




## Certificate of EU Food Contact Compliance

**Manufacturer:** **Agri Patria Sp. z o.o.**  
ul. Czesława Kłósia 14/1  
02-466 Warszawa  
Poland

**Product:** **SF360 & SF360AF**

**Date of Declaration:** **10 September, 2015**

This is to certify that the milking claw SF360 & SF360 AF are manufactured from compounds that are approved for contact with food and are comply with the EU Regulation 10/2011 (and in the legislation which it replaces; Commission Directive 2002/72/EC (06/08/2002) relating to plastic materials and articles intended to come into contact with foodstuffs and its amendments 2004/1/EC (06/01/2004), 2004/19/EC (01/03/2004), 2005/79/EC (18/11/2005), 2007/19/EC (30/03/2007), 2008/39/EC (06/03/2008) and Regulation (EC) No 975/2009 (19/10/2009)), within the framework defined by the Regulation 1935/2004/EC (27/10/2004) on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.



CEO Urban Górski  
10 September, 2015

# Radel® R-5000

## polyphenylsulfone

Radel® R-5000 is a transparent polyphenylsulfone (PPSU) which offers exceptional hydrolytic stability, and toughness superior to other commercially-available, high-temperature engineering resins. This resin also offer high deflection temperatures and outstanding resistance to environmental stress cracking. Radel® polymers are inherently flame

retardant, provide excellent thermal stability and possess good electrical properties.

- Clear: Radel® R-5000 CL 301
- Natural: Radel® R-5000 NT

### General

Material Status	• Commercial: Active		
Availability	• Asia Pacific • Europe	• Latin America • North America	
Features	• Acid Resistant • Autoclave Sterilizable • Base Resistant • Biocompatible • Detergent Resistant • E-beam Sterilizable • Ethylene Oxide Sterilizable • Flame Retardant • General Purpose	• Good Chemical Resistance • Good Dimensional Stability • Good Electrical Properties • Good Sterilizability • Good Thermal Aging Resistance • Good Thermal Stability • Heat Sterilizable • High ESCR (Stress Crack Resist.) • High Heat Resistance	• Hydrolytically Stable • Radiation (Gamma) Resistant • Radiation Sterilizable • Radiotranslucent • Steam Resistant • Steam Sterilizable • Ultra High Toughness
Uses	• Automotive Applications • Dental Applications • Food Service Applications	• Hospital Goods • Medical Devices • Medical/Healthcare Applications	• Membranes • Surgical Instruments
Agency Ratings	• FAA FAR 25.853a • ISO 10993	• NSF 51 <sup>1</sup> • NSF 61 <sup>2</sup>	
RoHS Compliance	• RoHS Compliant		
Automotive Specifications	• ASTM D6394 SP0312		
Appearance	• Clear/Transparent		
Forms	• Pellets		
Processing Method	• Blow Molding • Extrusion • Film Extrusion	• Injection Molding • Machining • Profile Extrusion	• Sheet Extrusion • Thermoforming

### Physical

	Typical Value	Unit	Test method
Specific Gravity	1.29		ASTM D792
Melt Mass-Flow Rate (MFR) (365°C/5.0 kg)	14 to 20	g/10 min	ASTM D1238
Molding Shrinkage - Flow (3.18 mm)	0.70	%	ASTM D955
Water Absorption			ASTM D570
24 hr	0.37	%	
Equilibrium	1.1	%	

# Radel® R-5000

polyphenylsulfone

<b>Mechanical</b>	<b>Typical Value</b>	<b>Unit</b>	<b>Test method</b>
Tensile Modulus (3.18 mm)	2340	MPa	ASTM D638
Tensile Strength (3.18 mm)	69.6	MPa	ASTM D638
Tensile Elongation			ASTM D638
Yield, 3.18 mm	7.2	%	
Break, 3.18 mm	60 to 120	%	
Flexural Modulus (3.18 mm)	2410	MPa	ASTM D790
Flexural Strength (5.0% Strain, 3.18 mm)	91.0	MPa	ASTM D790
<b>Impact</b>	<b>Typical Value</b>	<b>Unit</b>	<b>Test method</b>
Notched Izod Impact (3.18 mm)	690	J/m	ASTM D256
Tensile Impact Strength (3.18 mm)	399	kJ/m <sup>2</sup>	ASTM D1822
<b>Thermal</b>	<b>Typical Value</b>	<b>Unit</b>	<b>Test method</b>
Deflection Temperature Under Load			ASTM D648
1.8 MPa, Unannealed, 3.18 mm	207	°C	
Glass Transition Temperature	220	°C	ASTM E1356
CLTE - Flow (3.18 mm)	5.6E-5	cm/cm/°C	ASTM D696
<b>Electrical</b>	<b>Typical Value</b>	<b>Unit</b>	<b>Test method</b>
Volume Resistivity	9.0E+15	ohms·cm	ASTM D257
Dielectric Strength			ASTM D149
0.0254 mm	> 200	kV/mm	
3.18 mm	15	kV/mm	
Dielectric Constant (3.18 mm, 60 Hz)	3.44		ASTM D150
<b>Flammability</b>	<b>Typical Value</b>	<b>Unit</b>	<b>Test method</b>
Flame Rating <sup>3</sup> (0.762 mm)	V-0		UL 94
<b>Optical</b>	<b>Typical Value</b>	<b>Unit</b>	<b>Test method</b>
Refractive Index	1.672		ASTM D542
<b>Additional Information</b>	<b>Typical Value</b>	<b>Unit</b>	
Steam Sterilization - w/ Morpholine <sup>4</sup>	> 1000	Cycles	
<b>Injection</b>	<b>Typical Value</b>	<b>Unit</b>	
Drying Temperature	149	°C	
Drying Time	2.5	hr	
Processing (Melt) Temp	360 to 391	°C	
Mold Temperature	138 to 163	°C	
Screw Compression Ratio	2.2:1.0		
<b>Extrusion</b>	<b>Typical Value</b>	<b>Unit</b>	
Drying Temperature	171	°C	
Drying Time	4.0	hr	
Cylinder Zone 1 Temp.	338 to 388	°C	
Cylinder Zone 2 Temp.	338 to 388	°C	
Cylinder Zone 3 Temp.	338 to 388	°C	
Cylinder Zone 4 Temp.	338 to 388	°C	
Cylinder Zone 5 Temp.	338 to 388	°C	

# Radel® R-5000

polyphenylsulfone

## Extrusion

## Typical Value Unit

Adapter Temperature

327 to 371 °C

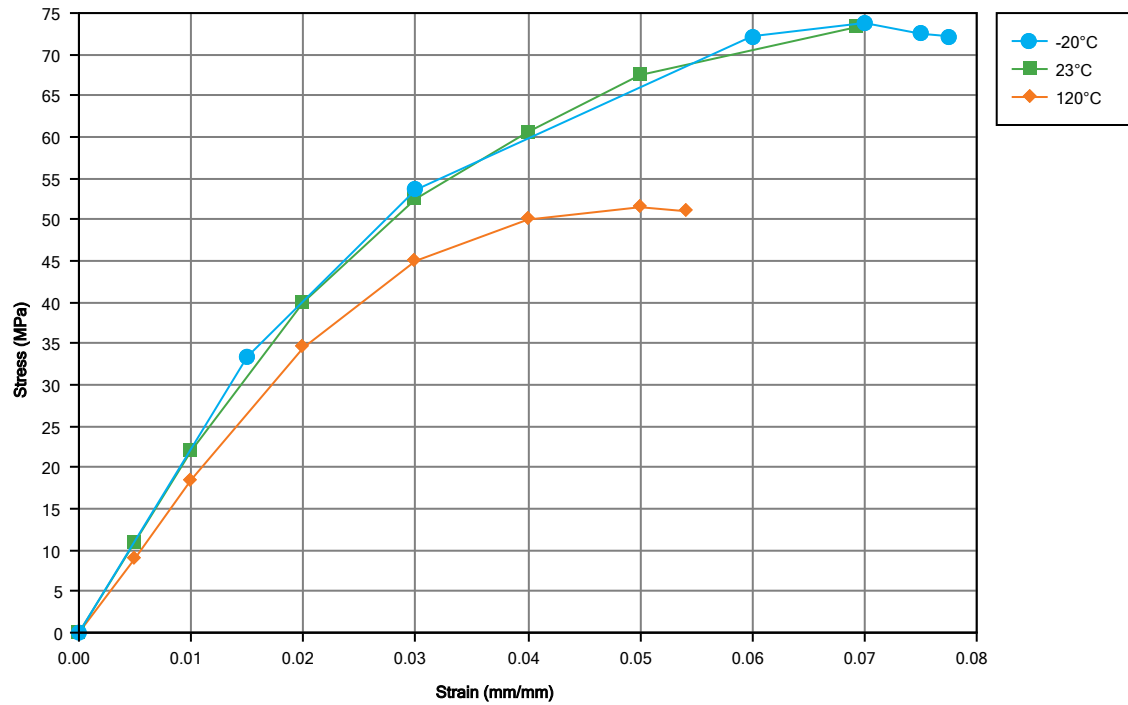
Melt Temperature

343 to 399 °C

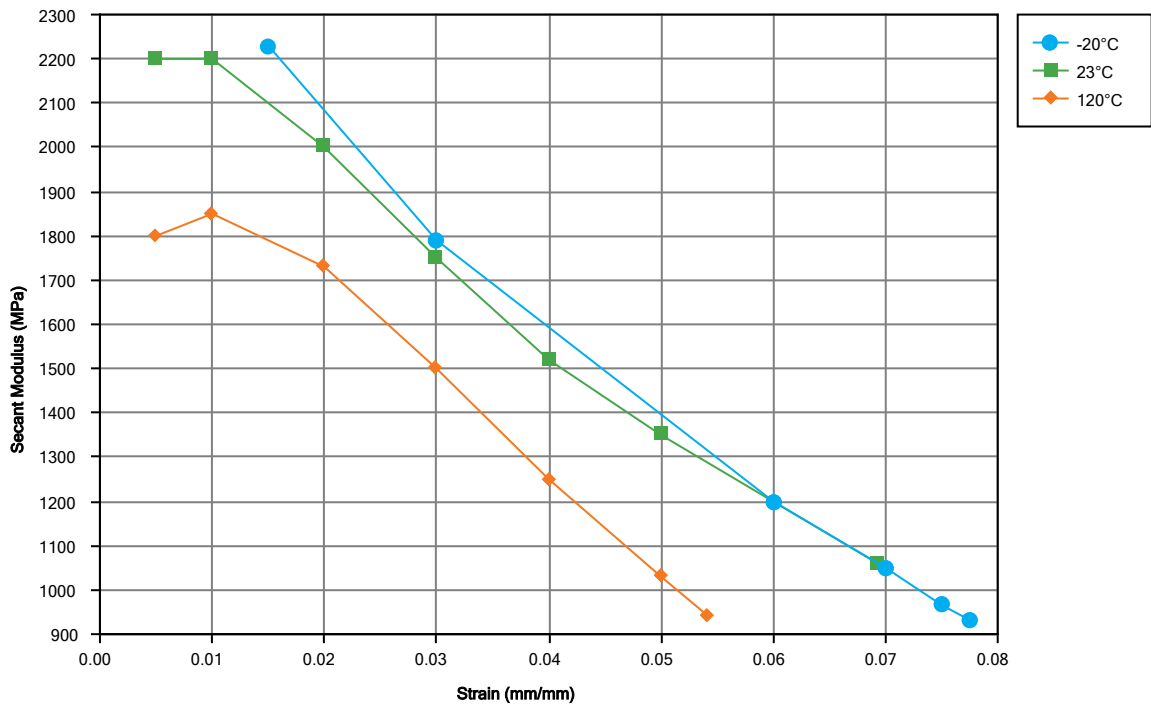
Die Temperature

327 to 371 °C

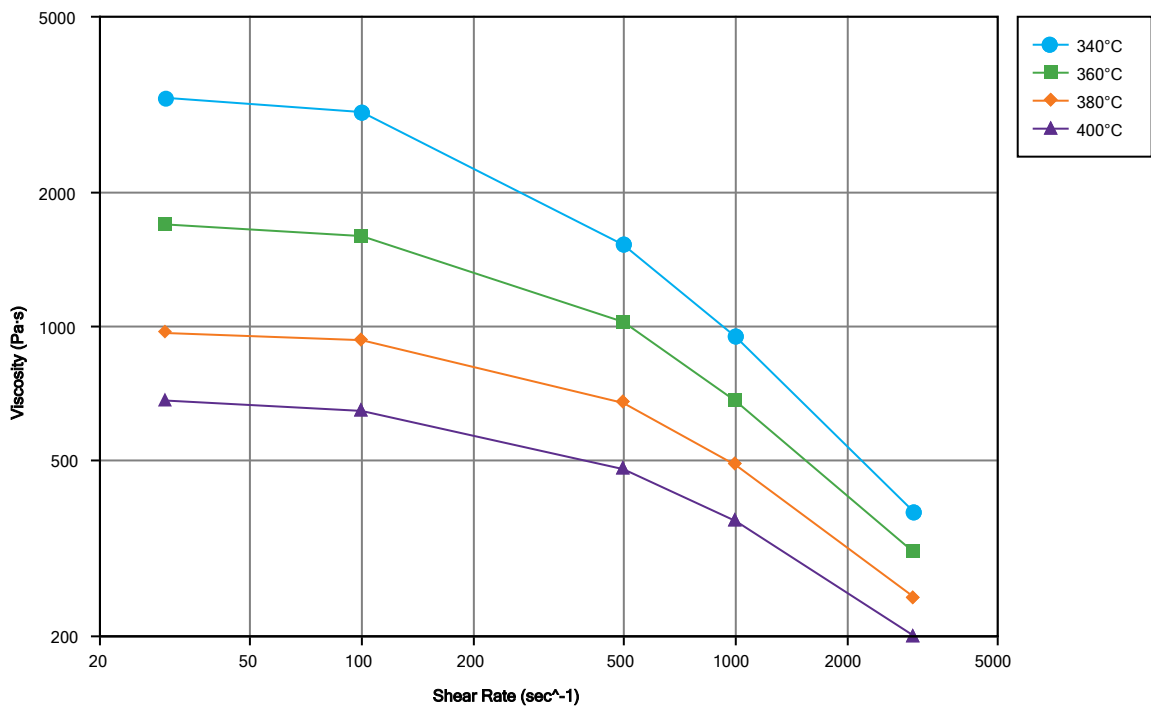
## Isothermal Stress vs. Strain (ISO 11403-1)



Secant Modulus vs. Strain (ISO 11403-1)



Viscosity vs. Shear Rate (ISO 11403-2)



# Radel® R-5000

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## Notes

Typical properties: these are not to be construed as specifications.

<sup>1</sup> Maximum Temperature of Use: 190°C (375°F)

<sup>2</sup> Tested at 82 °C (180 °F) (Commercial Hot)

<sup>3</sup> These flammability ratings are not intended to reflect hazards presented by these or any other materials under actual fire conditions.

<sup>4</sup> Cycles passed without cracking, crazing, or rupture.

Steam Autoclave Conditions:

- Temperature: 270°F (132°C)

- Time: 30 minutes/cycle

- Steam Pressure: 27 psig (0.19 MPa)

- Stress Level: 1000 psi (7.0 MPa) in flexure

- Additive: Morpholine at 50 ppm

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May 8, 2015

Re: FDA Status - Radel® R 5000 NT Polyphenylsulfone

The U.S. Food and Drug Administration has cleared Radel® R polyphenylsulfone resin for use in food contact applications. Radel® R polyphenylsulfone is the subject of Food Contact Notification (FCN) 000083, which became effective on September 23, 2000. Details concerning this clearance and specifications/limitations associated with it can be found in FDA's letter, which is attached. FCN 000083 has been added to the list of effective notifications for food contact substances available at FDA's Internet site at <http://www.cfsan.fda.gov/~dms/opa-fcn.html>.

Clearance of FCN 000083 permits the base resin Radel R polyphenylsulfone to be used in repeat use food contact applications with all food types, under FDA conditions of use B through H as described in Tables 1 and 2 of 21 CFR 176.170(c). However, the FDA status of individual Radel® R grades containing additives or pigments must be evaluated separately.

You have specifically requested information on the regulatory status of Radel® R-5000 NT. Radel® R-5000 NT, as manufactured, is compliant with FDA regulations based on clearances granted by FCN 000083. It is, however, the responsibility of the customer to determine that all conditions and specifications outlined in FCN 000083 are met, and that the products fabricated from these materials are acceptable to the FDA for use in their intended food-contact applications.

Any clearances granted by an FCN are proprietary to the submitter of the FCN, which is Solvay Specialty Polymers USA, L.L.C. in this case. These clearances may be extended to customers who use the FCN substance provided that documents linking the customer's product to the cleared FCN are maintained, and that the intended use is in accordance with the notification.

If you should require clarification or additional information, please contact your Account Manager directly.

Sincerely,

Migdalia Alvarado  
Product Stewardship Coordinator



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

September 22, 2000

Ralph A. Simmons  
Keller and Heckman LLP  
1001 G Street N.W.  
Suite 500 West  
Washington, DC 20001

Re: Food Contact Substance Notification FCN 000083

Dear Mr. Simmons:

This is in reference to your notification, submitted on behalf of BP Amoco Chemicals, Inc., for the food contact substance and use described as follows:

Food Contact Substance

Poly(oxy[1,1'-biphenyl]-4,4'-diyloxy-1,4-phenylenesulfonyl-1,4-phenylene) (CAS Reg. No. 25839-81-0).

Notifier

BP Amoco Chemicals, Inc.

Manufacturer/Supplier

BP Amoco Chemicals, Inc.

Intended Use

For repeated use in contact with food

Limitations/Specifications

1. The basic resins are produced by reacting 4,4'-biphenol and 4,4'-dichlorodiphenylsulfone according to the process described in your notification, so that the finished resin has a weight average molecular weight of at least 43,000.
2. The basic resins are to be used in contact with all food types under conditions of use B through H as described in Tables 1 and 2 of 21 CFR 176.170(c).



Page 2 - Mr. Simmons

This is to inform you that as of September 23, 2000, FCN 000083 will become effective. It will be added to the list of effective notifications for food contact substances available on the agency's internet site at <http://www.cfsan.fda.gov>.

The agency has determined that allowing this notification to become effective will not have a significant impact on the quality of the human environment and therefore an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, will be publicly available after the effective date of the notification.

This effective notification is applicable only to Poly(oxy[1,1'-biphenyl]-4,4'-diyloxy-1,4-phenylenesulfonyl-1,4-phenylene (CAS Reg. No. 25839-81-0, manufactured by BP Amoco Chemicals, Inc. and is limited to the use of the food contact substance identified above. You should inform the agency of any modification in the FCS limitations/specifications given in the notification or of any alteration in the manufacturing process that would result in a change in the impurities in the FCS. Such changes may require submission of a new notification.

The existence of an effective notification for a food contact substance does not relieve use of the subject substance from compliance with any other provision of the Federal Food, Drug, and Cosmetic Act or with 21 CFR §174.5 General provisions applicable to indirect food additives. For example, in accordance with section 402(a)(3) of the Act, use of the food contact substance should not impart odor or taste to food rendering it unfit for human consumption.

If new data or information become available to FDA demonstrating that the intended use of the food contact substance is no longer safe, the agency will inform you of its determination that the intended use of the food contact substance is no longer safe. In addition, if you become aware of data that raise questions about the safety of the intended use of the food contact substance, you should notify the agency immediately and be prepared to supply data necessary to resolve the questions.

If you have any further questions concerning this matter, please do not hesitate to contact us.

Sincerely,



Hortense S. Macon  
Division of Product Policy, HFS-205  
Center for Food Safety  
and Applied Nutrition



January 1, 2013

## **DECLARATION ON HAZARDOUS SUBSTANCES**

To the best of our knowledge on raw materials and production process used, we state that Solvay Specialty Polymers product

### **RADEL® R-5000 NT**

Supplied in the original sealed package complies with:

- Directive 2000/53/EC (“End of life vehicles”) as related to the content of Cadmium or Cadmium compounds, Lead, Mercury and hexavalent Chromium.
- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 (“on the restrictions of the use of certain hazardous substances in electrical and electronic equipment”) as related to the content of Cadmium or Cadmium compounds, Lead, Mercury and hexavalent Chromium, Polybrominated Biphenyl’s (PBB), Polybrominated Diphenylethers (PBDE).
- Complies with Directive 2002/96/EC (“Waste Electrical and Electronic Equipment – WEEE) as subsequently amended.
- Regulation 1907/2006 (Annex XVII as subsequently amended) repealing and replacing Directive 76/769/EEC (“Restrictions on the marketing and use of certain dangerous substances and preparations”).

Sincerely

A handwritten signature in black ink that reads 'Eric Zhu'.

Eric Zhu  
Product Stewardship Coordinator

**Alpharetta Materials Science & Testing Group**

LIMS RESULTS REPORT

Job Name : AUG2005ZRXH23-13296  
Description: Heavy Metals Testing

Report Date: July 26, 2005

Product Grade: RADEL R-5000 NT (204610) M-01178T  
Test Method: ICP-OES

COMPONENT NAME	RESULT VALUE	UNITS
=====		
CADMIUM	< 0.4	PPM-W
MERCURY	< 10	PPM-W
CHROMIUM	2.0	PPM-W
LEAD	< 10	PPM-W
TOTAL BROMINES	< 100	PPM-W

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March 5, 2013

## STATEMENT ON THE STATUS FOR FOOD-CONTACT APPLICATIONS

As specified below, the substances used to manufacture Solvay Specialty Polymers USA, L.L.C. Resin meet the requirements of Commission Regulation (EU) N° 10/2011 related to plastic materials and articles intended to come into contact with food and its subsequent amendments:

All monomers used for the manufacture of Radel<sup>®</sup> R-5000 NT. resin are listed in the “Union list of authorized monomers, other starting substances, macromolecules obtained from microbial fermentation, additives and polymer production aids.” (Annex 1 to Commission Regulation (EU) N°10/2011)

There are no additives present in Radel R-5000 NT.

Specific migration limits must be met by the final articles coming into contact with food for the following monomers:

Reference n°	CAS n°	Substance name	SML
16000	92-88-6	Biphenol	6 mg/kg
15610	80-07-9	4,4'- Dichlorodiphenylsulfone	0.05 mg/kg

Final articles must also be checked for overall migration limit which may not exceed 60 mg/kg of food or 10 mg/sq dm of surface area of article. Please be advised that Solvay Specialty Polymers has not conducted any migration testing to determine if our resin meets these migration limits.

It is the responsibility of the customer that all conditions and specifications outlined under the above mentioned regulation are met and the articles fabricated from the above mentioned grade are acceptable for use in their intended food contact applications.

If you should require clarification or additional information, please contact your Account Manager directly.

Sincerely,

*Migdalia Alvarado*  
Product Stewardship Coordinator

# Ideas and solutions in rubber compounding

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ZAKŁAD WYTWARZANIA ARTYKULOW  
Z GUMY DANUTA STOPCZYNSKA  
UL. JECZMIENNA 51  
56400 OLESNICA  
POLEN

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## Confirmation

The rubber compound used for the production of consumer articles in contact with food:

<b>Polymer:</b>	<b>EPDM</b>
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meets in its composition of active substances:

The positive list for aqueous food according CFR 21 § 177.2600 FDA "Rubber Articles Intended for Repealed Use" of the Food and Drug Administration, USA.

The positive list for latty foods (also for milk and edible oils) according CFR 21 §77.2600 FDA "Rubber Articles Intended for Repealed Use", of the Food and Drug Administration USA.

**Due to technically unavoidable conditions and/or application forms of of the raw materials, the elastomer compound may contain traces of materials, those correspond not above mentioned recommendations and guidelines.**

**In any case, therefore should take place the prescribed examinations of the final part.**