



Advanced Materials

Healthcare

COMPOUNDS
PLASTICIZERS
STABILIZERS
COLORANTS

alphagary



Polymer
Solutions

PVC compounds – **ALPHAMED®** ;
SUPERKLEEN™

TPU compounds – **VYTHENE®**

TPE compounds – **EVOPRENE® R**;
EVOPRENE® R ECO

Not available for ALBIS

Available for ALBIS

Please ask about our compounds
formulated with bio-based and/or
recycled content.



Compounds for Healthcare Applications

In this brochure, you will find an overview of the flexible and rigid PVC compounds, TPE compounds, and TPU compounds we offer for extruded and molded healthcare applications.

These compounds are formulated with ingredients sanctioned for indirect food contact (US FDA 21CFR, EU 10/2011, 1935/2004). We offer crystal-clear PVC compounds with various blue-tint levels (from water clear to opaque). Our TPE compounds are transparent or opaque, depending on the formulation chosen.

Since the 1960s, we have worked closely with our customers, often custom-formulating a material to optimize performance and consistency. To help navigate ever-changing regulatory requirements, we provide experienced regulatory advice from product conception up through commercialization and for years after.

Put our experience to work for you!



Committed to Sustainable Development

This mindset includes actions at our facilities, like adopting green energy and upgrading energy-efficiency, as well as how we approach material development by using recycled content and bio-based ingredients in our compounds and participating in programs that promote circularity

Compounds tested to USP Class VI Biocompatibility Testing

To streamline risk evaluation and device approval process, we provide test results conducted on our compounds to USP Class VI Biocompatibility standards. Some materials have been tested to Cytotoxicity standards and others have received ISO 10993 evaluation.

Phthalate Reporting Requirements

Yes, we offer DEHP-free compounds, non-phthalate compounds (including compounds formulated without ortho-phthalate plasticizers), and phthalate-free compounds. We encourage you to speak with our technical sales team to ensure we understand your requirements, because we often find these terms are used interchangeably which can cause confusion.

Typical Applications



Tubing, bags,
film, spouts,
drip chambers,
connectors
& seals



Needle
syringes, vial
stoppers &
needle wings

Regulatory Expertise

We have full-time regulatory expertise to help navigate ever-changing regulations. And we're transparent with reporting information. In our Safety Data Sheets, made for each product, we report Substances of Very High Concern, phthalate content, and REACH, RoHS, and Prop 65 information along with the necessary safety precautions typically found on a safety data sheets. Our customers find this information very helpful as they answer regulations and apply for third-party approval.

Formulated to be sterilized

We've carefully formulated compounds to withstand typical sterilization procedures – including EtO, autoclave, gamma or e-Beam – without discoloring. Please let our technical sales team know which method(s) is important and we'll steer you toward the most appropriate material.

Dedicated R&D Team

With fully appointed laboratory resources and decades of hands-on experience, we work closely with customers to choose the right candidates off-the-shelf or re-engineer based on performance requirements. Since our material portfolio includes PVC, TPE and blends, we have a broad range of solutions to choose from.

Consistency with every blend

We understand how important it is for materials to perform consistently and reliably. That's why we have adopted fixed practices that govern formulation integrity, process control and data acquisition. Customers trust us for this assurance so they can focus on creating dependable devices that are so critical to our health and wellbeing.



Tubing, masks,
cushions &
connectors



Syringe
bulbs & baby
pacifiers



Peristaltic
pump tubing,
cables & wires



Cables & wires

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PVC compounds – **ALPHAMED®** ;
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TPE compounds – **VYTHENE®**

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Our portfolio includes a wide range of PVC and TPU compounds formulated with ingredients sanctioned for indirect food contact (US FDA 21CFR, EU 10/2011, 1935/2004). Ask us for an off-the-shelf candidate or ask us to modify based on your specific requirements – we're happy to help!



Flexible PVC Compounds

Extrusion Available Hardness Range: 50-95 Shore A

Material	Base	Features	Applications	Sterilization Methods
ALPHAMED 1100 NP	Clear	NSF 51, formulated without BBP, DBP, DEHP, DINP, DIDP, DIBP	Tubing	ETO, Autoclave
ALPHAMED 2218	Clear	Static free, slip surface	Tubing	ETO, Autoclave
ALPHAMED 2222	Clear	High clarity	Tubing	ETO, Autoclave, Radiation (R series)
ALPHAMED 2222 FS	Translucent	Frosted surface, satin finish	Tubing, film	ETO, Autoclave
ALPHAMED 2222 BB	Clear	Blood bag, high clarity	Layflat tubing	ETO, Autoclave
ALPHAMED 2228	Clear	Blush resistant, formulated without BBP, DBP, DEHP, DINP, DIDP, DIBP	Tubing, film	ETO, Autoclave, Radiation (GBF series)
ALPHAMED 2233 AXLT	Clear	Low taste, low odour, formulated without DEHP	Beverage tubing	ETO, Autoclave
ALPHAMED 2235 L	Clear	Lipid resistant, formulated without phthalate plasticizers	Tubing, film	ETO, Autoclave, Radiation
ALPHAMED 3017, 3018	Opaque	Barium- or Bismuth-filled, radiopaque	Tubing	ETO, Autoclave
ALPHAMED 582	Clear	Migration resistance, formulated with non-phthalate plasticizers	Tubing	ETO, Autoclave, Radiation
SUPERKLEEN 2223	Clear	High clarity, formulated with a bio-based plasticizer	Tubing, film	ETO, Autoclave, Radiation (R series)

Molding Available Hardness Range: 50-95 Shore A

Material	Base	Features	Applications	Sterilization Methods
ALPHAMED 3006	Clear	High clarity, excellent stability	Drip chambers, respirator masks	ETO, Autoclave, Radiation (R series)
ALPHAMED 3009	Opaque	High flow, high gloss	Blender lids, appliance parts	ETO, Autoclave
ALPHAMED 3016	Clear	Blush resistant, formulated without BBP, DBP, DEHP, DINP, DIDP, DIBP	Baby pacifiers, ear plugs, connectors	ETO, Autoclave, Radiation (R series)
ALPHAMED 3019	Clear	Rubber-like feel, high gloss	Cannulas, connectors, face mask cushion	ETO, Autoclave
ALPHAMED 3071 BF	Clear	Non-marring, bovine free	Novelty toys, furniture parts	ETO, Autoclave
ALPHAMED 2235 LM	Clear	Lipid resistant, formulated without phthalate plasticizers	Drip chambers, bag spouts	ETO, Autoclave, Radiation
ALPHAMED 3022	Opaque	Rubber-like feel, low taste & odour	Syringe bulbs	ETO, Autoclave
ALPHAMED 3032	Clear	Blush resistant, formulated without phthalates	Drip chambers, bag spouts	ETO, Autoclave, Radiation (A/R series)
SUPERKLEEN 3003	Clear	High clarity, formulated with a bio-based plasticizer	Connectors, tubes, caps	ETO, Autoclave, Radiation (R series)

Phthalate Reporting Requirements

Reporting requirements for phthalates from the toy industry, RoHS, REACH, Prop 65 and medical device regulation continue to evolve. We work hard to stay current with ever-evolving industry standards and provide transparent reporting that gives our customers the visibility they need to choose the best material for their application(s).



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We are often asked for non-phthalate or phthalate-free compounds so that customers can comply with reporting requirements. We realize, however, that these terms could be misleading if they don't accurately identify the reportable phthalate content in a compound. In the spirit of transparency, we are publishing the below list which summarizes our understanding of the current reporting requirements. And we are identifying compliant compounds by providing the statement: "This product is not intentionally formulated with restricted phthalates".

January 2023 Status of Reporting Requirements	
When we state: "This product is not intentionally formulated with restricted phthalates", we are referring to this list:	
ORGANIZATION	REPORTABLE PHthalATES
EU Toy Industry Restricted Phthalates (1)	BBP, DBP, DEHP, DINP, DIDP, DIBP, DEHP, DINP, DIDP, DIBP
US Toy Industry Restricted Phthalates (2, CFSIA)	BBP, DBP, DEHP, DINP, DIDP, DIBP, DEHP, DINP, DIDP, DIBP
RoHS Restricted Phthalates (4)	BBP, DBP, DEHP, DINP, DIDP, DIBP, DEHP, DINP, DIDP, DIBP
REACH SVHC Restricted Phthalates (3)	BBP, DBP, DEHP, DINP, DIDP, DIBP, DEHP, DINP, DIDP, DIBP, DEHP, DINP, DIDP, DIBP, DEHP, DINP, DIDP, DIBP, DEHP, DINP, DIDP, DIBP
Prop 65 Phthalates requiring labeling (5)	BBP, DBP, DEHP, DINP, DIDP, DIBP, DEHP, DINP, DIDP, DIBP
EU Medical Device Regulation (12, EU MDR)	BBP, DBP, DEHP, DINP, DIDP, DIBP, DEHP, DINP, DIDP, DIBP, DEHP, DINP, DIDP, DIBP, DEHP, DINP, DIDP, DIBP, DEHP, DINP, DIDP, DIBP

Phthalates with ALBIS present that are not on this list are not restricted, and do not require reporting.

We team is happy to provide information specific to the compound(s) of interest.
email: info@alphagary.com
www.alphagary.com

January 2023 Rev 1

Please visit our website at www.alphagary.com or ask for a copy of our latest sell sheet **Phthalate Reporting Requirements**



Compounds for Healthcare Applications

Your customers turn to you for high-performing, cost-effective healthcare products. Count on us to understand the design challenges you face including today's stringent regulatory requirements. Our experienced team has decades of formulation and manufacturing expertise as well as up-to-date regulatory advice. We'll provide solutions that optimize performance and provide the consistency that is so critical to your manufacturing process.

Not available for ALBIS

Rigid PVC Compounds

Extrusion & Molding

Material	Grade	Application/Comment	BS Softness	Shore A
ALPHAMED 2212	Clear	High flow, stability, clarity	Chambers, luers, catheters, connectors, etc.	ETO, Autoclave, Radiation (R series)
ALPHAMED 202	Clear	High flow	Profiles, fittings	ETO, Autoclave
ALPHAMED 405	Clear	Low crease whitening	Pipe extrusion	ETO, Autoclave
ALPHAMED 725C	Clear	High flow, high impact	Blow molding	ETO, Autoclave
ALPHAMED R2116 /2 AND /5	Opaque	Formulated to pass NSF testing	Piping	ETO, Autoclave

Flexible TPU Compounds

Extrusion & Molding Available harness 50-90 Shore A

Material	Grade	Application/Comment	BS Softness	Shore A
VYTHENE 11X	Clear	Good resiliency	Blow molded mask cushions	ETO, Autoclave, Radiation (R series)
VYTHENE 13E	Clear	Good resiliency, soft (55A)	Peristaltic tubing, film	ETO, Autoclave
VYTHENE 21AX	Opaque	Radio-opaque for X-ray	Catheters, strips	ETO, Autoclave
VYTHENE 46	Clear	Good physical properties, 90A	Trays, small parts	ETO, Autoclave
VYNITE XPI	Opaque	Good elongation	Gaskets, tubing, film	ETO, Autoclave



TPE compounds –
EVOPRENE® R-90;
EVOPRENE® R-99

Please ask about our compounds
 formulated with bio-based and/or
 recycled content.

Since the 1980s, we have been developing and servicing our TPE compound series under the brand **EVOPRENE**. The result is a proven portfolio with hundreds of formulations designed for a vast array of applications.

TPE Compounds

R-90 Series

The **EVOPRENE R-90** series: Flexible TPE compounds for extrusion and molding for applications that **do not require biocompatibility testing**:

- Formulated with indirect food-grade ingredients US FDA 21 CFR, EU 10/2011, 1935/2004
- For food contact, skin contact, toys and other applications that do NOT require cytotoxicity testing
 - Migration testing should be performed as per application requirements
 - Application examples include respirator mask seals, dental guards, food storage, personal care products, skin contact products
- Free from heavy metals, phthalates, Bisphenol A, latex and other substances of concern
- Hardness range 12A to 95A
- Sterilization methods include Gamma, ETO, Autoclave
- Base material is translucent or opaque (easily colors into bright hues)
- Capable of adhering to rigid plastics such as PP and PE
- EVOPRENE R ECO series is formulated with bio-based ingredients 

Material	Appearance	Hardness Shore A	Adhesion Capability
EVOPRENE R 9036-12	Translucent	12	PP, PE
EVOPRENE R 9066-28	Opaque	28	PP, PE
EVOPRENE R 9067-40	Translucent	40	PP, PE
EVOPRENE R 9068-49	Translucent	49	PP, PE
EVOPRENE R 9069-67	Translucent	67	PP, PE
EVOPRENE R 9070-73	Translucent	73	PP, PE
EVOPRENE R 9087-92	Translucent	92	PP, PE

EVOPRENE R-90 series:
 Flexible TPE compounds for extrusion and
 molding applications that do not require
 biocompatibility testing.

R-99 Series

The **EVOPRENE R-99** series: Flexible TPE compounds for extrusion and molding for applications that **require biocompatibility testing**:

- Formulated with indirect food-grade ingredients US FDA 21 CFR, EU 10/2011, 1935/2004
- For healthcare medical and pharma applications that require biocompatibility and cytotoxicity testing
 - Representative compounds were submitted for third-party testing and demonstrated to be non-cytotoxic
 - Application examples include tubing, bags, needle syringe, vial stopper, gaskets, connectors and fittings
- Free from heavy metals, phthalates, Bisphenol A, latex and other substances of concern
- Sterilization methods include Gamma, ETO, Autoclave
- Can replace vulcanized rubber
- Low extractable and leachable content
- Puncture reseal-able
- EVOPRENE R ECO series is formulated with bio-based ingredients.



Material	Appearance	Hardness Shore A	Adhesion Capability
EVOPRENE R 9966-28	Opaque	28	PP, PE
EVOPRENE R 9967-40	Translucent	40	PP, PE
EVOPRENE R 9968-49	Translucent	49	PP, PE
EVOPRENE R 9969-67	Translucent	67	PP, PE
EVOPRENE R 9970-73	Translucent	73	PP, PE
EVOPRENE R 9987-92	Translucent	92	PP, PE

EVOPRENE R-99 series:
Flexible TPE compounds for extrusion and molding applications that require biocompatibility testing.



Since the 1960s, Alphagary has earned its reputation for providing innovative, functional and durable solutions to a broad marketplace, often custom formulating a material to meet end-user and market-specific requirements. We work with an extensive range of polymers, giving our global customer base a variety of features to choose from as they create products that we rely upon for safety, health and comfort in our everyday lives.

We are passionate about safety, dedicated to quality, and committed to harnessing the power of material science and innovation to serve customer needs, address world challenges and provide sustainable solutions.



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www.orbia.com

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