Product Information
On

Cavex Non Gamma-2
Silver Alloy for Dental Amalgam

Legal manufacturer:	**Cavex Holland BV** **Fustweg 5** **2031CJ Haarlem** **SRN: NL-MF-000000423**
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1. Introduction

Cavex Non Gamma-2 is a modern dispersed phase high-copper alloy. The copper content is higher than that of conventional alloy.

The composition chosen means, that Cavex Non Gamma-2 belongs to the group of non gamma-2 alloys. This indicates, that with Cavex Non Gamma-2, the mechanically weak and corrosion prone gamma-2 phase will not be present. This is why Cavex Non Gamma-2 excels in a high mechanical strength, low creep and high corrosion resistance.

It is presented in the form of pre-dosed capsules (I-, II- and III-spill). The alloy and mercury in these capsules are mixed in an electrical mixer, to form a homogeneous mass with a smooth consistency, that can be easily condensed into the cavity. After finishing and polishing, an amalgam filling is achieved, that will resist the oral conditions for a long time.

Cavex Non Gammma-2 is in full compliance with EN ISO 24234 Dental Amalgam.

Cavex Non Gamma-2 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 ISO13485.

Cavex Non Gamma-2 bears the CE-marking of conformity.

2. Composition

The overall chemical composition of Cavex Non Gamma-2 is as follows:

silver	: app. 69.2 %
tin	: app. 18.6 %
copper	: app. 11.9 %
zinc	: app. 0.3 %

The recommended mixing ratio is: 10 parts of alloy to 10.7 parts of mercury.

3. Manufacturing

As Cavex Non Gamma-2 is a mixture of two alloys with a different composition and a different particle shape, the manufacturing of both alloys is described:

The lathe-cut alloy
This alloy has the following composition:

silver	: app. 68.0 %
tin	: app. 26.5 %
copper	: app. 5.0 %
zinc	: app. 0.5 %

These metals are molten and mixed in a heat-resistant crucible, placed in a so-called: medium-frequency induction furnace. Compared with traditional ways of heating, this oven allows a very short melting time and thus a reduction of the possibility of oxidation.

The molten alloy is transferred into a mould, resulting in an ingot after cooling. The ingot is heat-treated for recrystallization, in order to enhance the reactivity towards mercury, and then machined with a cutting-tool to produce needle-shaped particles.

The spherical alloy
This alloy has the following, eutectic composition:

silver	: 71.9 %
copper	: 28.1 %

These metals are molten in the same way as already described. The molten alloy is then atomised in an inert gas atmosphere with the aid of special equipment to form extremely fine spherical particles with a max. diameter of app. 40 µm.

The lathe-cut alloy and the spherical alloy are then blended together in a ratio of 7:3 to form Cavex Non Gamma-2. During this blending-process, measures are taken to prevent the two alloys to stratify at a later stage.

4. Laboratory control

The control of Cavex Non Gamma-2 can be divided into two groups of properties:

Patient-related, or physical properties:
The following table gives typical values for the physical properties of Cavex Non Gamma-2. When available, the corresponding requirements of the EN-ISO Specifications are mentioned. The working time and setting time, mentioned in the table, cannot be considered as absolute values. The working time is only an indication of the maximum time available for mixing, applying and condensing the amalgam. The setting time is only an indication of the moment at which the finishing of the amalgam can be started.

Characteristic	EN ISO 24234	Cavex Non Gamma-2	
working time	–	3	min.
setting time	–	8	min.
dimensional behaviour (5 min - 24 hrs)	–0,10 +0,15	+0,1	%
static creep after 7 days/37 °C	Max 2,0	0,6	%
compressive strength after 2 hour after 24 hours	 min. 100 min. 350	 160 >400	 MPa MPa
Corrosion resistance	>80	82	%

Dentist-related, or handling properties:
For the latter, there is in fact no official specification available. We are therefore using, already for many years, our own methods of testing the dentist-related qualities of Cavex Non Gamma-2.
The alloy is mixed with mercury in the recommended ratio in a mechanical mixer. The resulting amalgam-mix is judged on the following points:

- amalgamation: the alloy should have a direct and sufficient reaction with mercury, the amalgam must be more than only a mixture of powder and liquid
- plasticity (or: consistency): the amalgam should form a smooth, plastic mass, but with sufficient body to allow for good condensation into the cavity
- working time: the maximum time available for manipulation and condensation is determined, in an arbitrary but reproducible way
- hardening time: the moment at which the dentist can start finishing the amalgam in the cavity is determined, in an arbitrary but reproducible way

The information that can be derived from these tests is of an arbitrary nature, has no absolute value and can therefore not be published. But, based on our experience with this type of testing for many years, and combined with the test-results according to the various specifications, it enables us to guarantee the perfect and constant quality of Cavex Non Gamma-2 from batch to batch over the years.

5. Shelf-life test

There is no specific shelf-life test described for amalgam alloys. Shelf life has never been a problem for conventional-composition alloys in view of the noble character of the silver alloy.

Alloys such as Cavex Non Gamma-2 are a little bit different in that the spherical eutectic particles are somewhat sensitive to oxidation, affecting the amalgamation with mercury. It is recommended therefore to store Cavex Non Gamma-2 in a dry and preferably cool place. Under those conditions we can guarantee a shelf life of 3 years.

6. Quality Control

A batch of Cavex Non Gamma-2, 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 Cavex Non Gamma-2 can be safely used and is non-toxic to the patient as well as to the dental team.
Cavex Non Gamma-2 will also normally not be irritant to oral tissues and does not contain any hazardous ingredients in sufficient concentration to be harmful to human beings, when used as directed.
It must be emphasised, however, that Cavex Non Gamma-2 alloy has to be mixed with mercury to form an amalgam. Mercury is known to be toxic, in particular mercury vapour, and should therefore be handled with care, maintaining appropriate hygienic measures.