



THE MARK OF ENVIRONMENTAL RESPONSIBILITY

GS-44

GREEN SEAL™ STANDARD FOR SOAPS, CLEANSERS, AND SHOWER PRODUCTS

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GREEN SEAL™

Green Seal is a non-profit organization whose mission is to use science-based programs to empower consumers, purchasers, and companies to create a more sustainable world. Green Seal sets leadership standards that aim to reduce, to the extent technologically and economically feasible, the environmental, health, and social impacts throughout the life-cycle of products, services, and companies. The standards may be used for conformity assessment, purchaser specifications, and public education.

Green Seal offers certification of products, services, and companies in conformance with its standards. For additional information on Green Seal or any of its programs, contact:

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FOREWORD

General. The final issued standard was developed in an open and transparent process with stakeholder input that included producers, users, and general interests.

The requirements in the standard are based on an assessment of the environmental, health, or social impacts associated with the products, services, or organizations covered in the scope of the standard. The requirements included in the standard are subject to revision. Provisions for safety have not been included in this standard. This standard neither modifies nor supersedes laws and regulations. Compliance with this Standard is not a substitute for, and does not assure, compliance with any applicable law or regulations. This standard (and any corresponding conformity assessment) presumes compliance with all applicable laws and regulations.

This standard neither modifies nor supersedes laws and regulations. Compliance with all applicable laws and regulations is a required prerequisite for the manufacturing and marketing of the products.

Products, services, or organizations that are substantially similar to those covered by this standard in terms of function and life cycle considerations may be evaluated against the intent of the requirements of this standard, accounting for relevant differences between the intended scope of the Standard and the actual product, service, or organization to be evaluated.

This standard may not anticipate features of the product that may significantly, and undesirably, increase its impact on the environment, health, or society. In such a situation, Green Seal will ordinarily amend its standards to account for the unanticipated environmental, health, and societal impacts.

Normative references (e.g., other standards) in this standard intend to refer to the most recent edition of the normative reference.

Edition. This version is the First Edition from May 7, 2009.

Disclaimer of Liability. Green Seal™, as the developer of this standard, shall not incur any obligations or liability for any loss or damages, including, without limitation, indirect, consequential, special, or incidental damages arising out of or in connection with the interpretation or adoption of, reliance upon, or any other use of this Standard by any party. Green Seal makes no express or implied warranty of merchantability or fitness for a particular purpose, nor any other express or implied warranty with respect to this Standard.

Tests may be required by the standard that involve safety considerations. Adequate safeguards for personnel and property should be employed in conducting such tests.

List of Acronyms

ACGIH. American Conference of Governmental Industrial Hygienists
AOEC. Association of Occupational and Environmental Clinics
ASTM. American Society for Testing and Materials
CFR. Code of Federal Regulations
DFG. German Deutsche Forschungsgemeinschaft
EPA. United States Environmental Protection Agency
FDA. The United States Food and Drug Administration
GHS. Globally Harmonized System for Classification and Labeling of Chemicals
IARC. International Agency for Research on Cancer
IRIS. Integrated Risk Information System
INCI. International Nomenclature of Cosmetic Ingredients
ISO. International Organization for Standardization
LLNA. Local Lymph Node Assay
MAK. Maximum Allowable Concentrations
NOAEL. No-Observed Adverse Effect Level
NSF. NSF International
NTP. National Toxicology Agency
OECD. Organization for Economic Co-operation and Development
OSHA. Occupational Safety and Health Administration
QSAR. Quantitative Structure-Activity Relationship
TLV. Threshold Limit Value
USDA. The United States Department of Agriculture
VOC. Volatile Organic Compound

GREEN SEAL™ STANDARD FOR SOAPS, CLEANSERS, AND SHOWER PRODUCTS (GS-44)

1.0 SCOPE

This standard establishes requirements for hand, hair, and body soaps and cleansers used and rinsed after use. This includes liquid and solid soap and cleansers, shampoo, conditioner, and related shower products for baby, child, adult, and professional-use. This standard does not apply to products used for animal or pet use, those used in commercial or institutional facilities where the products are not intended to be sold to consumers, or products required to be registered under the Federal Insecticide, Fungicide, and Rodenticide Act, such as those making claims as sterilizers, disinfectants, or sanitizers, or antimicrobial soaps and cleansers.

2.0 DEFINITIONS

2.1 Allergen. Allergenic substances listed by the European Commission in the Cosmetic Directive and those listed by the FDA (including food allergens).

2.2 Antimicrobial. Substances that are intended to kill or inhibit the growth of microorganisms including antiseptic, disinfectant, and sanitizer substances.

2.3 Antiseptic. Substances that are intended to prevent or arrest the growth of microorganisms.

2.4 Asthma. Asthma is a chronic inflammatory disorder of the airways that impairs breathing. Asthma affects children and adults, may be intermittent or persistent, and is further classified as mild, moderate, or severe. The chronic inflammation associated with variable airflow obstruction commonly causes difficulty breathing, coughing, wheezing, shortness of breath, and/or chest pain. Symptoms may resolve completely between active episodes. Symptoms may occur during exposure, immediately after exposure, or up to 24 hours later in a “late phase,” frequently interrupting sleep.

2.5 Asthmagens. Substances designated as asthma causing agents by the AOEC, which after review by AOEC have met the AOEC sensitization criteria.

2.6 Biobased. The content of a product that is from biological products or renewable materials, forestry, or agricultural materials (including plant, animal, and marine materials).

2.7 Carcinogens. Chemicals listed as a known, probable, reasonably anticipated, or possible human carcinogen by the IARC (Groups 1, 2A, and 2B),

NTP (Groups 1 and 2), EPA IRIS (weight-of-evidence classifications A, B1, B2, C, carcinogenic, likely to be carcinogenic, and suggestive evidence of carcinogenicity or carcinogen potential), or by OSHA (as carcinogens under 29 CFR 1910.1003(a)(1)).

2.8 Cleanser. A product intended to clean the body or hair that has detergent properties that are not necessarily due to alkali-fatty acid compounds, and may contain synthetic detergents.

2.9 Color Component. A product component, such as a dye or pigment, whose only function is to change the product's color.

2.10 Component. A deliberate addition to the product, where it is added for its continued presence in the final product to provide a specific characteristic, appearance, or quality. Naturally occurring elements and chlorinated organics, which may be present as a result of chlorination of the water supply, are not considered intentional components if the concentrations are below the applicable maximum contaminant levels in the National Primary Drinking Water Standards found in 40 Code of Federal Regulations (CFR) Part 141.

2.11 Concentrate. Product, as sold, that must be diluted by water prior to its intended use.

2.12 Conditioner. A product that is intended to alter the texture or appearance of hair or scalp, used after shampoo and rinsed off after use. This can include products called rinses but does not include leave-in products.

2.13 Contaminant. A product constituent that was not added for its functionality, but is known to be present.

2.14 Disinfectant. An antimicrobial agent intended to and capable of destroying pathogenic and potentially pathogenic microorganisms on inanimate surfaces.

2.15 Haber's Rule. For a given toxic gas, the concentration of the gas multiplied by the duration of exposure equals a constant ($C \times t = k$); for example, doubling the concentration will halve the time for a given toxic effect.

2.16 Halogenated Organic Solvents. Organic solvents containing halogens, including fluorine, chlorine, bromine, and iodine.

2.17 Fragrance. An additive, often (but not limited to) a multi-component additive, used in a product with the purpose of imparting or neutralizing a scent in the product.

- 2.18 Ingredient.** Any component of a product that is intentionally added or known to be a contaminant that comprises at least 0.01% by weight of the product.
- 2.19 Intentional Introduction.** The act of deliberately utilizing a material in the formation of a package or packaging component where its continued presence is desired in the final package or packaging component to provide a specific characteristic, appearance, or quality.
- 2.20 Mutagen.** A chemical that meets the criteria for category 1, chemicals known to induce heritable mutations or to be regarded as if they induce heritable mutations in the germ cells of humans, under GHS Chemicals Which Cause Mutations in Germ Cells.
- 2.21 Nanoscale Component.** Components that are roughly 1 to 100 nanometers in size, enabling novel applications that a larger-sized version of the component could not achieve.
- 2.22 Natural Components.** Components that come from materials and found in nature including mineral, forestry, agricultural, or biological materials; do not contain transgenic hybrid organisms; have been processed without irradiation; and are not chemically altered.
- 2.23 Naturally-Derived Components.** Components that are partially chemically altered without petroleum components and have been minimally processed such that they not be altered to such an extent that they are no longer biodegradable and non-toxic (examples of potentially acceptable processes are included in Appendix A).
- 2.24 Optical Brighteners.** Additives designed to enhance the appearance of colors and whiteness in materials by absorbing ultraviolet radiation and emitting blue radiation. These compounds are also known as fluorescent whitening agents.
- 2.25 Organic Components.** Components, produced and handled, certified by a USDA-accredited certifying agent.
- 2.26 Ozone-Depleting Compounds.** A compound with an ozone-depletion potential greater than 0.01 (CFC 11=1) according to the EPA list of Class I and Class II Ozone-Depleting Substances.
- 2.27 Post-Consumer Material.** Material that would otherwise be destined for solid waste disposal, having completed its intended end-use and product life cycle. Post-consumer material does not include materials and by-products generated from, and commonly reused within, an original manufacturing and fabrication process.

2.28 Product As Used. The amount of product directed for use and diluted in 1 liter of tap water. If no dose is suggested, 5 ml of liquid soap or cleansers shall be used and 0.9 ml of foam soap or cleansers shall be used, or the equivalent for solid or semi-solid products.

2.29 Professional-Use. Trained or paid workers, such as, but not limited to, hair stylists, that use the products included in the scope of this standard and such products are available for sale to the consumer.

2.30 Primary Package. A package that is the material physically containing and coming into contact with the product, not including the cap or lid of a bottle.

2.31 Recyclable. The package can be collected in a substantial majority of communities, separated or recovered from the solid waste stream and used again, or reused in the manufacture or assembly of another package or product through an established recycling program.

2.32 Reproductive Toxin. A chemical listed as a reproductive toxin (including developmental, female, and male toxins) by the State of California under the Safe Drinking Water and Toxic Enforcement Act of 1986 (California Code of Regulations, Title 22, Division 2, Subdivision 1, Chapter 3, Sections 1200, et. Seq., also known as Proposition 65).

2.33 Sanitizer. A product intended to reduce the level of microorganisms present to acceptable levels established by federal or provincial health authorities.

2.34 Secondary Packaging. Packaging used to contain primary package/s and typically used for merchandizing. This does not include case or shipping packaging or the primary package, cap, or lid.

2.35 Serious Eye Damage. The production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application.

2.36 Shampoo. A soap or cleanser used to clean the hair and scalp and rinsed off after use. This can include combination shampoo and conditioner or shampoo and rinse products.

2.37 Shower Products. Products that are used on the body or hair with the intention that they are washed off the body. This may include bubble bath, exfoliating scrubs, and other rinse-off products.

2.38 Skin Corrosion. The production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis, following the application of a test substance for up to 4 hours. Corrosive reactions are typified

by ulcers, bleeding, bloody scabs, and, by the end of observation at 14 days, by discoloration due to blanching of the skin, complete areas of alopecia, and scars.

2.39 Skin Sensitizer. A substance that will lead to an allergic response following skin contact.

2.40 Soap. A product used to clean the body or hair in which most of the nonvolatile matter consists of an alkali salt of fatty acids and whose detergent properties are due to these alkali-fatty acid compounds (21 CFR 701.20).

2.41 Source-Reduced Package. A package that has at least 50% less material (by weight) compared to containers commonly used for that product type.

2.42 Undiluted Product. The most concentrated form of the product produced by the manufacturer for transport outside its facility.

3.0 PRODUCT-SPECIFIC PERFORMANCE REQUIREMENTS

The product shall perform as well as or better than a conventional, nationally-recognized product in its category and at equivalent concentration using an objective, scientifically-validated method conducted under controlled and reproducible laboratory conditions. The testing protocol shall include, at a minimum: cleaning ability, lathering/rinsing, and skin or hair condition after use. A standard soil shall be used and conclusions shall be derived from at least six separate samples. All results, a summary of conclusions, and a description of how panelists were chosen shall be submitted.

4.0 PRODUCT-SPECIFIC HEALTH AND ENVIRONMENTAL REQUIREMENTS

4.1 Acute Toxicity. The *undiluted* product shall not be toxic to humans. A product is considered toxic if any of the following criteria apply:

Oral lethal dose (LD ₅₀)	≤ 5,000 mg/kg
Inhalation lethal concentration (LC ₅₀)	≤ 20 mg/L at 1 hr
Dermal lethal dose (LD ₅₀)	≤ 2,000 mg/kg

Toxicity shall be measured on the product as a whole. Alternatively, a mixture need not be tested if existing toxicity information demonstrates that each of the ingredients complies. The toxicity testing procedures should meet the requirements put forth by the OECD Guidelines for Testing of Chemicals. These protocols include Acute Oral Toxicity Test (TG 401), Acute Inhalation Toxicity Test (TG 403), and Acute Dermal Toxicity Test (TG 402).

Testing is not required for any ingredient for which sufficient information exists.

To demonstrate compliance with this requirement. It is assumed that the toxicity of the individual ingredients is additive. The toxicity values are adjusted by the weight of the ingredient in the product and summed using the following formula:

$$TP = \left(\sum_{i=1}^n \frac{wt_i}{TV_i} \right)^{-1}$$

Where,

TP = toxicity of the product

wt_i = the weight fraction of the ingredient

TV = the toxicity value for each ingredient (LD₅₀)

n = number of ingredients

For inhalation toxicity, it is determined from all ingredients with a vapor pressure greater than 1 mm Hg at standard conditions (1 atm and 20-25°C).

4.2 Carcinogens, Mutagens, and Reproductive Toxins. The *undiluted* product shall not contain any ingredients or components that are carcinogens, mutagens, or reproductive toxins. The product shall not contain any ingredients or components known to produce or release carcinogens, mutagens, or reproductive toxins.

4.3 Skin and Eye Irritation. The *undiluted* product shall not be corrosive or irritating to the skin or cause serious eye damage as defined by the GHS. Further, a product is considered corrosive to skin or to cause serious eye damage if it has a pH of 2 or less or a pH of 11.5 or greater, unless proven otherwise.

The product shall not be a skin irritant as tested by OECD Guidelines for Testing Chemicals, Section 404 or other peer-reviewed or standard test methods. The product shall not be considered a skin irritant under the following scenarios:

- if test data shows that the whole-product is not a skin irritant,
- if test data shows that each ingredient present at or above a concentration of 5% is not a skin irritant, or
- if test data shows that any known skin irritants are non irritating when present at 5% or greater in the product.

Further, a product shall be evaluated for skin corrosion and serious eye damage following the testing and evaluation strategy described in the GHS. Green Seal prefers that an *in vitro* test validated by the Interagency Coordinating Committee on the Validation of Alternative Methods or the European Centre for the Validation of Alternative Methods be used. Green Seal will also accept the results of other peer-reviewed or standard *in vitro* or *in vivo* test methods demonstrating that the product mixture is not corrosive. Testing is not required for any ingredient for which sufficient information exists.

4.4 Skin Sensitization. The *undiluted* product shall not be a skin sensitizer, as tested by the LLNA or following EPA test guidelines for skin sensitization (OECD Guideline 429, OPPTS 870.2600). The results of other standard test methods, such as the guinea pig maximization test (OECD Guideline 406) or the Buehler test (OECD 406), will be accepted as proof that the product in its most concentrated form is not a skin sensitizer when data from LLNA tests are not available. Any new product or ingredient testing should use the LLNA. Testing is not required for any ingredient for which sufficient information exists.

4.5 Skin Absorption. The *undiluted* product shall not contain ingredients, present at greater than or equal to 1% in the product, that are listed on the ACGIH TLV carrying a skin notation, or substances that are listed on the DFG MAK list with a skin absorption H notation. Further, the product shall not contain ingredients that sum to 1% in the formula that are listed on ACGIH or DFG with the same target organ.

4.6 Components that Cause Asthma. The *undiluted* product shall not contain any components that have been identified as asthmagens.

4.7 Ozone Depleting Compounds. The *undiluted* product shall not contain any ingredients that are ozone-depleting compounds.

4.8 Volatile Organic Compound Content. The *undiluted* product shall not contribute significantly to the production of photochemical smog, tropospheric ozone, or poor indoor-air quality by containing no more than 1% of VOC content. The VOC content shall be determined either by summing the percent by weight contribution from all components of the product that have a vapor pressure of greater than 0.1 mm mercury at standard conditions or by the California Air Resources Board Method 310 modified to not allow the exemption for fragrances specified under Method 310.

4.9 Chronic Inhalation Toxicity. The product *as used* shall not contain ingredients with a vapor pressure above 1 mm mercury at ambient conditions (1 atm pressure and 20-25° C) that cause chronic inhalation toxicity as evidenced by either of the following:

- Listed by the European Chemicals Bureau as R48/23: Danger of serious damage to health by prolonged exposure through inhalation.
- Classified as producing significant toxic effects in mammals from repeated inhalation exposure at or below 1.0 mg/L as a vapor according to OECD Harmonized Integrated Classification System for Human Health and Environmental Hazards of Chemical Substances and Mixtures. For the purposes of this standard, significant toxic effects in mammals from repeated inhalation exposure at or below 1.0 mg/L as a vapor shall be established by a NOAEL, based on a test duration of 90 days at 6 hours per day; values from other exposure regimes shall be estimated

- % CO₂ evolution of theoretical > 60%

Per OECD guidance the 10-day window requirement does not apply to structurally-related surfactant homologues. For organic ingredients that do not exhibit ready biodegradability in these tests the manufacturer may demonstrate biodegradability in sewage treatment plants using the Coupled Units Test found in OECD 303A by demonstrating DOC removal > 90%.

An exception shall be made for natural or naturally-derived components that do not exhibit ready biodegradability if it does not have acute aquatic toxicity <100 mg/L (according to 4.10), does not have a chronic toxicity <100 mg/L (tested according to OECD 210, 211, or 201), is not bioaccumulating (4.11), and exhibits biodegradation rates above 70% (measured as BOC, DOC, or COD), per ISO test methods 9887 or 9888; or OECD 302A, B, or C.

Testing is not required for any ingredient for which sufficient information exists concerning its biodegradability, either in peer-reviewed literature or databases.

4.13 Eutrophication. The *undiluted* product shall not contain phosphorus-containing ingredients.

4.14 Prohibited Components. The *undiluted* product shall not contain the following components:

- 2-butoxyethanol
- Alkylphenol ethoxylates
- Butylated hydroxytoluene
- Ethoxylated chemicals
- Ethylene diaminetetra-acetic acid or any of its salts
- Formaldehyde donors
- Heavy metals including, lead, hexavalent chromium, or selenium both in the elemental form or compounds
- Halogenated organic solvents
- Methylidibromo glutaronitrile
- Monoethanolamine, Diethanolamine, and Triethanolamine alone or in compounds
- Nitro-musks
- Parabens
- Phthalates
- Polycyclic musks

4.15 Fragrances. All fragrance components shall be disclosed to the certifying body. Any fragrances used shall have been produced and handled following the code of practice of the International Fragrance Association. The product shall declare any fragrances on the product label in the ingredient line (see 6.2 and 6.5).

4.16 Preservatives. The use of preservatives for purposes other than preservation of the product is not allowed. Documentation must be provided to demonstrate the dosage necessary to preserve the product.

4.17 Color Components. [Reserved]

4.18 Nanoscale Components. [Reserved]

4.19 Optical Brighteners. The *undiluted* product shall not contain any ingredients that are optical brighteners.

4.20 Animal Testing. To discourage animal testing, the results of past peer reviewed or standard tests demonstrating compliance with a criterion will be accepted. A mixture need not be tested if existing information demonstrates that each of the ingredients complies with a criterion. Additionally, non-animal (in-vitro) test results, modeling data, or data from structural analogs may be accepted, provided that the methods are peer-reviewed, applicable, and the manufacturer provides rationale for the particular method.

5.0 PACKAGING REQUIREMENTS

5.1 Primary Packaging.

5.1.1 Source Reduction in Primary Package. The primary package shall be a source-reduced package or recyclable and contain at least 25% post-consumer material or demonstrate that efforts were made to use the maximum available post-consumer material in the package.

5.1.2 Concentrated Product Packaging. Concentrates are prohibited from being packaged in ready-to-use forms, including but not limited to pump-dispenser bottles.

5.1.3 Heavy Metal Restrictions. Heavy metals, including lead, mercury, cadmium, and hexavalent chromium, shall not be intentionally introduced. Further, the sum of the concentration levels of these metals present shall not exceed 100 parts per million by weight (0.01%); an exception is allowed for refillable packages or packages that would not exceed this maximum level but for the addition of recovered materials. Further, intentional introduction does not include the use of one of the metals as a processing aid or intermediate to impart certain chemical or physical changes during manufacturing, where the incidental retention of a residual of that metal in the final packaging or packaging component is not desired or deliberate, if the final packaging or packaging component complies with the incidental concentration restrictions of 100 ppm.

5.1.4 Other Restrictions. Phthalates, Bisphenol A, and chlorinated packaging material are prohibited from being intentionally introduced; an exception is allowed for packages that would not have these added compounds but for the addition of recovered material.

5.2 Secondary Packaging. Secondary packaging shall only be used for concentrates. An exception may be made for packaging of multiple units when up to one of the units is a ready-to-use form, including but not limited to pump-dispenser bottles, and total packaging (primary plus secondary) is a reduction in packaging material use.

6.0 COMMUNICATION AND LABELING REQUIREMENTS

6.1 Antimicrobial Claims. The product shall make no antibacterial, disinfecting, antiseptic, or sanitizing product claims.

6.2 Ingredient Line. The product shall list the product components using the naming convention of the INCI in order of predominance. The general term ‘fragrance’ may be used for fragrance components. The product shall also follow any additional labeling regulations that apply to that product.

6.3 Organic Claims. Organic claims must be supported with documentation that they meet the USDA National Organic Program or meet the NSF 305 standard.

6.4 Natural and Biobased Claims. Only the following natural and biobased, or related, claims are allowed when the product meets the criteria outlined:

- “100 percent Natural,” “All Natural,” “100 percent Biobased,” or “All Biobased” shall only contain natural or biobased components, respectively, with no synthetic, petroleum, silicone, or artificial components. An exception is permitted for lye used to produce soap.
- "Natural" or “Biobased” products shall contain 95% natural, naturally-derived, or biobased components, respectively, with no synthetic, petroleum, silicone, or artificial components.
- Claims on specific product ingredients being “natural” or “biobased” may be permitted if it is a natural or biobased ingredient.

6.5 Fragrance and Allergen Labeling. The product label shall declare, separate from the ingredient line, if a fragrance has been added or if no fragrance has been added and if the product contains any allergen ingredients.

6.6 Consumer Communication. The product ingredient line (6.2) shall be made available to consumers in an easily accessible means besides the product package, such as the company website.

6.7 Use Labeling. The product shall be accompanied by detailed instructions for proper use to maximize product performance and minimize waste.

6.8 Disposal Labeling. The label must include proper disposal instructions including clear package recycling instructions, if applicable.

6.8.1 Plastic Labeling. If plastic, the packaging must be clearly marked with the appropriate Society of the Plastics Industry symbol to identify the type of plastic for recycling and appropriate qualification of recyclability as referenced in 5.1.1 such as “may be recyclable, see if accepted by your local program” or “only a few communities accept this package for recycling, check with your local program.”

6.9 Certification Mark. The Green Seal Certification Mark may appear on the packaging and may appear on the product itself. The Green Seal Certification mark shall not be used in conjunction with any modifying terms, phrases, or graphic images that might mislead consumers as to the extent or nature of the certification.

6.10 Statement of Basis for Certification. Whenever the Green Seal certification mark appears on a package, the package shall contain a description of the basis for certification. The description shall be in a location, style, and typeface that are easily readable. Unless otherwise approved in writing by Green Seal, the description shall read as follows:

“This product meets the Green Seal™ standard for soaps, cleansers, and shower products based on its low impact on aquatic life, minimized use of hazardous substances, and increased health protection.”

Appendix A

Examples of Potentially Acceptable Processing Methods of Naturally-Derived Components (which must also meet all the requirements in the standard)

- Esterification, Etherification, and Transesterification (to produce esters and ethers like polyglycerols)
- Glucosidation (to produce glucosides)
- Hydrogenation (of fats and oils)
- Hydrolysis and Hydrogenolysis (to produce hydrolyzed proteins, glycerin and fatty acids, and fatty alcohols)
- Other Condensation Reactions like Acylation of proteins and Sulfation of fatty alcohols
- Saponification (to produce soap)