

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau

(43) International Publication Date
24 February 2022 (24.02.2022)



(10) International Publication Number
WO 2022/040644 A2

(51) International Patent Classification:
A61K 31/19 (2006.01)

(21) International Application Number:
PCT/US2021/050302

(22) International Filing Date:
14 September 2021 (14.09.2021)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
16/996,509 18 August 2020 (18.08.2020) US
17/210,646 24 March 2021 (24.03.2021) US

(71) Applicant: **AXCESS GLOBAL SCIENCES, LLC**
[US/US]; 2157 Lincoln Street, Salt Lake City, Utah 84106
(US).

(72) Inventor: **MILLET, Gary**; 7810 South Prospector Drive,
Salt Lake City, Utah 84121 (US).

(74) Agent: **GUYNN, John, M.**; Workman Nydegger, 60 East
South Temple, Suite 1000, Salt Lake City, Utah 84111 (US).

(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ,
CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO,
DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN,
HR, HU, ID, IL, IN, IR, IS, IT, JO, JP, KE, KG, KH, KN,
KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD,
ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO,
NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW,
SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN,
TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ,
UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,
TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK,
EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,
MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
KM, ML, MR, NE, SN, TD, TG).

(54) Title: BETA-HYDROXYBUTYRIC ACID COMPOSITIONS AND METHODS FOR ORAL DELIVERY OF KETONE BODIES

(57) Abstract: Beta-hydroxybutyric acid compositions for oral delivery are substantially free of beta-hydroxybutyrate salts and are effective in rapidly raising blood ketone levels without causing acute acidosis or gastrointestinal (GI) distress when consumed in sufficiently dilute form and/or as a gel or suspension. By excluding beta-hydroxybutyrate salts (e.g., less than 1% by weight) containing alkali or alkaline earth metal ions, beta-hydroxybutyric acid solutions, gels, or suspensions can deliver exogenous ketone bodies without significantly altering electrolyte balance. Although aqueous beta-hydroxybutyric acid solutions are moderately acidic with a pH of about 3.5 to 4, when diluted with sufficient water, the water acts as a pseudo buffering agent that offsets otherwise harsh acidic effects when consumed orally. Gels and suspensions can also ameliorate acidic effects by partially encapsulating the beta-hydroxybutyric acid. Beta-hydroxybutyric acid can be enriched with the R- or the S-enantiomer, a racemic mixture, pure R-beta-hydroxybutyric acid, or pure S-beta-hydroxybutyric acid.



WO 2022/040644 A2