Received by NOP
January 4, 2013

Draco Natural Products

December 19, 2012

National List Coordinator
USDA/AMS/NOP, Standards Division
1400 Independence Ave. SW
Room 2646-So., Ag Stop 0268
Washington, DC 20250-0268

RE: Petition for the removal of "Glycerin—produced by hydrolysis of fats and oils" be removed from the National List at §205.605(b) because certified organic glycerin is now commercially available in sufficient quantities to meet the demand of the organic processed food and cosmetic products producers.

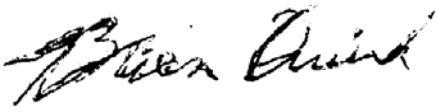
Dear National List Coordinator,

Draco Natural Products, Inc. is a supplier of certified organic glycerin produced by microbial fermentation of organic cornstarch by the yeast *Candida krusei* since March 2012. The supply of our product, as well as the supply from other operations is sufficient to meet the needs for glycerin in organic food and cosmetic products. However, §205.605 lacks a "commercial availability" clause so use of organic glycerin is unfortunately optional. The remedy for this deficiency is removal of glycerin from the National List at §205.605.

We believe that the process of microbial fermentation that is used to produce our organic glycerin is a superior method for the production of organic glycerin because it uses only mechanical and biological processes as required in §205.270(a) without the use of allowed synthetics listed in §205.605(b). We are aware that there is certified organic glycerin produced by hydrolysis of organic fats and oils using either steam splitting or traditional saponification with a catalytic amount of an alkali (sodium carbonate, sodium hydroxide, or potassium hydroxide) on the National List. Those that seek glycerin for their organic food or cosmetic products have a variety of suppliers and types of organic glycerin to choose from therefore the criteria of commercial availability – sufficient quantity, quality and appropriate form – can be met today and can easily be increased as demand requires. We have expanded our production and will have the capacity to produce 10-15 metric tons monthly. We are certain that there will be no disruption in the production of organic food and cosmetic product if glycerin is removed from the National List.

Since there is not a unique form for the removal of a material from the National List, our petition and its appendices provide answers to all of the questions in the Guidelines on Procedures for Submitting National List Petitions. We are available to provide any additional information that is required to complete your review process and recommendation.

Sincerely,



Brien Quirk,

Director of R&D

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Glycerin Petition

Item A:

This petition requests that "Glycerin—produced by hydrolysis of fats and oils" be removed from the National List at §205.605(b) because certified organic glycerin is now commercially available in sufficient quantities to meet the demand of the organic processed food and cosmetic products producers.

Four general methods of commercial glycerin production are or have been used:

1. Chemical synthesis by hydrogenolysis of carbohydrates (21 CFR 178.3500; 21 CFR 172.866)) or by synthesis from propylene (mentioned in the 1995 Technical Advisory Panel report on glycerin). Neither chemical synthetic process has ever been deemed worthy of serious consideration for use in organic.
2. Biodiesel production comprises reaction of natural fats and oils – triglycerides – with methyl alcohol or ethyl alcohol to produce the methyl or ethyl esters of fatty acids. These synthetic fatty acid esters are the diesel fuel. Glycerin is a synthetic waste byproduct of this chemical process. The commercialization of the biodiesel process in the past few years has created an enormous supply of biodiesel glycerin that has largely displaced chemical synthesis from propylene. In fact, the low cost of biodiesel glycerin has resulted in commercialization of processes to use it as a raw material to produce epichlorohydrin, acrolein, propylene glycol, and other organic chemicals. There are safety concerns with biodiesel glycerin, discussed in Section B-11.
3. Saponification of natural fats and oils, a process of hydrolyzing the agricultural products fat or oil with water (steam) under pressure (high-pressure splitting) or with a solution of sodium carbonate, sodium hydroxide, or potassium hydroxide (traditional process) to produce synthetic glycerin and fatty acids. The steam process is described in the 1995 Technical Advisory Panel Report on glycerin. The alkali process is the traditional process used to saponify fats and oils. The three sources of alkali used in this process are included in the National List. Glycerin produced by saponification was recommended by the NOSB in 1995 for inclusion on the National List with the annotation "produced by hydrolysis of fats and oils." It is currently included on the National List as a synthetic nonagricultural substance at §205.605(b) [and also for livestock used at §205.603(a)(12)]. Certified organic glycerin is being produced by saponification of organic fats and oils.
4. Microbial fermentation of carbohydrate substances (analogous to citric acid currently included in the National List at §205.605(a)) to produce nonsynthetic glycerin. This production method is briefly mentioned generically in the 1995 TAP

Report and referred to in the Merck Index monograph on glycerol (glycerin), which cites a U.S. Patent No. 3,012,945 issued to Noda in 1961 for yeast fermentation to produce glycerin. Currently, microbial fermentation of organic cornstarch by the yeast *Candida krusei*[1] is used commercially to produce certified organic glycerin as well as nonsynthetic non-organic glycerin.

Saponification comprises an allowed processing method and fats and oils are agriculturally produced commodities so "glycerin produced by hydrolysis of fats and oils" actually is an agricultural product that qualified for inclusion at §205.606. An important reason that glycerin produced by hydrolysis of fats and oils should have been included at §205.606 is that items listed at §205.606 are subject to the restriction that they can be used "only when the product is not commercially available in organic form." Certified organic glycerin is currently available, but there is no "commercial availability" requirement to incentivize processors to use it or certifiers to require it. This is why glycerin should be removed from the National List in order to encourage organic agricultural production.

Certified organic glycerin is produced both by microbial fermentation and by saponification of fats and oils. Consequently, this petition requests that the NOSB recommend that "Glycerin—produced by hydrolysis of fats and oils" be removed from §205.605(b).

Item B:

1. The substance's chemical or material common name.

Glycerin, also known as glycerol, glycerine, 1,2,3-Propanetriol, glyceritol, glycyl alcohol, trihydroxypropane, propanetriol, Osmoglyn, and 1,2,3-trihydroxypropane, has the Molecular Formula $C_3H_8O_3$, Molecular Weight 92.09382, INS Number 422, and CAS Number 56-81-5.

Glycerin USP grade comprises a minimum of 99.5% glycerin and less than 0.05% water. Glycerin USP meets the requirements of both the United States Pharmacopeia and the Food Chemicals Codex. Glycerin occurs as a clear, colorless, viscous liquid. It is hygroscopic, and its solutions are neutral. Glycerin is miscible with water and with alcohol. It is insoluble in chloroform, in ether, and in fixed and volatile oils.

Glycerin is a trihydroxy sugar alcohol that is an intermediate in carbohydrate and lipid metabolism.

[1] *Candida krusei* is a yeast used in chocolate production, where it produce enzymes to break down the pulp on the outside of the cacao beans. This makes acetic acid, killing the cacao embryo inside the seed, developing a chocolaty aroma, and eliminating the bitterness in the beans.

2. The manufacturer of glycerin made by fermentation of carbohydrate substrates.

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A North America contact is:

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3. Current use of glycerin

Glycerin, whether made by fermentation of carbohydrate substrates or by hydrolysis of fats and oils, is used as a solvent, emollient, bodying agent, plasticizer, pharmaceutical agent, and sweetening agent in a wide range of processed food and cosmetic products.

4. The mode of action of glycerin

Common food uses of glycerin are as a solvent, as part of emulsification systems, and as humectants. Glycerin is added to vanilla flavors and chocolate syrup, flavor pastes, food colors, distilled liquors (cordials), carbonated and non-carbonated beverages, frozen eggs and frozen egg yolks (as a cryoprotectant to reduce damage by ice crystals and thus to prevent lumps), food casings and coatings (as a plasticizer), jelly-like candies and fudge, peanut butter (to prevent oil separation), and dried fruits and shredded coconut (as a softener and humectant).

Glycerin is used in cosmetics creams and lotions as a moisturizer, taking advantage of its humectant (water-retentive) properties.

Glycerin U.S.P. is available as a consumer product and is used for direct application to the skin as a moisturizer.

5. The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product.

Glycerin can be produced in many ways. Appendix A is the description from the Hazardous Substance Data Bank of methods of manufacturing glycerin. The two ways that organic glycerin can be produced are by hydrolysis of fats and oils and by microbial fermentation from metabolizable substrates, which are described below.

Glycerin produced by hydrolysis of fats and oils

The steam process for producing glycerin by hydrolysis of fats and oils is described in the 1995 TAP Review for Glycerin[2]. Water (as steam) and fat are mixed and heated in a "pressure splitter" (analogous to a home pressure cooker), hydrolyzing the fat into glycerin and fatty acids. Traditional saponification relies upon alkali (sodium hydroxide, sodium carbonate, or potassium hydroxide ('potash')) to saponify fats and oils. These three sources of alkali are included on the National List.

The fatty acids are lighter than water whereas the glycerin-water solution, called "sweet water," is denser than water. After separation of the fatty acids, water is removed from sweet water by evaporation; water boils at 100°C (212°F) whereas glycerin boils at a temperature >250°C (>500°F) although it begins to decompose at temperatures >180°C (350°F). The glycerin is purified by passing through ion-exchange columns to remove minerals and through activated charcoal to remove color and impurities.

Glycerin produced by microbial fermentation from carbohydrate substrates

The process for producing organic glycerin by microbial fermentation from carbohydrate substrates begins with organic corn from which cornstarch is isolated. The cornstarch is treated with enzymes to hydrolyze the starch and liberate glucose. The glucose is then fermented with an appropriate microorganism to produce glycerin. The glycerin is purified by passing through ion-exchange columns to remove inorganic elements required for growth of the microorganism and through activated charcoal to remove color and impurities.

A flow sheet of the technical procedure is attached as Appendix B. A detailed description of the process of oxygenated fermentation of glycerin to produce organic glycerin is as follows.

1. QA of Starting raw material, Organic Corn: verification of NOP vendor certified lot paperwork, and quality assurance testing for specifications (starch content, aflatoxins (a hepatocarcinogenic product of the mold *Aspergillus flatus*), moisture level, etc.).

[2] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5066985&acct=nopgeninfo

2. Inspection and Cleaning: visual inspection of corn kernels; cleaning with water to remove residual cob pieces, dust, chaff and foreign materials.

3. Steeping and grinding. Corn kernels are soaked in 50°C (122°F) water for 20 to 40 hr. in a stainless steel steeping tank. Corn kernels absorb water during this time, resulting in an increase in their moisture level from about 15% to 45%. No sulfite is added. After steeping, the corn kernels are coarsely ground to break the germ loose from other components. Steeping water is condensed to capture nutrients in the water for use in animal feeds and as a yeast starter nutrient used later in the fermentation process. The ground corn-in-water slurry flows to the next step.

4. Germ Separation. A physical separator – ultracentrifuge - spins the low density corn germs out of the corn-in-water slurry. The germ, containing approximately 85% of the corn's oil, is pumped onto screens and washed repeatedly to remove any starch left in the mixture. (A series of mechanical processes extracts the oil from the germs. The oil can then be refined and filtered into finished corn oil.) The high protein germ residue is saved as another useful component of animal feeds.

5. Fine grinding and filtering: The corn-in-water slurry leaves the germ separator and goes through a more thorough grinding in an impact or attrition-impact mill to release the starch and gluten from the fiber. The suspension of starch, gluten and fiber flows over fine screens which catch fiber but allow starch and gluten to pass through. The fiber is piped to the feed house for drying and for later use as a major ingredient of animal feeds. The starch-gluten suspension, or mill starch, is piped to the next step.

6. Starch separation: Gluten has a low density compared to starch. By passing mill starch through a centrifuge, the gluten is readily spun out for use in animal feeds. The starch, now diluted, is washed an additional 8 to 14 times in hydrocyclones to remove the last trace of protein to yield high quality starch.

7. Liquefier (Syrup conversion): Starch, suspended in water, is liquefied in the presence of enzymes that convert the starch to a low-dextrose solution.

8. Sterilization: The syrup is sterilized by steam to kill microbes that may be present.

9. Inoculation: The sterile syrup is the substrate in the fermentation process. It is inoculated by the addition of a proprietary strain of the yeast *Candida krusei* that has specific glycerin-formation capability.

10. Fermentation: Since the glycerin formation process has a high demand for oxygen, an optimized aerobic fermentation process is performed with filtered aseptic air pumped into the fermentation chamber.

11. Centrifugation: Fat, yeast putty and other impurities in the fermented fluid are separated and removed as solids by centrifugation. The solid phase is collected for other uses with further processing. The liquid phase, on the other hand, is diverted to additional purification in the glycerin production.

12. Refining: Physical methods, such as settling overnight and separation by layers, are used to obtain crude glycerin in the upper layer. At this stage, the glycerin still contains a significant amount of water and/or impurities from the fermentation, which need to be removed in later steps.

13. Filtration (pressure filter): To further remove larger impurities in the crude glycerin, rapid filtration is performed with a high–efficiency pressure filter.

14. Vacuum evaporation: After filtration, glycerin water is concentrated by using a vacuum concentrator to remove excess water. The concentration process involves heating the hot liquid glycerin under pressure and subsequently spraying the glycerin into a vacuum chamber where water evaporates off as steam and glycerin remains a liquid.

15. Distillation and decolorization: Following removal from the vacuum concentrator, the glycerin is refined by distillation followed by treatment with fine activated charcoal. Charcoal treatment is repeated to ensure the removal of impurities in the glycerin.

16. Microfiltration and ultrafiltration: The glycerin at this stage is microfiltered and should be perfectly transparent. The filtrate is then subjected to ultrafiltration to further remove smaller impurities that may be present.

17. Technical grade glycerin: After filtration, a good technical grade glycerin is obtained.

18. Ion exchange: To obtain USP grade glycerin, the technical grade glycerin is first polished by ion exchange treatment to remove inorganic elements required for growth of the microorganism. Efficient treatment with food-grade ion exchange resins removes both cations (sodium, potassium, calcium, etc.) and anions (chloride, sulfate, phosphate, etc.) without changing the glycerin.

19. Vacuum evaporation: Following the ion exchange step, excess moisture in the glycerin is removed by vacuum evaporation.

20. Filtration: Additional filtration is performed to eliminate all remaining impurities that may be present. At the end of this step, the quality of glycerin meets USP standard, with excellent color stability upon heating.

6. A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance.

The National Organic Standards Board reviewed glycerin for processing in 1995 and for livestock use in 1999. Non-organic glycerin "produced by hydrolysis of fats and oils" was approved by the NOSB and is included in the National List at §205.605(b) and at §205.603(a)(12).

The Canadian Organic Regulation permits non-organic glycerin produced through the hydrolysis of fats or oils for use as a livestock teat dip and non-organic glycerin produced by hydrolysis of natural (vegetable or animal) fats and oils in organic foods as a non-organic ingredient classified as a food additive.

The COSMOS Standard for organic and/or natural cosmetics was developed at the European level by BDIH (Germany), COSMEBIO & ECOCERT (France), ICEA (Italy) and SOIL ASSOCIATION (UK) in order to define common requirements and definitions. The COSMOS Standard permits extractions of natural materials to include a non-organic solvent of plant origin such as glycerin.

The EU Standard for organic food does not specifically permit the addition of non-organic glycerin, but permits extractions of natural materials to include a solvent of plant origin such as non-organic glycerin. The EU considers glycerin made by saponification of organic fats and oils to be certifiable as organic.

The Japanese Standard does not permit non-organic glycerin as an ingredient in organic foods.

7. Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers.

Food and Drug Administration

Glycerin used as a multiple purpose GRAS food substance in food for human consumption is generally recognized as safe when used in accordance with good manufacturing practice. 21 CFR 182.1230.

Glycerin used as a general purpose food additive in animal drugs, feeds, and related products is generally recognized as safe when used in accordance with good manufacturing or feeding practice. 21 CFR 582.1320.

Glycerin is cited in various other FDA regulations in Parts 169 to 182 of Title 21, Code of Federal Regulations: §169.175; §172.811; §175.300; §175.320; §176.210; §177.1390; §177.2420; §177.2800; §178.3500; and §182.90.

Environmental Protection Agency (EPA)

Residues of glycerol (glycerin) are exempted from the requirement of a tolerance when used as a thickener in accordance with good agricultural practices as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest.

Glycerol (glycerin) is exempted from the requirement of a tolerance when used as a solvent and thickener, and meeting specifications of Food Chemical Codex, in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to animals.

EPA is conducting a comprehensive review of older pesticides to consider their health and environmental effects and make decisions about their future use. Under this pesticide reregistration program, Pesticides for which EPA had not issued Registration Standards prior to the effective date of FIFRA, as amended in 1988, were divided into three lists based upon their potential for human exposure and other factors, with List B containing pesticides of greater concern and List D pesticides of less concern. Glycerol is found on List D. Case No: 4044; Case Status: No products containing the pesticide are actively registered ... The case /is characterized/ as "cancelled." Under FIFRA, pesticide producers may voluntarily cancel their registered products. EPA also may cancel pesticide registrations if registrants fail to pay required fees or make/meet certain re-registration commitments, or if EPA reaches findings of unreasonable adverse effects; Active ingredient (AI): Glycerol; AI Status: The active ingredient is no longer contained in any registered pesticide products ... "cancelled."

8. The Chemical Abstract Service (CAS) number and labels of products that contains glycerin.

Glycerin has the INS Number 422, and the CAS Number 56-81-5. The label for a certified organic glycerin product is included as Appendix C.

9. The substance’s physical properties and chemical mode of action

(a) Chemical interactions with other substances, especially substances used in organic production;

Glycerin is used extensively as a solvent because of its relative chemical non-reactivity. Glycerin is unstable with strong oxidizing agents that may be used in cleaning and sanitation. The MSDS for glycerin specifically warns “Store away from strong oxidizing agents or combustible material.”

(b) Toxicity and environmental persistence; (c) Environmental impacts from its use and/or manufacture; and (e)(1) Effects on soil organisms and crops;

See Appendix D for the definitive and extensive "Environmental Fate & Exposure" report in the Hazardous Substance Data Base of the National Library of Medicine, which provides the basis for the "Environmental Fate/Exposure Summary" published by the National Center for Biotechnology Information (NCBI) for glycerin online[3], which reads as follows.

> "Glycerin is produced in large quantities synthetically and used in thousands of applications. It may be released to the environment in industrial effluent and during the use and disposal of the numerous products in which it is contained. If released to soil, glycerin is expected to undergo rapid biodegradation under aerobic conditions. It is expected to display very high mobility in soil and it is not expected to significantly volatilize to the atmosphere. If released to water, glycerin is expected to rapidly degrade under aerobic conditions. Biodegradation in seawater and under anaerobic conditions is also expected. Glycerin is not expected to bioconcentrate is fish and aquatic organisms nor is it expected to adsorb to sediment and suspended organic matter. Volatilization to the atmosphere is expected to be slower than for water itself. If released to the atmosphere, glycerin may undergo a gas-phase oxidation with photochemically produced hydroxyl radicals with a half-life of 33 hrs. It may also undergo atmospheric removal by wet deposition processes. Occupational exposure to glycerin may occur by dermal contact during its production and use. Exposure to the general population may occur by dermal contact or ingestion due to the wide variety of food and personal care products in which it is contained."

(d) Effects on human health;

NCBI summarized the (positive) health effects of glycerin as follows:

> *Absorption, Distribution and Excretion*
>
> *Following absorption from GI tract, glycerin is distributed throughout the blood. Although glycerin generally does not appear in ocular fluids, it may enter the orbital sac when the eye is inflamed, with a consequent decrease in osmotic effect.*
>
> *Most of an orally administered dose is incorporated into body fat. Approximately 7-14% of the dose is excreted unchanged in the urine within 2½ hours after administration.*

[3] http://pubchem.ncbi.nlm.nih.gov/summary/summary.cgi?cid=753 Accessed October 5, 2012.

> *Following oral administration, glycerin is rapidly absorbed from the GI tract, and peak serum concentrations occur with 60-90 minutes. Increased (due to inflammation) intraocular pressure begins to decline within 10-30 min following oral administration of glycerin.*

Glycerin (USP; 2.1 grams) in the form of rectal suppositories is used for its laxative effect. Glycerin relieves occasional constipation (irregularity) and generally produces bowel movement in ¼ to 1 hour. The pediatric dosage is 1.2 grams.

Allergenic extracts used for skin testing for allergy comprise 50% glycerin as a preservative and stabilizer.

Glycerin USP is used directly on human skin as an emollient.

See Appendix E for the more extensive "Human Health Effects" described in the Hazardous Substance Data Base of the National Library of Medicine.

(e) Effects on livestock.

The NOSB evaluated glycerin in October 1999 and recommended its allowance as a livestock teat dip, with the annotation that the glycerin "must be produced through the hydrolysis of fats or oils." Glycerin is currently on the National List for livestock use at §205.603(a)(12).

See Appendix F for the more extensive "Animal Toxicity Studies" described in the Hazardous Substance Data Base of the National Library of Medicine.

10. Safety information about glycerin produced by microbial fermentation of carbohydrate substrates.

A Material Safety Data Sheet (MSDS) is attached as part of Appendix G.

The National Center for Biotechnology Information (NCBI) published an "Environmental Fate/Exposure Summary" for glycerin, which is applicable to all forms of glycerin and is available at http://pubchem.ncbi.nlm.nih.gov/summary/summary.cgi?cid=753.

11. Research information about glycerin (glycerol)

A search for "glycerol" on PubMed [http://www.ncbi.nlm.nih.gov/pubmed/] yields 56,728 scientific references, attesting to the metabolic, biological, and nutritional importance of this substance.

The research information of greatest relevance to this petition relates to the source of the glycerin, so this aspect will be developed here.

Biodiesel can be made from the waste oil byproduct of restaurants as well as ordinary food fats and oils. Recall that the biodiesel process converts triglycerides into fatty acid methyl or ethyl esters by reaction with methyl alcohol[4] or ethyl alcohol, respectively. The glycerin waste product of a biodiesel process may be contaminated with methyl alcohol and other methyl derivatives.

Glycerin produced by a biodiesel process yields synthetic glycerin "produced by hydrolysis of fats and oils." The unaware observer might believe that the biodiesel process yields an acceptable source of glycerin in foods labeled as "organic."

12. Petition Justification Statement

Certified organic glycerin produced from organic vegetable fats and oils and certified organic glycerin produced by microbial fermentation are commercially available in the United States. However, §205.605 lacks a "commercial availability" clause so use of organic glycerin is unfortunately optional. The remedy for this deficiency is removal of glycerin from the National List at §205.605.

Glycerin produced by hydrolysis of natural fats and oils can be certified as organic using either steam splitting or traditional saponification with a catalytic amount of an alkali (sodium carbonate, sodium hydroxide, or potassium hydroxide) on the National List. Glycerin produced by microbial fermentation of carbohydrate substrates offers a second route to production of organic glycerin. The supply of organic glycerin is sufficient to provide the needs of organic food processors and organic cosmetic manufacturers.

The Organic Food Production Act of 1990 and the current regulation define "agricultural product" as "any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock, that is marketed in the United States for human or livestock consumption." Glycerin is produced from agricultural commodities – fats, oils, corn – so it should be "organic" when used in products labeled as "organic."

The need for including glycerin on the National List of non-organic substances used in or on foods labeled as "organic" no longer exists. The NOSB should recommend its removal.

[4] Some biodiesel processes use methyl acetate instead of methyl alcohol as the methyl donor to the esterification process.

13. Confidential Business Information Statement

This petition contains no Confidential Business Information (CBI) or confidential commercial information.

APPENDICES

Appendix A – Hazardous Substance Data Bank: Methods of Manufacturing for Glycerin

Appendix B – Flow Chart for Glycerin produced by microbial fermentation from carbohydrate substrates

Appendix C – Specimen Label for Certified Organic Glycerin Product

Appendix D – Hazardous Substance Data Bank: Environmental Fate & Exposure for Glycerin

Appendix E – Hazardous Substance Data Bank: Human Health Effects for Glycerin

Appendix F – Hazardous Substance Data Bank: Animal Toxicity Studies for Glycerin

Appendix G – MSDS for Glycerin

Hazardous Substance Data Bank - Methods of Manufacturing

Production from allyl chloride: ... This method became available once the high-temperature chlorination of propene to allyl chloride could be controlled properly. The allyl chloride produced is oxidized with hypochlorite to dichlorohydrin, which is converted without isolation to epichlorohydrin by ring closure with calcium or sodium hydroxide. Hydrolysis to **glycerol** is carried out with sodium hydroxide or sodium carbonate. Epichlorohydrin is hydrolyzed to **glycerol** at 80 - 200 deg C with a 10 - 15% aqueous solution of sodium hydroxide or sodium carbonate at atmospheric or overpressure. The residence time in one or a series of several closed, continuously operating reactors amounts to several minutes or several hours depending on the plant concerned. The yield of dilute (10 - 25%) **glycerol** solution is > 98%. The solution contains 5 - 10% sodium chloride and less than 2% of other impurities. This aqueous **glycerol** solution containing sodium chloride is evaporated in a multistage evaporation plant under vacuum to a **glycerol** concentration of > 75%; precipitated sodium chloride is separated at the same time. The **glycerol** solution is then distilled under high vacuum (about 0.5 - 1.0 kPa); co-distilled water is separated by fractional condensation. Residual inorganic salts and higher oligomers of **glycerol** remaining after the evaporation must be worked up further or discarded. The **glycerol**, practically free of water, is treated further to remove colored impurities and odorous material; this can be performed, for example, with activated carbon.
[Christoph R et al; Ullmann's Encyclopedia of Industrial Chemistry 7th ed. (1999-2011). New York, NY: John Wiley & Sons; Glycerol. Online Posting Date: April 15, 2006] **PEER REVIEWED**

Production from acrolein: ... Propene is oxidized to acrolein, which is then reduced to allyl alcohol (Meerwein-Ponndorf-Verley reduction). The allyl alcohol is epoxidized with hydrogen peroxide, and the resulting glycidol is hydrolyzed to **glycerol**.
[Christoph R et al; Ullmann's Encyclopedia of Industrial Chemistry 7th ed. (1999-2011). New York, NY: John Wiley & Sons; Glycerol. Online Posting Date: April 15, 2006] **PEER REVIEWED**

Production from propylene oxide: ... Propene is epoxidized to propylene oxide, which is then isomerized to allyl alcohol by the Progil process. A second epoxidation is carried out with peracetic acid, and the resulting glycidol is hydrolyzed to **glycerol**.
[Christoph R et al; Ullmann's Encyclopedia of Industrial Chemistry 7th ed. (1999-2011). New York, NY: John Wiley & Sons; Glycerol. Online Posting Date: April 15, 2006] **PEER REVIEWED**

Fermentation of sugar: ... The fermentation /is/ ... interrupted at the glyceraldehyde 3-phosphate stage with sodium carbonate or with alkali or alkaline earth sulfites. After reduction to **glycerol** phosphate, **glycerol** is obtained in yields up to 25% by hydrolysis.
[Christoph R et al; Ullmann's Encyclopedia of Industrial Chemistry 7th ed. (1999-2011). New York, NY: John Wiley & Sons; Glycerol. Online Posting Date: April 15, 2006] **PEER REVIEWED**

Hydrogenation of natural polyalcohols such as cellulose, starch, or sugar leads to mixtures of **glycerol** and glycols, which can be separated by distillation. Catalysts used in this high-temperature reaction include nickel, copper, cobalt, chromium, and tungsten, as well as oxides of some of the lanthanides.
[Christoph R et al; Ullmann's Encyclopedia of Industrial Chemistry 7th ed. (1999-2011). New York, NY: John Wiley & Sons; Glycerol. Online Posting Date: April 15, 2006] **PEER REVIEWED**

Hazardous Substance Data Bank - Methods of Manufacturing

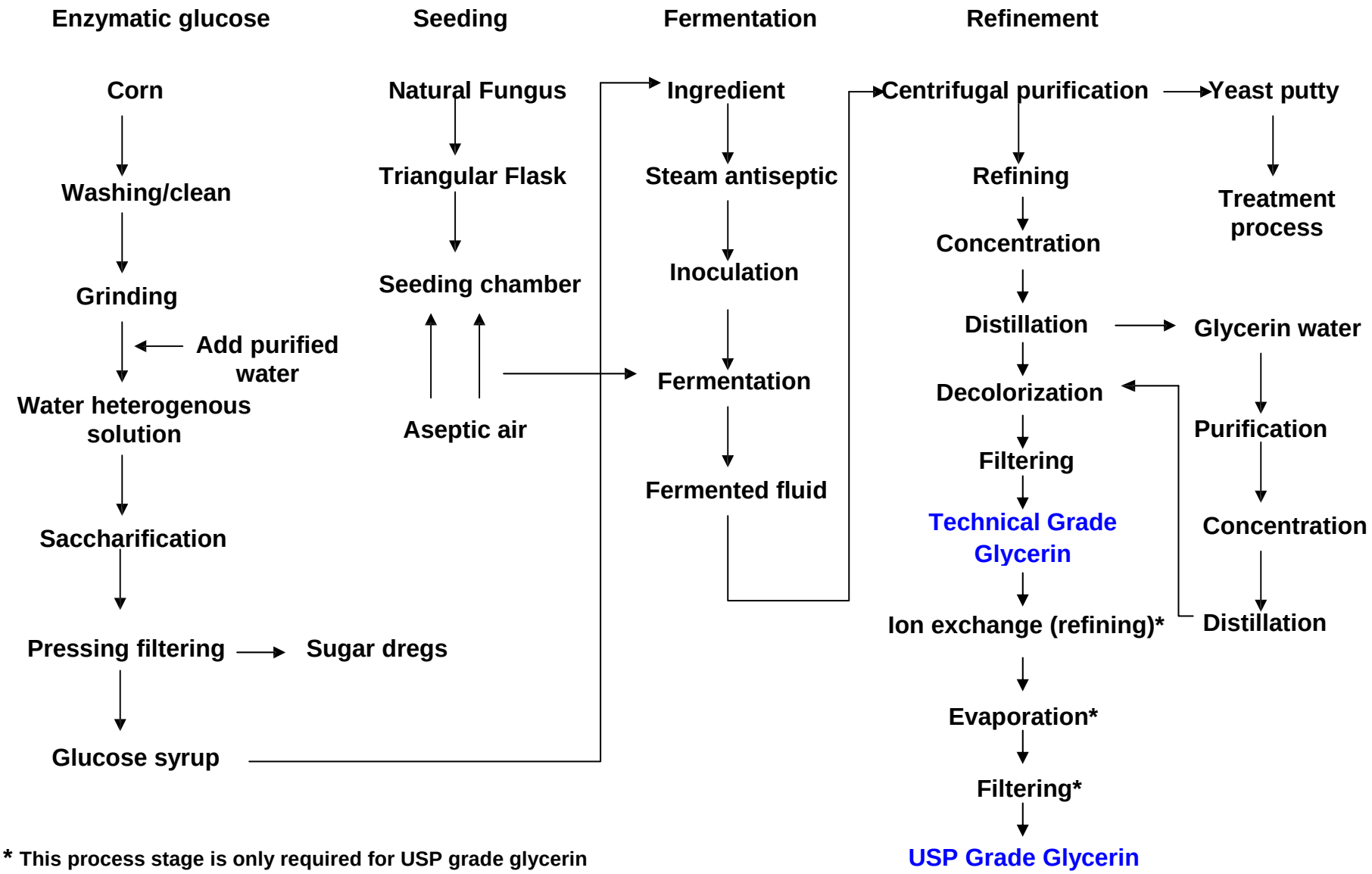
High-pressure splitting: ... Water and fat are fed into a splitting column in counter-current fashion at 2 - 6 MPa and 220 - 260 deg C, leading to about a 15% solution of **glycerol** in water, known as sweet water. This **glycerol** is marketed as 88% saponification- or hydrolysis-crude **glycerol**. Such **glycerol** is extremely low in ash: a typical value is about 0.1% or less of inorganic salts.
[Christoph R et al; Ullmann's Encyclopedia of Industrial Chemistry 7th ed. (1999-2011). New York, NY: John Wiley & Sons; Glycerol. Online Posting Date: April 15, 2006] **PEER REVIEWED**

Natural crude **glycerol** ... can be obtained from the transesterification (either high or lowpressure regime) of oils and fats to their methyl esters. Continuous processes are dominating. **Glycerol** from the low pressure transesterification process has a much higher salt content of 2 -5%. The crude **glycerol** is obtained directly at a concentration of about 90 - 92%.
[Christoph R et al; Ullmann's Encyclopedia of Industrial Chemistry 7th ed. (1999-2011). New York, NY: John Wiley & Sons; Glycerol. Online Posting Date: April 15, 2006] **PEER REVIEWED**

The splitting of fats by saponification of neutral oils is a traditional method; caustic alkali or alkali carbonates are used, as in the production of soap. The use of calcium hydroxide in the form of milk of lime is also possible.
[Christoph R et al; Ullmann's Encyclopedia of Industrial Chemistry 7th ed. (1999-2011). New York, NY: John Wiley & Sons; Glycerol. Online Posting Date: April 15, 2006] **PEER REVIEWED**

(Synthetic) hydration of epichlorohydrin followed by reaction with sodium hydroxide; reaction of allyl alcohol with hydrogen peroxide; reaction of allyl alcohol with peracetic acid followed by hydrolysis; (natural) by-product in soap or fatty acid mfr
[SRI] **PEER REVIEWED**

Technical procedure for the oxygenated fermentation of glycerin



* This process stage is only required for USP grade glycerin

Draco Natural Products

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Lot Number:
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For Further Processing Only.
Airtight! Please keep inner seal intact until use.
Store in a cool, dry place. Avoid heat/moisture.

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Hazardous Substances Data Bank - Environmental Fate & Exposure

Environmental Fate/Exposure Summary:
Glycerin's production and use in industrial, cosmetic, food, pharmaceutical and domestic products may result in its release to the environment through various waste streams. **Glycerin** was reported present in Cork Oak, Quercus suber L. If released to air, a vapor pressure of 1.68X10-4 mm Hg at 25 deg C indicates **glycerin** will exist in both the vapor and particulate phases in the atmosphere. Vapor-phase **glycerin** will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 7 hours. Particulate-phase **glycerin** will be removed from the atmosphere by wet or dry deposition. **Glycerin** does not contain chromophores that absorb at wavelengths >290 nm, and therefore is not expected to be susceptible to direct photolysis by sunlight. If released to soil, **glycerin** is expected to have very high mobility based upon an estimated Koc of 1. Volatilization from moist soil surfaces is not expected to be an important fate process based upon a Henry's Law constant of 1.73X10-8 atm-cu m/mole. **Glycerin** may not volatilize from dry soil surfaces based upon its vapor pressure. A 63% of theoretical BOD using activated sludge in the Japanese MITI test suggests that biodegradation is an important environmental fate process in soil and water. If released into water, **glycerin** is not expected to adsorb to suspended solids and sediment based upon the estimated Koc. Volatilization from water surfaces is not expected to be an important fate process based upon this compound's estimated Henry's Law constant. An estimated BCF of 3 suggests the potential for bioconcentration in aquatic organisms is low. Hydrolysis is not expected to be an important environmental fate process since this compound lacks functional groups that hydrolyze under environmental conditions. Occupational exposure to **glycerin** may occur through inhalation and dermal contact with this compound at workplaces where **glycerin** is produced or used. Use and limited monitoring data indicate that the general population may be exposed to **glycerin** via ingestion of food, some pharmaceuticals and drinking water, and dermal contact with consumer products containing **glycerin**. (SRC)
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Probable Routes of Human Exposure:
According to the 2006 TSCA Inventory Update Reporting data, the number of persons reasonably likely to be exposed in the industrial manufacturing, processing, and use of **glycerin** is 1000 or greater; the data may be greatly underestimated(1).
[(1) US EPA; Inventory Update Reporting (IUR). Non-confidential 2006 IUR Records by Chemical, including Manufacturing, Processing and Use Information. Washington, DC: U.S. Environmental Protection Agency. Available from, as of Jul 12, 2011: http://www.epa.gov/opptintr/iur/tools/data/index.html **PEER REVIEWED**

NIOSH (NOES Survey 1981-1983) has statistically estimated that 2,135,546 workers (1,346,631 of these were female) were potentially exposed to **glycerin** in the US(1). Occupational exposure to **glycerin** may occur through inhalation and dermal contact with this compound at workplaces where **glycerin** is produced or used. Use and limited monitoring data indicate that the general population may be exposed to **glycerin** via ingestion of food, some pharmaceuticals and drinking water, and dermal contact with consumer products containing **glycerin**(SRC).
[(1) NIOSH; NOES. National Occupational Exposure Survey conducted from 1981-1983. Estimated numbers of employees potentially exposed to specific agents by 2-digit standard industrial classification (SIC). Available from, as of Jul 12, 2011: http://www.cdc.gov/noes/ **PEER REVIEWED**

Hazardous Substances Data Bank - Environmental Fate & Exposure

Natural Pollution Sources:

Glycerin was reported present in Cork Oak, Quercus suber L.(1).

[(1) Dr. Duke's Phytochemical and Ethnobotanical Databases. Plants with a chosen chemical. Glycerin. Washington, DC: US Dept Agric, Agric Res Service. Available from, as of Jul 12, 2011: http://www.ars-grin.gov/duke/ **PEER REVIEWED**

Glycerol occurs in combined form in all animal and vegetable fats and oils. **Glycerol** is rarely found in the free state in those fats but is usually present as a triglyceride combined with such fatty acids as stearic, oleic, palmitic, and lauric acids, and these are generally mixtures or combinations of glycerides of several fatty acids. Such oil as coconut, palm kernel, cottonseed, soybean, and olive oil yield larger amounts of **glycerol** than do such animal fats as lard and tallow. **Glycerol** also occurs naturally as tryglycerides in all animal and vegetable cells in the form of lipids such as lecithin and cephalins.

[Morrison LR; Kirk-Othmer Encyclopedia of Chemical Technology. (1999-2011). New York, NY: John Wiley & Sons; Glycerol. Online Posting Date: 4 Dec 2000] **PEER REVIEWED**

Artificial Pollution Sources:

Glycerin's production and use in industrial, cosmetic, food, pharmaceutical and domestic products(1) may result in its release to the environment through various waste streams(SRC). It's many uses include use as a solvent, humectant, plasticizer, emollient, sweetener, in the manufacture of nitroglycerol (dynamite), cosmetics, liquid soaps, liqueurs, confectioneries, blacking, printing and copying inks, lubricants, elastic glues, lead oxide cements; to keep fabrics pliable; to preserve printing on cotton; for printing rollers, hectographs; to keep frost from windshields; as antifreeze in automobiles, gas meters and hydraulic jacks, in shock absorber fluids; in fermentation nutrients in the production of antibiotics and as a pharmaceutic aid(1).

[(1) O'Neil MJ, ed; The Merck Index. 14 th ed., Whitehouse Station, NJ: Merck and Co., Inc., p. 775 (2006)] **PEER REVIEWED**

Environmental Fate:

TERRESTRIAL FATE: Based on a classification scheme(1), an estimated Koc value of 1(SRC), determined from a structure estimation method(2), indicates that **glycerin** is expected to have very high mobility in soil(SRC). Volatilization of **glycerin** from moist soil surfaces is not expected to be an important fate process(SRC) given a Henry's Law constant of 1.73X10-8 atm-cu m/mole(3). **Glycerin** is not expected to volatilize from dry soil surfaces(SRC) based upon a vapor pressure of 1.68X10-4 mm Hg at 25 deg C(4). A 63% of theoretical BOD using activated sludge in the Japanese MITI test(5) suggests that biodegradation is an important environmental fate process in soil(SRC).

[(1) Swann RL et al; Res Rev 85: 17-28 (1983) (2) Meylan WM et al; Environ Sci Technol 26: 1560-67 (1992) (3) Hine J, Mookerjee PK; J Org Chem 40: 292-8 (1975) (4) Daubert TE, Danner RP; Physical and Thermodynamic Properties of Pure Chemicals Data Compilation. Washington, DC: Taylor and Francis (1989) (5) NITE; Chemical Risk Information Platform (CHRIP). Biodegradation and Bioconcentration. Tokyo, Japan: Natl Inst Tech Eval. Available from, as of Jul 12, 2011: http://www.safe.nite.go.jp/english/db.html **PEER REVIEWED**

Hazardous Substances Data Bank - Environmental Fate & Exposure

AQUATIC FATE: Based on a classification scheme(1), an estimated Koc value of 1(SRC), determined from a structure estimation method(2), indicates that **glycerin** is not expected to adsorb to suspended solids and sediment(SRC). Volatilization from water surfaces is not expected(3) based upon a Henry's Law constant of 1.73X10-8 atm-cu m/mole(4). According to a classification scheme(5), an estimated BCF of 3(SRC), from its log Kow of -1.76(6) and a regression-derived equation(7), suggests the potential for bioconcentration in aquatic organisms is low(SRC). A 63% of theoretical BOD using activated sludge in the Japanese MITI test(8) suggests that biodegradation is an important environmental fate process in water(SRC).
[(1) Swann RL et al; Res Rev 85: 17-28 (1983) (2) Meylan WM et al; Environ Sci Technol 26: 1560-67 (1992) (3) Lyman WJ et al; Handbook of Chemical Property Estimation Methods. Washington, DC: Amer Chem Soc pp. 15-1 to 15-29 (1990) (4) Hine J, Mookerjee PK; J Org Chem 40: 292-8 (1975) (5) Franke C et al; Chemosphere 29: 1501-14 (1994) (6) Hansch C et al; Exploring QSAR. Hydrophobic, Electronic, and Steric Constants. ACS Prof Ref Book. Heller SR, consult. ed., Washington, DC: Amer Chem Soc p. 7 (1995) (7) US EPA; Estimation Program Interface (EPI) Suite. Ver. 4.1. Jan, 2010. Available from, as of Jul 12, 2011: http://www.epa.gov/oppt/exposure/pubs/episuitedl.htm (8) NITE; Chemical Risk Information Platform (CHRIP). Biodegradation and Bioconcentration. Tokyo, Japan: Natl Inst Tech Eval. Available from, as of Jul 12, 2011: http://www.safe.nite.go.jp/english/db.html **PEER REVIEWED**

ATMOSPHERIC FATE: According to a model of gas/particle partitioning of semivolatile organic compounds in the atmosphere(1), **glycerin**, which has a vapor pressure of 1.68X10-4 mm Hg at 25 deg C(2), will exist in both the vapor and particulate phases in the ambient atmosphere. Vapor-phase **glycerin** is degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals(SRC); the half-life for this reaction in air is estimated to be 7 hours(SRC), calculated from its rate constant of 1.9X10-11 cu cm/molecule-sec at 25 deg C(SRC) that was derived using a structure estimation method(3). Particulate-phase **glycerin** may be removed from the air by wet or dry deposition(SRC). **Glycerin** does not contain chromophores that absorb at wavelengths >290 nm(4), and therefore is not expected to be susceptible to direct photolysis by sunlight(SRC).
[(1) Bidleman TF; Environ Sci Technol 22: 361-367 (1988) (2) Daubert TE, Danner RP; Physical and Thermodynamic Properties of Pure Chemicals Data Compilation. Washington, DC: Taylor and Francis (1989) (3) Meylan WM, Howard PH; Chemosphere 26: 2293-99 (1993) (4) Lyman WJ et al; Handbook of Chemical Property Estimation Methods. Washington, DC: Amer Chem Soc pp. 8-12 (1990)] **PEER REVIEWED**

Environmental Biodegradation:
AEROBIC: **Glycerin**, present at 100 mg/L, reached 63% of its theoretical BOD in 2 weeks using an activated sludge inoculum at 30 mg/L in the Japanese MITI test(1). Biodegradation rate constants of 0.258/day and 0.200/day in respirometric test systems employing activated sludge have also been reported, corresponding to 68% and 78% degradation, respectively(2).
[(1) NITE; Chemical Risk Information Platform (CHRIP). Biodegradation and Bioconcentration. Tokyo, Japan: Natl Inst Tech Eval. Available from, as of Jul 12, 2011: http://www.safe.nite.go.jp/english/db.html (2) Reuschenbach P et al; Water Res 37: 1571-1582 (2003)] **PEER REVIEWED**

AEROBIC: When incubated with a filtered effluent from a sanitary waste treatment plant,

glycerin displayed a 5 day BOD of 82%(1). Inoculation of **glycerin** with activated sewage sludge resulted in 43.5-52.9% 5 day BOD(2). **Glycerin** underwent 94-97% removal after 24 hrs when incubated with activated sludge from a waste water treatment plant(3-4). A 98.7% COD was observed in 120 hrs after inoculation with an adapted activated sludge seed(5). Incubation with an activated sludge seed gave a 5 day BOD of 68%(6). In screening studies, 5 day BODs for **glycerin** of 31%(7), 52% using activated sludge(8), 78.3% using domestic sludge(9), and 24.4% using seawater(10) were observed. **Glycerin** is listed as a substance easily degraded in a sewage treatment plant(11).
[(1) Bridie AL et al; Water Res 13: 627-30 (1979) (2) Belly RT, Goodhue CT; Proc Int Biodegrad Symp 3: 1103-7 (1976) (3) Matsui S et al; Prog Water Technol 7: 645-59 (1975) (4) Matsui S et al; Wat Sci Tech 20: 201-10 (1988) (5) Pitter P; Water Res 10: 231-5 (1976) (6) Placak OR, Ruchhoft CC; Sewage Works J 19: 423-40 (1947) (7) Dore M et al; Trib Cebedeau 28: 3-11 (1975) (8) Urano K, Kato Z; J Hazard Mater 13: 147-59 (1986) (9) Wagner R; Vom Wasser 47: 241-65 (1976) (10) Takemoto S et al; Suishitsu Odaku Kenkyu 4: 80-90 (1981) (11) Thom NS, Agg AR; Proc Royal Soc Lond B189: 347-57 (1975)] **PEER REVIEWED**

ANAEROBIC: **Glycerin** underwent 90% degradation after an 8 day lag period when incubated with enriched methane cultures under anaerobic conditions(1).
[(1) Chou WL et al; Biotech Bioeng Symp 8: 391-414 (1979)] **PEER REVIEWED**

PURE CULTURE: Pure cultures of Aerobacter and lactobacillus were found to degrade **glycerin** under anaerobic conditions(1,2).
[(1) Chou WL et al; Biotech Bioeng Symp 8: 391-414 (1979) (2) Kazanskaya TB, Anyukhina YG; Mikrobiologiya 49: 240-3 (1980)] **PEER REVIEWED**

Environmental Abiotic Degradation:
The rate constant for the vapor-phase reaction of **glycerin** with photochemically-produced hydroxyl radicals has been estimated as 1.9X10-11 cu cm/molecule-sec at 25 deg C(SRC) using a structure estimation method(1). This corresponds to an atmospheric half-life of about 7 hours at an atmospheric concentration of 5X10+5 hydroxyl radicals per cu cm(1). **Glycerin** is not expected to undergo hydrolysis in the environment due to the lack of functional groups that hydrolyze under environmental conditions(2). **Glycerin** does not contain chromophores that absorb at wavelengths >290 nm(2), and therefore is not expected to be susceptible to direct photolysis by sunlight(SRC).
[(1) Meylan WM, Howard PH; Chemosphere 26: 2293-99 (1993) (2) Lyman WJ et al; Handbook of Chemical Property Estimation Methods. Washington, DC: Amer Chem Soc pp. 7-4, 7-5, 8-12 (1990)] **PEER REVIEWED**

Environmental Bioconcentration:
An estimated BCF of 3 was calculated in fish for **glycerin**(SRC), using a log Kow of -1.76(1) and a regression-derived equation(2). According to a classification scheme(3), this BCF suggests the potential for bioconcentration in aquatic organisms is low(SRC).
[(1) Hansch C et al; Exploring QSAR. Hydrophobic, Electronic, and Steric Constants. ACS Prof Ref Book. Heller SR, consult. ed., Washington, DC: Amer Chem Soc p. 7 (1995) (2) US EPA; Estimation Program Interface (EPI) Suite. Ver. 4.1. Jan, 2010. Available from, as of Jul 12, 2011:

http://www.epa.gov/oppt/exposure/pubs/episuitedl.htm (3) Franke C et al; Chemosphere 29: 1501-14 (1994)] **PEER REVIEWED**

Soil Adsorption/Mobility:
Using a structure estimation method based on molecular connectivity indices(1), the Koc of **glycerin** can be estimated to be 1(SRC). According to a classification scheme(2), this estimated Koc value suggests that **glycerin** is expected to have very high mobility in soil.
[(1) Meylan WM et al; Environ Sci Technol 26: 1560-67 (1992) (2) Swann RL et al; Res Rev 85: 17-28 (1983)] **PEER REVIEWED**

Volatilization from Water/Soil:
The Henry's Law constant for **glycerin** is 1.73X10-8 atm-cu m/mole(1). This Henry's Law constant indicates that **glycerin** is expected to be essentially nonvolatile from water and moist soil surfaces(2). **Glycerin** is not expected to volatilize from dry soil surfaces(SRC) based upon a vapor pressure of 1.68X10-4 mm Hg(3).
[(1) Hine J, Mookerjee PK; J Org Chem 40: 292-8 (1975) (2) Lyman WJ et al; Handbook of Chemical Property Estimation Methods. Washington, DC: Amer Chem Soc pp. 15-1 to 15-29 (1990) (3) Daubert TE, Danner RP; Physical and Thermodynamic Properties of Pure Chemicals Data Compilation. Washington, DC: Taylor and Francis (1989)] **PEER REVIEWED**

Effluent Concentrations:
Glycerin was found but not quantified in the primary waste treatment effluent of the Oak Ridge treatment facility in 1974(1). It was identified in the influent to the industrial wastewater treatment plant of the Kashima petrochemical complex, Japan(2).
[(1) USEPA; Preliminary Assessment of Suspected Carcinogens in Drinking Water Interim Report to Congress (1975) (2) Matsui S et al; Wat Sci Tech 20: 201-10 (1988)] **PEER REVIEWED**

Sediment/Soil Concentrations:
SOIL: **Glycerin** was detected in fine soil and sand particles during winter in the metropolitan area of Riyadh, Saudi Arabia at percent relative concentrations of (percent relative concentration): 1.11 (outside of city, close to traffic; mostly sand), 1.48 outside city, palm tree farm; mostly soil), 7.95 (Ministry of Health locale in city; mixture of sand and soil), 0.61 (City center; mixture of soil and sand). It was not detected in the Azizia market place in the city nor in a sand dune 50 miles north of the city. Samples were collected in November 2002(1).
[(1) Rushdi AI et al; Arch Environ Contam Toxicol 49: 457-470 (2005)] **PEER REVIEWED**

Atmospheric Concentrations:
URBAN/SUBURBAN: **Glycerin** was present in daytime and nighttime samples at 1.4 to 9.6 (6 of 21 samples positive) and 19.9 ng/cu m (1 of 10 samples positive), respectively; samples were collected during southeastern aerosol and visibility study conducted at the Great Smoky Mountain National Park, TN from July 15 to August 25, 1995(1). **Glycerin** was detected in

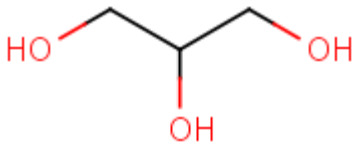
urban organic aerosols (PM2.5) from Nanjing, a "mega-city" in China. Samples were collected in July 2004 and January 2005. Mean daytime and nighttime summer concentrations were 56.5 and 44.9 ng/cu m, respectively; range of 12.1 to 220 and 26.0 to 76.3 ng/cu m, respectively. Mean daytime and nighttime winter concentrations were 25.0 and 26.1; range of 12.7 to 36.1 and 8.42 to 48.4 ng/cu m, respectively(2).
[(1) Yu LE et al; Environ Sci Technol 39: 707-715 (2005) (2) Wang G, Kawamura K; Environ Sci Technol 39: 7430-7438 (2005)] **PEER REVIEWED**

Plant Concentrations:
Glycerin was reported present in Cork Oak, Quercus suber L., in the cork at 65,000 ppm(1).
[(1) Dr. Duke's Phytochemical and Ethnobotanical Databases. Plants with a chosen chemical. Glycerin. Washington, DC: US Dept Agric, Agric Res Service. Available from, as of Jul 12, 2011: http://www.ars-grin.gov/duke/ **PEER REVIEWED**

Hazardous Substance Data Bank - Human Health Effects

GLYCERIN

CASRN: 56-81-5



Human Toxicity Excerpts:

/HUMAN EXPOSURE STUDIES/ Osmotic effect of **glycerin** may also produce tissue dehydration and decreases in cerebrospinal fluid pressure. **Glycerin** produces only very slight diuresis in healthy individuals receiving single dose of 1.5 g/kg or less.
[McEvoy, G.K. (ed.). American Hospital Formulary Service - Drug Information 93. Bethesda, MD: American Society of Hospital Pharmacists, Inc., 1993 (Plus Supplements, 1993)., p. 1773] **PEER REVIEWED**

/HUMAN EXPOSURE STUDIES/ Fertility study of 64 male employees engaged in the manufacture of **glycerol**. Compared with a control group of 63 workers, no significant differences were found in several sperm quality parameters of which sperm counts/mL and percent normal forms are considered to be most reliable.
[European Chemicals Bureau; IUCLID Dataset, Glycerol (56-81-5) (2000 CD-ROM edition). Available from, as of July 18, 2011: http://esis.jrc.ec.europa.eu/
PEER REVIEWED

/HUMAN EXPOSURE STUDIES/ Slightly irritating after 48 hours application of 0.05 mL on human skin in a closed patch test. Further the investigators observed a maximum score for irritation of 4 on a scale of 9 at day 14 during a 21 day application of a 10% solution on human skin.
[European Chemicals Bureau; IUCLID Dataset, Glycerol (56-81-5) (2000 CD-ROM edition). Available from, as of July 18, 2011: http://esis.jrc.ec.europa.eu/
PEER REVIEWED

/HUMAN EXPOSURE STUDIES/ Acute ingestion of **glycerol** in male subjects led to an increase in plasma glycerides, the same procedure in women led to no significant change in the glyceride concentration. When **glycerol** was ingested chronically (42 days), both men and women showed increased serum glyceride concentration, the increase was significantly greater in men, however.
[European Chemicals Bureau; IUCLID Dataset, Glycerol (56-81-5) (2000 CD-ROM edition). Available from, as of July 18, 2011: http://esis.jrc.ec.europa.eu/
PEER REVIEWED

/HUMAN EXPOSURE STUDIES/ 14 volunteers (10 men, 4 women) drank orange juice mixed with 30 mL of 95% **glycerol** after each of the 3 daily meals. No overt signs of toxicity or effect on food consumption.
[European Chemicals Bureau; IUCLID Dataset, Glycerol (56-81-5) (2000 CD-ROM edition). Available from, as of July 18, 2011: http://esis.jrc.ec.europa.eu/
PEER REVIEWED

/HUMAN EXPOSURE STUDIES/ In human eyes, specular microscopy has shown that repeated application of 100% **glycerin** to the surface of the eye causes extensive changes in the apperance of the endothelium, but most of these changes disappear within 90 min after exposure is ended.

Hazardous Substance Data Bank - Human Health Effects

[Grant, W.M. Toxicology of the Eye. 3rd ed. Springfield, IL: Charles C. Thomas Publisher, 1986., p. 463] **PEER REVIEWED**

/HUMAN EXPOSURE STUDIES/ Ten men and four women were given **glycerol** orally at a dose calculated to result in an average daily intake of 24 000 mg/kg bw per day, for 50 days. No toxic effects were reported. The only effect was a slight tendency towards an increase in body weight.
[WHO/FAO: Expert Committee on Food Additives. Summary of Toxicological Data of Certain Food Additives Series 48: Aliphatic acyclic diols, triols, and related substances (56-81-5) (2002). Available from, as of July 14, 2011: http://www.inchem.org/pages/jecfa.html **PEER REVIEWED**

/HUMAN EXPOSURE STUDIES/ In a briefly reported study, in which skin patch tests were conducted on workers in a foam rubber factory. No sensitising effects of a **glycerol**/water mixture became apparent.
[United Nations Environment Programme: Screening Information Data Sheets on Glycerol (56-81-5) (March 2002) Available from, as of July 14, 2009: http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html **PEER REVIEWED**

/CASE REPORTS/ A 46 year old male inadvertently consumed 500 mL of **glycerol** and presented with altered sensorium, focal neurologic signs and generalised seizures. He was managed conservatively and recovered fully within 48 hours. The case highlights the rare presentations of overdosage and neurologic effects with **glycerol**, an otherwise safe drug used in neurology.
[Singh R et al; Neurol India 49 (3): 320-1 (2001)] **PEER REVIEWED** PubMed Abstract

/CASE REPORTS/ The **glycerin** test has been proposed as an adjunct in the diagnosis of Meniere's disease. Complications of the test are rare and usually minor. /The authors/ describe a case in which a 20- to 40-dB hearing loss developed in the uninvolved ear of a patient during a standard **glycerin** test. He made a complete recovery within three days after the test. /Investigators/ discuss the possible mechanisms of the loss.
[Mattox DE, Goode RL; Arch Otolaryngol 104 (6): 359-61 (1978)] **PEER REVIEWED** PubMed Abstract

/CASE REPORTS/ A 73-year-old man was treated with oral **glycerol** solution for elevated intraocular pressure. Forty-five minutes later, he developed severe pulmonary edema. ...
[Almog Y et al; Ann Ophthalmol 18 (1): 38-9 (1986)] **PEER REVIEWED** PubMed Abstract

/CASE REPORTS/ /The authors/ report on a 72-year-old male who was referred to the Department of Neurology with progressive neurological symptoms that had developed 4 hr prior to admission. Temporally associated was the so-called **glycerol** test or Klockhoff test, which was performed for the diagnosis of suspected Meniere's disease. The test procedure starts with oral administration of **glycerol**, the maximal dose should not exceed 1.5 g/kg of body weight. Because of an apparently pathologically highly elevated serum concentration of triglycerides (3,465 mg/dL) measured 10 hr after **glycerol** administration, the suspicion of an overdose of **glycerol** rose. During the following day, the **glycerol** serum concentration was analyzed at three different times. Based on these measurements, /investigators/ determined pharmacokinetic

parameters and estimated the initially ingested amount of **glycerol** of about 3.88-3.95 g/kg body weight. /The authors/ conclude that an accidental overdose of **glycerol** must have occurred during the **glycerol** test to the patient.
[Andresen H et al; Clin Toxicol (Phila) 47 (4): 312-6 (2009)] **PEER REVIEWED** PubMed Abstract

/CASE REPORTS/ A three year old boy showed a unique intolerance to **glycerol**: 1-5 hrs after oral administration of **glycerol** in doses of 0.5-1.0 g/kg he had euphoria, mental confusion, drowsiness, nausea and vomiting, on one occasion the **glycerol** also provoked hypoglycemia; intravenously administered **glycerol** induced an immediate loss of consciousness with spontaneously recovery after 30 min., there were no changes in blood glucose values.
[European Chemicals Bureau; IUCLID Dataset, Glycerol (56-81-5) (2000 CD-ROM edition). Available from, as of July 18, 2011: http://esis.jrc.ec.europa.eu/ **PEER REVIEWED**

/CASE REPORTS/ A case of acute colonic ischemia following a **glycerin** enema in preparation for coronary artery bypass surgery was reported.
[European Chemicals Bureau; IUCLID Dataset, Glycerol (56-81-5) (2000 CD-ROM edition). Available from, as of July 18, 2011: http://esis.jrc.ec.europa.eu/ **PEER REVIEWED**

/CASE REPORTS/ Two cases of adverse effects after oral administration of **glycerine** in patients /were reported/. A 82-year old female (hypertensive, mentally senile) received 200 mL 50% **glycerine** orally for primary angle closure glaucoma. This woman developed headache, shaking of the arm, quivering of the eyes and nausea. A 68-year old female (diabetic) received 280 mL 50% **glycerine** orally within a period of 3 days. This **glycerine** was felt responsible for the ensuing severe diabetic acidosis.
[European Chemicals Bureau; IUCLID Dataset, Glycerol (56-81-5) (2000 CD-ROM edition). Available from, as of July 18, 2011: http://esis.jrc.ec.europa.eu/ **PEER REVIEWED**

/ALTERNATIVE and IN VITRO TESTS/ .../The study/ compared the effect of **glycerol** and glucose on the function of human peritoneal mesothelial cells (HPMC) in vitro. The viability of HPMC was not affected by **glycerol** (up to 250 mM), whereas it was reduced by glucose in a time- and dose-dependent manner, as assessed by the /lactate dehydrogenase/ release. Although the incubation of HPMC with **glycerol** induced a dose-dependent decrease in HPMC proliferation, the effect was significantly less inhibitory than that produced by glucose. In HPMC treated with 90 mM of **glycerol** or glucose the incorporation of (3)H-thymidine had reached 79.0 +/- 19.3% and 55.3 +/- 4.0% of the control ($p < 0.05$ and $p < 0.01$), respectively. As measured by the [methyl-(14)C]-choline incorporation, the intracellular amount of newly synthesized phospholipids was reduced from (cpm/ug cellular protein) 147 +/- 58 in control HPMC to 59 +/- 15 in cells exposed to 90 mM of glucose ($p < 0.01$), but not affected by **glycerol** (163 +/- 65). On the other hand, both **glycerol** and glucose (90 mM) decreased the synthesis of proteins (as assessed by the (3)H-proline incorporation) and interfered with potassium ((86)Rb) transport mechanisms in HPMC.
[Witowski J, Knapowski J; Int J Artif Organs 17 (5): 252-60 (1994)] **PEER REVIEWED** PubMed Abstract

/ALTERNATIVE and IN VITRO TESTS/ We exposed human corneas to various concentrations

of four cryoprotectants by one of two methods: a gradual increase to the final concentration (ramp method) and a series of steps to the final concentration (step method). Endothelial damage was manifest as a decrease in the number of endothelial cells per unit area. The highest concentrations that did not cause a loss of endothelial cells by the ramp and step methods, respectively, were 4.3 and 2.0 M **glycerol**, 2.0 and 4.3 M dimethylsulfoxide, 2.0 and 3.0 M 1,2-propanediol, and 2.0 and 2.5 M 2,3-butanediol. The ramp method achieved higher final concentrations with the more slowly permeating **glycerol**, but required low toxicity. The step method achieved higher final concentrations with the more toxic cryoprotectants by limiting the exposure time, but required more rapid permeation. None of the four cryoprotectants was tolerated at concentrations sufficient for vitrification at practical cooling and warming rates.
[Bourne WM et al; Cryobiology 31 (1): 1-9 (1994)] **PEER REVIEWED** PubMed Abstract

/OTHER TOXICITY INFORMATION/ The route of administration is of influence on the toxicity of **glycerol** in humans. Toxic effects, apart from nausea and vomiting, do not occur after oral administration. Toxic effects reported after intraperitoneal and subcutaneous administration are albuminuria, hemoglobinuria, anemia and renal damage. **Glycerol** has a dehydration effect on the central nervous system. Intraocular pressure begins to fall at plasma concentrations of 10 mmoles per liter. Concentration and dilutant used are also of influence on toxicity. Use of saline as dilutant diminishes the toxic effects of **glycerol**.
[European Chemicals Bureau; IUCLID Dataset, Glycerol (56-81-5) (2000 CD-ROM edition). Available from, as of July 18, 2011: http://esis.jrc.ec.europa.eu/ **PEER REVIEWED**

Skin, Eye and Respiratory Irritations:
Glycerin ... dropped on the human eye causes a strong stinging and burning sensation, with tearing and dilation of the conjunctival vessels, but no obvious injury.
[Grant, W.M. Toxicology of the Eye. 3rd ed. Springfield, IL: Charles C. Thomas Publisher, 1986., p. 463] **PEER REVIEWED**

Drug Warnings:
For rectal use only. May cause rectal discomfort or a burning sensation.
[US Natl Inst Health; DailyMed. Current Medication Information for ADULT GLYCERIN LAXATIVE (glycerin) suppository (February 2010). Available from, as of July 18, 2011: http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=f44d5cca-c28d-4f37-92db-510f6605be90 **PEER REVIEWED**

Do not use for more than one per day; for a period of longer than one week unless directed by a doctor; laxative products when abdominal pain, nausea, or vomiting are present unless directed by a doctor; if seal under product lid is damaged, missing or broken.
[US Natl Inst Health; DailyMed. Current Medication Information for ADULT GLYCERIN LAXATIVE (glycerin) suppository (February 2010). Available from, as of July 18, 2011: http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=f44d5cca-c28d-4f37-92db-510f6605be90 **PEER REVIEWED**

If you have rectal bleeding or fail to have a bowel movement after using a laxative. This may

indicate a serious condition.
[US Natl Inst Health; DailyMed. Current Medication Information for ADULT GLYCERIN LAXATIVE (glycerin) suppository (February 2010). Available from, as of July 18, 2011: http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=f44d5cca-c28d-4f37-92db-510f6605be90 **PEER REVIEWED**

Adverse effects occur rarely following rectal administration of **glycerin** or sorbitol. **Glycerin** may produce rectal discomfort, irritation, burning or griping, cramping pain and tenesmus. Hyperemia of the rectal mucosa with minimal amounts of hemorrhage and mucus discharge may also occur. These adverse effects occur less frequently following rectal administration of sorbitol.
[American Society of Health-System Pharmacists 2011; Drug Information 2011. Bethesda, MD. 2011] **PEER REVIEWED**

Stop use and ask a doctor if: you experience eye pain, changes in vision, continued redness or irritation of the eye; condition worsens or persists for more than 72 hours.
[US Natl Inst Health; DailyMed. Current Medication Information for SOOTHE (glycerin and propylene glycol) solution/ drops (August 2010). Available from, as of July 18, 2011: http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=fef002ea-c4bd-4486-a42e-1bbd9d73d28d **PEER REVIEWED**

Adverse effects following oral administration of **glycerin** include mild headache, dizziness, nausea, vomiting, thirst, and diarrhea.
[McEvoy, G.K. (ed.). American Hospital Formulary Service - Drug Information 93. Bethesda, MD: American Society of Hospital Pharmacists, Inc., 1993 (Plus Supplements, 1993)., p. 1774] **PEER REVIEWED**

... /It/ should be administered with caution to patients with cardiac, renal or hepatic disease, since shift in body water ... may aggravate these conditions and lead to pulmonary edema and/or congestive heart failure.
[McEvoy, G.K. (ed.). American Hospital Formulary Service - Drug Information 93. Bethesda, MD: American Society of Hospital Pharmacists, Inc., 1993 (Plus Supplements, 1993)., p. 1774] **PEER REVIEWED**

Side/adverse effects indicating need for medical attention only if they continue or are bothersome: incidence more frequent - headache, nausea or vomiting; incidence less frequent, diarrhea, dizziness, dry mouth or increased thirst.
[US Pharmacopeial Convention; US Pharmacopeia Dispensing Information (USP DI); Drug Information for the Health Care Professional 12th ed, V.I p.1456 (1992)] **PEER REVIEWED**

Side/adverse effects indicating need for medical attention: incidence less frequent - Confusion; incidence rare: irregular heartbeat.
[US Pharmacopeial Convention; US Pharmacopeia Dispensing Information (USP DI); Drug Information for the Health Care Professional 12th ed, V.I p.1456 (1992)] **PEER REVIEWED**

Severe dehydration, cardiac arrhythmias, and hyperosmolar nonketoic coma have been reported and may be fatal.

[US Pharmacopeial Convention; US Pharmacopeia Dispensing Information (USP DI); Drug Information for the Health Care Professional 12th ed, V.I p.1456 (1992)] **PEER REVIEWED**

Risk-benefit should be considered when the following medical problems exist: Cardiac disease (sudden expansion of extracellular fluid may lead to congestive heart failure); Confused mental states or severe dehydration or hypovolemia (conditions may be exacerbated); diabetes mellitus (patients may already be dehydrated); hypervolemia (expansion of extracellular fluid may lead to circulatory overload, which may produce congestive symptoms in patients with reduced cardiac function); Renal disease (accumulation may lead to overexpansion of extracellular fluid and circulatory overload).
[US Pharmacopeial Convention; US Pharmacopeia Dispensing Information (USP DI); Drug Information for the Health Care Professional 12th ed, V.I p.1456 (1992)] **PEER REVIEWED**

Populations at Special Risk:
Possibility of dehydration is increased in geriatric, senile, or already dehydrated patients.
[McEvoy, G.K. (ed.). American Hospital Formulary Service - Drug Information 93. Bethesda, MD: American Society of Hospital Pharmacists, Inc., 1993 (Plus Supplements, 1993)., p. 1774] **PEER REVIEWED**

Because slight hyperglycemia and glycosuria may occur as **glycerin** is metabolized, caution must be observed in admin drug orally to diabetic patients.
[McEvoy, G.K. (ed.). American Hospital Formulary Service - Drug Information 93. Bethesda, MD: American Society of Hospital Pharmacists, Inc., 1993 (Plus Supplements, 1993)., p. 1774] **PEER REVIEWED**

Although appropriate studies on the relationship of age to the effects of oral **glycerin** have not been performed in the geriatric population, the possibility of dehydration may be increased in elderly patients. In addition, elderly patients are more likely to have age-related renal function impairment, which may require caution in patients receiving **glycerin**.
[US Pharmacopeial Convention; US Pharmacopeia Dispensing Information (USP DI); Drug Information for the Health Care Professional 12th ed, V.I p.1456 (1992)] **PEER REVIEWED**

Appropriate studies on the relationship of age to the effects of oral **glycerin** have not been performed in the pediatric population. However pediatrics-specific problems that would limit the usefulness of this medication in children are not expected.
[US Pharmacopeial Convention; US Pharmacopeia Dispensing Information (USP DI); Drug Information for the Health Care Professional 12th ed, V.I p.1456 (1992)] **PEER REVIEWED**

Risk-benefit should be considered when the following medical problems exist: Cardiac disease (sudden expansion of extracellular fluid may lead to congestive heart failure); Confused mental states or severe dehydration or hypovolemia (conditions may be exacerbated); diabetes mellitus (patients may already be dehydrated); hypervolemia (expansion of extracellular fluid may lead to circulatory overload, which may produce congestive symptoms in patients with reduced cardiac function); Renal disease (accumulation may lead to overexpansion of extracellular fluid and circulatory overload).

Hazardous Substance Data Bank - Human Health Effects

[US Pharmacopeial Convention; US Pharmacopeia Dispensing Information (USP DI); Drug Information for the Health Care Professional 12th ed, V.I p.1456 (1992)] **PEER REVIEWED**

... /It/ should be administered with caution to patients with cardiac, renal or hepatic disease, since shift in body water ... may aggravate these conditions and lead to pulmonary edema and/or congestive heart failure.
[McEvoy, G.K. (ed.). American Hospital Formulary Service - Drug Information 93. Bethesda, MD: American Society of Hospital Pharmacists, Inc., 1993 (Plus Supplements, 1993)., p. 1774] **PEER REVIEWED**

Probable Routes of Human Exposure:
According to the 2006 TSCA Inventory Update Reporting data, the number of persons reasonably likely to be exposed in the industrial manufacturing, processing, and use of **glycerin** is 1000 or greater; the data may be greatly underestimated(1).
[(1) US EPA; Inventory Update Reporting (IUR). Non-confidential 2006 IUR Records by Chemical, including Manufacturing, Processing and Use Information. Washington, DC: U.S. Environmental Protection Agency. Available from, as of Jul 12, 2011: http://www.epa.gov/opptintr/iur/tools/data/index.html **PEER REVIEWED**

NIOSH (NOES Survey 1981-1983) has statistically estimated that 2,135,546 workers (1,346,631 of these were female) were potentially exposed to **glycerin** in the US(1). Occupational exposure to **glycerin** may occur through inhalation and dermal contact with this compound at workplaces where **glycerin** is produced or used. Use and limited monitoring data indicate that the general population may be exposed to **glycerin** via ingestion of food, some pharmaceuticals and drinking water, and dermal contact with consumer products containing **glycerin**(SRC).
[(1) NIOSH; NOES. National Occupational Exposure Survey conducted from 1981-1983. Estimated numbers of employees potentially exposed to specific agents by 2-digit standard industrial classification (SIC). Available from, as of Jul 12, 2011: http://www.cdc.gov/noes/ **PEER REVIEWED**

Hazardous Substances Data Bank - Animal Toxicity Studies

Non-Human Toxicity Excerpts:

/LABORATORY ANIMALS: Acute Exposure/ No deaths were observed in a group of 6 rabbits after occlusive dermal application for 8 hours of synthetic or natural **glycerol** at 18,700 mg/kg bw.

[United Nations Environment Programme: Screening Information Data Sheets on Glycerol (56-81-5) (March 2002) Available from, as of July 14, 2009: http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html **PEER REVIEWED**

/LABORATORY ANIMALS: Acute Exposure/ Twelve female rats received 27,260 mg natural or synthetic **glycerol**/kg bw by gavage. Cageside observations included muscle spasms and convulsions and survivors appeared normal within 2.5 hr of dosing. The number of deaths was not reported. Macroscopic examination of decedents and survivors showed hyperemia of the pylorus, small intestine and cerebral meninges (3 animals), congestion of the lungs and pale spleen.

[United Nations Environment Programme: Screening Information Data Sheets on Glycerol (56-81-5) (March 2002) Available from, as of July 14, 2009: http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html **PEER REVIEWED**

/LABORATORY ANIMALS: Acute Exposure/ /The authors/ investigated the acute toxicity of synthetic or natural **glycerol** in mice and guinea pigs. Again the reporting was limited, however both species showed similar clinical signs (tremor and convulsions) and macroscopic findings (hyperemia of pylores and small intestine, pale spleen, lung congestion).

[United Nations Environment Programme: Screening Information Data Sheets on Glycerol (56-81-5) (March 2002) Available from, as of July 14, 2009: http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html **PEER REVIEWED**

/LABORATORY ANIMALS: Acute Exposure/ It was demonstrated that dermal application of 0.5-mL **glycerol** to the rabbit's skin for 24 hours did not lead to signs of irritation 24 and 72 hours after application. Irritation scores according to Draize scale were 0-0.4, compared to a maximum score of 30 there was no evidence of irritation in rabbits following repeated applications of 4 mL over 30% of the surface area 8 hr/day for 90 days.

[United Nations Environment Programme: Screening Information Data Sheets on Glycerol (56-81-5) (March 2002) Available from, as of July 14, 2009: http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html **PEER REVIEWED**

/LABORATORY ANIMALS: Acute Exposure/ 0.1 mL undiluted **glycerol** was instilled in the eyes of 6 rabbit) caused no evidence of irritation after 1, 24 and 72 hours and after 7 days. The overall irritation score using the Draize system was 0-2 on a scale up to a maximum of 1-10. In another study of similar design, using 4 rabbits, irritation of unspecified severity observed at 1 hr after instillation of **glycerol** was absent after 24 hr. Another test with a similar design on a **glycerol**/water mixture (not further specified) gave a similar result and reactions, which were reversible within 24 hr. ... it is apparent from these studies that **glycerol** has a very low potential to irritate the eyes.

[United Nations Environment Programme: Screening Information Data Sheets on Glycerol (56-81-5) (March 2002) Available from, as of July 14, 2009: http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html **PEER REVIEWED**

/LABORATORY ANIMALS: Acute Exposure/ A group of male 24 Guinea pigs receiving 0.1 mL injections of 0.1 % synthetic or natural **glycerol** in isotonic saline every alternate day over 20 days showed no indication of sensitisation following challenge with further 0.05 mL injections of 0.1 % **glycerol** after a 2 week exposure-free period.

Hazardous Substances Data Bank - Animal Toxicity Studies

[United Nations Environment Programme: Screening Information Data Sheets on Glycerol (56-81-5) (March 2002) Available from, as of July 14, 2009: http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html **PEER REVIEWED**

/LABORATORY ANIMALS: Acute Exposure/ Subcutaneous injection of 1.75 mL of 50% **glycerol**/100g bw in rats caused severe hemolysis followed by necrosis of the tubular portions of the nephrons, but no apparent damage to the glomeruli. Effects were reversible within 6-12 weeks.
[European Chemicals Bureau; IUCLID Dataset, Glycerol (56-81-5) (2000 CD-ROM edition). Available from, as of July 18, 2011: http://esis.jrc.ec.europa.eu/ **PEER REVIEWED**

/LABORATORY ANIMALS: Acute Exposure/ Rats injected intraperitonealy with 1 mL 100% **glycerol**/100g bw had severe convulsions and died within 2 hours after injection. Rats injected with 1 mL 50% **glycerol**/100g bw also had severe convulsions and most of them died within 4 hours. Other signs of toxicity were hemoglobinuria, fluid in the peritoneal cavity, dehydrated tissues and renal damage (necrosis of epithelium of the proximal tubules, presence of eosinophilic casts in the loops of Henle, distal convoluted tubules and collecting tubules).
[European Chemicals Bureau; IUCLID Dataset, Glycerol (56-81-5) (2000 CD-ROM edition). Available from, as of July 18, 2011: http://esis.jrc.ec.europa.eu/ **PEER REVIEWED**

/LABORATORY ANIMALS: Acute Exposure/ Subcutaneous administration of 1 mL 100% **glycerol** or 50%/100 g bw to rats produced hemoglobinuria, severe edema at the site of injection, extremely hydrated tissues and renal tubular necrosis; in some animals at 100% **glycerol** mild convulsions were reported.
[European Chemicals Bureau; IUCLID Dataset, Glycerol (56-81-5) (2000 CD-ROM edition). Available from, as of July 18, 2011: http://esis.jrc.ec.europa.eu/ **PEER REVIEWED**

/LABORATORY ANIMALS: Acute Exposure/ Intravenous injection of both 100% **glycerol** and 50% **glycerol** at 1 mL/100g bw to rats led to severe convulsions and death in all animals (unless kept alive by dextrose-saline injection). Other signs included hemoglobinuria and occasionally renal damage.
[European Chemicals Bureau; IUCLID Dataset, Glycerol (56-81-5) (2000 CD-ROM edition). Available from, as of July 18, 2011: http://esis.jrc.ec.europa.eu/ **PEER REVIEWED**

/LABORATORY ANIMALS: Acute Exposure/ Female rats received a single i.p. injection of 3.5 mL **glycerol** (12.5% solution)/ kg bw. Urinary output, creatinine clearance, blood pressure, intrarenal blood flow and kidney histopathology were investigated during a 6 hour observation period. Urinary output and creatinine clearance were decreased. No effects on blood pressure and blood flow through the kidney became apparent. Incidental slight renal damage (necrosis of proximal tubular cells) was seen.
[European Chemicals Bureau; IUCLID Dataset, Glycerol (56-81-5) (2000 CD-ROM edition). Available from, as of July 18, 2011: http://esis.jrc.ec.europa.eu/ **PEER REVIEWED**

/LABORATORY ANIMALS: Acute Exposure/ When introduced into the anterior chamber of the rabbit eye, full strength **glycerin** causes an inflammatory reaction and edema of the cornea with wrinkling of the posterior surface and damage of endothelial cells.

Hazardous Substances Data Bank - Animal Toxicity Studies

[Grant, W.M. Toxicology of the Eye. 3rd ed. Springfield, IL: Charles C. Thomas Publisher, 1986., p. 463] **PEER REVIEWED**

/LABORATORY ANIMALS: Acute Exposure/ Aq 50% **glycerin** in the anterior chamber of rabbits causes significantly less reaction, though within 5 min it visibly dehydrates the lens, causing its capsule to become wrinkled.
[Grant, W.M. Toxicology of the Eye. 3rd ed. Springfield, IL: Charles C. Thomas Publisher, 1986., p. 463] **PEER REVIEWED**

/LABORATORY ANIMALS: Acute Exposure/ Enough rabbit corneal endothelial cells have survived to maintain normal deturgescence function after exposure of the epithelium to 30% **glycerin** for 20 min, 50% for 10 min, or 92% for 4 min, but 92% was observed to destroy the endothelium if exposure extended to 30 min. Endothelial damage in these circumstances can be explained on the basis of an osmotic, rather than a toxic, mechanism.
[Grant, W.M. Toxicology of the Eye. 3rd ed. Springfield, IL: Charles C. Thomas Publisher, 1986., p. 463] **PEER REVIEWED**

/LABORATORY ANIMALS: Acute Exposure/ **Glycerin** diluted with water to 43% and applied for 30 min to rabbit eyes with mechanically damaged corneal endothelium has apparently produced only edema of conjunctiva and nicitating membrane lasting a few hours, even when repeated daily for 20 days.
[Grant, W.M. Toxicology of the Eye. 3rd ed. Springfield, IL: Charles C. Thomas Publisher, 1986., p. 463] **PEER REVIEWED**

/LABORATORY ANIMALS: Subchronic or Prechronic Exposure/ Sprague-Dawley rats (10/sex/treatment) were exposed nose-only to a respirable aerosol of **glycerol** during 14 days (5 days/week, 6 hours/day). The mean exposure concentrations achieved were 0, 1000, 1930 and 3910 mg/cu m. The mass median aerodynamic diameter (MMAD) was reported to be < 1.5 micrometers. Two males at 1000 mg/cu m and 1 male and 1 female at 2000 mg/cu m died (which were incidental to treatment). Body weight gain was decreased in all treated animals. This effect may be attributed to stress due to nose-only exposure. Serum glucose was decreased in treated females, but since it did not appear in males and no relationship with concentration was established, the biological relevance of this effect is not considered to be of toxicological significance. There was no effect on lung, liver, kidney, brain and heart weight nor any macroscopic findings reported. Histopathological examination of the respiratory tract, liver, kidneys and heart of controls and high dose animals revealed an increased incidence of minimal to mild squamous metaplasia of the epiglottis in all treated animals (1/10, 13/18, 16/19 and 13/14 at 0, 1000, 1930, and 3910 mg/cu m, respectively). The frequency of animals with mild metaplasia was greatest at the highest exposure concentration. No systemic effects were seen at the highest dose tested.
[United Nations Environment Programme: Screening Information Data Sheets on Glycerol (56-81-5) (March 2002) Available from, as of July 14, 2009: http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html **PEER REVIEWED**

/LABORATORY ANIMALS: Subchronic or Prechronic Exposure/ Nose-only exposure of rats (SD 15/sex/treatment) 6hr/day, 5d/week for 13 weeks to a respirable aerosol (MMAD <2 micrometers) of **glycerol** at measured concentrations of 0, 33, 165 and 662 mg/cu m led to decreased triglyceride levels in males at 33 (34%) and 165 mg/cu m (22%). This effect appears to be of little toxicological significance as there was no dose-response relationship and was seen in males only. There were no treatment related effects on cageside observations, hematology,

organs weights or gross pathology. Microscopic evaluation of the tissues showed "minimal" (10 animals) or "mild" (one animal) squamous metaplasia of the epiglottis in 11 animals in total at the highest concentration. Since the effect on triglycerides did not show a relationship with concentration, was seen in males only and in the absence of any systemic target organ toxicity, the biological relevance of this effect is not considered to be of toxicological significance. Based on an increased incidence of "minimal" to "mild" squamous metaplasia of the epiglottis, the NOAEC for local irritant effects to the upper respiratory tract is 165 mg/cu m and 662 mg/cu m for systemic effects.
[United Nations Environment Programme: Screening Information Data Sheets on Glycerol (56-81-5) (March 2002) Available from, as of July 14, 2009: http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html **PEER REVIEWED**

/LABORATORY ANIMALS: Subchronic or Prechronic Exposure/ Rats injected iv with 10% **glycerol** for 9 consecutive days, developed an increase in succinate dehydrogenase and acid phosphatase activity in kidney and degeneration of renal tubular epithelium ultrastructure 1 and 4 days after last injection. 19 days later kidneys were similar to control.
[NOWAK H ET AL; PATOL POL 30 (1): 61 (1979)] **PEER REVIEWED** PubMed Abstract

/LABORATORY ANIMALS: Subchronic or Prechronic Exposure/ The effects of dietary crude **glycerin** on growth performance, carcass characteristics, meat quality indices, and tissue histology in growing pigs were determined in a 138-d ay feeding trial. Crude **glycerin** utilized in the trial contained 84.51% **glycerin**, 11.95% water, 2.91% sodium chloride, and 0.32% methanol. Eight days postweaning, 96 pigs (48 barrows and 48 gilts, average BW of 7.9 +/- 0.4 kg) were allotted to 24 pens (4 pigs/pen), with sex and BW balanced at the start of the experiment. Dietary treatments were 0, 5, and 10% crude **glycerin** inclusion in corn-soybean meal-based diets and were randomly assigned to pens. Diets were offered ad libitum in meal form and formulated to be equal in /metabolizable energy/, sodium, chloride, and Lysine, with other amino acids balanced on an ideal amino acidine basis. Pigs and feeders were weighed every other week to determine /average daily gain/, /average daily feed intake/, and /gain to feed ratio/. At the end of the trial, all pigs were scanned using real-time ultrasound and subsequently slaughtered at a commercial abattoir. Blood samples were collected pretransport and at the time of slaughter for plasma metabolite analysis. In addition, kidney, liver, and eye tissues were collected for subsequent examination for lesions characteristic of methanol toxicity. After an overnight chilling of the carcass, loins were removed for meat quality, sensory evaluation, and fatty acid profile analysis. Pig growth, feed intake, and /gain to feed ratio/ were not affected by dietary treatment. Dietary treatment did not affect 10th-rib backfat, /loin miuscle/ area, percent fat free lean, meat quality, or sensory evaluation. Loin ultimate pH was increased (P = 0.06) in pigs fed the 5 and 10% crude **glycerin** compared with pigs fed no crude **glycerin** (5.65 and 5.65 versus 5.57, respectively). Fatty acid profile of the /loin muscle/ was slightly changed by diet with the /loin muscle/ from pigs fed 10% crude **glycerin** having less linoleic acid (P < 0.01) and more eicosapentaenoic acid (P = 0.02) than pigs fed the 0 or 5% crude **glycerin** diets. Dietary treatment did not affect blood metabolites or frequency of lesions in the examined tissues. This experiment demonstrated that pigs can be fed up to 10% crude **glycerin** with no effect on pig performance, carcass composition, meat quality, or lesion scores.
[Lammers PJ et al; J Anim Sci 86 (11): 2962-2970 (2008)] **PEER REVIEWED** PubMed Abstract

/LABORATORY ANIMALS: Subchronic or Prechronic Exposure/ Groups of five young rats of

each sex were fed a diet containing **glycerol** at a concentration of 0, 1, 3, 6, 10, 15, 20, 30, 40, 50, or 60% (equivalent to 0, 1000, 3000, 6000, 10 000, 15 000, 20 000, 30 000, 40 000, 50 000, or 60 000 mg/kg bw per day) for 20 weeks. There was no significant difference in the body-weight gain at concentrations of **glycerol** 30%, but reduced body-weight gain was observed at >/= 40%. Histological examination revealed no treatment-related changes at < 10%. The pathological changes observed at concentrations >/= 10% were marked hydropic and fatty degeneration of liver parenchymal cells. The NOEL was 5% **glycerol** in the diet, equivalent to 5000 mg/kg bw per day.
[WHO/FAO: Expert Committee on Food Additives. Summary of Toxicological Data of Certain Food Additives Series 48: Aliphatic acyclic diols, triols, and related substances (56-81-5) (2002). Available from, as of July 14, 2011: http://www.inchem.org/pages/jecfa.html **PEER REVIEWED**

/LABORATORY ANIMALS: Chronic Exposure or Carcinogenicity/ In a study of the tumor promoting potential of **glycerol**, groups of male and female C3H mice, 6-8 weeks old, were given various carcinogens followed by 0, 0.5, or 1% (v/v) **glycerol** solution until they were 1 year old. Animals in the control group received either 5% (v/v) **glycerol** (equivalent to 5000 mg/kg bw per day) or water. The animals were killed, and the incidences of liver and lung tumors were recorded. Among males, the incidence of liver tumors was 23% in those given **glycerol** and 39% in those given water. The tumor incidence in the lung was 21% with **glycerol** and 41% with water. Similar results were obtained for female mice. Thus, lower incidences of liver and lung tumors were seen after **glycerol** treatment. No treatment-related adverse effects were reported.
[WHO/FAO: Expert Committee on Food Additives. Summary of Toxicological Data of Certain Food Additives Series 48: Aliphatic acyclic diols, triols, and related substances (56-81-5) (2002). Available from, as of July 14, 2011: http://www.inchem.org/pages/jecfa.html **PEER REVIEWED**

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/LABORATORY ANIMALS: Chronic Exposure or Carcinogenicity/ A study in which Sprague-Dawley rats were given **glycerol** in the diet at a concentration of 0, 5, 10, or 20% (equivalent to 0, 5000, 10 000 or 20 000 mg/kg bw per day) for 50 weeks was evaluated ... No significant treatment-related effects were found on growth rate or gross or histological appearance. The NOEL was 20 000 mg/kg bw per day.
[WHO/FAO: Expert Committee on Food Additives. Summary of Toxicological Data of Certain Food Additives Series 48: Aliphatic acyclic diols, triols, and related substances (56-81-5) (2002). Available from, as of July 14, 2011:

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http://www.inchem.org/pages/jecfa.html **PEER REVIEWED**

/LABORATORY ANIMALS: Chronic Exposure or Carcinogenicity/ In /a/ dietary study, groups of 22 rats (Long-Evans)/sex/treatment 4000 and 8000 mg/kg bw; females 2500, 5000 and 10000 mg/kg bw) for 2 years. Routine clinical observations were made, and bodyweight and food consumption was determined weekly. Deviations from the OECD guideline included the absence of clinical chemistry investigation and a limited range of hematological and urinary analyses were performed. A limited range of organs was investigated at necropsy and the liver, spleen, adrenals, small intestine, gonads and urinary bladder were examined microscopically. Glycogen and fat content of the liver was determined in surviving rats from the 0 and 20 % dose groups. No individual data were reported. For high dosed animals treatment was discontinued after 1 year (reason not stated in report, presumably as an 'interim' assessment for carcinogenicity). No data on mortality and clinical observations were reported. Food consumption was slightly increased in males treated with 5 and 10% natural **glycerol**. Incidental observations considered by the report-authors to be without relationship to treatment included: bronchiectasis, pneumonia, pulmonary abcesses, hydronephrosis and pyelonephritis. Although the results were not described in detail, based on this limited dietary study it can be concluded that no adverse effects were observed at up to 10,000 mg/kg bw.
[United Nations Environment Programme: Screening Information Data Sheets on Glycerol (56-81-5) (March 2002) Available from, as of July 14, 2009: http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html **PEER REVIEWED**

/LABORATORY ANIMALS: Chronic Exposure or Carcinogenicity/ In a limited and non OECD Guideline 12-24 month dietary study in rats, evidence of malignant neoplasms were reported in 5/26, 1/22, 5/22, 0/22, 0/21, 5/22 and 0/22 animals in controls and at 5%, 10% , 20% (natural **glycerol**) and at 5%, 10%, 20% (synthetic **glycerol**). At the top dose, the treatment period was one year. Benign neoplasms were encountered including pheochromacytomas and granulosa cell tumours in 0/26, 2/22, 1/22, 0/22, 4/21, 4/22 and 1/22 animals in controls and at 5%, 10%, 20% (natural **glycerol**) and at 5%, 10%, 20% (synthetic **glycerol**), respectively. The authors concluded that **glycerol** does not initiate tumor development in the rat.
[United Nations Environment Programme: Screening Information Data Sheets on Glycerol (56-81-5) (March 2002) Available from, as of July 14, 2009: http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html **PEER REVIEWED**

/LABORATORY ANIMALS: Chronic Exposure or Carcinogenicity/ In male ddY mice administration of **glycerol** (5% in drinking water during 1-20 weeks) after a single sc injection with 4-nitroquinoline 1-oxide (4-NQO) was reported to enhance lung tumor development. Histopathologically most lung tumors were identified as adenomas. The mechanism of tumor induction was independent from pulmonary cell kinetics.
[United Nations Environment Programme: Screening Information Data Sheets on Glycerol (56-81-5) (March 2002) Available from, as of July 14, 2009: http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html **PEER REVIEWED**

/LABORATORY ANIMALS: Developmental or Reproductive Toxicity/ A seven-generation study of reproductive toxicity in rats given **glycerol** at a concentration of 0 or 30% (equivalent to 15 000 mg/kg bw per day) was evaluated ... . On average, the pups of treated dams weighed 20% less than those of the control group.
[WHO/FAO: Expert Committee on Food Additives. Summary of Toxicological Data of Certain Food Additives Series 48: Aliphatic acyclic diols, triols, and related substances (56-81-5) (2002). Available from, as of July 14, 2011:

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http://www.inchem.org/pages/jecfa.html **PEER REVIEWED**

/LABORATORY ANIMALS: Developmental or Reproductive Toxicity/ In a two generation study, male and female rats (10/treatment) were dosed daily with **glycerol** (20% solution in water) during 8 weeks before mating. Females received **glycerol** throughout pregnancy or until weaning of the F1 generation (5 each). When the F1 generation was approximately 100 days of age, pups were killed except for 10/sex. These animals were used to produce the F2-generation. No effects were found on the reproductive efficiency of the parents, nor on the growth, fertility, reproductive performance of the untreated F1 generation, and no histological changes occurred in the tissues of both the F1 and F2 generation. Although the data are limited, a NOAEL of 2000 mg/kg bw was identified from this study.
[United Nations Environment Programme: Screening Information Data Sheets on Glycerol (56-81-5) (March 2002) Available from, as of July 14, 2009: http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html **PEER REVIEWED**

/LABORATORY ANIMALS: Developmental or Reproductive Toxicity/ Rats, mice and rabbits were treated daily with **glycerol** at dose levels up to 1310, 1280 and 1180 mg/kg bw (oral gavage), respectively, during part of the gestation period. The study protocol was in reasonable agreement with the requirements of the OECD 414. No maternal toxicity or teratogenic effects were seen at the highest dose levels tested. From these studies a NOAEL of 1180 mg/kg bw can be derived.
[United Nations Environment Programme: Screening Information Data Sheets on Glycerol (56-81-5) (March 2002) Available from, as of July 14, 2009: http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html **PEER REVIEWED**

/GENOTOXICITY/ **Glycerol** did not induce mutations in bacteria in an Ames test, which used four Salmonella typhimurium strains both with and without metabolic activation (rat and hamster S-9). ... No mutagenic effects were reported in an additional Ames test with 5 strains and rat S-9 as metabolic activation system.
[United Nations Environment Programme: Screening Information Data Sheets on Glycerol (56-81-5) (March 2002) Available from, as of July 14, 2009: http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html **PEER REVIEWED**

/GENOTOXICITY/ **Glycerol** was considered to be negative by the authors in a mammalian cell gene mutation test (HGPRT) since the increased number of mutations at the two highest dose levels was considered to be biologically irrelevant, because no concentration dependence was seen. However, it is unknown why the concentrations tested were not maximized to those recommended in the OECD guideline ...
[United Nations Environment Programme: Screening Information Data Sheets on Glycerol (56-81-5) (March 2002) Available from, as of July 14, 2009: http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html **PEER REVIEWED**

/GENOTOXICITY/ Chromosomal damage was investigated in the chromosomal aberration test using cultured mammalian cells (Chinese hamster ovary), which was reported as negative. In this test an isolated increase in number of aberrations was seen at 200 ug/mL (with metabolic activation). This finding was considered to be of no biological relevance, since there was no relationship with the concentration tested. **Glycerol** did not induce sister chromatid exchanges in CHO cells. In rat hepatocytes, the number of nuclear grains did not differ between **glycerol** treated and control cells. Therefore, it can be concluded that no unscheduled DNA synthesis occurred.

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[United Nations Environment Programme: Screening Information Data Sheets on Glycerol (56-81-5) (March 2002) Available from, as of July 14, 2009: http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html **PEER REVIEWED**

/GENOTOXICITY/ Two in vivo assays are available for **glycerol**. In a rat bone marrow chromosome aberration test **glycerol** did not induce a statistically significant increase in chromosomal aberrations compared to controls.
[United Nations Environment Programme: Screening Information Data Sheets on Glycerol (56-81-5) (March 2002) Available from, as of July 14, 2009: http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html **PEER REVIEWED**

Non-Human Toxicity Values:

LD50 Rat sc 0.1 g/kg
[Rowe, R.C., Sheskey, P.J., Quinn, M.E.; (Eds.), Handbook of Pharmaceutical Excipients 6th edition Pharmaceutical Press, London, England 2009, p. 285] **PEER REVIEWED**

LD50 Rat oral 12.6 g/kg
[Rowe, R.C., Sheskey, P.J., Quinn, M.E.; (Eds.), Handbook of Pharmaceutical Excipients 6th edition Pharmaceutical Press, London, England 2009, p. 285] **PEER REVIEWED**

LD50 Rat oral 5.57 g/kg
[Rowe, R.C., Sheskey, P.J., Quinn, M.E.; (Eds.), Handbook of Pharmaceutical Excipients 6th edition Pharmaceutical Press, London, England 2009, p. 285] **PEER REVIEWED**

LD50 Rat ip 4.42 g/kg
[Rowe, R.C., Sheskey, P.J., Quinn, M.E.; (Eds.), Handbook of Pharmaceutical Excipients 6th edition Pharmaceutical Press, London, England 2009, p. 285] **PEER REVIEWED**

LD50 Rabbit oral 27 g/kg
[Rowe, R.C., Sheskey, P.J., Quinn, M.E.; (Eds.), Handbook of Pharmaceutical Excipients 6th edition Pharmaceutical Press, London, England 2009, p. 285] **PEER REVIEWED**

LD50 Rabbit iv 0.05 g/kg
[Rowe, R.C., Sheskey, P.J., Quinn, M.E.; (Eds.), Handbook of Pharmaceutical Excipients 6th edition Pharmaceutical Press, London, England 2009, p. 285] **PEER REVIEWED**

LD50 Mouse sc 0.09 g/kg
[Rowe, R.C., Sheskey, P.J., Quinn, M.E.; (Eds.), Handbook of Pharmaceutical Excipients 6th edition Pharmaceutical Press, London, England 2009, p. 285] **PEER REVIEWED**

LD50 Mouse oral 4.1 g/kg
[Rowe, R.C., Sheskey, P.J., Quinn, M.E.; (Eds.), Handbook of Pharmaceutical Excipients 6th edition Pharmaceutical Press, London, England 2009, p. 285] **PEER REVIEWED**

Hazardous Substances Data Bank - Animal Toxicity Studies

LD50 Mouse iv 4.25 g/kg
[Rowe, R.C., Sheskey, P.J., Quinn, M.E.; (Eds.), Handbook of Pharmaceutical Excipients 6th edition Pharmaceutical Press, London, England 2009, p. 285] **PEER REVIEWED**

LD50 Mouse ip 8.70 g/kg
[Rowe, R.C., Sheskey, P.J., Quinn, M.E.; (Eds.), Handbook of Pharmaceutical Excipients 6th edition Pharmaceutical Press, London, England 2009, p. 285] **PEER REVIEWED**

LD50 Guinea pig oral 7.75g/kg
[Rowe, R.C., Sheskey, P.J., Quinn, M.E.; (Eds.), Handbook of Pharmaceutical Excipients 6th edition Pharmaceutical Press, London, England 2009, p. 285] **PEER REVIEWED**

LC50 Rat inhalation > 570 mg/cu m/1 hr
[United States Pharmacopeial Convention, Inc (USP); MSDS Database Online; Material Safety Data Sheet: Glycerin; Catalog Number: 1295607; (Revision Date: November 24, 2008)] **PEER REVIEWED**

Ecotoxicity Values:

Toxicity threshold (cell multiplication inhibition test) Algae (Microcystis aeruginosa) 2900 mg/l
[Verschueren, K. Handbook of Environmental Data of Organic Chemicals. 2nd ed. New York, NY: Van Nostrand Reinhold Co., 1983., p. 695] **PEER REVIEWED**

Toxicity threshold (cell multiplication inhibition test) Protozoa (Entosiphon sulcatum) 3200 mg/l
[Verschueren, K. Handbook of Environmental Data of Organic Chemicals. 2nd ed. New York, NY: Van Nostrand Reinhold Co., 1983., p. 695] **PEER REVIEWED**

LC50; Species: Goldfish; Concentration: >5000 mg/L for 24 hr - modified ASTM D 1345
[Verschueren, K. Handbook of Environmental Data of Organic Chemicals. 2nd ed. New York, NY: Van Nostrand Reinhold Co., 1983., p. 695] **PEER REVIEWED**

LC50; Species: Daphnia magna (Water flea, age < or = 24 hr); Conditions: freshwater, static, 20-22 deg C; Concentration: >10000 mg/L for 24 hr /formulated product/
[Bringmann G, Kuhn R; Z Wasser-Abwasser-Forsch 10 (5): 161-1 (1977) as cited in the ECOTOX database. Available from, as of July 7, 2011: http://cfpub.epa.gov/ecotox/ **PEER REVIEWED**

Draco Natural Products, Inc.
Material Safety Data Sheet

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME Organic Glycerin, USP
ITEM CODE TBD
SYNONYMS Glycerol
INCI NAME Glycerin
MATERIAL USES Multiple uses in cosmetics, drug and food products as emulsifier, emollient, plasticizer, humectant, sweetener and anti-freeze, etc.
EMERGENCY CONTACT Call 911 in case of emergency

SUPPLIER/MANUFACTURER
Draco Natural Products, Inc.
539 Parrott Street
San Jose, CA 95112 USA
TEl. 408-287-7871
FAX. 408-287-8838
www.dracoherbs.com

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

SUBSTANCE NAME	CAS NUMBER	EINECS NUMBER	CONTENT % BY WT	"R" PHRASE	"S" PHRASE
Glycerol	56-81-5	200-289-5	≥ 99.5 %	None	None

SECTION 3: HAZARDS IDENTIFICATION

Skin contact Unlikely to be irritant; however, heated product may cause thermal burns if contacted.
Eye contact Concentrated solutions may cause mild transient irritation.
Inhalation Not applicable at ambient temperature; however, glycerin mist may be irritative to respiratory tract.
Ingestion Unlikely to be harmful unless excessive amount is ingested.
Chronic Repeated excessive exposure may cause increased flat levels in blood.

CHIP/RISK/SAFETY classification
RISK PHRASES associated with the product None
SAFETY PHRASES associated with the product None

SECTION 4: FIRST AID MEASURES

Skin contact Irrigate thoroughly with soap and cold water. Seek medical attention if symptoms occur
Inhalation Remove person to fresh air, loosen clothing and seek expert medical help. Give artificial respiration if not breathing.
Eye contact Check for and remove any contact lens. In case of contact with eyes, irrigate thoroughly with cold water. Seek medical attention if irritation persists.
Ingestion Do not induce vomiting. Never give anything by mouth to an unconscious person. Get medical attention if symptoms appear.
Aggravation of Pre-existing Conditions Persons with pre-existing skin disorders or eye problems or impaired liver or kidney function may be more susceptible to the effects of the substance.

SECTION 5: FIRE-FIGHTING MEASURES

Fire Slight fire hazard when exposed to heat or flame. Slight fire hazard when exposed to heat or flame.
Explosion Above flash point, vapor-air mixtures may cause flash fire.
Extinguishing media
Suitable Use an extinguishing agent suitable for the surrounding fire.
Not Suitable Water jet
Special exposure hazards Toxic gases and vapors may be released if involved in a fire.
Special protective equipment for fire-fighters
Fire-fighters should wear a self-contained breathing apparatus (SCBA) pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear.

SECTION 6: ACCIDENTAL RELEASE MEASURES

General information Use suitable protective clothing and equipment (see Section 8)
Spills/Leaks Absorb spill with inert solids such as sand or soil. Dispose of in accordance with federal, state, and local regulations. For large spills, dike around spill and pump into suitable containers.

SECTION 7: HANDLING AND STORAGE

Handling Use appropriate personal protective equipment (PPE) in well ventilated areas and methods that minimize dust generation. Avoid breathing dust, mist, or vapor. Avoid contact with skin and eyes.
Storage Store in a cool, well-ventilated area in sealed containers. Glycerin should be kept above 64 F but below 130 F. Avoid excessive heat and open flames. Store away from strong oxidizing agents or combustible material.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Consult local authorities for acceptable exposure limits
Engineering measures Local exhaust recommended
Hygiene measures Follow good manufacturing practice standards. Wash hands, forearms, face, and any area exposed to this product before and after being in contact with this product.
Personal protection
Eyes Safety goggles
Skin Lab coats, boots, and appropriate laboratory appeal
Hands Disposable rubber or vinyl gloves

Respiratory A respirator is not needed under normal and intended conditions of product use

Exposure Limits

Australia	TWA 10 mg/m3	**Belgium**	TWA 10 mg/m3	**Canada**	TWA 10 mg/m3
France	TWA (VME) 10 mg/m3	**Finland**	8 hour limit 20 mg/m3	**Ireland**	8 hour OEL (TWA) 10 mg/m3
Italy	8 hour TWA 10 mg/m3	**Korea**	TWA 10 mg/m3	**Malaysia**	TWA 10 mg/m3
Mexico	TWA 10 mg/m3	**New Zealand**	TWA 10 mg/m3	**Singapore**	8-hour PEL (TWA) 10 mg/m3
Spain	8 hour daily exposure limit (VLA-ED) 10 mg/m3			**United Kingdom**	TWA 10 mg/m3
United States	OSHA Z-1 PEL Glycerin mist, respirable fraction - 5 mg/m3 OSHA Z-1 PEL Glycerin mist, total dust - 15 mg/m3 ACGIH – Glycerin mist - TLV-TWA 10 mg/m3			**The Netherlands**	MAC TWA (TGG) 10 mg/m3

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Liquid	**pH**	Neutral	**Decomposition temperature**	Not available
Color	Water white, clear	**Boiling point**	>554ºF (290ºC)	**Auto ignition temperature**	698ºF (370ºC)
Odor	Bland odor	**Melting point**	~64.4ºF (~18ºC)	**Explosive properties**	Not to be expected
Solubility	**Water** Miscible	**Freezing point**	Not available	**Oxidizing properties**	Not to be expected
	Fat Insoluble	**Specific gravity**	1.26 @ 20ºC/4ºC	**Explosive limits**	Not applicable
Molecular formula	$C_3H_5(OH)_3$	**Flash point**	>390ºF (199ºC)	**Evaporation rate**	Not available
Molecular weight	92.09	**Vapor density**	3.17 (Air=1)	**Specific density**	1,26 aprox
Viscosity	1410mPa.s@68ºF (20ºC)	**Vapor pressure**	0.0025mmHg @ 50ºC (122ºF)		

SECTION 10: STABILITY AND REACTIVITY

Chemical stability Stable under normal temperature, moisture level, and pressure.
Conditions to avoid Avoid excessive heat and open flames. Avoid contact with strong oxidizing agents or combustible material.
Incompatibilities with other materials Incompatible with perchloric acid, lead oxide, acetic anhydride, nitrobenzene, chlorine, peroxides, strong oxidizers, strong acids, strong bases. Combustible.
Hazardous decomposition products Thermal decomposition releases corrosive fumes or Acrolein. Decomposition may result in carbon monoxide and carbon dioxide formation.
Hazardous polymerization Has not been reported

SECTION 11: TOXICOLOGICAL INFORMATION

Routes of entry Ingestion, skin contact, inhalation
Acute effects **LD50** Not available **LC50** Not available
Potential chronic health effects Repeated excessive exposure may cause increased flat levels in blood.
Carcinogenic effects NOT Listed by IARC, NTP, OR OSHA as a carcinogen
Mutagenic effects Not available **Teratogenic effects** Not available

SECTION 12: ECOLOGICAL INFORMATION

No definitive information available on ecological impact if product is released to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste disposal Must be disposed of in accordance with federal, state and local environmental control regulations

SECTION 14: TRANSPORT INFORMATION

DOT classification Not a DOT controlled material (United States).
Customs classification International HTS# 1211.90.9190

SECTION 15: REGULATORY INFORMATION

Dangerous Substances Directive 67/548/EEC and Dangerous Preparations Directive 1999/45/EC:
This product is not classified as dangerous according to 67/548/EEC or 99/45/EC as amended.
OSHA Permissible Exposure Limit (PEL), ACGIH Threshold Limit Value (TLV), or other exposure limits:
See Section 8
US Food and Drug Administration (FDA)
This product is approved for use by the FDA under the following sections of 21 CFR:
Part 182.1320 as Generally Recognized as Safe (GRAS) when used in accordance with the specifications of this subpart.

SECTION 16: OTHER INFORMATION

Date created 2008-8-18 **Last updated** 2008-8-18 **Updated by** Wendy Chen
This product meets the requirements for glycerin as described in the United States Pharmacopoeia (USP) 27 (March 2004)
Note: THE INFORMATION ACCUMULATED HEREIN IS BELIEVED TO BE ACCURATE, BUT IS NOT WARRANTED TO BE, WHETHER ORIGINATING WITH THE COMPANY OR NOT. RECIPIENTS ARE ADVISED TO CONFIRM IN ADVANCE OF NEED THAT THE INFORMATION IS CURRENT, APPLICABLE, AND SUITABLE TO THEIR CIRCUMSTANCES.