

# Product Information On

## Quadrant Total Etch Tooth Conditioner

<b>Legal manufacturer:</b>	<b>Cavex Holland BV</b> Fustweg 5 2031CJ Haarlem
<b>Regulatory evaluator:</b>  <b>Signature:</b>	<b>Danny Stoelinga</b>  
<b>Regulatory manager:</b>  <b>Signature:</b>	<b>Richard Woortman</b>  
<b>Version:</b>	<b>2021-09</b>

- **Introduction.**

Quadrant Total Etch is a phosphoric acid based tooth conditioner. It is used in the so-called “total etch technique” for the pre-treatment of both enamel and dentine, in combination with a bonding agent such as Quadrant UniBond. This enables the dentist to operate according to the principles of adhesive dentistry, adopting the minimal invasive technique for maximal preservation of sound tooth tissue.

The normal procedure, after a “lege artis” cavity preparation, is to apply Quadrant Total Etch to enamel and dentine simultaneously and leave it for 15-30 seconds. Then rinse off with water for 15 seconds and blow dry with air. Finally the cavity can be treated with bonding agent and filled with a composite filling material according to the manufacturer’s instruction.

Quadrant Total Etch is developed and manufactured by Cavex Holland B.V., a Company that is certified according to the provisions of the Council Directive 2017/745 concerning Medical Devices, against ISO 9001 and ISO 13485.

Quadrant Total Etch bears the CE-Mark of conformity.

- **Composition.**

The basic ingredients of Quadrant Total Etch are:

Orthophosphoric acid	35.0	% w
Thickening agents	5.3	% w
Water	59.5	% w
Pigment	0.2	% w

- **Manufacturing.**

Basically, all ingredients are carefully weighed and dissolved or dispersed in water.

- **Laboratory control.**

At present, a product standard for etching agents is not available. Therefore, quality control is carried out according to a number of in-house standards.

- **Shelf-life test.**

There is no official shelf-life test described for etching agents. Based on the results of in-house tests, we can guarantee the good qualities of Quadrant Total Etch for a period of 3 years, provided the product is stored below 25 °C/77 °F when not in use.

- **Quality Control.**

A batch of Quadrant Total Etch, that has passed all the tests, is released for sales. In case of one or more requirements being not in specification, that batch is withdrawn and not sold.

- **Statement of non-toxicity.**

We hereby declare that Quadrant Total Etch can be safely used and is non-toxic to the dentist, the dental assistant as well as to the patient.

Quadrant Total Etch will also normally not be irritant to oral tissues. Quadrant Total Etch does not contain any poisonous ingredients in sufficient concentration to be harmful to human beings, when used as directed.