

Document Detail

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Title: Allergen letter for plastics (ESSIX A+ C+ ACE & PLUS; Duraclear Duraforce UltraFit; Ideal Clear, Comfort & Premium)
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Approvals

<u>Role</u>	<u>Sign-off By</u>	<u>Sign-off Date</u>	
REG Document Control	Nancy R Gordon	08-Apr-2016 12:11 pm	GMT
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Director QA/RA	Scott Lurgio	08-Apr-2016 12:36 pm	GMT
GAC Marketing Director	Elizabeth Malson	08-Apr-2016 12:16 pm	GMT
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Dear Valued Customer,

RE: **ESSIX® A+, C+, ACE and PLUS Duraclear, Duraforce, UltraFit Ideal Clear, Comfort and Premium**

To support DENTSPLY's commitment to product satisfaction and patient safety, below are answers to frequently asked questions related to potential allergens. While Safety Data Sheets (SDS) for these products may have been provided in the past, their availability will be discontinued in 2016 as these products are not considered hazardous materials and are stable under prescribed storage and use conditions. We encourage you to read the Directions for Use provided with each product for safe and effective use and storage. You can find additional safety and use information on the product packages and labels. To communicate as much as possible, potential allergen information is being provided below. To the best of our knowledge, the above mentioned plastic sheets are not made with nor do they come in contact with the following known allergens:

Benzoyl Peroxide (C ₆ H ₅ C(O ₂)] ₂ O ₂)	Persulfates
BPA	Potassium dichromate (K ₂ Cr ₂ O ₇)
Corn	Pesticides
Corn derivatives	Peanuts
DEHP	Sesame
Dimethyl fumarate (C ₆ H ₈ O ₄)	Shellfish
Eggs	Silica Gel
Gluten	Soybeans
Latex	Talc
Milk (dairy)	Tree nuts
Nickel	Wheat

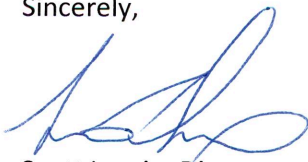
Please note that we have not specifically analyzed these products for the presence of the above mentioned substances. However, based on our current knowledge of the raw materials and manufacturing processes, we have not reason to suspect that these substances would be present at any appreciable level.

For additional information or direct customer service/support, please contact:

DENTSPLY Raintree Essix
1-800-883-8733

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1-800-645-5530

Sincerely,



Scott Lurgio, Director
Quality Assurance & Regulatory Affairs