



**Celanese**  
The chemistry inside innovation™



**VITAL Dose**®  
Controlled Release  
Excipient

A custom solution for innovative  
controlled release pharmaceutical  
and drug delivery devices

# A MULTI-USE PHARMACEUTICAL COPOLYMER

VitalDose® controlled release ethylene vinyl acetate (EVA) polymer excipients deliver reliable performance for pharmaceutical drug delivery applications. Our technical support experts work with customers to help them realize their product objectives from conception through design and regulatory approval.

We combine the unique properties of EVA polymers with high-touch service, in-depth technical expertise and comprehensive regulatory support. EVA controlled release excipients are developed for a wide variety of pharmaceutical products with varying routes of administration, including:

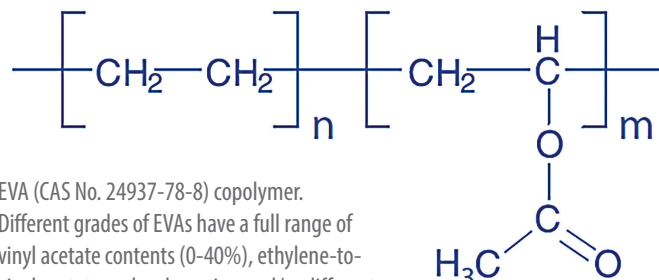
- Transdermal
- Subcutaneous
- Intravaginal
- Ocular
- Buccal
- Intraoral
- Rectal

## CUSTOM SOLUTIONS

VitalDose offers pharmaceutical manufacturers new product possibilities. Our thermoplastic, inert, controlled release polymers deliver substantial benefits over reactive liquid chemistries, such as silicones, and thermoplastic polyurethanes (TPU), allowing pharmaceutical companies peace of mind, simplified processing, and the flexibility to develop novel controlled release products.

### VitalDose® Advantages:

- Customizable release properties
- Potential for new delivery routes to create product line extensions
- Highly compatible with many active pharmaceutical ingredients, including those sensitive to high temperatures
- Favorable biocompatibility profile
- Free of phthalates, heavy metals, PFOA and halogenated substances



EVA (CAS No. 24937-78-8) copolymer. Different grades of EVAs have a full range of vinyl acetate contents (0-40%), ethylene-to-vinyl acetate molecular ratios, and/or different melt indices (molecular weights).



**We Invite You to Contact Us to Discuss Your Material Requirements.**

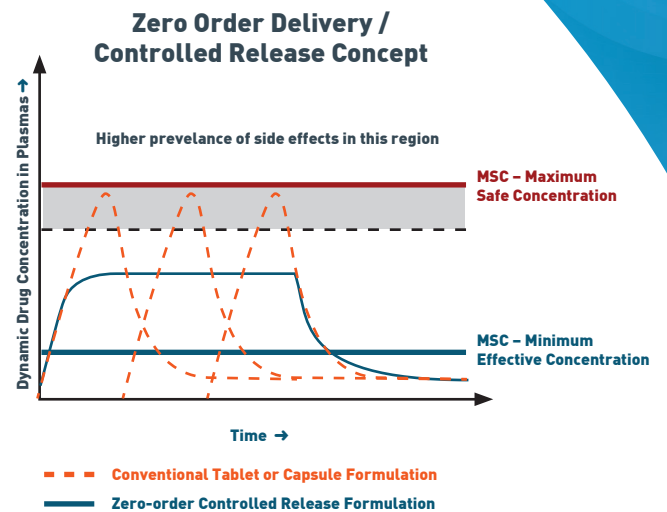
# FLEXIBLE DELIVERY SYSTEMS

## VitalDose® controlled release excipients offer flexible delivery system advantages:

- Zero-order, first-order or hybrid release profiles to suit your delivery strategy
- Better control of blood plasma levels than immediate release formulation
- Customizable delivery rates to meet desired needs of a particular therapy

## Process Versatility and Regulatory Support

VitalDose® excipients can be sterilized and converted to emulsion solution or powder forms and processed using conventional pharmaceutical unit operations.



### Mixing Processes

- Melt mixing
- Solution
- Emulsion
- Impregnation

### Melt Processes

- Compression molding
- Injection molding
- Blow molding
- Extrusion

### Solution Processes

- Spraying
- Dipping
- Spin coating

Drug master files are available for reference by Celanese customers, along with full regulatory support. VitalDose excipients are manufactured according to agreed manufacturing practices that align with pharmaceutical requirements.

Our EVA polymers have been approved for use in numerous pharmaceutical and medical devices around the world. Certifications and approvals may include but are not limited to:

- USP Class VI biocompatibility
- European Pharmacopeia certification
- ISO 10993 biocompatibility
- Drug master file listed
- Acute Oral Toxicity tested
- FDA food contact
- European food contact
- REACH compliant

# SUPPORTING YOUR SUCCESS

As a strategic partner in supporting your controlled-release technology, we provide a variety of value-added support solutions, including:

- A customized development support program that helps you expedite the product development process, approvals and commercialization
- Regulatory support throughout your development process
- Technical expertise ensuring that the critical factors of functionality for your unique solution are quickly identified and addressed



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