

**CLASS 435, CHEMISTRY: MOLECULAR BIOLOGY AND MICROBIOLOGY****SECTION I - CLASS DEFINITION**

## STATEMENT OF CLASS SUBJECT MATTER

This class provides for the following subject matter when not provided for elsewhere:

A. A process of using a microorganism or enzyme to synthesize a chemical product.

B. A process of treating a material with a microorganism or enzyme to separate, liberate, or purify a preexisting substance.

C. An in vitro process of measuring and testing in which: (1) A microorganism or enzyme is used to determine the presence or identity of a compound or composition in a sample; (2) A microorganism is identified by propagation; (3) An enzyme is identified by its catalytic activity; (4) The presence of microorganisms is detected; (5) A live microorganism is used in an antigen antibody test as an antigen; (6) Fixed or stabilized non-living microorganisms, cells, or tissues are involved.

D. A process of propagating a microorganism.

E. A process in which the genetic structure of a microorganism or extrachromosomal genetic structure is altered.

F. A process of organ or tissue maintenance.

G. A process of mashing or malting.

H. Apparatus claimed or solely disclosed as for A-G.

I. Microorganisms, per se, or the subcellular parts thereof.

J. Enzymes, immobilized enzymes or enzyme containing compositions not otherwise provided for and the processes for purifying enzymes or forming immobilized enzymes.

K. Compositions claimed or solely disclosed as for the propagation of microorganisms or for measuring and testing processes in C above.

L. Using microorganisms to destroy hazardous or toxic waste.

## CLASSIFICATION GUIDELINES FOR THIS CLASS

## APPARATUS

This class takes only apparatus claimed or solely disclosed as for fermentation or enzymology, organ, and tissue maintenance or genetic engineering not otherwise provided for. Apparatus by name only which is claimed as a collection of compounds or compositions in a kit without structure is classified as described below in Lines With Other Classes and Within This Class.

## COMPOSITIONS

In general, this class will not provide for compositions other than an immobilized or insolubilized enzyme or a test or culture media.

## COMPOUNDS

In general, this class does not provide for compounds other than an immobilized or insolubilized enzyme or an enzyme, per se. Production of metal or ammonium salts of a compound are classified with the production of that compound.

## AMINO ACID RESIDUES

If upon hydrolysis of an unidentified product the only residues are amino acids, it should be presumed that the product is a protein or peptide. If other organic moieties are present after hydrolysis of the product then placement should be made upon the basis of the presence of such structure in the product.

## PRESUMPTION

In the absence of a clearly claimed step of killing or inactivating a microorganism in an antigen-antibody test the microorganism should be treated as a living antigen.

**SECTION II - LINES WITH OTHER CLASSES AND WITHIN THIS CLASS**

See References to Other Classes, below, for lines with classes providing for the use of a microorganism, an enzyme and the apparatus therefor and the composition classes providing for the products of a microorganism or enzyme and for lines with other related classes.

The rules for determining Class placement of the Original Reference (OR) for claimed chemical compositions

are set forth in the Class Definition of Class 252 in the section LINES WITH OTHER CLASSES AND WITHIN THIS CLASS, subsection COMPOSITION CLASS SUPERIORITY, which includes a hierarchical ORDER OF SUPERIORITY FOR COMPOSITION CLASSES.

### SECTION III - SUBCLASS REFERENCES TO THE CURRENT CLASS

SEE OR SEARCH THIS CLASS, SUBCLASS:

- 4+, Apparatus by name only which is claimed as a collection of compounds or compositions in a kit without structure is classified on the basis of the compositions into the subclasses 4+ area.
- 84+, and indented subclasses 95, 96, 98, and 99 for compounds produced by hydrolysis of larger structures with subclasses
- 94, reserved for the enzymatic interconversion of isomers.
- 97, 100 - 105 provide for building up from smaller saccharide units.

### SECTION IV - REFERENCES TO OTHER CLASSES

SEE OR SEARCH CLASS:

- 8, Bleaching and Dyeing; Fluid Treatment and Chemical Modification of Textiles and Fibers, provides for processes of (a) dyeing employing a microorganism or enzyme (b) treating hides or skins by use of a microorganism or enzyme with subsequent tanning of the hides or skins or subsequent operations that are preliminary and peculiar to tanning of hides or skins or peculiar to making leather.
  - (a) Class 435 provides for a process of using an enzyme or microorganism to treat a hide or skin particularly depilating or bating as well as treating feathers or animal tissue with a microorganism or enzyme not otherwise provided for.
- 8, Bleaching and Dyeing; Fluid Treatment and Chemical Modification of Textiles and Fibers, provides for compositions for dyeing materials of any kind which may contain a microorganism or enzyme.
- 15, Brushing, Scrubbing, and General Cleaning, provides for dust cloths, mops, or other cleaning devices which include detergents which may contain enzymes.

- 34, Drying and Gas or Vapor Contact With Solids, provides for processes and apparatus for drying of a solid which may include a microorganism enzyme or media composition.
  - (a) Class 435 provides for processes of culture or propagation of microorganisms including the production of enzymes and media and provides for the combination of culture or production with drying or another Class 34 operation.
- 48, Gas: Heating and Illuminating, for gaseous compositions for heating or illuminating by combustion which may be the result of a process using a microorganism or enzyme.
- 47, Plant Husbandry, which provides for mushrooms or processes of or apparatus for cultivating or culturing mushrooms; sprouting or germinating seeds for planting, or testing the sprouting or germinating power of seeds; articles or compositions that include seeds and either a microorganism or enzyme and process of making such articles or compositions; processes of cultivating or culturing seed plants, or other nonfungal plants that include the use of a microorganism or enzyme, articles, compositions, or apparatus, for use in the above processes, or in making articles or compositions, that include seeds and microorganism or enzymes or processes of making articles or compositions for use in the above noted processes.
  - (a) Class 435 provides for materials that contain germinated seeds, for processes that include germinating seeds or for apparatus for use therein, e.g., malting grain and malting apparatus, etc., as well as processes involving propagation of unicellular algae or undifferentiated plant cells where there is no plant propagation and for the extraction of enzymes from plants or plant products. Class 435 also provides for the production of starter culture for mushrooms or for the propagation of undifferentiated plant cells as well as the culture of unicellular algae.
- 48, Gas: Heating and Illuminating, for fuel gas compositions when the processes of making such compositions involve a microorganism; processes of producing fuel gas compositions that include a microorganism; articles, compositions, or apparatus, for uses in such processes; or processes of making such articles or compositions for such uses.

- (a) Class 435 provides for the production or purification of a gas by the use of microorganisms or enzymes if such process is not ancillary to the production of fertilizer or a Class 210 liquid purification by living organisms or directed to the production of a fuel gas by living organisms.
- 62, Refrigeration, for processes or apparatus for preserving an organ, microorganism, or enzyme by the removal of heat and the cooled or frozen product resulting. The process may involve the use of a composition to eliminate or minimize cooling or freezing damage, e.g., sperm preservation, etc.
- (a) Class 435 provides for methods and apparatus of maintaining the viability of an animal organ tissue including blood and sperm or cells as well as the process and apparatus for the treatment or propagation of animal cells or tissue.
- 71, Chemistry: Fertilizers, provides for processes of producing a composition or article having utility as a fertilizer by use of a microorganism or enzyme as well as the composition containing a microorganism or enzyme.
- (a) Class 435 provides for the production of microorganisms having utility for fertilizer production and microorganism containing starter compositions useful in a Class 71 process.
- 73, Measuring and Testing, provides for processes and apparatus for determining the physical properties of the product of fermentation or enzymology and include process and apparatus for measuring the rate of sedimentation of elements in blood.
- 75, Specialized Metallurgical Processes, Compositions for Use Therein, Consolidated Metal Powder Compositions, and Loose Metal Particulate Mixtures, provides for processes and compositions containing a microorganism or enzyme for use in processes of obtaining free metals from metal compounds or ores. Class 75, in particular, provides for processes of hydrometallurgy processes of beneficiating ores or recovery of elemental metal from waste in which a microorganism or enzyme is used when the reduction to elemental metal is claimed.
- (a) Class 435 provides for the process of producing a microorganism or enzyme useful in ore treating and for processes of cultivating microorganisms on sulfur containing media.
- 99, Foods and Beverages: Apparatus, for apparatus adapted for the preparation of a beverage or beverage intermediate by carrying out primary ethyl alcoholic fermentations and apparatus for the aging, refining, and purification of alcoholic beverages.
- (a) Class 435 provides for apparatus claimed or solely disclosed as used for propagating a microorganism or for use of an enzyme.
- 106, Compositions: Coating or Plastic, provides for processes which use an enzyme or microorganism to produce a coating or plastic composition.
- (a) Class 435 provides for the use of a microorganism or enzyme to produce a product which may be a composition not otherwise provided for.
- 127, Sugar, Starch, and Carbohydrates, provides for the hydrolysis of carbohydrates including their conversion to sugar by chemical means or process using an enzyme or microorganism only where the hydrolysis by microorganism or enzyme is followed by steps of concentration purification or treatment (such as crystallization) to make a sugar or syrup. Additionally, Class 127 provides for the products of such processes.
- (a) Class 435 provides for hydrolysis of a carbohydrate by a microorganism or enzyme when not followed by steps of concentration, purification, or treatment to make a sugar or syrup. Class 435 also provides for hydrolysis by any method when followed by treatment with a microorganism or enzyme to produce alcohol.
- 128, Surgery, appropriate subclasses provide for methods of blood transfusion and insemination by artificial means as well as for methods of treatment of the living body or a test which involves contact with a body and apparatus used in the inspection and treatment of diseases of the bodies of men and animals which apparatus is provided with means for connection to the living body.
- (a) Class 435 provides for the maintenance of blood or sperm and viable tissue and virus cultures and the media for such processes.
- 131, Tobacco, for tobacco-containing articles, or compositions, or articles or compositions when tobacco is used in the making thereof, when the processes of making such articles or compositions involve the use of a microorganism or

- enzyme; processes of making such articles or compositions, or treating tobacco, that include the use of a microorganism or enzyme; or articles, compositions, or apparatus, for uses in such processes, or processes of making the latter articles or compositions for uses in above noted processes.
- (a) Class 435 provides for processes of growing a microorganism or using an enzyme the media for which may comprise plant material.
- 137, Fluid Handling, is the residual place for processes, systems, combinations, and subcombinations for fluid material handling. Lines With Other Classes and Within This Class, Automatic Control, in the class definition of Class 137 provide a guide to the automatic control provided for therein.
- (a) Class 435 will provide for condition responsive control of a process with a step of microbial growth or enzymology and for condition responsive control apparatus when claimed or solely disclosed as involving a microorganism or enzyme.
- 159, Concentrating Evaporators, provides for the concentration of solids held in solution or suspension by evaporation of liquid and the recovery of a concentrate or a dry solid which include the treatment of a feed stream to or the treatment of a product of a microorganism or enzyme.
- (a) Class 435 is superior to Class 159 and will provide for the concentration of a solid by the evaporation of liquid when combined with process or apparatus involving a microorganism or enzyme.
- 162, Paper Making and Fiber Liberation, provides for processes and apparatus which includes use of a microorganism or enzyme when combined with a step peculiar to Class 162 as well as the use of a microorganism or enzyme as a component of a paper or fiber pulp.
- (a) Class 435 provides for fiber paper pulping and textile treatment by a microorganism or enzyme, per se. For an exhaustive listing of fiber treatment classes, see the notes immediately following the class definition of Class 162.
- 166, Wells, provides for processes and apparatus for treating oil or an oil bearing mineral with a microorganism or enzyme while in the ground.
- 204, Chemistry: Electrical and Wave Energy, provides for processes and apparatus involving electrical or wave energy. Class 204 provides for electrophoretic or electro-osmotic separation and purification of a compound or element and for other electrical separation or purification of a liquid when not provided for elsewhere, for the use of electrophoretic or electro-osmotic techniques to immobilize a compound or element where not provided for elsewhere, and for processes for use of an electrode containing a microorganism or enzyme for measuring or testing.
- (a) Class 435 provides for processes and apparatus for measuring or testing in which a microorganism is cultured or an enzyme functions catalytically when a nonelectrical or nonwave energy property is measured, or when an electrical or wave energy property is measured separate and apart, but in combination with Class 435 subject matter; and for processes and apparatus for electrical or wave energy treatment of microorganisms or enzymes when the treatment is solely disclosed for use with viable microorganisms or catalytically active enzymes.
- 205, Electrolysis: Processes, Compositions Used Therein, and Methods of Preparing the Compositions, appropriate subclasses for processes of measuring and testing in which the activity of a microorganism or enzyme is measured by change in electrolytic action, for electrolytic separation and purification of a compound or element when not provided for elsewhere, for the use of electrolytic techniques to immobilize a compound or element where not provided for elsewhere, and for processes of use of an electrode containing a microorganism or enzyme for measuring or testing.
- (a) Class 435 provides for processes and apparatus for measuring or testing in which a microorganism is cultured or an enzyme functions catalytically when a nonelectrolytic property is measured, or when an electrolytic property is measured separate and apart, but in combination with Class 435 subject matter; and for processes and apparatus for electrical or wave energy treatment of microorganisms or enzymes when the treatment is solely disclosed for use with viable microorganisms or catalytically active enzymes.
- 210, Liquid Purification or Separation, provides for processes of treating impure liquids by processes including a microorganism, e.g., bacteri-

- ological digestion of sewage including the use of an immobilized microorganism and the apparatus for such processes, as well as methods of physical separation of microorganisms and viruses from liquid media.
- (a) Class 435, provides for the growth of a microorganism on a liquid media and the apparatus therefor as well as providing for process utilizing an immobilized microorganism, per se.
- 241, Solid Material Comminution or Disintegration, provides for processes and apparatus for the comminution or disintegration of solids which includes the comminution of the feed material to or the product of a microorganism or enzyme.
- (a) Class 435, provides for the combination of comminution or disintegration with a process or apparatus for microorganism use or enzymology.
- 250, Radiant Energy, provides for all methods and apparatus for using, generating, controlling, or detecting radiant energy including radioactivity not elsewhere provided for. Class 250 provides a comprehensive guide in References to Other Classes for classes providing for similar subject matter.
- (a) Class 435, provides for the use of radiant energy to alter the genetic structure of a microorganism as part of a measuring and testing process or in combination with microbial growth or enzymology.
- 260, Chemistry of Carbon Compounds, provides for the synthesis and liberation and purification by chemical or physical means of compounds and extracts falling within the class definition of Class 260 where such processes do not include a step of treatment by a microorganism or enzyme. Processes of making chemical compounds that include the use of a microorganism or enzyme are controlling for classification over other processes of making chemical compounds.
- (a) Class 435, provides for a process of synthesis or liberation, separation, or purification of a compound utilizing a microorganism or enzyme, per se. Class 435, provides for an enzyme, per se, and the process of recovering the enzyme from a natural source or immobilizing or insolubilizing an enzyme. Class 435, provides for a process utilizing a microorganism or enzyme combined with a physical separation or purification. Class 435, will provide for preliminary chemical treatment to produce a starting material which is subjected to the action of a microorganism or enzyme or a chemical reaction simultaneously with or subsequent to the action of a microorganism or enzyme which perfects or improves the action of the microorganism or enzyme.
- 260, Chemistry of Carbon Compounds, provides for organic compounds, per se, and methods of synthesizing them by means other than a microorganism or enzymes.
- 366, Agitating, provides for apparatus and processes restricted to causing fluid or particulate material to move irregularly and commingle.
- (a) Class 435, provides for apparatus with agitators claimed or solely disclosed as useful for microorganism propagation or enzymology and for processes of microorganism propagation or enzymology which may include an agitation step.
- 423, Chemistry of Inorganic Compounds, provides for processes of purification of fermentation off gas by chemical means as well as the recovery of metal values by means other than microorganisms or enzymes.
- (a) Class 435, provides for processes of synthesis of organic or inorganic compounds involving a microorganism or enzyme.
- 424, Drug, Bio-Affecting and Body Treating Compositions, for: compositions (A) for preventing, alleviating, treating, or curing abnormal and pathological conditions of the living body, for maintaining, increasing, decreasing, limiting, or destroying a physiologic body function, for diagnosing a physiological condition or state by an in vivo test, for controlling or protecting an environment or living body by attracting, disabling, inhibiting, killing, modifying, repelling, or retarding an animal or microorganism, (B) for deodorizing, protecting, adorning, or grooming a body, (C) for fermentates and extracts for use in A or B and not elsewhere provided for, and (D) such compositions defined in terms of specific structure; methods of making the above compositions; methods of using the class defined compositions for purposes in A and B; and methods of using compounds, per se, for purposes in A and B; subclasses 85.1+ for a lymphokine composition; subclasses 130.1+ for a bioaffecting or body-treating composition of an immunoglobulin, antiserum, antibody, or antibody fragment and

- for methods of immunizing to produce antibodies for recovery, which antibodies are characterized as being useful as bioaffecting or body-treating agents (e.g., to provide passive immunity); subclasses 184.1+ for a bio-affecting or body-treating composition comprising an antigen, an epitope, or another immunospecific immunoeffector, such as an immunospecific vaccine, an immunospecific stimulator of cell-mediated immunity, an immunospecific tolerogen, or an immunospecific immunosuppressor, and for methods of immunizing to produce protective immunity in vivo (i.e., for vaccination purposes); subclasses 93.1+ for a composition including whole live microorganism or virus; and subclass 94 for a composition containing an enzyme or co-enzyme.
- (a) Class 435, provides for a process of propagating a microorganism or using an enzyme to produce a drug or bio-affecting composition. Class 435 provides for virus culture and attenuation, for the virus or microorganism, per se, and their culture and propagation and for in vitro diagnostic tests involving a microorganism or enzyme and antigen antibody tests which involve a living microorganism or use of an enzyme label.
- 426, Food or Edible Material: Processes, Compositions, and Products, provides for fermentation processes that are solely disclosed or claimed as preparing an edible, and for mixtures of enzymes or ferments solely disclosed or claimed as edible or used in the preparation of an edible. Class 426 provides for compositions and processes of preparation relating to compositions which have the capacity to ferment and produce an edible, but which are claimed as being in an inactive state, and also provides for compositions which are undergoing a fermentation to produce an edible product. See especially subclasses 11+ for alcoholic beverages, or other beverages, milk or other alimentary articles or compositions, when the beverage or other alimentary articles contain bacteria or enzymes; processes of making the same which include microorganisms or enzymes. Processes of autolysis or microbial or enzymic destruction of yeasts or other living organisms are in Class 435, subclasses 262+, but processes of preparing foods including such autolysis are in Class 426. Processes of making vinegar by methods including use of a microorganism or enzyme are in Class 426.
- (a) Class 435, provides for processes and apparatus of production of nonpotable ethanol and acetic acid and for processes and apparatus for diastatic mashing as well as fermentation other than primary fermentations. Class 435 also provides for compositions and processes of producing a microorganism containing starter culture useful in the production of an edible product. Class 435, will provide for production of protein from a single source by fermentation or enzymology even if the product is claimed as having a Class 426 utility. For an elaboration of the line regarding the placement of yeast patents, see (1) Note in subclass 255 of this class.
- 427, Coating Processes, provides for significant coating or impregnating processes when not involving subject matter proper for Class 435.
- (a) Class 435 provides for processes having a significant or nonsignificant coating (or impregnating) step and otherwise proper for the class.
- 429, Chemistry: Electrical Current Producing Apparatus, Product, and Process, provides for a current producing device having a microorganism as an integral part and the process of operating the device and a process involving the device.
- (a) Class 435, provides for processes of producing microorganisms in bulk, i.e., propagation of microorganisms. Class 435, Chemistry: Molecular Biology and Microbiology, provides for a photo imaging process in which an enzyme whose activity is altered upon exposure to light is used and the material therefor.
- 436, Chemistry: Analytical and Immunological Testing, provides for a measurement or test in which an enzyme reacts chemically, i.e., non-catalytically and antigen antibody tests for the identification of chemical species that are non-diagnostic and do not involve a living antigen.
- (a) Class 435, provides for a test or measurement involving a microorganism or enzyme which functions catalytically as well as antigen antibody tests involving a living microorganism.
- (1) Note. The burden of showing an enzyme is functioning noncatalytically is on Class 436, i.e., the presumption, as between Class 435 and Class 436, is that an enzyme in a test functions catalytically until rebutted.

436, Chemistry: Analytical and Immunological Testing, provides for testing compositions (a) which contain an enzyme if the enzyme participates in a chemical reaction in a noncatalytic manner; and (b) which are of use in an antigen-antibody test and do not involve a microorganism or enzyme and are not diagnostic.

(a) Class 435 provides for in vitro testing by or for a microorganism or enzyme or tests involving the propagation of a microorganism or catalytic use of an enzyme. Class 435 provides for antigen-antibody tests wherein a living antigen, i.e., a microorganism is involved or an enzyme label is present. Class 435, provides for processes and apparatus and material for measuring and testing blood which involve the propagation of a microorganism or catalytic functioning of an enzyme.

- (1) Note. The burden of showing an enzyme is functioning noncatalytically is on Class 436, i.e., the presumption, as between Class 435 and Class 436, is that an enzyme in a testing composition functions catalytically until rebutted.

504, Plant Protecting and Regulating Compositions, provides for processes of producing a composition or article having plant stimulating or eradicating utility by using a microorganism or enzyme as well as the composition containing a microorganism or enzyme.

(a) Class 435, provides for the production of microorganisms having utility for plant growth regulator production and microorganism containing starter compositions useful in a Class 504 process.

Class 510, Cleaning Compositions for Solid Surfaces, Auxiliary Compositions Therefor, or Processes of Preparing the Compositions, provides for detergent compositions containing enzymes.

Class 435, provides for process of production of enzymes and enzymes, per se, and enzyme compositions not otherwise provided for.

Class 516, Colloid Systems and Wetting Agents; Subcombinations Thereof; Processes of Making, Stabilizing, Breaking, or Inhibiting, subclasses 113+ for compositions for or subcombination compositions for or breaking of or inhibiting of colloid systems (e.g., foam breaking, emulsion breaking, dispersion inhibiting, suspension settling, gel breaking, smoke sup-

pressing, coagulating, flocculating), when generically claimed or when there is no hierarchically superior provision in the USPC for the specifically claimed art. Nominal recitation of a Class 435 process (e.g., fermentation or fermentation step) combined with a process otherwise classifiable in Class 516 is proper for Class 516, while recitation of a significant Class 435 step combined with a step or composition otherwise classifiable in Class 516 is proper for Class 435 with a discretionary cross-reference to Class 516.

Class 435, provides for processes of making chemical compounds which involve microorganisms or enzymes, other processes relating to cell, organ, or tissue growth or maintenance, compositions for use in such processes, in vitro processes of testing or measuring, certain apparatus for class provided for processes.

506, Combinatorial Chemistry Technology: Method, Library, Apparatus, for a chemical or biological library, a process of creating said library, a process of testing involving said library, or an apparatus specially adapted for creating or testing involving said library.

588, Hazardous or Toxic Waste Destruction or Containment, provides for the storage to contain pathogenic organisms, e.g., virus, bacteria and medical waste, see subclass 258.

## SECTION V - GLOSSARY

### ACTIVITY

Rate of metabolic or anabolic action, speed or efficiency. Mere suppression of competing strains is not viewed as increasing the activity.

### BIOCHEMICAL

By means of a bacteria, yeast, animal or plant cell, or virus, or the parts thereof.

### CONDENSED

Bridged or fused.

### DERIVATIVE

For purposes of this class derivatives included with the production of a named compound are only the inorganic anion or inorganic cation salts thereof, e.g., metal, ammonium, halogen, carbonate, etc.

**DIASTACE**

For purposes of this class classified as an amylase.

**FERMENTATION**

The use of a microorganism or enzyme to carry a molecular transformation.

**HAZARDOUS WASTE**

Material that when present in the environment produces for man and other living organisms a dangerous, risky, or perilous environmental situation in so far as the physiological well being of the organism is concerned (e.g., all caustic chemicals, irritants, cancer causing agents, and other tumor producing materials).

**HETERO**

Containing only O, N, S, Se, or Te in addition to carbon in a ring.

**MEDIA**

Material which supports or sustains growth of microorganisms which material may contain substances which will not support or may inhibit the growth of selected microorganisms.

**MICROORGANISM**

For purposes of this class, bacteria, actinomycetales, cyanobacteria (unicellular algae), fungi, protozoa, animal cells or plant cells or virus.

**NUCLEIC ACID**

A polynucleotide or more than two nucleotides.

**TEST MEDIA**

Distinguished from (propagation) media by the presence of an indicator, e.g., chromophore, etc.

**TOXIC WASTE**

Materials that are direct physiological poisons to living organisms (e.g., pesticides, heavy metal ion solutions, and other materials that are poisonous to life.

**SUBCLASSES**

**1.1 DIFFERENTIATED TISSUE OR ORGAN OTHER THAN BLOOD, PER SE, OR DIFFERENTIATED TISSUE OR ORGAN MAINTAINING; COMPOSITION THEREFOR:**

This subclass is indented under the class definition. Processes or compositions for the maintenance of a differentiated tissue or organ, or the differentiated tissue or organ, per se.

- (1) Note. Maintenance includes keeping an organ under conditions in which it produces a product (e.g., hormone, etc.) which is later recovered.
- (2) Note. Tissue is presumed to be undifferentiated in the absence of a clear showing to the contrary. The fact that a tissue continues to produce hormones, etc., is to be taken as an indication that the tissue retains its differentiation.
- (3) Note. For a process to be classified in this subclass, the organ must be maintained in a viable state (e.g., in a nutrient or life sustaining media) and the tissue must contain an integral membrane. Thus, the preservation of blood plasma provided for in subclass 2 is excluded from this subclass.

**SEE OR SEARCH THIS CLASS, SUBCLASS:**

- 235.1+, for virus culture and treatment.  
325+, for animal cells, per se, and compositions thereof; processes of propagating, maintaining, preserving, isolating, etc. animal cells or compositions; culture media therefore.

**SEE OR SEARCH CLASS:**

- 34, Drying and Gas or Vapor Contact With Solids, for methods of preserving by freeze drying.  
62, Refrigeration, for methods of cooling.  
623, Prosthesis (i.e., Artificial Body Members), Parts Thereof, or Aids and Accessories Therefor, appropriate subclasses for implantable living glands encapsulated in a porous membrane.



**1.2 Including perfusion; composition therefor:**

This subclass is indented under subclass 1.1. Processes for the maintenance of differentiated tissue or organs by continuously perfusing with a fluid, or compositions useful in such processes.

SEE OR SEARCH THIS CLASS, SUBCLASS:

284.1, for differentiated tissue (e.g., organ) perfusion or preservation apparatus.

**1.3 Including freezing; composition therefor:**

This subclass is indented under subclass 1.1. Processes for the maintenance of differentiated tissue or organs by freezing, or compositions useful in such processes

**2 MAINTAINING BLOOD OR SPERM IN A PHYSIOLOGICALLY ACTIVE STATE OR COMPOSITIONS THEREOF OR THEREFOR OR METHODS OF IN VITRO BLOOD CELL SEPARATION OR TREATMENT:**

This subclass is indented under the class definition. Processes or compositions for the maintenance of blood or sperm in a physiologically active state or for the in vitro separation or treatment of blood cells.

(1) Note. This subclass includes methods for preserving the viability of sperm by chemical means.

(2) Note. This subclass provides for compositions for artificial insemination.

SEE OR SEARCH THIS CLASS, SUBCLASS:

235.1+, where the tissue or cell culture is concomitant with virus propagation.

243+, for culture media for propagating microorganism.

SEE OR SEARCH CLASS:

62, Refrigeration, for methods of maintaining the viability of living tissue and cells including sperm under refrigeration or in a frozen state. These processes may include the addition of chemical agents to prevent or minimize cellular damage from the refrigeration.

128, Surgery, appropriate subclasses for a method of blood transfusion or artificial insemination.

424, Drug, Bio-Affecting and Body Treating Compositions, subclasses 184.1+ for therapeutic compositions containing a living cell which functions as an antigen; and subclass 529 for therapeutic compositions containing viable blood cells and a therapeutically active ingredient. See subclass 1.17 for compositions comprising a radio-labeled cell or sub-cellular structure, including red blood cells, intended for class defined uses such as in vivo diagnosing (e.g., imaging), methods of making such compositions, and nominal methods of using such compositions.

**3 CONDITION RESPONSIVE CONTROL PROCESS:**

This subclass is indented under the class definition. Process in which a process parameter is measured and that or another process parameter is varied responsive to such measurement.

(1) Note. The measurement should be by a nonsubjective means, i.e., mere observation by an operator is not sufficient to constitute measurement for purposes of this subclass.

SEE OR SEARCH THIS CLASS, SUBCLASS:

289, and 290, for condition or time responsive control apparatus.

SEE OR SEARCH CLASS:

700, Data Processing: Generic Control Systems or Specific Applications, subclasses 266 through 274 for chemical process control or monitoring system.

702, Data Processing: Measuring, Calibrating, or Testing, subclasses 19+ for data processing in biological or biochemical applications, and subclasses 22+ for chemical analysis data processing.

**4 Measuring or testing process involving enzymes or microorganisms; composition or**

**test strip therefore; processes of forming such composition or test strip:**

This subclass is indented under the class definition. Processes in which there is a direct or indirect qualitative or quantitative measurement or test of a material which contains an enzyme or microorganism or processes in which a material containing an enzyme or microorganism is used to perform a qualitative or quantitative measurement or test and compositions therefor and the processes of making such compositions.

- (1) Note. "Involving" in this and the indented subclasses includes (a) the use of a known microorganism or enzyme to detect or identify a chemical compound or composition, (b) the use of a chemical compound or composition to detect or identify a microorganism or enzyme, (c) a composition containing a microorganism or enzyme for use as in (a), and (d) a composition distinguished by the presence of an indicator for use as in (b). Thus, "involving" in this and the indented subclasses means that the steps in the measurement or test either use the designated chemical compound, microorganism, or individual plant or animal cells or enzyme or the steps in the measurement or test indicate the presence or absence of the designated chemical compound, microorganism, plant or animal cell or enzyme.
- (2) Note. The enzyme herein can be free or immobilized or present in a cell, tissue, or organ.
- (3) Note. Compositions herein may include inert carriers that have either a single or multiple zones or chemical agents. Included as carriers are bibulous or absorbent materials and films.

**SEE OR SEARCH THIS CLASS, SUBCLASS:**

- 174+, for immobilized enzymes, per se.  
 183+, for enzymes.  
 188, for stabilized enzymes, enzyme conjugates or compositions thereof.  
 235.1+, for viruses, per se.  
 287+, for apparatus for measuring and testing.

**SEE OR SEARCH CLASS:**

- 73, Measuring and Testing, for processes and apparatus for making a test or measurement of any kind not provided for in other classes. In general, the classes superior to 73 are 435, 422, 424, 204, 350, and 356.
- 128, Surgery, for methods of treatment of the living body or a test which involves contact with a body and apparatus used in the inspection and treatment of diseases of the bodies of men and animals which apparatus is provided with means for connection to the living body.
- 137, Fluid Handling, subclasses 2+ for processes of controlling the flow of a fluid in response to the sensing of a condition or characteristic of a fluid.
- 204, Chemistry: Electrical and Wave Energy, subclasses 400 through 435 for electrolytic analysis or testing apparatus, especially subclasses 403.01-403.15 for electrolytic analysis or testing apparatus including biological material or analyzing or testing for biological material (e.g., microbe, enzyme, antigen, etc.).
- 205, Electrolysis: Processes, Compositions Used Therein, and Methods of Preparing the Compositions, subclasses 775+ for electrolytic analysis or testing processes, especially subclasses 777.5+ for electrolytic analysis or testing involving an enzyme or microorganism (e.g., animal or plant cells, bacteria, virus, etc.).
- 208, Minerals Oils: Processes and Products, for chemical tests claimed in association with processes for recovery or treatment of naturally occurring mineral oil.
- 252, Compositions, subclass 408 for testing compositions.
- 260, Chemistry of Carbon Compounds, for chemical tests claimed in association with processes for the treatment or modification of carbon compounds.
- 324, Electricity: Measuring and Testing, appropriate subclasses for methods and apparatus for testing an electrical property or condition of a material by electrical means, even though the

- result of the test may be used as an indication of some other physical or chemical property or condition.
- 346, Recorders, subclasses 2+ for phenomenal apparatus and processes recording.
- 356, Optics: Measuring and Testing, especially subclasses 28, 139.04 through 139.08, 141.1 through 141.5 and 152.1 through 152.3, 205+, and 218 for methods and apparatus for optical testing with a photoelectric light detector with either an indicator or structure to support or contain the specimen or sample under test. Class 356 provides for methods and apparatus for visual counting of bacteria colonies, etc., with a scale or spacer to aid the eye without an optical element or statistical analysis procedures for the sizing and counting of particles, such as bacteria colonies by visible light and the counting of particles one by one with a microscope having a graticule rather than a cross hair or reticle.
- 359, Optics: Systems (Including Communication) and Elements, subclasses 396+ for transparent microscope slides with means to contain and support the life functions of a microorganism.
- 377, Electrical Pulse Counters, Pulse Dividers, or Shift Registers: Circuits and Systems, subclass 10 for sizing or counting of discrete particles such as bacteria colonies one at a time by numerical counting apparatus which registers the counts.
- 424, Drug, Bio-Affecting and Body Treating Compositions, subclasses 1.11+ for class defined compositions and methods comprising a radionuclide or intended radionuclide, including those for in vivo diagnosing, and subclasses 9.1+ for a composition or method of in vivo testing (diagnosing) a living body or for an in vivo method of testing or analyzing a composition of that class (424).
- 436, Chemistry: Analytical and Immunological Testing, subclasses 1+ for processes for analysis involving steps for causing or promoting a chemical reaction, regulating or controlling a chemical reaction. This includes tests dependent upon the chemical, i.e., proteinaceous reactivity of an enzyme as opposed to its catalytic functioning provided for in Class 435. Measurements and tests when claimed in association with chemical processes provided for in other Classes, e.g., 435, 208, 260, 423, etc., are classified in the class providing for the chemical process.
- 506, Combinatorial Chemistry Technology: Method, Library, Apparatus, for a process of testing involving a chemical or biological library or an apparatus specially adapted for testing involving said library.
- 700, Data Processing: Generic Control Systems or Specific Applications, subclasses 266 through 274 for significant data processing system for chemical process control.
- 702, Data Processing: Measuring, Calibrating, or Testing, subclasses 19 through 21 for significant data processing system for biological or biochemical measurement and subclasses 22-32 for significant data processing system for chemical analysis to analyze the results of a chemical reaction which is only nominally claimed.
- 5 Involving virus or bacteriophage:**  
This subclass is indented under subclass 4. Subject matter where the material to be measured or tested contains a virus or bacteriophage or the agent used for the measurement or test contains a virus or bacteriophage.
- 6 Involving nucleic acid:**  
This subclass is indented under subclass 4. Subject matter where the material to be tested or the composition in which the test is conducted contains nucleic acid or the agent used for the measurement or test contains nucleic acid.
- (1) Note. The tests provided for in this subclass may involve the determination of the mutagenic effect of drugs on nucleic acid containing genetic materials such as genes and chromosomes.

- (2) Note. Nucleic acids for the purpose of this subclass are defined as polynucleotides of three or more nucleotides.
- (3) Note. Proper for this subclass is subject matter involving the staining of microorganisms, cells, or tissues specifically for and only for nucleic acid (e.g., DNA, RNA, etc.) with stains such as Feulgen stain or acridine orange.

**SEE OR SEARCH THIS CLASS, SUBCLASS:**

40.5+, for subject matter involving microorganisms, cells, or tissues stained with a composition providing contrasting stains for the cell nucleus and cytoplasm (e.g., hematoxylin, eosin, etc.).

**SEE OR SEARCH CLASS:**

506, Combinatorial Chemistry Technology: Method, Library, Apparatus, for a process of testing involving a chemical or biological library or an apparatus specially adapted for testing involving said library.

536, Organic Compounds, appropriate subclasses for saccharides, polysaccharides, nucleosides, nucleotides, and polynucleotides like RNA or DNA compounds as well as chemical methods of synthesizing such compounds. Search specifically subclasses 23.1+ for fragments of RNA or DNA which could have utility as genes in recombinant processes and subclass 24.3 for probes.

**7.1 Involving antigen-antibody binding, specific binding protein assay, or specific ligand-receptor binding assay:**

This subclass is indented under subclass 4. Subject matter in which a measurement or test utilizes an enzyme or microorganism or plant or animal cells in an antibody binding, specific binding protein or other specific ligand-receptor binding test or assay.

- (1) Note. Cross-Reference Art Collections 960 through 975 provide for different aspects of the subject matter of this and the indented subclasses.

- (2) Note. The enzyme or microorganism may function for example, as an antigen, separating agent or detection label in a test or assay.

- (3) Note. Subject matter directed to identifying a specific enzyme in a microorganism or tissue is appropriate for subclass 7.4 below, however, determining an enzyme as an indirect indication of a specific microorganism being present is appropriate for the microorganism subclass.

- (4) Note. Subject matter directed to determining the presence of a specific microorganism is appropriate for the specific microbial subclass below. For example, an assay for determining a bacteria in an animal tissue sample is appropriate for the bacteria subclass rather than the animal cell subclass.

- (5) Note. An indirect microbial determination, such as a determination of a microbial product as an indication of the presence of the microbe, is appropriate for the microbial subclasses below. However, it is strongly suggested that a patent containing such an indirect microbial determination be cross-referenced to the subclass appropriate for the assay of the product of the microbe.

- (6) Note. Terminology used in this and the indented subclasses is found at the end of this subclass definition.

**SEE OR SEARCH THIS CLASS, SUBCLASS:**

5, for processes in which a virus is involved, as for example, as an antigen.

174+, for immobilized enzymes.

183+, for enzymes, per se, and methods of isolating enzymes.

188, for enzyme conjugates.

**SEE OR SEARCH CLASS:**

424, Drug, Bio-Affecting and Body Treating Compositions, subclasses 184.1+ for methods of immunizing with an antigen to induce protective immunity

- in vivo. Class 424 provides for in vivo antigen-antibody tests.
- 436, Chemistry: Analytical and Immunological Testing, for a measurement or test involving antigen-antibody tests and other ligand-receptor binding tests for the identification of chemical species that do not involve a microorganism or enzyme.
- 506, Combinatorial Chemistry Technology: Method, Library, Apparatus, for a process of testing involving a chemical or biological library or an apparatus specially adapted for testing involving said library.
- 530, Chemistry, Natural Resins or Derivatives Peptides or Proteins; Lignins or Reaction Products Thereof, subclasses 387+ for antibodies, per se, subclasses 403+ for protein antigens or the use of antigenic proteins as an immunogenic carrier for a hapten, subclass 413 for immunological separation and affinity chromatography, cross-reference art collections 806 for antigenic peptides or protein, and 807 for hapten conjugated with peptide or protein, and 808 for monoclonal antibodies.
- 600, and 604, Surgery, provides for methods including the use of claimed specific structure adapted to be placed on or in the living body and further include diagnostic or therapeutic methods and apparatus when the only disclosed utility is for diagnosis or treatment of a living body.

## GLOSSARY

### ANALYTE

The compound or composition to be measured.

### SPECIFIC LIGAND-RECEPTOR BINDING ASSAY

The interaction between a ligand material and a receptor which is specific to a class of compounds or a single compound.

### EPITOPE

A single antigenic determinant portion of the antigen which combines with the antibody site.

### LABEL

A member of a signal producing system which is usually bound to or incorporated in the ligand. Measurement of the label activity is an indication of the amount of unknown in the sample.

### LIGAND

Any organic compound for which a receptor naturally exists or can be prepared; a linking or binding molecule.

### RECEPTOR

Any compound or composition capable of recognizing a particular spatial and polar organization of a molecule, i.e., epitopic site on an antigen. The receptor material can be isolated from a cellular material from a living body such as a membrane or organ and exhibits great specificity to the species to be tested for. A cell surface molecule which binds specifically to particular proteins or peptides in the fluid phase.

### 7.2 Involving a microorganism or cell membrane bound antigen or cell membrane bound receptor or cell membrane bound antibody or microbial lysate:

This subclass is indented under subclass 7.1. Subject matter involving a microorganism or cell membrane bound antigen, or cell membrane bound receptor or cell membrane bound antibody, or lysate of a microorganism.

### 7.21 Animal cell:

This subclass is indented under subclass 7.2. Subject matter involving animal cells.

- (1) Note. Though "whole blood" contains animal cells, the mere presence of a "whole blood sample" in an assay or test is not sufficient for placement in this and the indented subclasses. Since "whole blood" is a complex mixture of cells and liquid, classifying based on its presence might be inconsistent. Furthermore, the "whole blood" aspect is rarely of main importance, therefore, patents using whole blood samples are more appropriately placed based on the analyte of interest or on a reagent which is more specific, i.e., cancer cell, lymphocyte, red blood cell, enzyme label, etc., to one of the subclasses below.

- (2) Note. "Animal cell" in this and the indented subclasses is also intended to include tissue.
- 7.22 Parasite or protozoa:**  
This subclass is indented under subclass 7.21. Subject matter involving a parasite or protozoa.
- (1) Note. Parasite is intended to include those animals which live in or on and at the expense of a host such as certain nematodes, cestodes, trematodes (e.g., tapeworm, heartworm, Trichinella, etc.).
- (2) Note. A protozoa is a single-celled animal.
- SEE OR SEARCH THIS CLASS, SUBCLASS:  
7.32+, for bacteria which may be parasitic.
- 7.23 Tumor cell or cancer cell:**  
Subject matter under 7.21 involving tumor or cancer cells.
- 7.24 Leukocyte (e.g., lymphocyte, granulocyte, monocyte, etc.):**  
This subclass is indented under subclass 7.21. Subject matter involving leukocytes such as lymphocytes, granulocytes, monocytes, etc.
- (1) Note. The subject matter intended for this subclass includes, for example, a test wherein the leukocyte is a reagent, the leukocyte type is determined, a leukocyte surface antigen is determined, etc.
- 7.25 Erythrocyte:**  
This subclass is indented under subclass 7.21. Subject matter involving red blood cells or reticulocytes.
- (1) Note. Examples of subject matter in this subclass are red blood cell carriers, red cell surface antigen testing, etc.
- 7.3 Flagellar-antigen or pili-antigen:**  
This subclass is indented under subclass 7.2. Subject matter involving flagellar-antigen (e.g., (H)-antigen, etc.) or pili-antigen, (e.g., (K)-antigen, etc.).
- (1) Note. Flagellar - or pili-antigens are those which are or are part of the flagella or pili of certain motile microorganisms.
- 7.31 Fungi (e.g., yeast, mold, etc.):**  
This subclass is indented under subclass 7.2. Subject matter involving fungi such as yeast or mold.
- 7.32 Bacteria or actinomycetales:**  
This subclass is indented under subclass 7.2. Subject matter involving bacteria or actinomycetales.
- 7.33 Staphylococcus:**  
This subclass is indented under subclass 7.32. Subject matter involving bacteria of the genus Staphylococcus.
- 7.34 Streptococcus:**  
This subclass is indented under subclass 7.32. Subject matter involving bacteria of the genus Streptococcus.
- 7.35 Salmonella:**  
This subclass is indented under subclass 7.32. Subject matter involving bacteria of the genus Salmonella.
- 7.36 Sexually transmitted disease (e.g., chlamydia, syphilis, gonorrhea, etc.):**  
This subclass is indented under subclass 7.32. Subject matter involving a sexually transmitted disease caused by bacteria.
- (1) Note. Common bacteria involved include Chlamydiae, Treponema pallidum, and Neisseria gonorrhoeae.
- SEE OR SEARCH THIS CLASS, SUBCLASS:  
5, for a sexually transmitted disease involving a virus.
- 7.37 Escherichia coli:**  
This subclass is indented under subclass 7.32. Subject matter involving Escherichia coli (E. coli.).

**7.4 To identify an enzyme or isoenzyme:**

This subclass is indented under subclass 7.1. Subject matter in which the measurement or test determines the identity or quantity of an enzyme or group of isoenzymes.

- (1) Note. Immunological identification of enzymatic coagulation factors is proper for this subclass.
- (2) Note. Determination of complement or complement components is proper for this subclass.

SEE OR SEARCH THIS CLASS, SUBCLASS:

- 7.6, for an assay or test involving a modified enzyme in a capacity other than that of being identified or quantified.
- 7.7, through 7.8, for an assay or test in which an enzyme is involved as a reagent.
- 7.8, through 7.95, for an assay or test in which an enzyme is involved as a detection label.

**7.5 Involving avidin-biotin binding:**

This subclass is indented under subclass 7.1. Subject matter involving the binding of avidin to biotin.

- (1) Note. The binding of avidin and biotin derivatives such as streptavidin or iminobiotin is also included in this subclass.

**7.6 Involving a modified enzyme (e.g., abzyme, recombinant, chemically altered, etc.):**

This subclass is indented under subclass 7.1. Subject matter involving a modified enzyme which has been functionally changed through recombinant DNA techniques, chemical treatment, etc.

- (1) Note. This subclass is not intended to include a mere conjugation of an enzyme to an antigen or antibody, since the function of the enzyme has not been changed.
- (2) Note. An abzyme is an antibody with enzymatic activity.

SEE OR SEARCH THIS CLASS, SUBCLASS:

- 7.4, for a test or assay for determining the identity or quantity of a modified enzyme.

**7.7 Assay in which a label present is an apoenzyme, prosthetic group, or enzyme cofactor:**

This subclass is indented under subclass 7.1. Subject matter in which a label is present in the assay and is an apoenzyme, prosthetic group or enzyme cofactor.

- (1) Note. See subclass 7.1 for the definition of label.

- (2) Note. An enzyme cofactor is a nonprotein substance whose presence is required for an enzyme to exhibit its catalytic activity and which undergoes a chemical change during the catalytic cycle of the enzyme involved. A coenzyme is a type of enzyme cofactor which is chemically modified in the course of the reaction catalyzed by the parent enzyme. Regeneration of the original form of the cofactor requires its participation in a separate reaction that is catalyzed by an enzyme other than the parent enzyme. A prosthetic group is an enzyme cofactor which is chemically modified in the course of the reaction catalyzed by the parent enzyme and is regenerated by a second reaction catalyzed by the parent enzyme. Prosthetic groups are bound to the protein portion of the parent enzyme, such protein portion being known as the apoenzyme and the catalytically active parent enzyme being known as the holoenzyme.

- (3) Note. Prosthetic groups and Holoenzymes. In the list below, the prosthetic group (underlined) is first, followed by the conjugated enzyme.

(a) flavine adenine, glutathione;

(b) dinucleotide (FAD), reductase (human erythrocytes);

(c) flavin mononucleotide (FMN), cytochrome reductase (yeast);

(d) FMN, NADPH: oxidoreductase (“old yellow enzyme”);

(e) FAD, glucose oxidase (*Aspergillus niger*);

(f) FAD, lipoamide dehydrogenase;

(g) FMN, pyridoxine phosphate oxidase;

(h) heme, peroxidase (horseradish);

(i) heme, cytochrome C.

**7.71 Assay in which a label present is an enzyme inhibitor or functions to alter enzyme activity:**

This subclass is indented under subclass 7.1. Subject matter in which a label is present in the assay and is an enzyme inhibitor or otherwise functions to alter the function of the enzyme present in the analysis.

SEE OR SEARCH THIS CLASS, SUBCLASS:

7.1, for the definition of label.

**7.72 Assay in which a label present is an enzyme substrate or substrate analogue:**

This subclass is indented under subclass 7.1. Subject matter in which a label is present in the assay and is an enzyme substrate or substrate analogue.

SEE OR SEARCH THIS CLASS, SUBCLASS:

7.1, for the definition of label.

**7.8 Involving nonmembrane bound receptor binding or protein binding other than antigen-antibody binding:**

This subclass is indented under subclass 7.1. Subject matter in which the measurement or test includes nonmembrane bound receptor binding or ligand-receptor binding other than antigen-antibody binding.

(1) Note. This subclass provides for enzyme-inhibitor binding where the inhibitor is not a label, binding to soluble or nonmembrane bound receptors or transport proteins, etc. Specific exam-

ples include thyroxine-thyroxine binding globulin, B12-intrinsic factor, cortisol-transcortin, lectin-carbohydrate, etc.

SEE OR SEARCH THIS CLASS, SUBCLASS:

7.71, for an assay where an enzyme inhibitor is present as a label.

**7.9 Assay in which an enzyme present is a label:**  
This subclass is indented under subclass 7.1. Subject matter in which an enzyme present is a label in the assay.

SEE OR SEARCH THIS CLASS, SUBCLASS:

7.1, for the definition of label.

**7.91 Enzyme produces product which is part of another reaction system (e.g., cyclic reaction, cascade reaction, etc.):**

This subclass is indented under subclass 7.9. Subject matter in which the enzyme label produces a product which is part of another reaction system.

(1) Note. The reaction system may be chemical or enzymatic.

**7.92 Heterogeneous or solid phase assay system (e.g., ELISA, etc.):**

This subclass is indented under subclass 7.9. Subject matter in which the assay system requires at least one separation step which allows differentiation of reacted from unreacted material or requires that at least one of the immunochemicals in the system be bound to an insoluble support material.

SEE OR SEARCH THIS CLASS, SUBCLASS:

174+, for carrier-bound or immobilized enzymes.

188, for enzyme conjugates.

SEE OR SEARCH CLASS:

436, Chemistry: Analytical and Immunological Testing, subclasses 518+ for immunoassays, not including Class 435 subject matter, wherein a solid phase carrier is utilized.



**7.93 Competitive assay:**

This subclass is indented under subclass 7.92. Subject matter in which the heterogeneous or solid phase assay involves competitive binding of immunologically similar or identical compounds.

**7.94 Sandwich assay:**

This subclass is indented under subclass 7.92. Subject matter in which the heterogeneous or solid phase assay involves the binding of polyvalent analyte antigen to an antibody and a labeled antibody to obtain a measurable antibody-antigen-antibody complex; alternatively, a second unlabeled antibody and a third labeled anti-antibody can be reacted with the antigen-antibody complex to obtain a measurable result.

**7.95 Indirect assay:**

This subclass is indented under subclass 7.92. Subject matter in which the heterogeneous or solid phase assay involves the binding of antigen with analyte antibody and a labeled anti-antibody thereby forming a complex.

**8 Involving luciferase:**

This subclass is indented under subclass 4. Subject matter where the material to be measured or tested contains luciferase or the agent used for the measurement or test contains luciferase.

- (1) Note. Firefly extract or firefly lantern extract contains luciferase.

**9 Geomicrobiological testing (e.g., for petroleum, etc.):**

This subclass is indented under subclass 4. Subject matter where the measurement or test is for the presence or absence of mineral deposits or for the presence of microorganisms which thrive in the presence of such minerals.

- (1) Note. This subclass provides for detection of underground deposits of petroleum or natural gas.

**SEE OR SEARCH CLASS:**

73, Measuring and Testing, subclasses 152.02+ for well logging, per se, wherein the logging is not determined by making a purely electrical mea-

surement or a purely magnetic measurement.

**10 Involving uric acid:**

This subclass is indented under subclass 4. Subject matter where the material to be measured or tested contains uric acid or the agent used for the measurement or test contains uric acid.

**11 Involving cholesterol:**

This subclass is indented under subclass 4. Subject matter where the material to be measured or tested contains cholesterol or the agent used for the measurement or test contains cholesterol.

**12 Involving urea or urease:**

This subclass is indented under subclass 4. Subject matter where the material to be measured or tested contains urea or urease or the agent used for the measurement or test contains urea or urease.

**13 Involving blood clotting factor (e.g., involving thrombin, thromboplastin, fibrinogen, etc.):**

This subclass is indented under subclass 4. Subject matter where the material to be measured or tested contains a blood clotting factor or the agent used for the measurement or test contains a blood clotting factor.

**SEE OR SEARCH CLASS:**

73, Measuring and Testing, subclass 64.41 for apparatus used for testing the ability of blood to clot.

**14 Involving glucose or galactose:**

This subclass is indented under subclass 4. Subject matter where the material to be measured or tested contains glucose or galactose or the agent used for the measurement or test contains glucose or galactose.

**15 Involving transferase:**

This subclass is indented under subclass 4. Subject matter where the material to be measured or tested contains a transferase or the agent used for the measurement or test contains a transferase.

- 16 Involving transaminase:**  
This subclass is indented under subclass 15. Subject matter subclass where the material to be measured or tested contains a transaminase or the agent used for the measurement or test contains a transaminase.
- 17 Involving creatine phosphokinase:**  
This subclass is indented under subclass 15. Subject matter where the material to be measured or tested contains creatine phosphokinase or the agent used for the measurement or test contains creatine phosphokinase.
- (1) Note. Creatine Phosphokinase is also known as creatine kinase.
- 18 Involving hydrolase:**  
This subclass is indented under subclass 4. Subject matter where the material to be measured or tested contains a hydrolase or the agent used for the measurement or test contains a hydrolase.
- 19 Involving esterase:**  
This subclass is indented under subclass 18. Subject matter where the material to be measured or tested contains an esterase or the agent used for the measurement or test contains an esterase.
- 20 Involving cholinesterase:**  
This subclass is indented under subclass 19. Subject matter where the material to be measured or tested contains cholinesterase or acetylcholinesterase or the agent used for the measurement or tests contains cholinesterase or acetylcholinesterase.
- 21 Involving phosphatase:**  
This subclass is indented under subclass 19. Subject matter where the material to be measured or tested contains a phosphatase or the agent used for the measurement or test contains a phosphatase.
- (1) Note. Phosphatase includes all of the phosphoric monoester hydrolases (ICE classification 3.1.3) including the phytases and the nucleotidases.
- 22 Involving amylase:**  
This subclass is indented under subclass 18. Subject matter where the material to be measured or tested contains amylase or the agent used for the measurement or test contains amylase.
- 23 Involving proteinase:**  
This subclass is indented under subclass 18. Subject matter where the material to be measured or tested contains proteinase (endopeptidase) or the agent used for the measurement or test contains a proteinase (endopeptidase).
- (1) Note. Enzymes included in this subclass are trypsin, pepsin, ficin, bromelin, papain, renin.
- (2) Note. Where the hydrolytic activity of an enzyme on a protein or polypeptide is unclear it should be presumed to be an endopeptidase, classifiable in subclass 23.
- 24 Involving peptidase:**  
This subclass is indented under subclass 18. Subject matter where the material to be measured or tested contains a peptidase (exopeptidase) or the agent used for the measurement or test contains a peptidase (exopeptidase).
- 25 Involving oxidoreductase:**  
This subclass is indented under subclass 4. Subject matter where the material to be measured or tested contains an oxidoreductase or the agent used for the measurement or test contains an oxidoreductase.
- 26 Involving dehydrogenase:**  
This subclass is indented under subclass 25. Subject matter where the material to be measured or tested contains a dehydrogenase or the agent used for the measurement or test contains a dehydrogenase.
- 27 Involving catalase:**  
This subclass is indented under subclass 25. Subject matter where the material to be measured or tested contains catalase or the agent used for the measurement or test contains catalase.

**28 Involving peroxidase:**

This subclass is indented under subclass 25. Subject matter where the material to be measured or tested contains peroxidase or the agent used for the measurement or test contains peroxidase.

**29 Involving viable microorganism:**

This subclass is indented under subclass 4. Subject matter where the material to be tested contains a microorganism or the agent used for the measurement or test contains a microorganism.

- (1) Note. A microorganism for the purposes of this subclass includes actinomycetes, unicellular algae, bacteria, fungi (including yeast), plant cells, and animal cells.
- (2) Note. If there is no clear disclosure as to whether the microorganism or cell is viable or nonliving, it shall be presumed to be viable and therefore appropriate for this or the indented subclasses. However, due to the uncertainty of the viability of the microorganism or cell, placement of a cross reference in the most appropriate place in this class, subclasses 40.5+ for nonliving microorganisms or cells is strongly recommended.

SEE OR SEARCH THIS CLASS, SUBCLASS:

40.5+, for measuring or testing processes involving fixed or stabilized nonliving microorganisms, cells, or tissues.

SEE OR SEARCH CLASS:

- 8, Bleaching and Dyeing; Fluid Treatment and Chemical Modification of Textiles and Fibers, subclass 94.11 for reactive treatment of biological specimens as by a bleach or dye.
- 250, Radiant Energy, for methods and apparatus for detecting radiant energy.
- 427, Coating Processes, subclasses 2.1+ for coating a biological specimen for a medical test and when not provided for in Class 435.

**30 Methods of sampling or inoculating or spreading a sample; methods of physically isolating an intact microorganism:**

This subclass is indented under subclass 29. Processes in which (a) a series of sampling steps are claimed in which a sample containing a microorganism is separated or recovered from a larger body of material before or while performing a measurement or test, or (b) a sample is brought into contact with a measuring or testing media to result in a particular geometric pattern or at a particular varying flow rate.

- (1) Note. This subclass provides for sampling when claimed by a series of sampling process steps, i.e., not sampling by name only.
- (2) Note. This subclass provides for applying the sample in a particularly claimed varying flow rate or pattern or path other than merely a single straight line.
- (3) Note. Mere nonpattern applications such as dipping or spaying is not included herein.
- (4) Note. Included in this subclass is a test or measurement which includes a swab streaking procedure or centrifugal density separation step.

SEE OR SEARCH THIS CLASS, SUBCLASS:

- 243, for sampling, inoculating, spreading a sample or physical isolation of samples which are not claimed as part of a test.
- 292, for inoculation and sampling apparatus.

**31 Testing for sterility condition:**

This subclass is indented under subclass 29. Subject matter wherein the efficacy of a prior step intended to destroy living organisms is assessed by attempting to culture a microorganism which has been exposed to such treatment and determining subsequent growth or by exposing an enzyme to such treatment and subsequently testing for enzymatic activity.

- (1) Note. Included in this subclass is the use of a living microorganism as the test agent or the use of enzymes which simulate the living microorganism's ability to survive as a test agent.
- 32 Testing for antimicrobial activity of a material:**  
This subclass is indented under subclass 29. Subject matter where the in vitro ability of a material to kill or inhibit the growth of microorganisms is determined.
- (1) Note. This subclass provides for (a) a determination of the sensitivity of a microorganism to known antibiotics, and (b) determining the presence or amount of an antibiotic or toxicant in a sample.
- 33 Using multifield media:**  
This subclass is indented under subclass 32. Subject matter where the test field contains more than one zone or area.
- (1) Note. Zones or areas can contain different concentrations of the same antibiotic or different antibiotics and are generally separated by an identifiable boundary.
- (2) Note. Media as used in this subclass includes culture media which sustains growth and medias which kill or inhibit certain microorganisms.
- 34 Determining presence or kind of microorganism; use of selective media:**  
This subclass is indented under subclass 29. Subject matter where the presence of or identity of a microorganism is determined.
- (1) Note. Included herein are test media that contains chemicals which change or remain unchanged in color or other physical appearance due to the action of or the absence of action of the microorganisms on the test media.
- (2) Note. This subclass includes but is not restricted to testing of biological samples.
- (3) Note. Test media includes culture media plus a chromosphere.
- (4) Note. This subclass includes determining the metabolic character of a microorganism, i.e., the production or consumption of a particular metabolite.
- SEE OR SEARCH THIS CLASS, SUBCLASS:  
32, and 33, for similar process used to test for antimicrobial sensitivity.
- 35 Using radioactive material:**  
This subclass is indented under subclass 34. Subject matter where the test media contains an assimilable radioactive labeled compound.
- 36 Streptococcus; staphylococcus:**  
This subclass is indented under subclass 34. Subject matter where the microorganisms involved are Streptococcus or Staphylococcus or the agent is specific for indicating the presence or absence of Streptococcus or Staphylococcus.
- 37 Nitrate to nitrite reducing bacteria:**  
This subclass is indented under subclass 34. Subject matter where the microorganisms involved are nitrite forming bacteria or the agent is specific for indicating the presence or absence of nitrite forming bacteria.
- (1) Note. It should be generally presumed that the presence of the nitrite is due to bacterial conversion of nitrate to nitrite.
- (2) Note. Included here are detection of nitrite in materials, such as an indication of bacteria.
- 38 Enterobacteria:**  
This subclass is indented under subclass 34. Subject matter where the microorganism involved is an enterobacteria or the agent is specific for indicating the presence or absence of enterobacteria.
- 39 Quantitative determination:**  
This subclass is indented under subclass 34. Subject matter where the number or concentration of living microorganisms in the material is found.
- (1) Note. The identity of the microorganism is not necessarily known.

- (2) Note. Included herein are tests for the purity of water.

SEE OR SEARCH CLASS:

359, Optics: Systems (Including Communication) and Elements, for the use of an optical element such as a lens of a microscope for magnification for counting particles such as bacteria colonies one by one.

**40 Using multifield media:**

This subclass is indented under subclass 39. Subject matter which uses a test substrate that has more than one test zone or area.

- (1) Note. Zones or areas can contain different concentrations of the same antibiotic or different antibiotic and are generally separated by an identifiable boundary.

**40.5 Involving fixed or stabilized, nonliving microorganism, cell, or tissue (e.g., processes of staining, stabilizing, dehydrating, etc.; compositions used therefore, etc.):**

This subclass is indented under subclass 4. Subject where the material to be tested contains fixed or stabilized, nonliving microorganisms, cells, or tissues or the agent used for the measurement or test contains fixed or stabilized, nonliving microorganisms, cells, or tissues.

- (1) Note. If there is no clear disclosure as to whether the microorganism or cell is nonliving or viable, it shall be presumed to be viable and therefore appropriate for this class, subclasses 29+. However, due to the uncertainty of the viability of the microorganism or cell, placement of a cross reference in this or the indented subclasses is strongly recommended.
- (2) Note. This and the indented subclasses are intended to take compositions used to aid in the microscopic study (e.g., light, scanning or transmission electron microscopy, etc.) of microorganisms, cells, and tissues such as those used for staining, clarifying, firming, fixing, or dehydrating a microorganism, cell, or tissue for microscopic examination as well as the methods for preparing the microorganisms, cells, and tissues for

examination and the processes of examining them not specifically provided for elsewhere.

- (3) Note. Fixation or stabilization of the microorganisms, cells, or tissues on a slide may involve merely air drying rather than a chemical fixation process.
- (4) Note. Subject matter involving the staining of microorganisms, cells, or tissues specifically and only for nucleic acid (e.g., DNA or RNA, etc.) with stains such as Feulgen stain or acridine orange is proper for this class, subclass 6. Subject matter involving microorganisms, cells, or tissues stained with a composition providing contrasting stains for the cell nucleus and cytoplasm (e.g., hematoxylin, eosin, etc.) is proper for this or the indented subclasses.

SEE OR SEARCH THIS CLASS, SUBCLASS:

- 6, for measuring or testing processes or compositions therefore involving nucleic acid, nucleotide, or nucleoside which includes processes of staining microorganisms, cells, or tissues via in situ nucleic acid hybridization.
- 7.1+, for test methods or compositions therefore involving the staining of microorganisms, cells, or tissue with labelled antibodies, ligands, or receptors.
- 14+, for test methods or compositions therefore involving the staining of microorganisms, cells, or tissues for endogenous enzyme activity.
- 29+, for test methods or compositions therefore involving the staining of microorganisms, cells, or tissues with vital stains; methods or compositions involving the microscopic observation of live microorganisms or cells; methods or compositions involving the counting of intact, live microorganisms or cells not provided for elsewhere.

## SEE OR SEARCH CLASS:

- 8, Bleaching and Dyeing; Fluid Treatment and Chemical Modification of Textiles and Fibers, subclasses 94.1+ for treatment of hides, skins, feathers and animal tissues, e.g., tanning, particularly subclass 94.11 pertaining to treatment of subcutaneous or internal tissues of animals, e.g., the production of sutures, racket strings, etc., from gut and various subclasses for compositions for dyeing materials of any kind which may contain a microorganism or enzyme.
- 156, Adhesive Bonding and Miscellaneous Chemical Manufacture, appropriate subclass for a process of mounting a specimen by a lamination process which process may or may not include the step of staining, clarifying, firming or fixing the tissue; and subclass 57 for the combination of coating a biological specimen and then interposing the coated specimen between glass plates.
- 250, Radiant Energy, for methods and apparatus for detecting radiant energy not classified elsewhere.
- 356, Optics: Measuring and Testing, for methods and apparatus for analyzing light, determining the optical or non-optical properties of materials, measuring optically dimensions, determining optically spatial relations and inspecting optically for flaws and imperfections within the scope of this class and not otherwise classifiable. This includes visual counting of blood particles, etc. with a scale or spacer to aid the eye, counting and sizing particles with visible light by statistical analysis procedures rather than one by one numerical particle counting, etc.
- 359, Optics: Systems (Including communication) and Elements, for microscopes and microscope slides.
- 377, Electrical Pulse Counters, Pulse Dividers, or Shift Registers: Circuits and Systems, for a numerical counting means for counting and/or sizing discrete particles such as blood particles or bacteria colonies one at a time.

- 424, Drug, Bio-affecting and Body Treating Composition, subclass 75 for an embalming and undertaking composition.
- 427, Coating Processes, subclasses 2+ for coating processes wherein a medical or dental product is produced and subclass 4 for processes of coating a plant member or animal specimen.
- 434, Education and Demonstration, subclasses 295+ for method, apparatus or product related to teaching and pertinent to biology and taxidermy, including models, cells, mounting and preserving means, processes and taxidermy devices.
- 436, Chemistry: Molecular Biology and Microbiology, subclass 10 for particle count standards or controls such as platelet count standards; subclass 521 for fixed or stabilized red blood cells used as an insoluble carrier for immunochemicals (e.g., hemagglutination, etc.).

**40.51 Involving a monolayer, smear or suspension of microorganisms or cells:**

This subclass is indented under subclass 40.5. Subject where the fixed or stabilized, nonliving microorganisms or cells are in the form of a monolayer, smear, or a suspension.

- (1) Note. Included in this subclass is subject matter in which the microorganisms or cells may be placed on a slide or other surface for histological or microscopic examination or may be automatically examined such as by flow cytometry.
- (2) Note. Included in this subclass is subject matter involving blood cell smears; cells prepared for cytopathological analysis, e.g., analysis of cells that are spontaneously exfoliated, mechanically dislodged by irrigation, brushing, or scraping, or forcibly removed by needle aspiration (e.g., Pap smears, etc.); urine sediments, etc.

**40.52 Involving tissue sections:**

This subclass is indented under subclass 40.5. Subject matter wherein the fixed or stabilized, nonliving tissue is in the form of a tissue section.

- (1) Note. Since tissues and organs are usually too thick for microscopic study, techniques have been developed which result in thin, translucent sections. Therefore, for the purpose of this subclass, tissue sections are tissues which have been sliced so that they may be microscopically observed.
- (2) Note. Included in this subclass are all stages of tissue processing in the preparation for and examination of tissue sections, e.g., fixation, dehydration, embedding, sectioning, etc.

**41 MICROORGANISM, TISSUE CELL CULTURE, OR ENZYME USING PROCESS TO SYNTHESIZE A DESIRED CHEMICAL COMPOUND OR COMPOSITION:**

This subclass is indented under the class definition. Processes wherein the product is synthesized by a biochemical transformation of matter, i.e., a transformation wherein the transforming agent is a microorganism, or an enzyme or an immobilized enzyme or an animal or plant cell culture or organelles.

- (1) Note. microorganism for the purpose of this subclass includes bacteria, fungi (including yeast), virus, actinomycetales unicellular algae, plant cells, actinomycetales, and protozoa.
- (2) Note. Synthesis for purposes of this subclass involves the preparation of a composition or compound which did not exist in the starting material, and does not include an ancillary operation wherein a material is chemically modified by an enzyme, cell bound free or immobilized, or microorganism or animal or plant cell so as to degrade or change the chemical structure thereof so that another material which is in initial intimate contact with the modified material can be recovered in a nonmodified form. See in particular, subclasses 262+ of this schedule for such liberation or purification processes.
- (3) Note. As between Class 260 and this class (435) provide an original home for

all synthesis which include action by a microorganism or enzyme.

- (4) Note. Enzymes for the purpose of this subclass are polypeptides or proteins or material containing the same which are capable of chemically transforming matter, e.g., oxidation, etc., without undergoing a transformation itself.
- (5) Note. Processes for producing an enzyme or microorganism are excluded herefrom and are found in subclasses 183+ and 243+.
- (6) Note. Processes for the production of products in which the structure is not disclosed should be placed in this and the indented subclasses in the first appearing subclass which takes an identified constituent of the product. Should such a placement prove impossible, then placement is on the basis of the microorganism's identity.

**SEE OR SEARCH CLASS:**

- 204, Chemistry: Electrical and Wave Energy, for chemical processes including electrical or wave energy methods.
- 260, Chemistry of Carbon Compounds, for the synthesis of carbon compounds by means not including a microorganism or enzyme.
- 423, Chemistry of Inorganic Compounds, for the synthesis of inorganic compounds or elements other than metals by means not including the use of a microorganism or enzyme.
- 426, Food or Edible Material: Processes, Compositions, and Products, for fermentation processes that are solely disclosed or claimed in preparing an edible, and for mixtures of enzymes or ferments solely disclosed or claimed as edible or used in preparation of an edible. Class 426 provides for compositions and processes of preparation relating to compositions which have the capacity to ferment and produce an edible, but which are claimed as being in an inactive state, and also provides for compositions

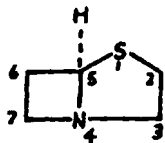
which are undergoing a fermentation to produce an edible product.

**42 Process involving microorganisms of different genera in the same process, simultaneously:**

This subclass is indented under subclass 41. Processes wherein microorganisms of different genera are simultaneously propagated on the same culture media.

**43 Preparing compound having a 1-thia-4-aza-bicyclo (3.2.0) heptane ring system (e.g., penicillin, etc.):**

This subclass is indented under subclass 41. Processes wherein the product synthesized contains a 1-thia-4-aza-bicyclo (3.2.0) heptane polycyclic ring system, i.e.,



(1) Note. The media of the processes included in subclass 45 must contain the 1-thia-4-aza-bicyclo heptane ring system compound.

**44 By desacylation of the substituent in 6-position:**

This subclass is indented under subclass 43. Processes wherein the product synthesized is prepared by the hydrolysis of an acetyl group in the 6-position.

**45 By acylation of the substituent in 6-position:**

This subclass is indented under subclass 43. Processes wherein the product synthesized is prepared by substituting an acyl group in the 6-position.

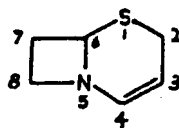
(1) Note. The media of the processes included herein must contain the 1-thia-4-aza-bicyclo heptane ring system compound.

**46 In presence of phenyl acetic acid or phenyl acetamide or their derivatives:**

This subclass is indented under subclass 43. Processes wherein phenyl acetic acid or substituted phenyl acetic acid or salts thereof or phenyl acetamide or substituted phenyl acetamide or salts thereof is present during the synthesis.

**47 Preparing compound having a 1-thia-5-aza-bicyclo (4.2.0) octane ring system (e.g., cephalosporin, etc.):**

This subclass is indented under subclass 41. Processes wherein the product synthesized contains a 1-thia-5-aza-bicyclo (4.2.0) octane polycyclic ring system, i.e.,

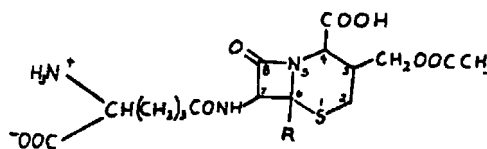


**48 Di-substituted in 7-position:**

This subclass is indented under subclass 47. Processes wherein the polycyclic ring system synthesized contains two substituents other than hydrogen in the 7-position.

**49 Cephalosporin C:**

This subclass is indented under subclass 47. Processes wherein the product contains 7-(D-5-amino-5-carboxy valer-amido)-3-(hydroxy methyl)-8-oxo-1-thia-5-aza-bicyclo (4.2.0) -oct-3-ene-3-carboxylic acid acetate, i.e.



(1) Note. For purposes of this subclass, derivatives include only metal and ammonium salts.



**50 By acylation of the substituent in the 7-position:**

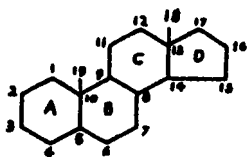
This subclass is indented under subclass 47. Processes wherein the product synthesized is prepared by amide bond formation, present with the nitrogen attached at the 7-position.

**51 By desacylation of the substituent in the 7-position:**

This subclass is indented under subclass 47. Processes wherein the product synthesized is prepared by cleaving the amide bond with the nitrogen attached to the 7-position.

**52 Preparing compound containing a cyclopentanohydrophenanthrene nucleus; nor-, homo-, or D-ring lactone derivatives thereof:**

This subclass is indented under subclass 41. Processes wherein the product synthesized contains a cyclopentanophenanthrene ring system, i.e., or the nor or homo or D-ring lactone derivatives.



(1) Note. The phenanthrene ring system contains more hydrogen than is present in phenanthrene.

(2) Note. Common atoms of two rings are considered to belong to the rightmost ring.

(3) Note. Homo derivatives wherein the D-ring is expanded to 6-carbons such as in Hellebrin are found here.

**53 Containing heterocyclic ring:**

This subclass is indented under subclass 52. Processes wherein the cyclopentanophenanthrene ring system synthesized contains an additional ring which is a hetero ring.

(1) Note. The hetero ring may be fused or bridged with the cyclopentanophenanthrene ring system.

**54 Acting on D-ring:**

This subclass is indented under subclass 52. Processes wherein the product synthesized is formed by biochemical transformation within the D-ring.

(1) Note. The hetero ring may be fused or bridged with the cyclopentanophenanthrene ring system.

**55 Acting at 17-position:**

This subclass is indented under subclass 54. Processes wherein the product synthesized is formed by biochemical transformation at the 17-position.

(1) Note. This subclass includes cleavage of the 17-side chain with the formation of keto or hydroxyl groups at the cleaved position.

**56 Hydroxylating at 17-position:**

This subclass is indented under subclass 55. Processes wherein the product synthesized has a hydroxyl group at the 17-position and is formed by the addition of an oxygen atom to the pendant hydrogen atom.

**57 Hydroxylating at 16-position:**

This subclass is indented under subclass 54. Processes wherein the product synthesized has a hydroxyl group at the 16-position and is formed by the addition of oxygen to the ring pendant hydrogen atom.

**58 Hydroxylating:**

This subclass is indented under subclass 52. Processes wherein a carbon atom on the substrate nucleus is hydroxylated by the addition of oxygen to the ring pendant hydrogen atom.

**59 At 11-position:**

This subclass is indented under subclass 58. Processes wherein the product synthesized has a hydroxyl group formed at the 11-position.

**60 At 11 alpha position:**

This subclass is indented under subclass 59. Processes wherein the product synthesized has a hydroxyl group formed at the 11 Alpha position.

**61 Dehydrogenating; dehydroxylating:**

This subclass is indented under subclass 52. Processes wherein the product synthesized is produced by the removal from the nucleus of a pair of hydrogen atoms creating an unsaturated bond or the product is synthesized by removal or addition of a hydroxyl group.

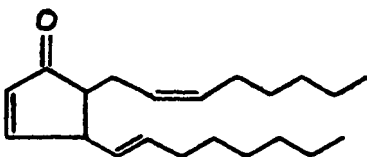
- (1) Note. The mere shifting of unsaturated bonds from adjacent positions such as from the 5, 6 position to the 4, 5 position is not a dehydrogenation.

**62 Forming an aryl ring from "A" ring:**

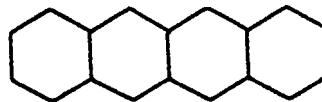
This subclass is indented under subclass 61. Processes wherein the product synthesized contains an aromatic "A" ring which is formed by dehydrogenation.

**63 Preparing compound containing a prostaglandin nucleus:**

This subclass is indented under subclass 41. Processes wherein the product synthesized contains a five membered ring having two side-chains in ortho position to each other, and having at least one oxygen atom directly bound to the ring in ortho position to one of the side-chains, one side-chain containing, not directly bound to the ring, a carbon atom having three bonds to hetero atoms with at the most one bond to halogen, and the other side-chain having at least one oxygen atom bound in position to the ring, i.e., prostaglandins having the structure,

**64 Preparing compound other than saccharide containing a tetracycline nucleus (e.g., naphthacene, etc.):**

This subclass is indented under subclass 41. Processes wherein the product synthesized contains a naphthacene ring system (i.e., see figure below) and nonsaccharide ring unsaturated derivatives thereof.



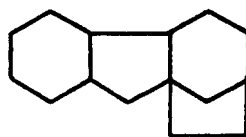
- (1) Note. Tetracyclines are properly classified here.
- (2) Note. Saccharide derivatives are excluded herefrom.

SEE OR SEARCH THIS CLASS, SUBCLASS:

78, for saccharide derivatives.

**65 Preparing compound other than saccharide containing a gibberellin nucleus (i.e., gibbane):**

This subclass is indented under subclass 41. Processes wherein the product synthesized contains other than the saccharide.



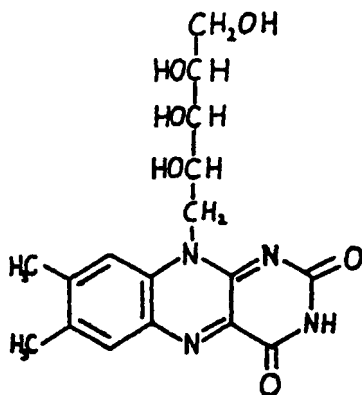
- (1) Note. Gibberellic acid and gibberellins are properly classified here.
- (2) Note. Saccharide derivatives are excluded herefrom.

SEE OR SEARCH THIS CLASS, SUBCLASS:

78, for saccharide derivatives.

**66 Preparing compound other than saccharide containing alloxazine or isoalloxazine nucleus:**

This subclass is indented under subclass 41. Processes wherein the product synthesized contains an alloxazine or isoalloxazine ring system, e.g., and is not a saccharide.

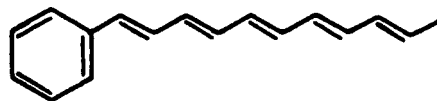
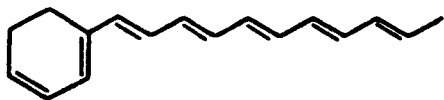


- (1) Note. Riboflavin is not considered a saccharide derivative for the purpose of this subclass and is therefore provided for here.
- (2) Note. Saccharide derivatives are excluded herefrom.

SEE OR SEARCH THIS CLASS, SUB-CLASS:  
72+, for saccharide derivatives of these compounds.

**67 Preparing compound containing a carotene nucleus (i.e., carotene):**

This subclass is indented under subclass 41. Processes wherein the product synthesized contains either the first or second structures below.



- (1) Note. Carotenoids having a cyclic group are properly classified here.
- (2) Note. Structures above can be partially hydrogenated such as Phytofluene.

SEE OR SEARCH THIS CLASS, SUB-CLASS:

166, for the acyclic carotenoid, lycopene.

**68.1 Enzymatic production of a protein or polypeptide (e.g., enzymatic hydrolysis, etc.):**

This subclass is indented under subclass 41. Processes wherein the enzymatically produced product is a high molecular weight polypeptide of alpha amino acids or consists of two or more amino acids linked by a peptide bond.

- (1) Note. This subclass provides for peptones which are the result of partial protein hydrolysis.
- (2) Note. A peptide bond is defined as an amide linkage between two amino acid residues.

SEE OR SEARCH CLASS:

- 106, Compositions: Coating or Plastic, for protein containing coating or plastic compositions, particularly subclasses 4, 31.24, 31.57, 31.82, 31.94, 124+, 645+ and indented subclasses.
- 426, Food or Edible Material: Processes, Compositions, and Products, appropriate subclasses, especially subclasses 63, 92, 105, 211, and 212 for edible protein compositions or products and related process involving the same.
- 428, Stock Material or Miscellaneous Articles, subclasses 474.4+ for a non-structural stock material product in the form of a composite web or sheet including a layer comprising protein,

- and other appropriately titled subclasses (e.g., subclasses 435 and 458).
- 530, Chemistry: Natural Resins or Derivatives Peptides or Proteins, Lignins or Reaction Products Thereof, subclasses 300 and 345 for peptides and reaction products thereof; subclasses 350 to 427 for proteins and the reaction products thereof; and cross-reference art collections 800 through 859 for antigenic peptides or proteins, methods of immobilizing peptides or proteins, and the source materials from which peptides or proteins are isolated.
- 536, Organic Compounds, appropriate subclasses, for nucleic acids and processes of chemical synthesis thereof.
- 930, Peptide or Protein Sequence, subclasses 10+ for peptide or protein sequence of four or more amino acids.

**69.1 Recombinant DNA technique included in method of making a protein or polypeptide:**

This subclass is indented under subclass 41. Processes which involve the use of recombinant DNA techniques in a process of synthesis of a protein or polypeptide.

- (1) Note. An example of the subject matter in this subclass is a process of producing a polypeptide which includes the alteration of the genetic structure of a cell by use of recombinant DNA techniques.
- (2) Note. See this class, subclass 68.1 for the definition of polypeptide or protein.

SEE OR SEARCH THIS CLASS, SUBCLASS:

- 440+, for processes using recombinant DNA techniques to alter the genetic structure of a living microorganism.

SEE OR SEARCH CLASS:

- 514, Drug, Bio-Affecting and Body Treating Compositions, subclasses 1.1 through 21.92 for a therapeutic or bio-affecting body treating composition containing a peptide as a designated organic active ingredient (DOAI).

- 530, Chemistry: Natural Resins or Derivatives Peptides or Proteins; Lignins or Reaction Products Thereof, subclass 808 for the product produced by the processes of this subclass.
- 800, Multicellular Living Organisms and Unmodified Parts Thereof and Related Processes, subclasses 4+ for a method of using a living transgenic nonhuman animal to manufacture a protein which is to be isolated or extracted from the animal.
- 930, Peptide or Protein Sequence, subclasses 10+ for peptide or protein sequence of four or more amino acids.

**69.2 Enzyme inhibitors or activators:**

Processes under subclasses 69.1 wherein the product synthesized is an enzyme inhibitor or activator which is a protein or polypeptide.

- (1) Note. Examples of the subject matter included in this subclass are the cloning and expression of antagonists to enzymes for amino acid biosynthesis.

SEE OR SEARCH THIS CLASS, SUBCLASS:

- 106, through 116 and 183-234, for enzyme inhibitors employed in the production of amino acids.

**69.3 Antigens:**

This subclass is indented under subclass 69.1. Processes wherein the product synthesized is claimed or solely disclosed as functioning as an antigen.

- (1) Note. Examples of the subject matter included in this subclass are cloning and expression of all polypeptide antigens (e.g., viral subunit antigens).

SEE OR SEARCH THIS CLASS, SUBCLASS:

- 7.1+, for antigens involved in an enzyme immunoassay.

SEE OR SEARCH CLASS:

- 424, Drug, Bio-Affecting and Body Treating Compositions, subclasses 184.1+ for compositions of that class which contain antigens.

436, Chemistry: Analytical and Immunological Testing, subclasses 543 through 546 for antigens used as a testing material in an in vitro test.

530, Chemistry: Natural Resins or Derivatives Peptides, or Proteins; Lignins or Reaction Products Thereof, subclasses 806 and 807 for the product produced by the processes of this subclass.

**69.4 Hormones or fragments thereof:**

This subclass is indented under subclass 69.1. Processes wherein the product synthesized is a hormone or a part of a hormone.

- (1) Note. Examples of the subject matter included in this subclass are cloning and expression of polypeptide hormones (e.g., mammalian growth stimulating hormones).

SEE OR SEARCH CLASS:

514, Drug, Bio-Affecting and Body Treating Compositions, subclasses 9.7 through 13.1 for therapeutic or bio-affecting compositions containing a peptide hormone.

530, Chemistry: Natural Resins or Derivatives Peptides or Proteins; Lignins or Reaction Products Thereof, subclass 399 for the product produced by the processes of this subclass.

**69.5 Lymphokines or monokines:**

This subclass is indented under subclass 69.1. Processes wherein the product synthesized is a lymphokine or monokine.

- (1) Note. Examples of the subject matter included in this subclass are cloning and expression of interferon, interleukin, lymphotoxin, or tumor necrosis factor.

SEE OR SEARCH CLASS:

424, Drug, Bio-Affecting and Body Treating Compositions, subclass 85 for bioactive compositions containing interferon.

530, Chemistry: Natural Resins or Derivatives Peptides or Proteins; Lignins or Reaction Products Thereof, subclass 351 for the product produced by the processes of this subclass.

**69.51 Interferons:**

This subclass is indented under subclass 69.5. Processes wherein the product synthesized is an interferon.

SEE OR SEARCH CLASS:

424, Drug, Bio-Affecting and Body Treating Compositions, subclasses 85.4 through 85.7 for compositions of that class containing an interferon.

530, Chemistry: Natural Resins or Derivatives Peptides or Proteins; Lignins or Reaction Products Thereof, subclass 351 for the product produced by the processes of this subclass.

**69.52 Interleukins:**

This subclass is indented under subclass 69.5. Processes wherein the product synthesized is an interleukin.

SEE OR SEARCH CLASS:

424, Drug, Bio-Affecting and Body Treating Compositions, subclass 85.2 for compositions of that class containing interleukin.

530, Chemistry: Natural Resins or Derivatives Peptides or Proteins; Lignins or Reaction Products Thereof, subclass 351 for the product produced by the processes of this subclass.

**69.6 Blood proteins:**

This subclass is indented under subclass 69.1. Processes wherein the product synthesized is a blood protein.

- (1) Note. Examples of the subject matter included in this subclass are cloning and expression of polypeptide of immunoglobulin origin.

SEE OR SEARCH THIS CLASS, SUBCLASS:

70.4, for processes including the culture of blood cells.

SEE OR SEARCH CLASS:

424, Drug, Bio-Affecting and Body Treating Compositions, subclasses 85.1+ for composition of that class containing a blood protein.

514, Drug, Bio-Affecting and Body Treating Compositions, subclasses 13.5-15.3 for therapeutic or bio-affecting compositions containing blood proteins, especially subclass 13.4 for a blood substitute.

530, Chemistry: Natural Resins or Derivatives Peptides or Proteins; Lignins or Reaction Products Thereof, subclasses 380 through 394 for the product produced by the processes of this subclass.

**69.7 Fusion proteins or polypeptides:**

This subclass is indented under subclass 69.1. Processes wherein the product synthesized is a fusion protein or fusion polypeptide.

(1) Note. Examples of the subject matter included in this subclass are the cloning and expression of a fused polypeptide (e.g., tribrid protein).

SEE OR SEARCH CLASS:

530, Chemistry: Natural Resins or Derivatives Peptides or Proteins; Lignins or Reaction Products Thereof, subclasses 300+ for the product produced by the processes of this subclass.

**69.8 Signal sequence (e.g., beta-galactosidase, etc.):**

This subclass is indented under subclass 69.1. Process wherein the product synthesized is a protein or polypeptide with a signal sequence such as beta-galactosidase.

SEE OR SEARCH THIS CLASS, SUBCLASS:

183, through 234, for enzymatic signal sequences.

SEE OR SEARCH CLASS:

530, Chemistry: Natural Resins or Derivatives Peptides or Proteins; Lignins or Reaction Products Thereof, subclasses 300+ for the product produced by the processes of this subclass which includes fused polypeptides.

**69.9 Yeast derived:**

This subclass is indented under subclass 69.8. Processes wherein the product synthesized is a protein or polypeptide with a yeast derived signal sequence.

(1) Note. Examples of the subject matter included in this subclass are cloning and expression of polypeptides attached to a yeast signal sequence (e.g., alpha-amylase).

SEE OR SEARCH THIS CLASS, SUBCLASS:

183, through 234, for enzymatic signal sequence of yeast.

SEE OR SEARCH CLASS:

530, Chemistry: Natural Resins or Derivatives Peptides or Proteins; Lignins or Reaction Products Thereof, subclasses 300+ for the product produced by the processes of this subclass which include fused polypeptides.

**70.1 Using tissue cell culture to make a protein or polypeptide:**

This subclass is indented under subclass 41. Processes wherein an in vitro tissue cell culture is used to produce a protein or polypeptide.

(1) Note. An example of the subject matter included in this subclass is use of a plant or animal cell culture to produce polypeptides.

(2) Note. See this class, subclass 68.1 for the definition of polypeptide or protein.

SEE OR SEARCH THIS CLASS, SUBCLASS:

325+, for the culture of animal cells absent the production of a protein or polypeptide product.

SEE OR SEARCH CLASS:

930, Peptide or Protein Sequence, subclasses 10+ for peptide or protein sequence of four or more amino acids.

**70.2 Fused or hybrid cells:**

This subclass is indented under subclass 70.1. Processes wherein the product is synthesized by culture of fused or hybrid cells.

- (1) Note. Fused or hybrid cells include those resulting from (a) the fusion of two cells, (b) the insertion of the nucleus or chromosome of one cell into another or (c) the treatment of a cell with an immortalizing agent which results in a cell which will proliferate in long-term culture.
- (2) Note. Examples of the subject matter included in this and the indented subclass are use of lymphoblastoid hybridoma cells to produce peptide hormones (e.g., insulin, calcitonin, growth hormone, etc.) or monoclonal anti-bodies or use of cells transformed with a virus or oncogene to produce a cell line which will proliferate and produce proteins or polypeptides in long term culture.

SEE OR SEARCH THIS CLASS, SUBCLASS:

- 326+, for fused or hybrid animal cells, per se, which express immunoglobulin, antibody, or fragment thereof.
- 346, for fused or hybrid cell, per se.
- 373, through 403, for various processes of culturing animal cells.

SEE OR SEARCH CLASS:

- 530, Chemistry: Natural Resins or Derivatives Peptides or Proteins; Lignins or Reaction Products Thereof, subclasses 303, 307, 399, for the product produced by the processes of this subclass which includes insulin, calcitonin, and hormones.

**70.21 Producing monoclonal antibody:**

This subclass is indented under subclass 70.21. Processes wherein the product synthesized by the fused or hybrid cell is a monoclonal antibody.

- (1) Note. Subject matter in this subclass includes production of monoclonal antibodies by hybridoma cells.

SEE OR SEARCH THIS CLASS, SUBCLASS:

- 7.1+, for use of monoclonal antibodies in testing methods involving a microorganism or enzyme.
- 326+, for fused or hybrid animal cells, per se, which express immunoglobulin, antibody, or fragment thereof. 373 through 403, for various processes of culturing animal cells.

SEE OR SEARCH CLASS:

- 424, Drug, Bio-Affecting and Body Treating Compositions, subclasses 131.1+ for bio-affecting compositions containing monoclonal antibodies.
- 436, Chemistry: Analytical and Immunological Testing, subclass 548 for monoclonal antibodies used in a process of immunoassay.
- 530, Chemistry: Natural Resins or Derivatives Peptides or Proteins; Lignins or Reaction Products Thereof, subclasses 387.2+ for the product produced by the processes of this subclass and subclass 413 for the process of using monoclonal antibody to separate a protein.

**70.3 Animal tissue cell culture:**

This subclass is indented under subclass 70.2. Processes wherein the protein or polypeptide product synthesized is derived from the culture of animal tissue cells.

- (1) Note. The term tissue cells is intended to differentiate cells cultivated as a contiguous mass as opposed to individual cells or fused cells.

SEE OR SEARCH THIS CLASS, SUBCLASS:

- 326, through 372.3, for animal cells, per se.
- 373, through 403, for techniques of culturing animal cells.

SEE OR SEARCH CLASS:

- 424, Drug, Bio-Affecting and Body Treating Compositions, subclasses 95+ for medicinal compositions containing animal cell extracts.

530, Chemistry: Natural Resins or Derivatives Peptides or Proteins; Lignins or Reaction Products Thereof, subclasses 350+, for proteins, per se.

#### 70.4 **Blood (lymphoid) cell culture:**

This subclass is indented under subclass 70.3. Processes wherein the product synthesized is produced by culture of blood cells.

(1) Note. Examples of the subject matter included in this subclass are interleukins produced by culture of blood cells.

SEE OR SEARCH THIS CLASS, SUBCLASS:

69.5, for processes of producing lymphokines or monokines through use of recombinant DNA techniques.

SEE OR SEARCH CLASS:

530, Chemistry: Natural Resins or Derivatives Peptides or Proteins; Lignins or Reaction Products Thereof, subclass 351 for the product produced by the processes of this subclass.

#### 70.5 **Producing interferons:**

This subclass is indented under subclass 70.4. Processes wherein the product synthesized is an interferon.

SEE OR SEARCH THIS CLASS, SUBCLASS:

69.51, for processes of producing interferon through use of recombinant DNA techniques.

SEE OR SEARCH CLASS:

424, Drug, Bio-Affecting and Body Treating Compositions, subclass 85 for compositions of that class containing interferon.

530, Chemistry: Natural Resins or Derivatives Peptides or Proteins; Lignins or Reaction Products Thereof, subclass 351 for the product produced by the processes of this subclass.

#### 71.1 **Using a microorganism to make a protein or polypeptide:**

This subclass is indented under subclass 41. Processes wherein a protein or peptide synthesized is produced by a culture of a microorganism.

(1) Note. Examples of the subject matter included in this subclass are eucaryotic antibiotics.

(2) Note. See this class subclass 68.1 for the definition of polypeptide or protein.

SEE OR SEARCH THIS CLASS, SUBCLASS:

243, through 261, for process of culturing microorganisms and for microorganisms, per se.

SEE OR SEARCH CLASS:

530, Chemistry: Natural Resins or Derivatives Peptides or Proteins; Lignins or Reaction Products Therefore, subclasses 820+ for the product produced by the process of this subclass.

930, Peptide or Protein Sequence, subclasses 10+ for peptide or protein sequence of four or more amino acids.

#### 71.2 **Procaryotic microorganism:**

This subclass is indented under subclass 71.1. Processes wherein the microorganism is procaryotic.

(1) Note. Examples of the subject matter included in this subclass are bacterial antigens and periplasmic proteins.

SEE OR SEARCH THIS CLASS, SUBCLASS:

252.1+, for process of culture of bacteria and for bacteria, per se.

SEE OR SEARCH CLASS:

530, Chemistry: Natural Resins or Derivatives Peptides or Proteins; Lignins or Reaction Products Thereof, subclasses 820+ for the product produced by the processes of this subclass.



**71.3 Antibiotic or toxin:**

This subclass is indented under subclass 71.2. Processes wherein the product synthesized is an antibiotic or toxin.

- (1) Note. Examples of the subject matter in this subclass are procaryotic antibiotics (e.g., polymyxin).

**SEE OR SEARCH CLASS:**

514, Drug, Bio-Affecting and Body Treating Compositions, subclasses 1.1 through 21.92 for compositions of that class containing an antibiotic or toxin which is a protein or polypeptide.

**72 Preparing compound containing saccharide radical:**

This subclass is indented under subclass 41. Processes wherein the product synthesized contains a saccharide or polysaccharide, the monomeric units of which contain at least five-carbon atoms, or their reaction products wherein the carbon skeleton of the saccharide or polysaccharide of the unit is not destroyed.

- (1) Note. Included herein is cellulose, derivatized cellulose, starch, derivatized starch, sugars, lignins, tannins, o-glycosides, n-glycosides, and s-glycosides.
- (2) Note. Processes wherein the product synthesized is a degradation product which contains fewer than five-carbon atoms are not provided for in this subclass but are provided for in an appropriate subclass below.

**SEE OR SEARCH THIS CLASS, SUBCLASS:**

137, for sugar acids.  
158+, for sugar alcohols.  
262, for processes of liberation or purification of carbohydrates using a biochemical reaction.

**SEE OR SEARCH CLASS:**

127, Sugar, Starch, and Carbohydrates, for the hydrolysis of carbohydrates including their conversion to sugar by means other than a microorganism or enzyme. Class 127 will provide for

such processes using an enzyme or microorganism only where the hydrolysis by microorganism or enzyme is followed by steps of concentration, purification, or treatment (such as crystallization) to make a sugar or syrup.

536, Organic Compounds, for the chemical manufacture or synthesis of sugar or carbohydrates by a process other than hydrolysis and the rearrangement of one carbohydrate to form another carbohydrate by means other than a microorganism or enzyme. Search subclasses 22.1+ for N-glycosides (e.g., nucleosides, nucleotides, polynucleotides) and more specifically subclasses 23.1+ for fragments of RNA or DNA which could have utility as genes in recombinant processes and subclasses 26.4+ for vitamin B-12 and its derivatives.

**73 Preparing S-glycoside (e.g., lincomycin, etc.):**

This subclass is indented under subclass 72. Processes wherein the product synthesized is a thioacetal derivative of a cyclic form of sugar in which the hydrogen atom of the hemithioacetal sulfhydryl group has been replaced by an alkyl, aralkyl, or aryl group.

- (1) Note. An S-glycoside is a compound having a sugar moiety connected to an aglycone moiety via a sulfur.
- (2) Note. The aglycone is a nonsaccharide material, e.g., benzene, indoxyl, anthracene, etc.
- (3) Note. On complete hydrolysis S-glycosides yield one or more monosaccharides, and a mono or a polyhydric thiol or thiol phenol.
- (4) Note. The cyclic sugars referred to in the definitions are normally pyranoses or furanoses.
- (5) Note. Glycosides derived from aldoses are referred to as aldoses, and those from ketoses are ketosides.

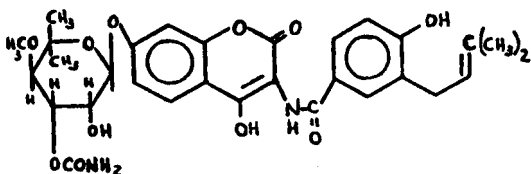
**74 Preparing O-glycoside (e.g., glucosides, etc.):**

This subclass is indented under subclass 72. Processes wherein the product synthesized is an acetal derivative of a cyclic form of sugars in which the hydrogen atom of the hemiacetal hydroxyl has been replaced by an alkyl, aralkyl, or aryl group.

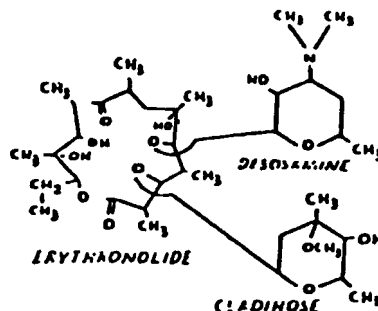
- (1) Note. An O-glycoside is a compound having a sugar moiety connected to an aglycone moiety via oxygen.
- (2) Note. The aglycone is a nonsaccharide material, e.g., benzene, indoxyl, anthracene, etc.
- (3) Note. On complete hydrolysis O-glycosides yield one or more monosaccharides, and a mono or polyhydric alcohol or phenol.
- (4) Note. The cyclic sugars referred to in the definitions are normally pyranoses or furanoses.
- (5) Note. Glycosides derived from aldoses are referred to as aldoses, and those from ketoses are ketosides.

**75 Oxygen of the saccharide radical is directly bonded to a nonsaccharide heterocyclic ring or a fused- or bridged-ring system which contains a nonsaccharide heterocyclic ring (e.g., coumermycin, novobiocin, etc.):**

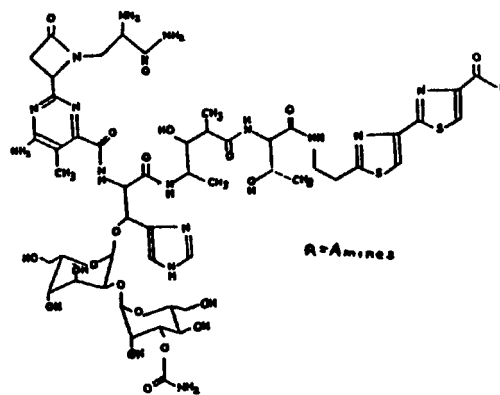
This subclass is indented under subclass 74. Processes wherein a nonsaccharide heterocyclic ring or a fused or bridged-ring system which contains a nonsaccharide heterocyclic ring is attached to an oxygen of the saccharide radical, e.g.,

**76 The hetero ring has eight or more ring members and only oxygen as ring hetero atoms****(e.g., erythromycin, spiramycin, nystatin, etc.):**

This subclass is indented under subclass 75. Processes wherein the nonsaccharide heterocyclic ring has eight or more ring members and only oxygen as the ring heteroatom, e.g.,

**77 Oxygen atom of the saccharide radical is directly linked through only acyclic carbon atoms to a nonsaccharide heterocyclic ring (e.g., bleomycin, phleomycin, etc.):**

This subclass is indented under subclass 74. Processes wherein the Heterocyclic ring is directly linked to an oxygen atom of the saccharide radical directly through only acyclic carbon atoms, e.g.,

**78 Oxygen atom of the saccharide radical is directly bonded to a condensed ring system having three or more carbocyclic rings (e.g., daunomycin, adriamycin, etc.):**

This subclass is indented under subclass 74. Processes wherein a condensed ring system having three or more carbocyclic rings is





















































































































































































































