



AIBMR Life Sciences, Inc.
Natural and Medicinal Products Research

GRAS Dossier:

**The Independent Conclusion that the
Intended Use of Dynamine® Is Generally
Recognized as Safe (GRAS)**

Independent Conclusion of GRAS Status By:

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Prepared by:

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July 1, 2019



A. Expert Evaluation

Compound Solutions, Inc., the proponent of this GRAS conclusion, engaged AIBMR Life Sciences, Inc. to convene a panel of experts ("GRAS Panel") who are qualified by training and experience to evaluate the safety of food ingredients for the purpose of evaluating whether the available scientific data, information, and methods establish that Dynamine® (methylliberine) is safe under its intended conditions of use in food. The GRAS panel report is attached as Exhibit 1. The appendices to the GRAS panel report are included in the GRAS dossier as Exhibit 2.

B. Responsible Individual and Principal Address

Matthew Titlow
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C. Name of the Substance

Methylliberine (InChI Key: ZVQXCXPGLSBNCX-UHFFFAOYSA-N; CAS RN: 51168-26-4; IUPAC Name: 2-methoxy-1,7,9-trimethylpurine-6,8-dione)

Tradename: Dynamine®

D. Intended Conditions of Use

Dynamine® is intended to be used as an ingredient to replace caffeine in energy drinks and energy drink concentrates and powders (to be reconstituted for consumption) at addition levels up to 150 ppm as prepared for consumption (i.e., as ready-to-serve). Dynamine® is not intended for use in foods where standards of identity would preclude such use, infant formula, or any products that would require additional regulatory review by USDA.

E. Basis for GRAS Conclusion

The general availability and general acceptance, throughout the scientific community of qualified experts, of the data and information that establish the safety



of Dynamine® under its intended conditions of use establish the general recognition of this data and information. Together, the establishment of safety based on scientific procedures and its general recognition form the basis for Compound Solution Inc.'s conclusion of GRAS status of Dynamine® for its intended use.

E.i Statutory Basis

The conclusion of GRAS status of Dynamine® for its intended conditions of use has been made based on scientific procedures as detailed in the report of the GRAS Panel (Exhibit 2).

E.ii General Recognition

The scientific data, information, and methods evaluated by the GRAS Panel, that provide the basis of this GRAS conclusion by scientific procedures are published and available in the public domain. Part 7 of the GRAS Panel Report contains the citations for the published studies. These publicly available data and information fulfill the requirement of the GRAS standard for general availability of the scientific data, information, and methods relied on to establish the safety of Dynamine® for its intended conditions of use. The peer-review of the published studies and lack of Letters to the Editor or other dissenting opinions, together with the opinion of the GRAS Panel convened to evaluate the aforementioned data, provide ample evidence of general recognition among qualified experts that there is reasonable certainty that consumption of Dynamine® for its intended use is not harmful. The general availability and acceptance of these scientific data, information, and methods satisfy the criterion of the GRAS standard that general recognition of safety requires common knowledge throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food that there is reasonable certainty that the substance is not harmful under the conditions of its intended use.

F. Not Subject to Premarket approval

The conclusion of GRAS status of Dynamine® for its intended conditions of use excludes such use from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act.



G. Independent Conclusion of GRAS Status

Compound Solutions, Inc. has considered the view of the GRAS Panel and all factors pertaining to eligibility criteria and has concluded that Dynamine® is Generally Recognized as Safe (GRAS) for its intended use, consistent with section 201(s) of the Federal Food, Drug and Cosmetic Act. Compound Solutions, Inc. hereby certifies that, to the best of our knowledge, this independent conclusion of GRAS status is a complete, representative, and balanced evaluation of safety that includes unfavorable information, as well as favorable information, known to us and pertinent to the evaluation of the safety and GRAS status of the use of Dynamine®.

Matthew Titlow
Chief Executive Officer
Compound Solutions, Inc.

July 1, 2019

Date