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Information for End Users of Food Grade Silicone Rubber Products

INTRODUCTION:

Many silicone rubber articles are designed for applications that bring them into direct contact with food or drinking water. These goods should not contain chemicals that are hazardous to health, nor should they impart unacceptable taste or odour.

There are a number of international organisations involved with the regulation of issues such as these.

The organisations most often referred to are:

- FDA - Food and Drug Administration, USA
- BGA - German Health Authorities (Bundes Gesundheits Amt),

FDA:

The FDA Recommendations are published in the Code of Federal Regulations.

The materials used in BFM Global Silicone Rubber intended for Food contact are covered in Chapter 177.2600, “Rubber articles intended for repeated use”.

The vulcanising agent used in the manufacture of this compound is withinthe prescribed maximum of 1.5% by weight of rubber product.

BGA:

The BGA Recommendations are subdivided into classes determined by the nature of the polymer used in the article. The BGA recommendations are published (in German) in “Franck, Kunstoffe”.

Each of the classes specifies a list of chemicals recommended for the manufacture of rubber articles that come into contact with food. For each chemical of group of chemicals maximum concentrations are given; in some cases they refer to the chemicals added, in other cases to the decomposition products in the finished article. In each of these recommendations it is stated that the finished article must not adversely affect taste and odour of the food coming into contact with it.

The relevant class for Silicone Rubber is - Class XV

The organic peroxide used as a vulcanising agent is specifically covered by these recommendations and state that “the ecomposition products originating from the cross-linking peroxide must not exceed 0.5% in the finished article”. BFM Global post cure food grade articles to ensure that this requirement is met.

BFM GLOBAL SILICONE SEAL

The seal is manufactured from a compound where it is post cured. The material is cured using no more than 1.5% 2:4 Di-Chloro Benzoyl Peroxide (50% active in silicone oil), which is within the limits prescribed by the FDA regulatory standards.

This FDA regulation deals with rubber articles intended for repeated use in contact with food. (See Above)

The regulations contain limitations on extractables, which apply to the finished fabricated article.

Due to the wide variation of end uses to which the material is used, compliance with individual regulations must, of necessity, rest with the end user.

The materials are subject to post curing to ensure the minimum level of residual reaction by-products.

This post curing consists of 2 hrs @ 150°C and then 8 hrs at 200°C.