



## WHY GLYCERIN USP?

FOR • FOODS • DRUGS • COSMETICS • TOILETRIES • PERSONAL CARE

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The purpose of this brochure is to provide information, in a convenient Q&A format, about glycerin USP and the comparable food grade glycerin. Glycerin USP and food grade glycerin meet the requirements mandated by U.S. Food & Drug Administration (FDA) regulations for use in foods, drugs, medical devices and certain other products requiring ingredients of the highest purity.

### WHAT IS GLYCERIN?

Glycerin, sometimes spelled glycerine, is a commercial product whose principal component is glycerol. The terms glycerin, glycerine, and glycerol are often used interchangeably in the literature.

Glycerin is one of the most versatile and valuable chemical substances known to man. It possesses a unique combination of physical and chemical properties that are utilized in myriad products. Glycerin has over 1,500 known end uses, including many applications as an ingredient or processing aid in cosmetics, toiletries, personal care, drugs, and food products. In addition, glycerin is highly stable under typical storage conditions, compatible with many other chemical materials, virtually non-toxic and non-irritating in its varied uses, and has no known negative environmental effects.

A water clear, odorless, viscous liquid with a sweet taste, glycerin is derived from both natural and petrochemical feedstocks. It occurs in combined form (triglycerides) in all animal fats and vegetable oils and constitutes, on average, about 10 percent of these materials. Glycerin is obtained from fats and oils during soap and fatty acid production and by transesterification (an interchange of fatty acid groups with another alcohol). It is subsequently concentrated and

purified prior to commercial sale. Synthetic glycerin is produced from petrochemical building blocks via several processing steps designed to achieve the desired concentration and high product quality. Glycerin, whether recovered from triglycerides or synthesized, is principally used as a highly refined and purified product, with a very high concentration of glycerol.

Glycerol, the main component of glycerin, has the chemical formula  $C_3H_5(OH)_3$ . It is a trihydric alcohol, possessing two primary and one secondary hydroxyl groups, which are its potential reaction sites and the basis for glycerin's versatility as a chemical raw material. For example, glycerol esters, the reaction products of glycerin with various fatty acids form an important class of derivatives that are extensively used in the food industry. The physical properties and characteristics of glycerin are as significant as its chemical properties for many applications. These qualities enable glycerin to be used as a humectant, plasticizer, emollient, thickener, solvent, dispersing medium, lubricant, sweetener, bodying agent, antifreeze and processing aid. It is not unusual for glycerin to contribute two or more features or attributes to a product or application. In all applications, whether as a reactant or as an additive, the virtual non-toxicity and overall safety of glycerin is always of significant benefit. Glycerin applications appear to be limited only by the imagination and creativity of the scientific and technical communities.

Most of the glycerin marketed today is manufactured to meet the stringent requirements of the United States Pharmacopeia (USP) and the Food Chemicals Codex (FCC). However, technical grades of glycerin that are not certified as USP or FCC are available. Glycerin is used in many consumer products such as personal care preparations, cosmetics, pharmaceuticals and foods because of its

contribution to product properties, stability and compatibility with a wide variety of chemicals, and relative non-toxicity. For these consumer-oriented applications, the quality and purity of the ingredients is crucially important. The use of USP and FCC- certified glycerin, versus technical grade glycerin, in consumer product applications ensures that the manufacturer has specified the glycerin quality and consistency required for these products.

### **WHAT DOES USP MEAN?**

The abbreviation USP stands for United States Pharmacopeia, a document first published in 1820 by the Medical Society of New York State. Recognized as official by Congress in 1848, this document was used as a standard reference by physicians for prescribing medicines. Today, the USP includes chemical descriptions, identifying tests, and purity tests, primarily for active ingredients. All materials listed in the USP are considered drugs by law and subject to all the U.S. Food & Drug Administration requirements pertaining to drugs. Labeling a product or a substance as USP implies that it conforms to all the legal requirements of the FDA and that it was produced in accordance with the principles outlined in FDA's Good Manufacturing Practices (GMP). A new edition of the USP is published every five years in the years ending in "0" and "5," with ongoing revisions and additions issued during the interim years.

Many other nations also have compiled an official national pharmacopeia, similar in scope and content to the USP. Currently, there is a collaborative international program to harmonize the glycerin monographs in the USP and in the European Pharmacopeia, which may later be expanded to include other nations.

### **WHAT ABOUT THE FCC?**

The FCC or the Food Chemicals Codex is an internationally recognized compendium of monographs covering food ingredients. It contains specifications for many direct food additives, such as glycerin. The Institute of Medicine of the National Academy of Sciences developed and maintains the FCC. The FDA also supports this compendium. The specifications for food grade glycerin given in the FCC are generally comparable to those given in the USP.

### **WHAT KINDS OF PRODUCTS DOES FDA REGULATE?**

The FDA has jurisdiction over foods, drugs, cosmetics, and medical devices. Title 21 of the Code of Federal Regulations (CFR) contains the regulations promulgated by the FDA within its authority over foods, drugs, cosmetics, and medical devices. "Drugs," as construed in 21CFR, include materials listed in the currently official edition of the United States Pharmacopeia. Certain personal care products may become "drugs" by virtue of the advertising claims made for them, such as cosmetics or other personal care products that promise to cure or claim to have other disease treating or preventing properties.

### **WHAT DIFFERENTIATES USP AND FOOD GRADE GLYCERIN FROM TECHNICAL GRADE GLYCERIN?**

Glycerin USP is closely regulated by FDA in all aspects of manufacturing, testing, inspection, distribution, and warehousing. Glycerin USP is subject to FDA rules requiring registration and listing, and glycerin FCC as well as USP are also subject to Good Manufacturing Practices, a series of appropriate procedures prescribed by FDA, while the technical grade is not under such regulatory control.

FDA requires all domestic owners or operators of all establishments that manufacture or process glycerin USP to register and list, unless specifically exempted (21CFR §207.20). For glycerin USP of foreign origin, the foreign manufacturer and the importer share the responsibility of FDA compliance (21CFR§207.4). The Agency's definition of "manufacturer" includes the original producer as well as re-packagers and/or distributors (21CFR§207.4). Additional information on drug registration and listing instructions is available from FDA at <http://www.fda.gov/cder/drls/introduc.htm#top>.

Further, under FDA regulations, the quality and purity of USP and FCC glycerin products must be supported by systematic and complete record keeping on the part of the manufacturer. For example, every shipment of USP and FCC glycerin must be referenced to a lot number, which permits tracing back to the plant in which the product was produced. These requirements are designed to assure a level of product integrity that cannot be achieved strictly by reliance only on physical and chemical testing.

Technical grades of glycerin, on the other hand, are not subject to the same FDA regulatory oversight. Although produced by similar processes, the technical grades of glycerin do not have to comply with USP and FCC requirements or with FDA regulations. This quality grade of glycerin must conform only to the specifications and terms agreed upon in the transaction between buyer and seller.

### **WHAT ARE SOME OF THE KEY PRACTICES THAT MUST BE FOLLOWED TO ASSURE THAT GLYCERIN WILL MEET USP AND FCC REQUIREMENTS?**

Compliance with USP and FCC requirements means more than meeting the specifications given in the USP and FCC glycerin monographs as determined by analysis. It also means strict compliance with FDA regulations, most particularly with the procedures outlined in the current Good Manufacturing Practices to assure plant and equipment cleanliness and to avoid contamination during handling, distribution or packaging. Plants, warehouses and clean rooms, where repackaging is done, are subject to FDA inspection. Complete record keeping is obligatory to ensure that every shipment of product is traceable by lot number. A Certificate of Analysis also accompanies every shipment of USP and FCC glycerin.

### **WHAT IS GOOD MANUFACTURING PRACTICES?**

Current Good Manufacturing Practices (GMP) is a series of documents governing every aspect of the production and shipment of FDA regulated products, from personnel management to the cleanliness of manufacturing facilities to labeling. GMP is mandatory. Glycerin USP is produced in accordance with the principles outlined in GMP. For foods and active drugs, the GMP guidelines are given in the Code of Federal Regulations (CFR), Title 21, and are referenced in the current editions of USP and FCC.

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### **WHAT DOES GMP SAY ABOUT THE MANUFACTURING FACILITIES?**

GMP requires separate or defined areas for raw materials, in-process materials, and completed products to prevent contamination or mix-ups. Traffic must also be controlled to minimize contamination. Requirements for lighting, ventilation, water supply, building maintenance, and refuse containment and disposal are also outlined in GMP documents.

### **HOW DOES GMP REGULATE SHIPPING AND WAREHOUSING OF GLYCERIN USP?**

Systematic and complete record keeping is mandatory to ensure that every shipment of product is traceable to a lot number from raw material supplier to end product manufacturer. GMP also provides strict guidelines governing the proper labeling and packaging of products.

### **IS THERE AN ALTERNATIVE TO USP AND FCC GRADE GLYCERIN?**

There is an alternative to buying USP and FCC grade glycerin, but it may not be practical. Manufacturers of end products containing glycerin may fulfill their own GMP requirements for raw materials by proving through their own analyses that their glycerin is uncontaminated, safe, and suitable for the intended application. However, many of the analytical methods involved are extensive, time-consuming, and costly. Thus, the cost-benefit ratio must be carefully considered, if glycerin that is not USP or FCC certified is used in sensitive and/or regulated applications.

### **WHAT IS THE OPTIMUM CHOICE?**

Obviously, Glycerin USP is the optimum choice for all applications requiring USP grade glycerin by FDA regulation. The USP designation on the label assures that the glycerin product is traceable by lot to the original manufacturer, is supported by documentation attesting to its compliance with USP standards of quality, and has been produced in accordance with GMP principles.

