

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Terwey, Theis                      Confirmation No.: 1023  
 Serial No.: 17/801,389                                      Group No.:  
 Filing or 371(c) Date: August 22, 2022              Examiner:  
 Entitled: Aerosol Comprising 5-Methoxy-N,N-Dimethyltryptamine

**THIRD-PARTY PRE-ISSUANCE SUBMISSION**

Examiner:

The following documents, which are also identified in the Form PTO/SB/429 filed herewith, are submitted for your consideration as being of potential relevance to the examination of the present application:

1. Reddit, "Volcano?", December 18, 2019.  
<https://www.reddit.com/r/5MeODMT/comments/ebxb1h/volcano/>
2. Reddit, "comment on deleted post", January 08, 2020.  
<https://www.reddit.com/r/5MeODMT/comments/elvrpt/comment/fdkizfn/>
3. HAZEKAMP (2006) "Evaluation of a Vaporizing Device (Volcano) for the Pulmonary Administration of Tetrahydrocannabinol" Journal of Pharmaceutical Sciences. Vol. 19(6):1308-1317.
4. Int'l. Pat. App. Pub. No. WO/2003/094900 "Delivery of Drug Amines Through an Inhalation Route" (Published November 20, 2003)
5. Int'l Pat. App. Pub. No. WO/2017/122196 "Personalized Vaporizing Device" (Published July 20, 2017)

Attached hereto is a claim chart providing a concise description of the relevance of each reference in the document list to the elements of the presently pending claims.

U.S.S.N. 17/801,389 Pending Claims	References
<p>1. An aerosol comprising (a) a pharmaceutically acceptable gas; (b) aerosol particles of 5-ethoxy-N,N-dimethyltryptamine (5-MeO-DMT) or a pharmaceutically acceptable salt thereof, wherein the aerosol has an aerosol particle mass density of about 0.5 mg/l to about 12.5 mg/l.</p>	<p><i>From application of interest: Example 1. 5-MeO-DMT Aerosol Generation and Administration</i>  <i>"A 5-MeO-DMT aerosol was generated by volatilization of the drug by way of the Volcano Medic Vaporization System (Storz &amp; Bickel, Germany). The device consists of a hot air generator and a detachable valve balloon from which the aerosol is inhaled by the patient. The hot air generator can generate temperatures adjustable between about 40° C. to about 210° C., with an airflow rate of about 12 liters per minute."</i></p> <p>1. Reddit, "Volcano?", December 18, 2019.  <a href="https://www.reddit.com/r/5MeODMT/comments/ebxb1h/volcano/">https://www.reddit.com/r/5MeODMT/comments/ebxb1h/volcano/</a></p> <p>"First time I smoked <b>5meo</b>, was through a <b>volcano</b>. 20mg of oxalate, filled the whole bag; took it all in three hits."</p>

	<p>2. Reddit, “comment on deleted post”, January 08, 2020.  <a href="https://www.reddit.com/r/5MeODMT/comments/elvrpt/comment/fdkizfn/">https://www.reddit.com/r/5MeODMT/comments/elvrpt/comment/fdkizfn/</a></p> <p>“Are you referring to the actual toad venom, or the synthetic <b>5meo</b>? I have vapourized synthetic 5 (oxalate) in a <b>volcano</b> and it works quite well.”</p> <p>3. HAZEKAMP (2006) “Evaluation of a Vaporizing Device (Volcano) for the Pulmonary Administration of Tetrahydrocannabinol” Journal of Pharmaceutical Sciences. Vol. 19(6):1308-1317.</p> <p>From <b>Page 1316</b> “It is likely that the <b>Volcano</b> also produces an <b>aerosol</b>, that is, droplets of various sizes in a gas phase made up of vapor and air.”</p>
<p>2. The aerosol according to <b>claim 1</b>, wherein the aerosol particle mass density is between about 1.3 g/l and about 10 mg/l.</p>	<p>4. Int’l. Pat. App. Pub. No. WO/2003/094900 “Delivery of Drug Amines Through an Inhalation Route” (Published November 20, 2003)</p> <p>From <b>Page 14</b> “Typically, the delivered aerosol has an <b>inhalable aerosol drug mass density of between 0.1 mg/L and 100 mg/L</b>. Preferably, the aerosol has an inhalable aerosol drag mass density of between 0.1 mg/L and 75 mg/L. More preferably, <b>the aerosol has an inhalable aerosol drug mass density of between 0.1 mg/L and 50 mg/L.</b>”</p>
<p>3. The aerosol according to <b>claim 1</b>, wherein the pharmaceutically acceptable gas is air.</p>	<p>4. Int’l. Pat. App. Pub. No. WO/2003/094900 “Delivery of Drug Amines Through an Inhalation Route” (Published November 20, 2003)</p> <p>From <b>Page 15</b> “A number of gases can be used in the invention, including but not limited to <b>air</b>, nitrogen, argon, and carbon dioxide. The preferred embodiment includes <b>air as a gas.</b>”</p>
<p>4. The aerosol according to <b>claim 1</b>, wherein the fine particle fraction (FPF), determined as the weight percentage of aerosol particles having an aerodynamic diameter of less than or equal to 5 µm, relative to the total of mass of the aerosol particles, is at least 90 wt %</p>	<p>4. Int’l. Pat. App. Pub. No. WO/2003/094900 “Delivery of Drug Amines Through an Inhalation Route” (Published November 20, 2003)</p> <p>From <b>Page 14</b> “Typically, the particles comprise <b>less than 90 percent by weight of water.</b>”</p> <p>From <b>Page 14</b> “Typically, the particles of the delivered condensation aerosol have a <b>mass median aerodynamic diameter of less than 5 microns</b>. Preferably, the particles have a mass median aerodynamic diameter of less than 3 micrometers. More preferably, the particles have a mass median aerodynamic diameter between the range of 1-3 micrometers.</p> <p>From <b>Page 14</b> “Typically, the particles of the delivered condensation aerosol have a mass median aerodynamic diameter of</p>

	greater than 0.01 micrometers. Preferably, the particles have a mass median aerodynamic diameter of greater than 1 micrometers.”
5. The aerosol according to <b>claim 1</b> , wherein the aerosol particles contain less than 1 wt % impurities.	4. Int’l. Pat. App. Pub. No. WO/2003/094900 “Delivery of Drug Amines Through an Inhalation Route” (Published November 20, 2003)  See Example 2, Volatization, Table 1
6. The aerosol according to <b>claim 1</b> , containing less than 0.5 wt % 5-MeO-DMT degradation products resulting from a chemical modification of 5-MeO-DMT as a result of a chemical reaction during aerosol formation.	4. Int’l. Pat. App. Pub. No. WO/2003/094900 “Delivery of Drug Amines Through an Inhalation Route” (Published November 20, 2003)  From <b>Page 13</b> “Typically, the particles comprise less than 10 percent by weight of drag amine degradation products relative to drag amine. Preferably, the particles comprise less than 5 percent by weight of drag amine degradation products relative to drag amine. More preferably, the particles comprise 2.5, 1, <b>0.5, 0.1 or 0.03 percent by weight of drug amine degradation products relative to drag amine.</b> ”
7. The aerosol according to <b>claim 1</b> essentially consisting of (a) air; (b) aerosol particles of 5-MeO-DMT or a pharmaceutically acceptable salt thereof.	1. Reddit, “Volcano?”, December 18, 2019. <a href="https://www.reddit.com/r/5MeODMT/comments/ebxb1h/volcano/">https://www.reddit.com/r/5MeODMT/comments/ebxb1h/volcano/</a>  “First time I smoked <b>5meo</b> , was through a <b>volcano</b> . 20mg of oxalate, filled the whole bag, took it all in three hits.”  2. Reddit, “comment on deleted post”, January 08, 2020. <a href="https://www.reddit.com/r/5MeODMT/comments/elvrpt/comment/fdkizfn/">https://www.reddit.com/r/5MeODMT/comments/elvrpt/comment/fdkizfn/</a>  “Are you referring to the actual toad venom, or the synthetic 5meo? I have vapourized synthetic 5 (oxalate) in a <b>volcano</b> and it works quite well.”  3. HAZEKAMP (2006) “Evaluation of a Vaporizing Device (Volcano) for the Pulmonary Administration of Tetrahydrocannabinol” Journal of Pharmaceutical Sciences. Vol. 19(6):1308-1317.  From <b>Page 1316</b> “It is likely that the <b>Volcano</b> also produces an <b>aerosol</b> , that is, droplets of various sizes in a gas phase made up of <b>vapor and air.</b> ”  4. Int’l. Pat. App. Pub. No. WO/2003/094900 “Delivery of Drug Amines Through an Inhalation Route” (Published November 20, 2003)  From <b>Page 15</b> “A number of gases can be used in the invention, including but not limited to <b>air</b> , nitrogen, argon, and carbon dioxide. The preferred embodiment includes <b>air</b> as a gas.”

<p><b>8.</b> The aerosol according to <b>claim 1</b>, wherein the aerosol particles contain 5-MeO-DMT in the form of the free base.</p>	<p>4. Int'l. Pat. App. Pub. No. WO/2003/094900 "Delivery of Drug Amines Through an Inhalation Route" (Published November 20, 2003)</p> <p>From <b>Page 6</b> "'Drug" refers to <b>any chemical compound</b> that is used in the prevention, diagnosis, treatment, or cure of disease, for the relief of pain, or to control or improve any physiological or pathological disorder in humans or animals."</p>
<p><b>9.</b> The aerosol according to <b>claim 1</b>, wherein the aerosol has a mass median aerodynamic diameter of less than 3 micron and more than 0.1 micron.</p>	<p>4. Int'l. Pat. App. Pub. No. WO/2003/094900 "Delivery of Drug Amines Through an Inhalation Route" (Published November 20, 2003)</p> <p>From <b>Page 14</b> "'Typically, the particles of the delivered condensation aerosol have a <b>mass median aerodynamic diameter of less than 5 microns</b>. Preferably, the particles have a mass median aerodynamic diameter of <b>less than 3 micrometers</b>. <b>More preferably, the particles have a mass median aerodynamic diameter between the range of 1-3 micrometers</b>."</p> <p>From <b>Page 14</b> "Typically, the particles of the delivered condensation aerosol have a <b>mass median aerodynamic diameter of greater than 0.01 micrometers</b>. Preferably, the particles have a mass median aerodynamic diameter of greater than 1 micrometers."</p>
<p><b>10.</b> The aerosol according to <b>claim 1</b>, wherein the aerosol is formed by a) exposing a thin layer of 5-MeO-DMT or a pharmaceutically acceptable salt thereof, configured on a solid support, to thermal energy, and b) passing air over the thin layer of 5-MeO-DMT to produce aerosol particles.</p>	<p>4. Int'l. Pat. App. Pub. No. WO/2003/094900 "Delivery of Drug Amines Through an Inhalation Route" (Published November 20, 2003)</p> <p>"From <b>Page 25</b> "The substrate, consisting of a hollow stainless steel cylinder with thin walls, typically having a wall thickness of 0.12 mm, diameter 13 mm, and length 36 mm and conducive to resistance heating, was dip-coated with an amine drag salt coating solution (prepared as disclosed in Example 1) typically using a computerized dip-coating machine to produce a <b>thin layer of drug</b> on the outside of the substrate surface."</p> <p>5. Int'l Pat. App. Pub. No. WO/2017/122196 "Personalized Vaporizing Device" (Published July 202, 2017)</p> <p>From <b>Page 32</b> "In some embodiments, the source material includes a <b>support structure</b> (not shown). Optionally, the support structure is <b>air permeable</b>"</p>
<p><b>11.</b> The aerosol according to <b>claim 10</b>, where the thin layer has a thickness of less than about 10 μm, wherein the thickness is calculated based on the amount 5-MeO-DMT</p>	<p>5. Int'l Pat. App. Pub. No. WO/2017/122196 "Personalized Vaporizing Device" (Published July 202, 2017)</p> <p>From <b>Page 2</b> "In some embodiments, a layer of source material contained within each section is <b>no more than 1 mm thick</b>, no more than 0.5 mm thick, no more than 2 mm thick, no more than 5</p>

<p>or the pharmaceutically acceptable salt thereof and the surface area of the support.</p>	<p>mm thick or intermediate, higher or lower thicknesses. For example the layer may be between 0.5-5 mm, or between 0.5-2 mm, or between 0.5-1.5 mm along the path of airflow through the material.”</p>
<p><b>12.</b> The aerosol according to <b>claim 11</b>, wherein the thin layer has a thickness in the range of 0.1 µm to 10 µm.</p>	<p>5. Int’l Pat. App. Pub. No. WO/2017/122196 “Personalized Vaporizing Device” (Published July 202, 2017)</p> <p>From <b>Page 2</b> “In some embodiments, a layer of source material contained within each section <b>is no more than 1 mm thick</b>, no more than 0.5 mm thick, no more than 2 mm thick, no more than 5 mm thick or intermediate, higher or lower thicknesses. For example the layer may be between 0.5-5 mm, or between 0.5-2 mm, or between 0.5-1.5 mm along the path of airflow through the material.”</p>
<p><b>13.</b> The aerosol according to <b>claim 10</b>, wherein the thin layer of 5-MeO-DMT, configured on a solid support, is exposed to thermal energy via the air passing over the thin layer.</p>	<p>4. Int’l. Pat. App. Pub. No. WO/2003/094900 “Delivery of Drug Amines Through an Inhalation Route” (Published November 20, 2003)</p> <p>From <b>Page 30</b> “In some embodiments, the <b>air flows</b> from lumen 1008 in a radially inward direction through the outer foil, <b>through a section of the source material currently being heated</b>, through the inner foil, and into cannula 1012 from which it continues towards mouthpiece 1022 positioned at proximal end 1014 of the device. Airflow entering mouthpiece 1022 comprises the at least one active substance, for example in the form of vapors extracted from the heated section of the source material. “</p>
<p><b>14.</b> The aerosol according to <b>claim 10</b>, wherein the thin layer of 5-MeO-DMT, configured on a solid support, is exposed to thermal energy via the solid support.</p>	<p>4. Int’l. Pat. App. Pub. No. WO/2003/094900 “Delivery of Drug Amines Through an Inhalation Route” (Published November 20, 2003)</p> <p>From <b>Page 31</b> “In some embodiments, the source material includes a support structure (not shown). Optionally, the support structure is air permeable. Optionally, the support structure is heat resistant. In some embodiments, the movable heating element is configured to attach to the support structure. In some embodiments, the movable heating element is configured as a part of and/or comprises an airflow element, for example as further described herein, directing airflow 304 through the heated active substance section.”</p>
<p><b>15.</b> The aerosol according to <b>claim 14</b>, where the air passing over the thin layer has a temperature in the range of about 180° C. to about 240° C.</p>	<p>4. Int’l. Pat. App. Pub. No. WO/2003/094900 “Delivery of Drug Amines Through an Inhalation Route” (Published November 20, 2003)</p> <p>From <b>Page 4</b> “These thermal vapors typically further contain a supersaturated amine drug vapor. Preferably such vapor is warmer than ambient temperature, and more preferably such vapor is warmer than 100°C, 200°C, 250°C, or 300°C.”</p>
<p><b>16.</b> The aerosol according to <b>claim 15</b>, where the air</p>	<p><i>From application of interest: Example 1. 5-MeO-DMT Aerosol Generation and Administration</i></p>

<p>passing over the thin layer has a temperature of about 210° C. and passes over the thin layer at a rate of about 12 l/min for a duration of about 15 seconds.</p>	<p><i>“A 5-MeO-DMT aerosol was generated by volatilization of the drug by way of the Volcano Medic Vaporization System (Storz &amp; Bickel, Germany). The device consists of a hot air generator and a detachable valve balloon from which the aerosol is inhaled by the patient. The hot air generator can generate temperatures adjustable between about 40° C. to about 210° C., with an airflow rate of about 12 liters per minute.”</i></p> <p>1. Reddit, “Volcano?”, December 18, 2019.  <a href="https://www.reddit.com/r/5MeODMT/comments/ebxb1h/volcano/">https://www.reddit.com/r/5MeODMT/comments/ebxb1h/volcano/</a></p> <p>“First time I smoked <b>5meo</b>, was through a <b>volcano</b>. 20mg of oxalate, filled the whole bag, took it all in three hits.”</p> <p>Reddit, “comment on deleted post”, January 08, 2020.  <a href="https://www.reddit.com/r/5MeODMT/comments/elvrpt/comment/fdkizfn/">https://www.reddit.com/r/5MeODMT/comments/elvrpt/comment/fdkizfn/</a></p> <p>“Are you referring to the actual toad venom, or the synthetic 5meo? I have vapourized synthetic 5 (oxalate) in a <b>volcano</b> and it works quite well.”</p>
<p>17. The aerosol according to <b>claim 1</b> wherein said aerosol particles are contained in a volume of equal or less than about 3 liters.</p>	<p><i>From application of interest: Example 1. 5-MeO-DMT Aerosol Generation and Administration</i></p> <p><i>“A 5-MeO-DMT aerosol was generated by volatilization of the drug by way of the Volcano Medic Vaporization System (Storz &amp; Bickel, Germany). The device consists of a hot air generator and a detachable valve balloon from which the aerosol is inhaled by the patient. The hot air generator can generate temperatures adjustable between about 40° C. to about 210° C., with an airflow rate of about 12 liters per minute.”</i></p> <p>1. Reddit, “Volcano?”, December 18, 2019.  <a href="https://www.reddit.com/r/5MeODMT/comments/ebxb1h/volcano/">https://www.reddit.com/r/5MeODMT/comments/ebxb1h/volcano/</a></p> <p>“First time I smoked <b>5meo</b>, was through a <b>volcano</b>. 20mg of oxalate, filled the whole bag, took it all in three hits.”</p> <p>2. Reddit, “comment on deleted post”, January 08, 2020.  <a href="https://www.reddit.com/r/5MeODMT/comments/elvrpt/comment/fdkizfn/">https://www.reddit.com/r/5MeODMT/comments/elvrpt/comment/fdkizfn/</a></p> <p>“Are you referring to the actual toad venom, or the synthetic 5meo? I have vapourized synthetic 5 (oxalate) in a <b>volcano</b> and it works quite well.”</p>

<p><b>18.</b> The aerosol according to <b>claim 1</b> for use in therapy.</p>	<p>4. Int'l. Pat. App. Pub. No. WO/2003/094900 "Delivery of Drug Amines Through an Inhalation Route" (Published November 20, 2003)</p> <p>"The present invention relates to the delivery of drug amines through an inhalation route. Specifically, it relates to aerosols containing drug amines that are used in inhalation therapy."</p>
<p><b>19.</b> The aerosol according to <b>claim 18</b>, wherein said aerosol is delivered to a patient via a single inhalation.</p>	<p>4. Int'l. Pat. App. Pub. No. WO/2003/094900 "Delivery of Drug Amines Through an Inhalation Route" (Published November 20, 2003)</p> <p>"Optionally, the heating element is sized to contact a portion of the source material comprising an amount of active substance which when vaporized provides a <b>single predetermined dose</b>."</p>

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	48154724
<b>Application Number:</b>	17801389
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	1023
<b>Title of Invention:</b>	AEROSOL COMPRISING 5-METHOXY-N,N-DIMETHYLTRYPTAMINE
<b>First Named Inventor/Applicant Name:</b>	Theis TERWEY
<b>Customer Number:</b>	125155
<b>Filer:</b>	Taylor Kurtzweil
<b>Filer Authorized By:</b>	
<b>Attorney Docket Number:</b>	P66767
<b>Receipt Date:</b>	14-JUN-2023
<b>Filing Date:</b>	22-AUG-2022
<b>Time Stamp:</b>	18:40:26
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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Concise Description of Relevance	Concise-description-generated.pdf	39178	no	5
			5473c194c8a40d4991fab39331d39914f8e12f0a		

**Warnings:**

**Information:**

2	Third-Party Submission Under 37 CFR 1.290	Third-party-preissuance-submission.pdf	62115	no	3
			bb8908a641e5c8cd55c7ad06aee8b2f042277b9d		

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3	Request for Notification of Non-compliant Third-Party Submission	Third-party-notification-request.pdf	23740	no	1
			818adf3a344b2ccb56cfe7d6a788f1b3f215559e		

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4	Concise Description of Relevance	US20230075124_Claims_Chart.pdf	173222	no	7
			ecaadca0dc4a94e000a6de32a086d601ffad8587		

**Warnings:**

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5	Evidence of Publication	Hazekamp2006.pdf	214691	no	10
			eb4cf7054753bf6ff9b95b6c3bb9c020eb1fa7b6		

**Warnings:**

**Information:**

6	Evidence of Publication	WO2003094900.pdf	2263673	no	43
			ba5f4f99fbc81a7861d49024fbb92a907a81337		

**Warnings:**

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7	Evidence of Publication	WO2017122196.pdf	6577484	no	121
			4b451dba84d8811592dd90762a42fb251783cc10		

**Warnings:**

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8	Evidence of Publication	1RedditVolcano.pdf	210937	no	1
			fe4243fb8a8a0d5b99f22be0042ab6f6258002a2		

**Warnings:**

**Information:**

9	Evidence of Publication	2RedditComment.pdf	163138	no	1
			91f837cee37a2352b60c9b76fcf113e33e41d8f6		

**Warnings:**

**Information:**

10	Fee Worksheet (SB06)	fee-info.pdf	37831	no	2
			99f65f7f78200d9ce43d544e9fd5a0d8e5013155		

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**New Applications Under 35 U.S.C. 111**

**If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.**

**National Stage of an International Application under 35 U.S.C. 371**

**If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.**

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