

## FATTY ACID-CONTAINING COMPOSITION

## FIELD OF THE INVENTION

The present invention relates to a pharmaceutical composition containing a fatty acid and a water-soluble silicate polymer in a pharmaceutically effective amount for use as a medicine such as an anti-allergic agent. The present invention relates to a method of enhancing the activity of a water-soluble silicate polymer in a pharmaceutical composition by mixing a saturated fatty acid and a water-soluble silicate polymer.

## BACKGROUND OF THE INVENTION

Every cell, which is the fundamental unit of the living body, is surrounded by membrane. The membrane is not only useful as a protective envelope so that the activity inside the cell can be normally carried out but also plays a role as a door for taking the nutrients therein and for excreting the waste products and also as a transmitter of information into and from the cell. In the cells of higher animals, organelles of an internal membrane system are present inside in addition to the surrounding cell membrane. Organelles have variously differentiated roles. For example, mitochondria have a function of energy production, catabolic metabolism, cell respiration, etc.; the lysosome carries out digestion of substances inside and outside the cells since it contains many hydrolases therein; the endoplasmic reticulum is a place where biosubstances such as protein and lipid are produced; and the Golgi apparatus carries out transport and secretion of the biosubstances synthesized in endoplasmic reticulum to the outside of the cells.

The main components of each of the plasma membrane of the cells and of the organelle membrane are polar lipids and membrane proteins. Most of the lipids contained in the biomembrane are phospholipids in which phosphatidylcholine (PC) and phosphatidylethanolamine (PE) occupy 60-90% thereof. When the fatty acid composition of the phospholipid in hepatic cells of rat was investigated, palmitic acid was 37% and stearic acid was 32% in the PC of the plasma membrane while, in PE, palmitic acid was 26% and stearic acid was 33%. In the PC and PE of mitochondria, the amount of palmitic acid was 27% in both phospholipids and that of stearic acid was 22% and 27%, respectively. As such, saturated fatty acids such as palmitic acid and stearic acid have been known as important constituent components for the biomembrane.

Silicon is a natural element which is widespread in organisms of the animal and plant kingdoms. In particular, it exists as silicate in animal tissues like hair, feather, bone and skin and is known as an essential element in osteogenesis. In animal tissues, it is involved in cross linkage of collagen tissues and comprises one of the components of acidic mucopolysaccharides. Silicon is thus an essential element for a living body. However, few pharmacological activities of the administration to animals are presently known, for example, immuno-suppressing activity through its anti-macrophage effect and antidiabetic activity. As a medicine, some silicates like magnesium silicate and aluminum silicate are just used as antacids.

The present inventor has previously carried out continued studies taking note of the functions and the pharmacological actions of silicic acid and silicon-containing compounds in vivo. With regard to silicate polymers, a water-soluble silicate polymer manufactured by polymerization of water-soluble silicic acids by a method originated by the present

inventor has been found to have excellent actions whereby any abnormality of the nervous system, endocrine system and immune system caused by cellular dysfunction of the living body occurring in a diseased state is adjusted and repaired whereby biofunction can be normalized.

The above pharmacological activities are not available in the state of a monomer but they have been found to be exhibited by water-soluble silicate polymers. For example, a water-soluble silicic acid polymer and a method for manufacturing the polymer are disclosed in Japanese Patent 2,698,908 and its medical uses as an analgesic agent, anti-allergic agent, paresthesia improving agent, peripheral blood flow improving agent and anti-inflammatory agent are mentioned in Japanese Patents 2,588,109, 2,727,441, 2,727,442, 2,948,784 and 3,113,619, respectively, and corresponding U.S. Pat. Nos. 5,534,509, 5,658,896, and 5,807,951 each to Konishi et al. However, it is desirable to improve the pharmacological activity of the said silicate polymer.

The present inventor has further carried out a study for the above-mentioned water-soluble silicate polymer and, as a result, has found that an increased pharmacological activity of the said silicate polymer can be obtained from a combination of the water-soluble silicate polymer with a saturated fatty acid which is a main constituting component of the cell membrane whereupon the present invention has been achieved.

## SUMMARY OF THE INVENTION

The present invention relates to a pharmaceutical composition which is useful as a medicine such as an anti-allergic agent or an anti-inflammatory agent, wherein a water-soluble silicate polymer and a saturated fatty acid are contained in a pharmaceutically effective amount. The present invention also provides a method for enhancing the activity of a water-soluble silicate polymer by adding a saturated fatty acid to a product containing the water-soluble silicate polymer. The water-soluble silicate polymers employed in the invention may have a molecular weight distribution in the range of about 4,800 to about 2,000,000, preferably about 13,000 to about 1,000,000, which distribution is unimodal and which is determined by gel-filtration, ultrafiltration, electrophoresis and the like. The degree of polymerization of the said silicate polymers may be in the range of about 75 to about 33,000, preferably about 210 to about 16,500, wherein the monomer unit is  $-(SiO_2)-$ .

The saturated fatty acid contained as an effective ingredient in the pharmaceutical compositions of the present invention is a general name for a fatty acid having neither a double bond nor a triple bond in a molecule and is represented by the chemical formula  $C_nH_{2n+1}COOH$ . Preferably, it is a straight chain or branched chain saturated fatty acid having about 8 carbon atoms to about 26 carbon atoms. Such a fatty acid may be used solely or as a mixture of plural fatty acids. The acid may be used either in a free form or as a salt such as a sodium salt and potassium salt and it is preferred to use it in a water-soluble form.

For the purpose of making a pharmaceutical composition of the invention, an aqueous solution containing one or more water-soluble silicate polymers is preferably dried to a powder. The pharmaceutical compositions of the present invention may be formed by a method of adding a solution of the saturated fatty acid to the water soluble silicate polymer to form a solution. By this method, the pharmacological activity of a water soluble silicate polymer or polymers is greatly increased with respect to treatment of allergies and inflammation. The saturated fatty acid and water-