both from Sigma-Aldrich). Case 3 was initially patch tested with the Swedish baseline series and the glucose sensor series by the use of 8-mm Finn Chambers AQUA. Because of numerous patch test reactions, repeated testing with the glucose sensor series, SLM 0.1% pet. and extracts of Finn Chambers AQUA and adhesive agents was performed 6 months later with 8-mm Finn Chambers attached to Scanpor tape. On D3, additional testing was performed with DMAA 0.032% and 0.010% pet. Only the results from the second test occasion are reported here. Case 4 was additionally patch tested with separate acetone extracts of the FreeStyle Libre sensor

and patch. The extracts were prepared as described above. Case 5 was additionally patch tested with acetone extracts of the Enlite glucose sensor, the Enlite overtape and the Sure-T Paradigm infusion set (all from Medtronic Minimed, Northridge, California), and also with Skin-Prep wipes and Remove adhesive remover (both from Smith & Nephew, Fort Worth, Texas) tested "as is." Twenty dermatitis patients served as controls, and they were patch tested with DMAA 0.032% (wt/wt) and 0.010% (wt/wt) pet.

2.3 | Chemical investigations

The extracts of the FreeStyle Libre patch and sensor tested in case 1 were each evaporated to a volume of ≈ 100 μ L, and were then analyzed with GC-MS.¹ The National Institute of Standards and Technology (Gaithersburg, Maryland) library of mass spectra was used for identification of substances. Dilutions of IBOA and DMAA in acetone were used as reference standards.

3 | RESULTS

3.1 | Patch tests

The patch test results are summarized in Table 1. In case 1, positive reactions to IBOA, DMAA, SLM, costunolide and both FreeStyle Libre extracts (sensor and patch) were observed on D3. On supplementary testing with a dilution series of DMAA, a + reaction to DMAA 0.032% in acetone was observed, but lower test concentrations gave negative results. In case 2, positive reactions to *Myroxylon pereirae*, IBOA, and DMAA were observed. The tests with acrylamide and *N*-methylolacrylamide gave negative results.

TABLE 1 Summary of patch test reactions in seven patients who reacted positively to *N,N*-dimethylacrylamide (DMAA)

Test preparation	Case no.						
	1	2	3	4	5	6	7
FreeStyle Libre patch "as is"	NT	NT	NT	NT	NT	++	+
FreeStyle Libre patch acetone extract	+	NT	NT	–	NT	NT	NT
FreeStyle Libre sensor acetone extract	++	NT	NT	–	NT	NT	NT
DMAA 0.1% pet.	++	+++	++	+	+	++	++
DMAA 0.032% pet.	+ ^a	NT	+	NT	NT	NT	NT
DMAA 0.01% pet.	– ^a	NT	?+	NT	NT	++	++
IBOA 0.1% pet.	++	+++	–	+	+	++	++
IBOA 0.01% pet.	+	+++	–	–	–	NT	NT
Baseline series	SLM +	MP ++	NT	–	NT	MP + SLM ++ CM +	–
Sesquiterpene lactones							
Alantolactone 0.1% ethanol	–	NT	NT	+	–	++ ^b	– ^b
Costunolide 0.1% ethanol	+	NT	NT	–	+	+ ^b	– ^b
Dehydrocostus lactone 0.1% ethanol	–	NT	NT	–	–	– ^b	– ^b
Acrylate series	NT	–	NT	NT	NT	–	–
Other positive substances	Oxidized limonene +	–	–	–	Hydroxyethyl acrylate +	Hydroquinone + Resorcinol monobenzoate +	–

Abbreviations: CM, Compositae mix; IBOA, isobornyl acrylate; MP, *Myroxylon pereirae*; NT, not tested; SLM, sesquiterpene lactone mix. The strongest reaction on either day (D) 3 or D7 (cases 1–5) or D2 or D4 (cases 6 and 7) is given.

^aVehicle: acetone.

^bVehicle: petrolatum.

Case 3 showed positive reactions to DMAA 0.10 and 0.032% pet., and a doubtful reaction to 0.010% DMAA. Tests with IBOA and sesquiterpene lactones gave negative results. The results for the Finn Chambers AQUA extracts are reported elsewhere. Case 4 reacted positively to DMAA, IBOA and alantolactone. Case 5 reacted positively to IBOA, DMAA, hydroxyethyl acrylate, and costunolide. She had a doubtful reaction with redness and infiltration in the margins of the test preparation to the extract of the Enlite glucose sensor. All other tests with products brought by the patient gave negative results. Case 6 reacted positively to IBOA, DMAA, *M. pereirae*, *Compositae* mix, SLM, alantolactone, costunolide, hydroquinone, resorcinol monobenzoate, and the adhesive patch from FreeStyle Libre. Case 7 reacted positively to IBOA, DMMA, and the adhesive patch from FreeStyle Libre. No reactions to the DMAA preparations patch tested in 20 controls were observed.

3.2 | Chemical investigations

In the GC-MS analyses, IBOA was found both in the extract of the patch ($\approx 6 \mu\text{g}/\text{cm}^2$) and in the sensor ($\approx 6 \mu\text{g}/\text{cm}^2$). DMAA was found in the extract of the sensor ($\approx 2 \mu\text{g}/\text{cm}^2$) but was not found in the patch ($< 0.5 \mu\text{g}/\text{cm}^2$). The presence of DMAA was indicated from the library spectra, and further confirmed by comparison of retention time and mass spectra of a DMAA reference and also by spiking the FreeStyle Libre extract with DMAA (Supporting Information Figures 1 and 2).

4 | DISCUSSION

Medical devices for insulin infusion and monitoring of blood glucose levels, which are attached to the skin with an adhesive for up to 14 days, have been reported to cause severe contact allergic reactions in diabetics. IBOA has been identified as a sensitizer in both FreeStyle Libre¹ and the OmniPod insulin pump.² Furthermore, there are reports of contact allergic reactions to 2-ethyl cyanoacrylate in the Dexcom G4 Platinum glucose sensor,^{6–8} but the manufacturer has since abandoned the use of the adhesive containing 2-ethyl cyanoacrylate.⁹

This report highlights DMAA as an additional sensitizer in FreeStyle Libre. Both DMAA and IBOA are used as monomeric diluents in ultraviolet (UV) curing adhesives.¹⁰ We tried to obtain information on the adhesives used in FreeStyle Libre from the manufacturer, but failed to do so. However, IBOA and DMAA frequently appear to be present together in high concentrations in medical-grade UV curing adhesives. One example is an adhesive from Loctite that contains 25% to 50% IBOA and 20% to 40% DMAA.¹¹ It is likely that IBOA and DMAA found in the extract of the FreeStyle Libre sensor originate from an adhesive used to join the top and bottom parts of the plastic cover of the sensor. According to the manufacturer of the adhesive patch, no IBOA is used in the adhesive in contact with the skin or in the adhesive used to fix the patch to the sensor.¹² However, in our analyses, we found that IBOA was also present in the extract of the adhesive patch that had been removed from the sensor, suggesting that IBOA migrates from the sensor itself to the adhesive patch. Although the presence of DMAA could not be shown in the extract of

the patch, it is possible that small amounts of DMAA migrate from the sensor to the adhesive patch.

To the best of our knowledge, there is only one previous report of contact allergy to DMAA. This case was a worker at a factory assembling surgical needles who reacted to a medical device adhesive used at the factory. When patch testing was performed, positive reactions to DMAA and tetrahydrofurfuryl acrylate, which were both ingredients of the adhesive, were observed.¹³

Contact allergy to acrylamide, *N,N'*-methylenebisacrylamide and *N*-methylolacrylamide has been reported in printers handling photopolymerizing printing plates.¹⁴ Contact allergy to acrylamide has also been described in a “batch-mixer” employed at a plastics factory.¹⁵ Acrylamide^{16–18} and piperazine acrylamide¹⁹ have been reported as sensitizers in laboratory workers handling polyacrylamide electrophoresis gels. Contact allergy to *N*-(2-ethylamino)ethyl acrylamide and *N,N'*-methylenebisacrylamide has been reported in laboratory technicians producing microspheres for embolization of human cardiovascular or neurosurgical procedures.²⁰ Case 2 was patch tested with both acrylamide and *N*-methylolacrylamide, but no reactions to these compounds were observed.

Although we have identified two sensitizers in FreeStyle Libre, we cannot rule out the possibility that other sensitizers are present in the sensor. However, we observed no reactions to other substances indicated by our chemical analyses to be present in the FreeStyle Libre sensor. Case 6 reacted to hydroquinone and resorcinol monobenzoate, but these substances were not observed in the analyses of the extracts. A high proportion of positive reactions to SLM has previously been described in patients reacting to IBOA.¹ We found positive reactions to SLM and/or its constituents in four of the seven patients presented here. The reason for this overrepresentation of simultaneous reactions is yet to be explained, and will be discussed in a separate article.

Our cases were presumably sensitized to DMAA present in an adhesive used in the FreeStyle Libre sensor. Six of them were also sensitized to IBOA, which is also found in the sensor. The high number of concomitant reactions to DMAA and IBOA is probably explained by simultaneous exposure to these substances during use of the FreeStyle Libre sensor. Owing to structural differences, cross-reactions between IBOA and DMAA seem to be unlikely. As both IBOA and DMAA are ingredients of adhesives used for medical devices, they should be patch tested when suspected contact allergic reactions to medical devices such as glucose sensors and insulin pumps are investigated.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to report.

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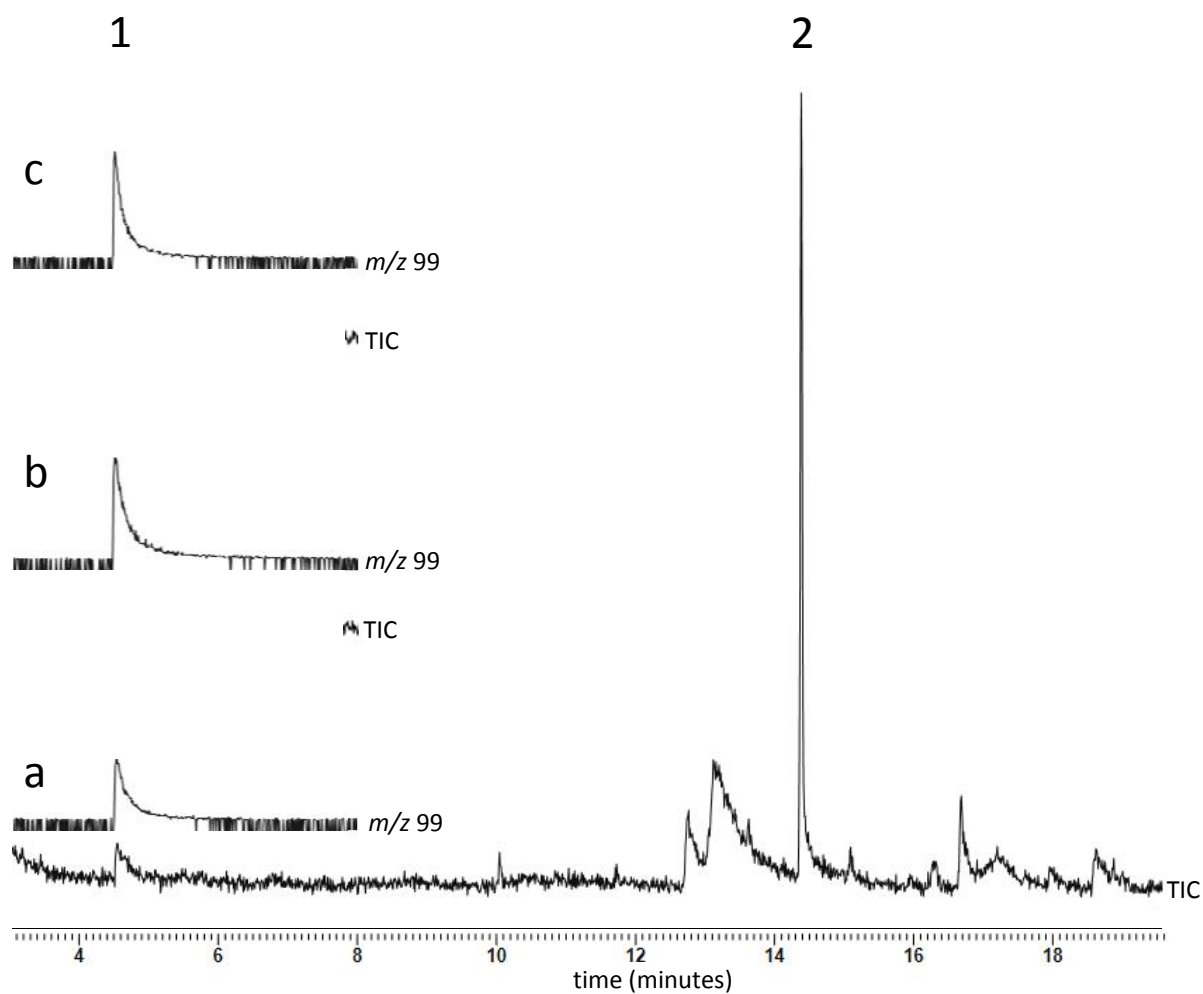
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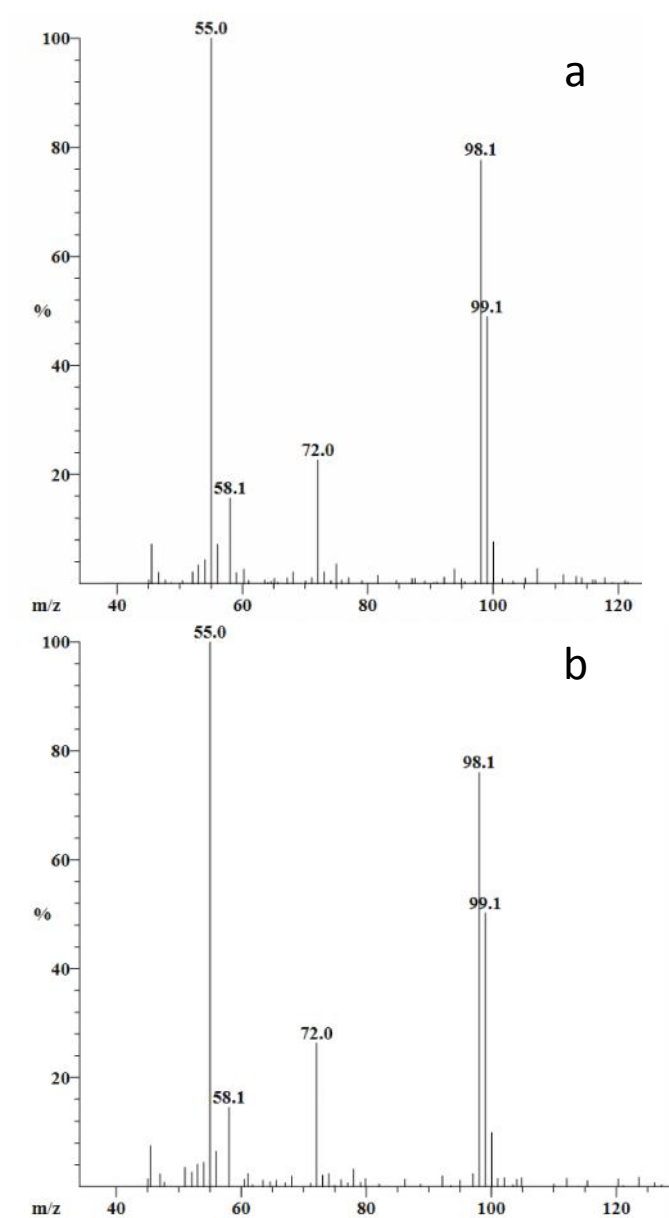
SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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Online supplemental Figure 2. Total ion chromatograms (TIC) of a) an acetone extract of a FreeStyle Libre sensor (without adhesive patch), b) N,N-dimethylacrylamide (DMAA) 0.05% (w/v) in acetone, and c) a FreeStyle Libre sensor extract spiked with DMAA. Above each TIC is an extracted ion chromatogram of m/z 99 corresponding to the molecular ion of DMAA. The peaks of DMAA and isobornyl acrylate is labelled 1 and 2, respectively.



Online supplemental Figure 3. Mass spectra of the N,N-dimethylacrylamide (DMAA) peak in a) 0.05% (w/v) DMAA in acetone and b) an acetone extract of the FreeStyle Libre sensor.