Bisphenols

What are Bisphenols?
Bisphenols are a class of chemical compounds that are structurally related. Bisphenol A (2,2-bis(4-hydroxyphenyl) propane or 4,4'-isopropylidenediphenol) is the "parent" structure. Other bisphenols can be considered as derivatives of Bisphenol A (but not necessarily made from Bisphenol A) though there are some exceptions.

Uses of Bisphenols
The primary uses of Bisphenol A are in polycarbonate plastics and epoxy resins. It is also used for making other bisphenols, as an additive, and in polymers other than polycarbonate and epoxy. Other bisphenols are also used in polymer-making and have other specialized uses.

What are the Concerns About Bisphenols?
Bisphenol A may damage fertility, is skin sensitizing, is toxic to aquatic life, and an endocrine disruptor. Thus, Bisphenol A is harmful to both humans and the environment. Bisphenol AF (which contains fluorine) may also damage fertility and is toxic to aquatic life. Because of their close structural relationship, many bisphenols are suspected of being harmful to human health and/or the environment.

Exposure to humans and the environment may occur through migration of unreacted bisphenol monomer in the polymer or through degradation of the polymer into smaller molecules including the bisphenol monomer. The largest concern is for Bisphenol A because it is used in the largest amount, and because it is the bisphenol for which most data on its harmful effects are available.

Legal Status in Food Contact Materials
In the EU, Bisphenol A is allowed as a monomer for making plastics for food contact (specific migration limit 0.05 mg/kg), except in polycarbonate bottles and drinking cups for infants and young children (EC/10/2011 as amended). However, in December 2024 a ban on Bisphenol A and other hazardous bisphenols was introduced (EU/2024/3190). As regards Bisphenol A, the ban is not complete as there are a few exceptions. For other hazardous bisphenols (like Bisphenol AF and S), the ban is currently complete, however, their use could be allowed following an application for authorisation. Products made from hazardous bisphenols may be sold until January 2029.

In the absence of EU-wide legislation on rubber as a food contact material, some member states have made their own legislation/recommendations. Bisphenols are not allowed in Germany (BfR), the Netherlands (Warenwet), and France. Bisphenol (type not indicated) is allowed under Italian law and Bisphenol A is allowed in Spain for silicone rubber only.

Under US food contact material legislation, Bisphenol A is allowed in a number of polymers (but not rubbers falling under § 177.2600). Bisphenol AF has a Threshold of Regulation Exemption and is allowed for vulcanizing FKM rubber.

Legal Status in General
Bisphenols are regulated specifically or may be regulated based on their toxic properties (i.e., being toxic to reproduction means that they are so-called CMR-substances which are regulated by various legislation). Under REACH, Bisphenol A and Bisphenol S (and eventually Bisphenol AF) is part of the group entry 30 in Annex XVII; Bisphenol A is listed separately in entry 66. None of the restrictions apply to our products. Four bisphenols are on the REACH candidate list: A, B, S, and TBBPA (tetrabromobisphenol A).

Bisphenols in M Seals' Products

Though we do not have a complete overview, based on the information we have received from our suppliers so far, Bisphenol A is not used in our products. Based on the typical uses of Bisphenol A, we do not expect it to be in our products. One exception is polyurethane, as bisphenols could potentially be used in making polyurethanes (we do not have any indication that bisphenols are used).

Bisphenol AF is used for curing FKM rubbers (Viton®); FKM rubbers cured by other means are also available.

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