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- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: A PRESERVATIVE AND METHOD FOR PRESERVING CELLS

(57) Abstract: A method for stabilizing a biological material (e.g., blood platelets, cells, etc.) comprising treating a biological material with an amphiphilic agent (e.g., an amphiphilic compound, such as a surfactant, or pluronic or arbutin) to stabilize the biological material. At least one carbohydrate (e.g., trehalose or a trehalose-sucrose mixture) may be combined with the amphiphilic agent for treating the biological material. The treated biological material may be dehydrated. A biological material produced in accordance with the method for treating the biological material.



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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/16586

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A01N 1/00, 1/02, 43/04, 65/00; A61K 31/70, 35/78;
US CL : 424/195.1; 435/1.1, 2; 514/23

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 424/195.1; 435/1.1, 2; 514/23

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
US-PATS, US-PPUBS, CAPLUS, MEDLINE, BIOSIS, WPIDS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,834,254 A (SHEN et al) 10 November 1998 (10.11.1998), column 9, line 4-column 13, line 43.	1-3, 13
X	OLIVER, A.E., et al. The effect of arbutin on membrane integrity during drying is mediated by stabilization of the lamellar phase in the presence of nonbilayer-forming lipids. Chemistry and Physics of Lipids, May 2001, Vol. 111, pages 37-57, especially pages 40-48.	1-4, 13
A	OLIVER, A.E., et al. Non-disaccharide-based mechanisms of protection during drying. Cryobiology, September 2001, Vol. 43, pages 151-167, especially pages 154-156.	1-4, 13
A	OLIVER, A.E., et al. Looking beyond sugars: the role of amphiphilic solutes in preventing adventitious reactions in anhydrobiotes at low water contents. Comparative Biochemistry and Physiology. Part A, March 2002, Vol. 131, pages 515-525, especially pages 519-523.	1-4, 13

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another claim or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"Z" document member of the same patent family

Date of the actual completion of the international search

09 February 2005 (09.02.2005)

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Name and mailing address of the ISA/US

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/16586

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-4 and 13

Remark on Protest ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/16586

BOX III. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

Group I, claim(s) 1-4 and 13, drawn to a stabilized biological material and a process for making it.

Group II, claim(s) 5-12 and 14, drawn to a protected biological material and a process for making it.

Group III, claim(s) 15-25, drawn to a solution comprising an amphiphilic agent and a carbohydrate.

Group IV, claim(s) 26-43, drawn to a loaded biological sample and a process for making it.

An international application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) a product and a process specially adapted for the manufacture of said product; or
- (2) a product and a process of use of said product; or
- (3) a product, a process specially adapted for the manufacture of said product, and a use of said product; or
- (4) a process and an apparatus specifically designed for carrying out said process; or
- (5) a product, a process specially adapted for the manufacture of said product and an apparatus specifically designed for carrying out said process. 37 C.F.R. § 1.475.

Group I falls into category (1), a product and a process specially adapted for the manufacture of said product.

Groups II and IV are drawn to multiple methods of use, which are distinct from that of Group I, because said methods do not share process steps or starting materials and have different functions and endpoints. Group III is drawn to a composition that does not share components with the product of Group I. PCT Rule 13 does not provide for multiple compositions or multiple methods of use within a single application. Thus, the first appearing composition is combined with a corresponding first method of use, and the additional composition and method claims each constitute a separate group.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: They do not relate to a single general inventive concept.

Groups I-IV are not united by a single inventive concept because they do not share any process steps or materials; the methods of Groups I and II require an amphiphilic agent, while the method of Group IV requires an amphiphilic agent and a solute. The composition of Group III comprises both an amphiphilic agent and a carbohydrate, which are not specifically required for the methods of Groups I, II and IV. The methods of Groups I, II and IV do not share any process steps or a common endpoint, so they cannot be seen as being unified by a single inventive concept. While Groups I and II both require an amphiphilic agent, the processes do not share common steps or outcomes.