

Product Information
On

Quadrant Total Etch
(Tooth conditioner)



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1. 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 Uni-1-Bond. 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.

Quadrant Total Etch is meant to be used multiple times (approximately 10 applications per syringe). When Quadrant Total Etch is applied using a brush or cannula, both brushes and cannulas are to be disposed after use.

Quadrant Total Etch is developed and manufactured by Cavex Holland B.V. of Haarlem, The Netherlands, a Company that is certified according to the provisions of the Regulation (EU) 2017/745 concerning Medical Devices, against ISO 9001 and ISO 13485.

Quadrant Total Etch bears the CE marking of conformity.

2. Composition

The following materials are used in Quadrant Total Etch:

Function	Raw Material	% Mass
Acid	Ortho phosphoric acid 85%	40.1
Filler	Silica	5,9
Additive	Fatty alcohol polyglycol ether	0.3
Pigment	CI Pigment blue 15	0.1
Solvent	Distilled water	53,6

3. Manufacturing

The manufacturing of Quadrant Total Etch is the result of gradually mixing all raw materials into a homogeneous blue substance. Quality controls ensure the good quality of Quadrant Total Etch after the manufacturing process.

4. Laboratory control

Of every single batch of Quadrant Total Etch the Appearance & O-Phosphoric acid is tested according to an in-house test method. 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.

The following tests are performed to ensure the good quality of the raw materials on the product Quadrant Total Etch:

Characteristic	Product specifications	Release specifications	
Filling weight	2 x 2,5	2 x 2,5	ml
O-phosphoric acid	34 - 36	34 - 36	%

5. Shelf-life test

Based on all this experience, we are able to guarantee the good quality of Quadrant Total Etch for a period of 3 years, when kept in its original packaging, provided the syringe is unopened and stored in a cool and dry place.

6. 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.

7. Statement of non-toxicity

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