Bio-compatible color matches for polyarylamides are stable under high-energy gamma ray radiation during sterilization of medical articles

Polyarylamides. Amongst high-performance polymers polyarylamide (PARA) compounds which contain suitable fillers are unique in their ability to replace zinc, aluminum die castings and other metals in an almost 1:1 ratio. Stabilized compounds can also withstand gamma radiation sterilization with very little color shift or reduction of mechanical properties. This paves the way for metal substitution in applications in areas such as medical technology or as construction materials in transportation systems.

From Metal Substitution to Sterilization

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In the early 1990s the group of aliphatic polyamides (e.g. PA6 and PA66), in common use since 1950, was joined by the partially aromatic polyamides. An inherent advantage of this class of polyamides is good chemical and service temperature resistance combined with higher strength and stiffness properties as well as low creep. The low and slow water absorption rate of partially aromatic polyamides allows them to maintain good mechanical properties and dimensional stability in use. As a result, design engineers can now specify this injection moldable plastic for complex applications and take advantage of a high degree of part consolidation.

The trend towards miniaturization, the evolutionary progressive reduction in component wall thickness and the realization of complex and daring design requirements were already a great challenge for cost-effective metal processing technology. When OEMs brought in additional requirements, such as corrosion prevention and thermal or electrical insulation, high-performance polymers were able to demonstrate their strengths. The trend to replace metal with polymers is not just limited to industrial applications, but also applies to consumer articles. A survey by SpecialChem (Q1 2009) showed that component part weight reduction was the principle motivation for metal substitution, followed by reduction in cost for part integration as well as the overall system.

Alternatives to Zinc and Aluminum Die Castings

Solvay S.A., Brussels, Belgium, launched its polyarylamide Ixef in 1988. The special structure of the base polymer **(Fig. 1)** in combination with suitable fillers results in compounds **(Fig. 2)** that are suitable as almost 1:1 replacements in zinc and aluminum die casting applications. The unique feature of compounded polyaryl- →

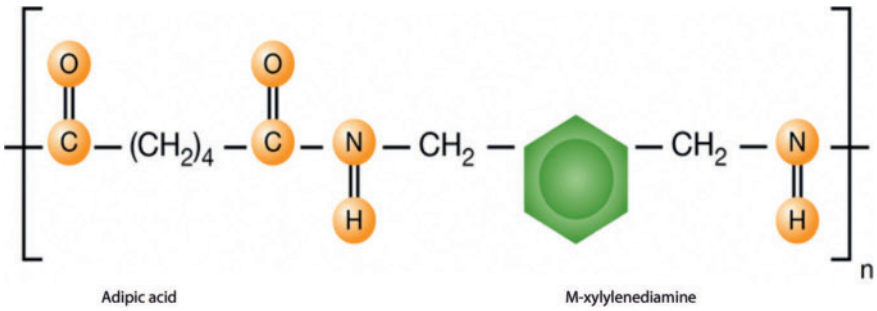

Fig. 1. The structure of polyarylamide MXD6 is determined by the aromatic units in the chain that are responsible for the unique properties of these partially aromatic polyamides

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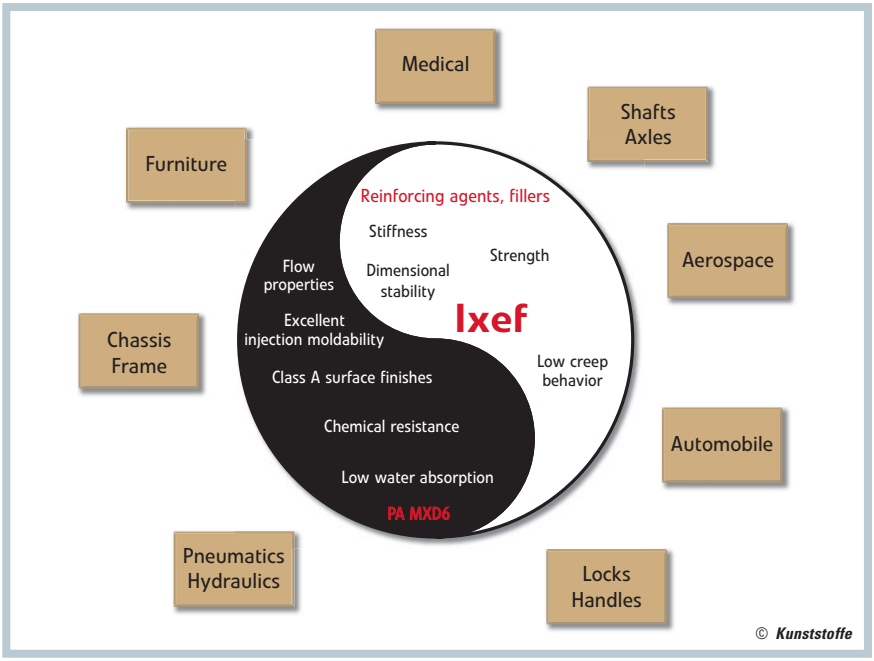

Fig. 2. The specific composition of MXD6 with fillers and reinforcing agents opens ever more application areas for polyarylamide

amides is the excellent combination of properties such as

- high stiffness (E_z up to 24 GPa),
- high strength (σ_b up to 400 MPa),
- very high fatigue resistance,
- a coefficient of thermal expansion similar to aluminum,
- very low creep,
- low and slow water absorption,
- low and uniform shrinkage,
- exceptional flow and high reproducibility as well as
- excellent surface finish (Class A).

A very good example of this range of properties is given by Ixef 1022, a polyarylamide compound with a glass fiber content of 50 %. The use of Ixef 1022 in various market segments underlines the versatility of this grade. In pneumatics and hydraulics, its good dimensional stability, low creep and production stability are highly regarded. The furniture and fittings industry values the fatigue resistance, good mechanical properties and aesthetic surface finishes. The automobile and bicycle industries require uniformly high mechanical properties, a high degree of component integration, resistance to environmental influences and media, a Class A surface finish as well as good paintability and the option of metallization **(Fig. 3)**.

Fig. 3. The housing of the Move Control Compact caravan mover (manufacturer: Reich GmbH) transfers large forces and can withstand extreme loading and weather conditions

The aerospace and rail sectors look for stiff, lightweight, flame and heat resistant materials that when heated have low toxic gas and smoke emissions as well as strength and an attractive appearance. Ixef 1521, a flame retardant grade, was developed from Ixef 1022. However, in order to preempt future regulations Ixef 1524, a halogen free, flame retardant formulation, has already been included in the portfolio. Ixef 1521 as well as Ixef 1524 have demonstrated that in specific applications they can meet FAR 25.853d (Smoke Density), FAR 25.853a (60s Vertical Burn), ABD 0031 & BSS 7239 (Toxic Gas Emission) as well as many specifications from the rail sector. Ixef 1524 is also increasingly establishing itself in the electronic and electrical segment and its excellent flow properties even at the thinnest wall thicknesses support the increasing levels of miniaturization **(Fig. 4)**.

The color matches Ixef 1022/0006 (natural) and Ixef 1022/9006 (black) provide users with EU-Food, ISO 10993 certified grades in accordance with the KTW guidelines (German requirements for polymers in contact with potable water) with which sensitive applications in the health sector can be realized. In this area Ixef's remarkable aging and creep resistance are also welcome. The TECElogo water fitting shown in **Figure 5** has to remain water tight for decades.

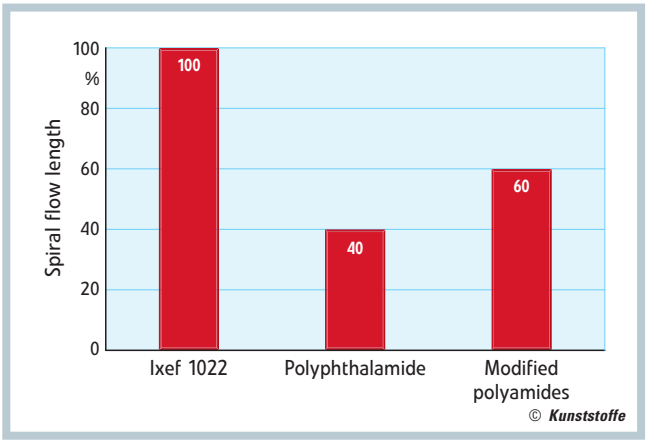

Fig. 4. Melt flow properties of Ixef 1022 polyarylamide in comparison to other aromatic and aliphatic polyamides

Stable even during Sterilization

The demographic trends in the industrialized countries are overwhelmingly towards a reduction and aging of the

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Fig. 5. The union nuts of TECElogo fittings are manufactured in a 2-component process in polyarylamide with an insert molded viewing port

population. Illnesses due to modern civilization are on the increase. Whilst in the developed world for example diabetes increases at an annual rate of 6 % this illness is growing overproportionally in the industrial areas of developing countries. Retaining the health of the population and therefore the workforce is going to be a central theme in our knowledge-based society, thus the importance of medical technology is increasing.

The risk of infection in clinics and hospitals has been shown to be high and so the cleaning and sterilization overhead for medical instruments is growing. The danger of infection during and after an operation has to be minimized so that patients can recover as quickly as possible. Ixef GS-1022 polyarylamide is suitable for various sterilization methods. In addition to disinfection with commercial disinfectants Ixef GS-1022 can also be professionally sterilized. Potential sterilization methods are autoclaving for up to ten cycles over a period of 18 min at 134 °C in steam, up to 100 cycles with ethylene oxide gas, up to 24 cycles with hydrogen peroxide gas and with cost-effective high-energy gamma rays.

An increasingly popular way to minimize the risk of infection transmission is the use of disposables. These can be appropriately collected after use and thermally recycled.

Due to economic considerations medical disposables with demanding geometries are predominantly manufactured by injection molding and subsequently sterilized in their packaging with high-energy gamma ray radiation. The desire for color coding of medical disposables, whether for marketing reasons or to differentiate size and application in the operating room, has in the past been a limitation for parts that were gamma ray sterilized. With light colors, for example, a green color shift was seen.

In order to support the trend toward aesthetically attractive medical disposables Solvay Advanced Polymers has developed gamma stabilized colors of Ixef PARA **(Table 1)** that meet the requirements of ISO 10993. ΔE is used to quantify shifts in the color in terms of light/dark = L, red/green = a and yellow/blue = b. The mathematical equation is: $\Delta E = (\Delta L^2+\Delta a^2+\Delta b^2)^{1/2}$. The color details are referenced to the Pantone Matching System (PMS), RAL color standards as well as RGB color values. Ixef GS color plaques can be supplied if required.

Figure 6 and **Table 2** show numerically how the color changes as a result of gamma ray sterilization. The lighter the color, the greater the manufacturing and stabilization overhead. This also affects the mechanical properties of light color matches. **Figure 7** shows that the mechanical properties of Ixef GS-1022/WH01 (white) in comparison to Ixef 1022/0006 (natural) remain very good. The impact of the gamma ray irradiation on the mechanical properties of both Ixef grades is negligible.

Quo Vadis?

As yet no limits in respect of the application fields for polyarylamide compounds can be seen. Quite the reverse: the demands for widespread component integration up to and including hybrid applications, the continuing miniaturization →

	Ixef grade	PMS	ΔE	RAL	ΔE	RGB
	Ixef GS-1022/WH01	Cool Gray 1 C	7.5	9010	3	241 241 241
	Ixef GS-1022/GY51	7546 C	5	7024	2	57 74 88
	Ixef GS-1022/GY01	Cool Gray 6 C	4	7004	3	165 172 175
	Ixef GS-1022/GY02	5305 C	5	7035	4.5	210 211 219
	Ixef GS-1022/BU01	299 C	10	5012	6.5	0 152 219
	Ixef GS-1022/BN01	476 C	5	8017	3.5	76 51 39
	Ixef GS-1022/GN01	3285 C	7.5	6016	13	0 133 102
	Ixef 1022/9006	Black C	3	9004	2	73 44 38

Table 1. The color matches of Ixef polyarylamide serve as guidance and show the color shifts after an irradiation with 40 kGy

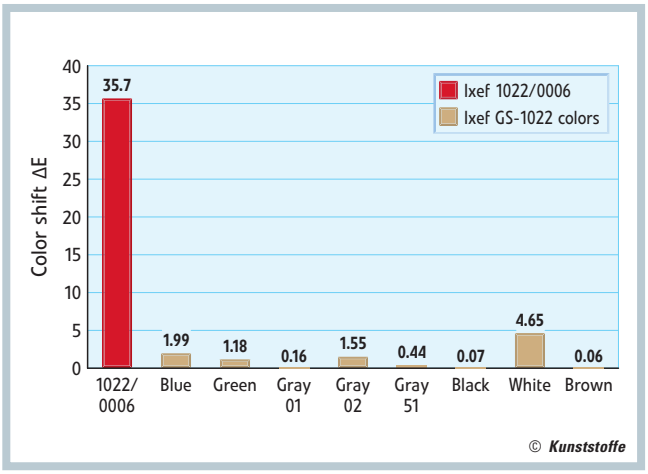

Fig. 6. Following gamma irradiation with 40 kGy the variation in the shift of the stabilized colors has a ΔE of 0.06 and 4.65 compared to the original color and during long term storage of the articles the ΔE falls

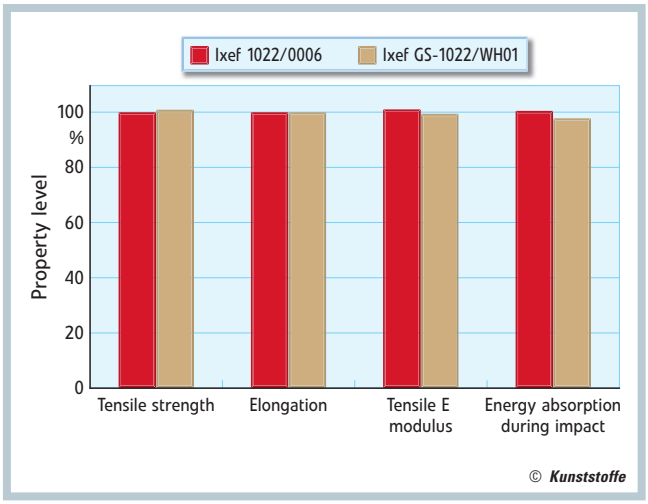

Fig. 7. The mechanical properties of Ixef 1022/0006 (natural) and Ixef GS-1022/WH01 are not affected by the gamma irradiation

CIE	Ixef 1022/0006		Ixef GS-1022-WH01	
	0 kGy	40 kGy	0 kGy	40 kGy
L	80.97	65.93	94.42	91.34
a	-4.42	0.34	-1.88	-1.35
b	6.65	38.68	3.36	6.83
ΔE		35.7		4.65

Table 2. Ixef 1022/0006, with an unstabilized natural color, shows a significant color shift after an irradiation with 40 kGy (high ΔE of 35.7); the white and color stabilized GS-1022/WH01 on the other hand has a respectable ΔE of 4.65

of component parts as well as the demand for lightweight highly mechanically loadable and aesthetically pleasing parts are driving unbroken growth for semi-aromatic polyamides (nylons).

Particularly for polyarylamide compounds application designers often only know and consider properties given in data sheets. This is however comparable with the tip of the iceberg emerging from the water, since these only cover part of the performance envelope of the material. The much larger part of the iceberg is below the waterline and this is also the case with the material properties of polyarylamide compounds that are not considered. There is much to be discovered here. ■

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