

USP Class VI & ISO 10993 & Food grade and skin safe silicones

Introduction

Because of their often biocompatible properties, anti-bacterial properties, oxygen permeability and because they often do not contain any large amounts of dangerous ingredients, silicones are deemed quite safe in their use and many end products made out of silicone are used for their skin friendliness, biocompatibility etc. Silicones are used in products that come into contact with food, in contact lenses, implants, prosthetics and even scar tissue bandages.

It is however important to note what silicones may be used for what purpose and who is responsible for the actual testing whether or not the end product complies with the regulations concerning the intended use.

Different silicones

Chemically we can divide the silicone into 2 larger groups:

- 1) Condensation curing silicone. These silicones react often with a tin or tin based catalyst. They can be made as
 - a. a ready to use 1 component silicone kit (often silicone caulk) or
 - b. a 2 component (RTV 2) silicone.

These silicones are most often used for making moulds for artists and industry that do not come into contact with food. Most of these silicones are not suitable for food contact. There are a few exceptions like Wacker E41 and E43.

- 2) Addition curing silicone. These silicones react with the use of a platinum or peroxide catalyst. These silicones often come in the form of
 - a. a 2 component set that cures at room temperature (also known as RTV 2). These are often used for mould making by artisans, hobbyists and smaller businesses or projects that do not merit the high cost of purchasing and maintaining a LSR injection machine.
 - b. a 2 component set that is injected by pressurized injection machines and mostly use a platinum catalyst. These are typical less fluid than the RTV 2 silicones but also a lot stronger. These silicones are often used for food grade or baby safe products and sanitary products.
 - c. 1 component HTV (high temperature vulcanising) silicones with a peroxide or platinum catalyst. Often used for food grade moulds, but also other strong end products.

Of the above only some of the silicones in the second category are considered food grade, skin and medical compatible. Almost all silicones from category 1 (condensation curing silicones) are not considered so. This is because the chemical reaction of condensation curing silicones will keep on going which will make the silicone exude rest material, next to the fact that the ingredients in general are less safe than those used in addition curing silicones.

Of the silicones in category 2 the addition curing silicones, the ones that use a peroxide catalyst always need to be post cured and possibly even a scavenger needs to be added to make the silicone free of unallowed peroxide/ acid rest material, before the product can be tested for its application.

Responsibility

Please note that we nor most suppliers will ever certify that a product made with silicones and silicone dyes and other additions provided will be food grade, skin friendly, medical grade and so on.

This is because the final result of the end product depends too much on the right handling process of all ingredients. No matter how 'friendly and clean' these materials may be, they cannot be certified because these certifications are only referring to final products. Only finished parts or goods which are 'clean, pure, non-toxic etc' formulated, processed with suitable, dedicated equipment in a belonging environment, many times in clean rooms, fully cured and post cured, packed in a suitable way and finally sterilized completely and reliable are reviewed, tested and if all criteria are passed certified. Only a finished product can be certified in total.

The common sense and logic behind that is that only the behaviour of the part used in a human body or in the food mould and so on is relevant, anything related to the process before that is considered irrelevant.

Because of the above Nedform BV will never accept liability for any outcome or test result nor for the possible success or failure of a project and its outcome.

How to move forward

The only thing we can advise is that all our products that have the added note in their description of being food grade or skin friendly in general comply with regulations like FDA and Bfr as applicable to these products on their own and are therefore unlikely to be the cause of failing the respective certifications of the end product if handled the right way.

In short, if you would like to produce a medical or food grade or skin friendly product with our silicones or silicone additives, we advise to use silicones labelled FDA or food grade or skin friendly, process them exactly as they are meant to be, do the same with all your other ingredients and in fact also with quality reviews, packaging etc and then test the end product yourself with a knowledgeable 3rd company.

This will give you the best possible chance to reach the desired result. If not, you might need to find out what the problem is and tweak your process or change some ingredients and try again. This procedure might be time consuming and costly, but the end result will be yours completely and cannot be passed on to or copied by others. It will give you the extra edge trying to win customers over that prefer certified goods.

Repeated due diligence

Please note that tested and certified end products will need to be quality reviewed regularly, your process has to be precise and repeatable (which often requires some ISO standards) and you will need to do external tests periodically too.

Help

If you need information, or require help or want to discuss anything concerning your project and the possible use of our products, we will be happy to be of service.

Please contact us at

Email: info@nedform.com or Phone: +31(0) 464106260