

PLUESS-STAUFER (CALIFORNIA) INC.



P. O. BOX 825, LUCERNE VALLEY, CA 92356

TEL. (714) 248-7306

TLX WU 676 344

May 4, 81

Petitions Control Branch
Food & Drug Administration
Department of Health, Education, and Welfare
Washington, D.C. 20204, 200 C Street, S.W.

Attn.: Mr. John Thomas, Regulatory Guidance

YOUR REF.

OUR REF.

LUCERNE VALLEY

Petition re OMYALENE
Extender for plastic material

Addendum to Food Additive
Petition No. 1B3565

Dear Sirs:

The undersigned, Norman B. Collett, submits this petition pursuant to section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act with respect to OMYALENE to be used as a polymer resin extender.

Attached hereto, in triplicate, and constituting a part of this petition, is the information as requested in Code of Federal Regulations, Title 21, Part 171, Sec. 171.1 and .6

Yours very truly,

Petitioner : Pluess-Staufer (California) Inc.

by Norman B. Collett, Product Development

Enclosures A, B, C, D, E, and H

- Please treat the contents of this petition confidential -

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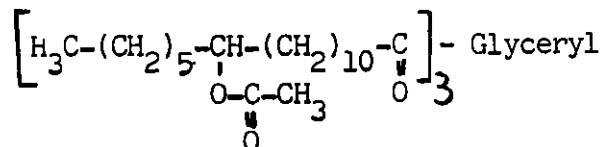
to A:

The name of the product is OMYALENE.

It consists of surface treated Calcium Carbonate to be used as extender and reinforcing agent in thermoplastic materials: films, containers, bottles, mouldings, etc.

A specification sheet for OMYALENE is given in exhibit 1.

The treatment agent of the CaCO_3 consists of glyceryl tri-acetoxy stearate in the amount of 1%:



The identity of the treatment agent has been established by analysis performed by F.J.Weck Co., Contract Research, City of Industry, CA. (exhibit 2) and of the active ingredient as such submitted as an oil under the name "Code 08 Beta", analyzed by the same company.

The surface treatment strengthens the bond between the calcium carbonate and polymer to which it is added, resulting in a packaging material with improved physical properties. The surface treated CaCO_3 is suitable for use in a wide variety of plastics, i.e., PE, HDPE, PP, Polyester, PVC, Nylon, ABS, SAN, Polystyrene, etc.

In general it is advantageous to incorporate 10% to 50% of OMYALENE, depending on the use.

Thus far the calcium carbonate is produced in our own plants and surface treated with the castor oil derivative which is prepared by [REDACTED]

[REDACTED] Oral toxicity tests have shown that neither the OMYALENE nor the treatment agent "Code 08 Beta" are toxic. Omyalene treatment agent will be synthesized and quality monitored by our company.

There are no known shelf life limitations. As this material is incorporated into thermoplastics, it is expected to have excellent stability.



OMYA, INC.

11 Main Street
 Proctor, Vermont 05765
 (802) 459-3311
 TLX 954628 OMYA PRTR

OMYALENE

Omyalene is an ultrafine ground limestone with a special surface treatment.

Omyalene is recommended for polyolefins, including injection molded PP and HDPE, extruded and blow molded HDPE and LDPE film and sheeting, and polyester applications.

Properties of Omyalene

Typical Physical Characteristics

Dry Brightness Elrepho Green Filter	95
DOP-PASTE Brightness Blue Filter	54
*Specific Gravity	2.7
*pH of 10% Slurry	9
Oil Absorption g Of Oil/100 g Pigment (rub-out method, ASTM D 281-31)	16
DOP Absorption g Of DOP/100 g Pigment (rub-out method, ASTM D 281-31)	26

*Moisture Loss At 110° C (%)	less than 0.2
Apparent Bulk Density g/cc	
Loose Bulk Density	0.77
Packed Bulk Density	1.00
*Top Cut	10 Microns
*Mean Particle Size	3 Microns

Particle Size Distribution

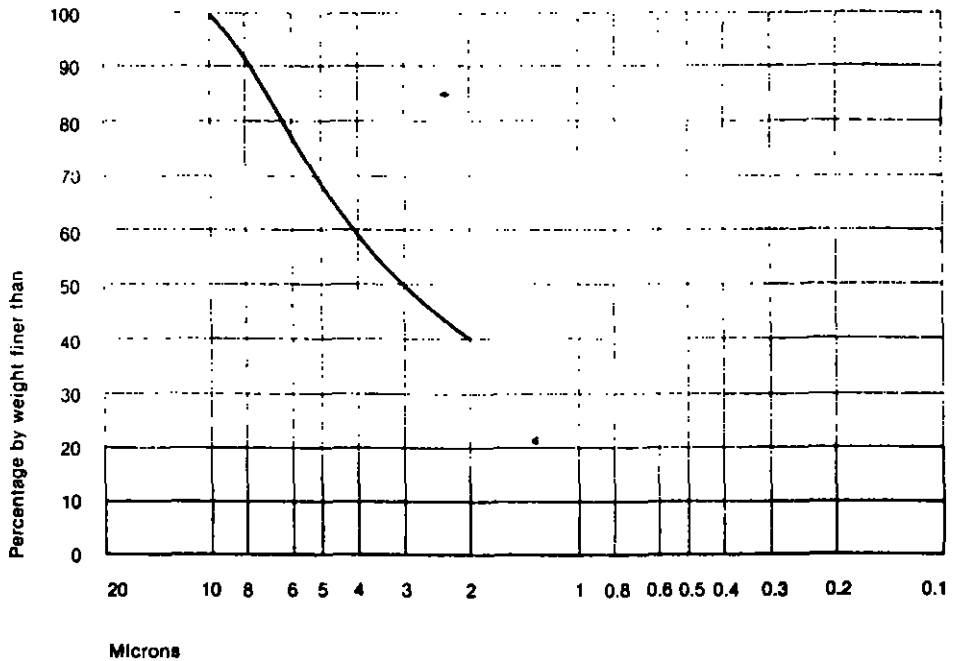
% Minus 2 Microns	40
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Typical Chemical Analysis

CaCO ₃ (%)	99
MgCO ₃ (%)	0.5

*Measured on untreated material

Typical particle size distribution curve



A PLUSS-STALFER COMPANY

Other than a representation that the products sold by Company will, on the average, meet the criteria set forth above, Company makes no warranty, guarantee or representation of any kind, express or implied, and makes no warranty as to merchantability and fitness for a particular purpose. Company disclaims any liability arising from use of the products which may infringe upon patents applied for, pending or existing.



to Food Additive Petition No. 1B3565

Exhibit 2

Friedrich J. Weck Company

Contract Research

ANALYTICAL SERVICES
PRODUCT & PROCESS DEVELOPMENT
CUSTOM SYNTHESIS
CONSULTING
STATE OF CALIFORNIA
APPROVED WATER LABORATORY

R & D LABORATORY 14859 E. CLARK AVE., INDUSTRY, CALIF. 91746 • PHONE: (213) 336-2139

CLIENT PLUESS-STAUFER (CALIFORNIA), INC.
P.O.Box 825
Lucerne Valley, CA 92356

DATE April 24, 81

RECEIVED March 24, 81

SAMPLE of OMYALENE Beta- extender

LABORATORY NO.

810325-OMYALENE

INVESTIGATION Composition

REPORT

Preliminary evaluation:

Appearance: soft, whitish powder; hydrophobic.
Odor: slight varnish odor
Pyrolysis in test tube: decomposition only at high heat with odor of over-heated cooking oil.
Treatment with HCl: gas development; powder dissolves on agitation; forms oily layer on aq. HCl solution; some floating acid and hexane insoluble dark colored particles.

Quantitative evaluation:

500 g OMYALENE extender was dissolved in conc. HCl in presence of a small amount of water, diluted with water and then extracted with hexane. The extract was washed with water, dried over Na_2SO_4 , and evaporated.

The residue (4.5 g oil, incomplete recovery) was evaluated by IR; compared with varnish, vegetable oil, cotton-seed oil, and castor oil. It appeared closest to castor oil despite the fact that most of the strong OH-bands at 3400 cm^{-1} did not show.

Another sample of 20 g was extracted as such with hexane in a Soxhlet for - hours with the objective to see if the HCl had caused changes in the extract. The IR curve of this extract was very similar to the first one, although recovery was incomplete.

Insoluble residue of the 500 g HCl treated sample: Blackish particles,
0.585 g = 0.12%

Ignition residue of above: 53.3%

HNO₃/HCl soluble part of residue consists of Fe, Na, K, Ca;
no Cr, Cd, or Pb found.

Glyceride characterization of Hexane extraction residue:

Saponification number 287 .. (average of 2)
(Koetstorffer)

Iodine absorption number: 4.7 (average of 2)
(Hanus)

Conclusion :

The extracted oil is a modified triglyceride with unusually high saponification - and low iodine number . The IR curves of the extract and the Code 08 Beta Oil were compared and found to be identical. Thus it is concluded that the treatment agent of OMYALENE consists of Code 08 Beta material = glyceryl tri-acetoxy stearate.

F. J. Weck

F. J. Weck