

ARKEMA

RILSAN[®]
MED

WHEN PERFORMANCE MEETS SUSTAINABILITY
RILSAN[®] FKZM 65 0 TD MED
HIGHLY GLASS FILLED
ADVANCED BIO-BASED POLYMER



INTRODUCING

RILSAN® FKZM 65 O TD MED THE SUSTAINABLE SOLUTION FOR SURGICAL TOOLS MANUFACTURERS

WHEN DESIGNING A MEDICAL DEVICE, PERFORMANCE IS THE NUMBER ONE CRITERION. WHEN A MATERIAL COMBINES PERFORMANCE AND SUSTAINABILITY, IT BECOMES A GAME CHANGER FOR THE INDUSTRY.

AT ARKEMA, WE ARE PASSIONATE ABOUT PERFORMANCE AND SUSTAINABILITY.

With the new Rilsan® FKZM 65 O TD MED, Arkema brings the medical device market a truly advanced, sustainable material with >98% bio-based carbon that allows companies to replace metal and traditional polymers without compromising on performance. Mindful of the end of life of its products, Arkema has designed the Rilsan® FKZM 65 O TD MED to be fully recyclable. The brochure will take you from the feedstock (castor beans) to our Virtucycle® recycling program. The circle of life meets the circular economy.

Thanks to a 70+ year legacy of polyamide 11 materials, the Arkema team has put its decades of expertise in motion to bring this new extreme material to life. We hope you are as excited as we are to enable advanced sustainable developments in the medical market!

Sustainably yours,

The Arkema High Performance Polymers Healthcare Team

THE ARKEMA OFFER **ADVANCED MATERIALS DESIGNED TO SUSTAINABLY MEET THE CHALLENGES OF AN EVOLVING WORLD**

ADVANCED MATERIALS

Arkema is a pioneer in amino 11 chemistry. Its flagship Rilsan® polyamide 11 and Pebax® Rnew® thermoplastic elastomers have a proven legacy in meeting some of the world's most demanding material challenges. Their trademark properties include light weight, flexibility, durability, energy return, and overall toughness.

They represent two families of highly differentiated advanced materials with a wide portfolio of options, including grades that are tailored for higher temperatures, high transparency, as well as functional characteristics like breathable and antistatic properties.

BIO-BASED

Arkema's amino 11 chemistry is derived from the castor bean, a sustainable, renewable crop that does not compete with food and does not cause deforestation.

Arkema is a leading driver of sustainable castor farming in India.

CIRCULAR

The castor bean is actually a seed. When planted, more seeds grow – the circle of life. Further, Rilsan® and Pebax® Rnew® grades are recyclable. Arkema offers its Virtucycle® services to partner customers.

ADVANCED BIO-CIRCULAR MATERIALS

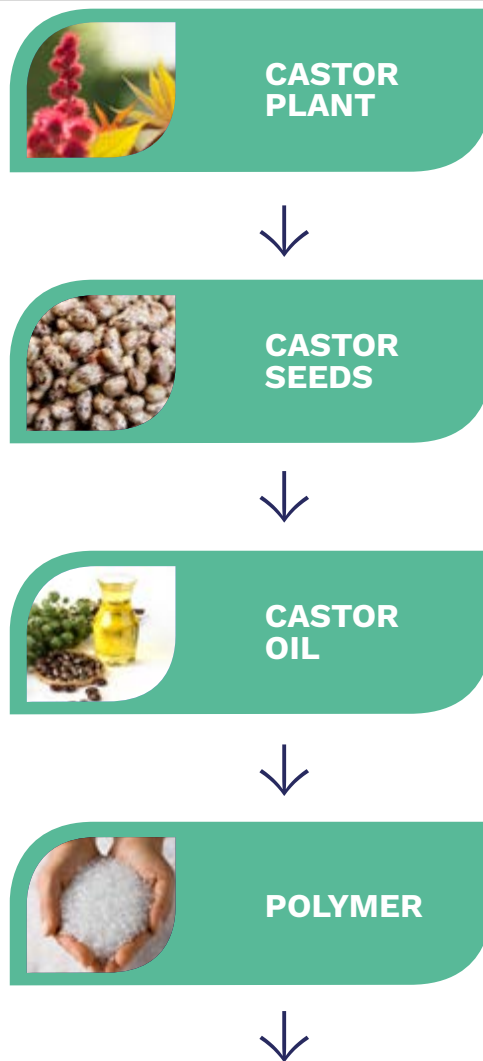
THE CIRCLE OF LIFE MEETS THE CIRCULAR ECONOMY



ARKEMA

From castor bean to advanced polymers

A MIRACLE OF MODERN SCIENCE



THE CASTOR BEAN TRULY SUSTAINABLE !



NO COMPETITION WITH FOOD / FEED



NO DEFORESTATION



HIGHLY PROFITABLE FOR THE FARMERS (THE MAIN REASON THEY GROW CASTOR)



GROWN MAINLY IN INDIA ONLY IN THE POOREST SOIL



THE BEANS ARE CRUSHED TO MAKE ~45% OIL AND 55% CAKE (SOLD AS FERTILIZER)

“

A ‘kharif crop’, castor takes full advantage of India’s natural monsoon phenomenon ”

ARKEMA is the world’s largest processor of castor oil

RENEWABLE FEEDSTOCK

Reducing dependence on fossil fuels



OIL

→ “GEOLOGIC carbon”

Carbon is derived from ancient fossils

> 1M years to produce



CASTOR BEANS

→ “ATMOSPHERIC carbon”

Carbon is derived from atmospheric CO₂

< 1 year to produce

RILSAN® FKZM 65 0 TD MED

Technical properties

PROPERTY	TYPICAL VALUE	UNIT	TEST METHOD
Nature & designation	PA11 - GF65		
Density	1.69	g/cm³	ISO 1183
Melting Point	190	°C	ISO 11357
Tensile Test (*)			
Stress at Break (23°C) (DAM)	208	MPa	ISO 527
Strain at Break (23°C) (DAM)	3.9	%	ISO 527
Tensile Modulus (*)			
23°C	18 500	MPa	ISO 527
Charpy Impact (*)			
V-notched 23°C (cond 15d)	19	kJ/m ²	ISO 179
V-notched -30°C (cond 15d)	24	kJ/m ²	ISO 179
MFI 235°C, 5Kg	6.7	g/10 min	

Table 1 Main characteristics

* Sample dried as molded

PROCESSING CONDITIONS

Condition	Typical Value
Injection	
Melt temperature (Min / Recommended / Max)	270°C / 285°C / 300 °C
Mold	
Temperature	30-90°C
Drying (only necessary for bags/containers opened for more than 2 hours)	
Time	4-8 hours
Temperature	80-90°C

Table 2 Processing conditions

STERILIZATION RESISTANCE

	Steam (100 cycles)		Gamma	Ethylene Oxide	E-Beam
	121C, 30min, 1bar	134C, 12min, 2bar	50 kGy		50 kGy
Rilsan® FKZM 65 O TD MED	+++	+++	+++	+++	++

Table 3 Sterilization Resistance

- +++ Suitable - No change
- ++ Suitable - Change in color but no change in mechanical performance
- 0 Not suitable

CHEMICAL RESISTANCE

	Bleach	H ₂ O ₂	IPA	Phenol	QAC	Ether	Detergent	DMSO
Rilsan® FKZM 65 O TD MED	+++	+++	+++	+++	+++	+++	+++	+++

→ **TABLE 4** demonstrates the qualitative performance of chemical resistance based on surface aspect (the appearance of cracks) and coloration. Environmental stress cracking resistance tests (ESCR) were performed using elliptical Bergen jig, which applies a range of strains to a single sample bar and injected plates immersed into the indicated chemical agent at room temperature (23°C) for 24 hours.

QUALITATIVE KEY FOR CHEMICAL RESISTANCE

- +++ Resistant. No or little change in weight or dimensions, no damage
- ++ Limited resistance. Change in weight or dimensions after longer periods, possibly irreversible changes of properties. We recommend contacting us before use
- + Not resistant. May still sometimes be used under specific conditions (short exposure time, contact droplets)
- 0 Soluble or attacked after brief contact

MATERIAL SWELLING PERFORMANCE

	Bleach	H ₂ O ₂	IPA	Phenol	QAC	Ether	Detergent	DMSO
Rilsan® FKZM 65 O TD MED	+++	+++	+++	+++	+++	+++	+++	+++

→ **TABLE 5** demonstrates the solvent absorption of all the medical grades based on standard ASTM D543. Sample injected plates (1 mm thickness) were immersed in the designated solvent. The samples were maintained at room temperature (23°C) until the swelling reached a complete saturation of the material (approximately 1,300 hours). The weight absorption was measured regularly by removing the sample from the solvent, wiping it and weighing.

QUALITATIVE KEY FOR MATERIAL SWELLING

- +++ Resistant. No or little change in weight, no damage ($-2\% < \Delta m < 5\%$)
- ++ Limited resistance. Change in weight after longer periods ($5\% < \Delta m < 15\%$)
- + Not resistant ($\Delta m > 15\%$)
- Δm Mean of relative weight change (short exposure time, contact droplets)
- 0 Soluble or attacked after brief contact

COLORS



PANTONE
419 C



PANTONE
420 C



PANTONE
424 C



PANTONE
2905 C



PANTONE
7592 C



PANTONE
7742C



PANTONE
3025 C



PANTONE
000 C

Rilsan® FKZM 65 TD O MED color masterbatches are available in 8 shades developed by our partner Foster Corporation.

All colors have been formulated using pigments that have passed biocompatibility testing

Customized color matching service available on demand

ENVIRONMENTAL DATA

Life Cycle Analysis data available on demand, please contact your Arkema sales representative

CARBON BIO-BASED CONTENT

>98% bio-based carbon (calculated according to ASTM 6866)

BIOCOMPATIBILITY ASSESSMENT

- USP Class VI
- ISO10993-4 Hemocompatibility
- ISO10993-5 Cytotoxicity
- ISO10993-10 Skin sensitization

APPLICATIONS

Surgical Tools



Interview with

MARK JESSUP, MANAGING DIRECTOR AT SURGICAL DYNAMICS



WHAT ARE THE MAIN CHARACTERISTICS OF RILSAN® FKZM 65 O TD MED THAT MAKE IT A PERFECT FIT FOR THE PRODUCTION OF SURGICAL TOOLS?

Initially, we were looking for a replacement to the PARA we were using due to supply issues and selected the Rilsan® FKZM 65 O TD MED. We have found in this new polymer an ideal material for our surgical tools due to its excellent mechanical characteristics and bio compatibility.

DO YOU SEE A DIFFERENCE IN TERMS OF PROCESSABILITY AND PRODUCTIVITY WITH RILSAN® FKZM 65 O TD MED COMPARED TO OTHER MATERIALS YOU ARE RUNNING?

The Rilsan® FKZM 65 O TD MED is an easier material to process compared to PARA . It requires lower mould temperatures and injection pressure, and we have been able to decrease cycle times significantly whilst maintaining component integrity.

RILSAN® FKZM 65 O TD MED IS >98% BIO BASED, IS IT IMPORTANT FOR SURGICAL DYNAMICS TO OFFER MORE SUSTAINABLE SOLUTIONS TO THE MEDICAL MARKET?

We believe that our customers are becoming more interested in sourcing product which has been manufactured from bio based materials, and this has given us a marketing advantage, and a different angle to the sales proposal, allowing us to help customers reaching their CSR goals.

DO YOU INTEND TO CONTINUE TO SUBSTITUTE OR DEVELOP NEW PRODUCTS USING RILSAN® FKZM 65 O TD MED?

Yes we have other products planned for production using the Rilsan® FKZM 65 O TD MED, the material is able to withstand autoclaving which is useful for some of the devices we are currently selling and which we are planning for the future.

ARKEMA'S VIRTUOUS RECYCLING PROGRAM

Specifically built for our partner customers



→ Arkema plays the role of “matchmaker” – matching customers who want to recycle, with those who want to source recycled materials

→ Agiplast, our expert partner in compounding and recycling is now part of the Arkema family

→ Case-by-case basis

→ Mechanical recycling = ~80% further reduction in CO₂

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