aerosol product. Other drawbacks are e.g. the inherent risk of loss to the surrounding air when using the spray, and the environmentally detrimental need for packaging material in the spray canisters.

From the above it appears that there still is a need for a smoking cessation product that at the same time is capable of releasing free base nicotine in a way that more or less emulates cigarettes, and still is stable against evaporation or degradation of the nicotine.

SUMMARY ~~OF THE INVENTION~~

It is an object of the present ~~invention~~ disclosure to provide a product for nicotine delivery that essentially solves the above-mentioned problems of the prior art nicotine delivery products.

One important object of the present ~~invention~~ disclosure is to provide a nicotine formulation capable of keeping its nicotine content during storage, yet being able to deliver nicotine free base when administered to a human subject.

Thus, according to a first aspect a nicotine containing mucoadhesive film is provided, obtainable by

- preparing an aqueous solution at a pH of from 9.5 to 13, said solution comprising
(i) a nicotine salt,
(ii) an alkaline pH-regulating agent, and
(iii) a film-forming agent comprising an alginate salt of monovalent cation or a mixture of alginate salts of monovalent cations, the film-forming agent having a mean guluronate (G) content of from 50 to 85% by weight, a mean mannuronate (M) content of from 15 to 50% by weight, a mean molecular weight of from 30,000 g/mol to 90,000 g/mol and being such that a 10% aqueous solution thereof at a temperature of 20°C has a viscosity of 100-1000 mPas, as measured at a shear rate of 20 rpm by use of a Brookfield viscometer with a spindle No. 2;

- distributing the solution onto a solid surface; and

- permitting the solution to dry on said surface.

According to another aspect, there is provided a nicotine dosage unit comprising a film as disclosed herein.

According to another aspect, there is provided a method of manufacturing a nicotine-containing mucoadhesive film, comprising:

- preparing an aqueous solution at a pH of from 9.5 to 13, said solution comprising
(i) a nicotine salt,
(ii) an alkaline pH-regulating agent, and
(iii) a film-forming agent comprising an alginate salt of monovalent cation or a mixture of alginate salts of monovalent cations, the film-forming agent having a mean guluronate (G) content of from 50 to 85% by weight, a mean mannuronate (M) content of from 15 to 50% by weight, a mean molecular weight of from 30,000 g/mol to 90,000 g/mol and being such that a 10% aqueous solution thereof at a temperature of 20°C has a viscosity of 100-1000 mPas, as measured at a shear rate of 20 rpm by use of a Brookfield viscometer with a spindle No. 2;

- distributing the solution onto a solid surface; and

- permitting the solution to dry on said surface.

The film of the ~~invention~~ present disclosure is useful for buccal transmucosal delivery of nicotine.

Some advantages of the methods and formulations of the present ~~invention~~ disclosure are that:
- pH buffering systems can be omitted from the formulation of the ~~invention~~present disclosure;
- high systemic uptake of nicotine free base is obtained through the oral mucosa;
- the dry formulation contains only very small amounts of free base nicotine available to reactions induced by air and light, keeping the product stable over time;
and
- nicotine is incorporated in the formulation in the form of water soluble salt, and as such is easy to distribute evenly throughout a solution, thereby providing a homogeneous distribution of nicotine in the formulation.

The nicotine film of the present ~~invention~~ disclosure suitably is a stand-alone, one layer film.

BRIEF DESCRIPTION OF THE DRAWING

FIGURE 1 is a graph showing nicotine concentration (mean +/- SEM), in ng/ml, in blood samples collected from 5 healthy subjects over a 2-hour period after administration of a film