

LAW OFFICES
KELLER AND HECKMAN LLP

1001 G STREET, N.W.
SUITE 500 WEST
WASHINGTON, D.C. 20001
TELEPHONE (202) 434-4100
FACSIMILE (202) 434-4646

—
25 RUE BLANCHE
B-1060 BRUSSELS
TELEPHONE 32(2) 541 05 70
FACSIMILE 32(2) 541 05 80

—
WWW.KHLAW.COM

JOSEPH E. KELLER (1907-1994)
JEROME H. HECKMAN
WILLIAM H. BORGHESE, JR.
MALCOLM D. MACARTHUR
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FRANK J. VITOLO*

*NOT ADMITTED IN D.C.
**RESIDENT BRUSSELS

SCIENTIFIC STAFF
DANIEL S. DIXLER, Ph. D.
CHARLES V. BREDER, Ph. D.
ROBERT A. MATHEWS, Ph. D., D.A.B.T.
JOHN P. MODDERMAN, Ph. D.
(1944-1998)
HOLLY HUTMIRE FOLEY
JANETTE HOUK, Ph. D.
LESTER BORODINSKY, Ph. D.
THOMAS C. BROWN
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ANDREW P. JOVANOVIĆ, Ph. D.
ANNA GERGELY, Ph. D.
STEFANIE M. CORBITT
JUSTIN J. FREDERICO, Ph. D.
RACHEL F. JOYNER
ELIZABETH A. HEGER
TELECOMMUNICATIONS
ENGINEER
RANDALL D. YOUNG

WRITER'S DIRECT ACCESS

(202) 434-4120

Simmons@khlaw.com

June 11, 1999

Via Messenger

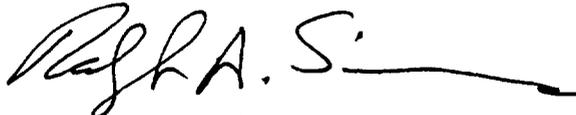
Ms. Maribeth LaVecchia
Division of Petition Control (HFS-215)
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Re: FAP No. 9A4655; Environmental Assessment;
Our File No. HE03743

Dear Ms. LaVecchia:

Following up on your recent telephone conversation with David Joy of our office, enclosed please find the abbreviated Environmental Assessment we have prepared as a supplement to the above-referenced Food Additive Petition. Please do not hesitate to contact us if you have any questions regarding the Environmental Assessment or any other aspect of the Petition.

Sincerely yours,


Ralph A. Simmons

cc: Gary L. MacCallister

99F-2533

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Environmental Assessment
Food Additive Petition No. 9A4655
Technical Amendment to 21 C.F.R. § 172.615

1. **Date:** This environmental Assessment was prepared on June 1, 1999.

2. **Name of Petitioner:** Hercules Inc.

3. **Address:** Hercules Plaza
1313 Market Street
Wilmington, Delaware 19894

All communications related to the Petition are to be sent in care of Counsel for Petitioner, Ralph A. Simmons, Keller and Heckman, LLP, 1001 G Street, N.W., Washington, D.C. 20001

4. Description of the Proposed Action

a. Requested Approval

Food Additive Petition No. 9A4655 seeks to amend the softening point specifications for several of the gum rosin derivatives currently cleared for use in chewing gum base under 21 C.F.R. § 172.615.

b. Need for Action

The current softening point specifications, particularly the upper limits, do not accommodate rosin and rosin derivatives obtained from new geographic sources such as China.

c. Locations of Use

The rosin derivatives will be used at industrial sites where chewing gum and chewing gum base are manufactured. This Petition seeks no change in use and will have no effect on current patterns of use for the rosin derivatives or chewing gum base. There will be little or no introduction of the rosin derivatives into the environment as a result of their use because they are almost completely incorporated into chewing gum and remain with the chewing gum until disposal, usually as part of municipal solid waste.

d. Location of Disposal

Disposal of chewing gum is expected to occur nationwide with the gum usually being deposited in municipal solid waste landfills or combusted.

5. Identification of Substances that are the subject of the proposed action

The action requested in this Petition affects the following six rosin derivatives currently listed in Section 172.615:

glycerol ester of partially dimerized rosin
glycerol ester of partially hydrogenated gum or wood rosin
glycerol ester of polymerized rosin
glycerol ester of gum rosin
pentaerythritol ester of partially hydrogenated gum or wood rosin
pentaerythritol ester of gum or wood rosin

a. Formal chemical names

The chemical names provided above are generally used and understood and currently appear in Section 172.615. We note for the sake of clarity that in practice the term "polymerized rosin" appears to be synonymous with the term "dimerized rosin." This is because the rosin acids do not form groups of more than two repeating units.

b. Common names, synonyms and trade names.

The Hercules trade name Ester Gum is generally associated with this family of rosin derivatives. The trade name is used in combination with various suffixes to designate the different members of the family, e.g., Ester Gum 8BG, Ester Gum 10D, Ester Gum LD, etc.

c. Chemical Abstracts Service (CAS) Registry Number

Petitioner has identified only the following CAS Registry Numbers that correspond to the rosin derivatives that are the subject of this Petition.

CAS Number	CAS Name
68475-37-6	Resin acids and Rosin acids, polymd., esters with glycerol (glycerol ester of polymerized rosin)

65997-13-9	Resin acids and rosin acids, hydrogenated, esters with glycerol (glycerol ester of hydrogenated rosin)
8050-26-8	Resin acids and rosin acids, esters with pentaerythritol
64345-17-9	Resin acids and rosin acids, hydrogenated, esters with pentaerythritol
8050-31-5	Resin acids and rosin acids, esters with glycerol (glycerol ester of rosin)

In each of these cases, the source of the rosin (wood, gum, or tall oil) is not specified by CAS.

d. Chemical Formula

Because they are derived from a naturally occurring source material that is primarily a mixture of rosin acids, the rosin derivatives cannot be easily defined by a single chemical formula. A full description of rosin chemistry may be found in the book: Naval Stores, Production, Chemistry and Utilization, Duane F. Zinkel and James Russell, Editors, published by the Pulp Chemicals Association, New York, New York, 1989.

6. Environmental Impact of the Proposed Action

a. Environmental Impact as a Result of Manufacture

No extraordinary circumstances apply to the manufacture of the food additives that are the subject of this Petition.

b. Environmental Impact as a Result of Use

The action requested in this Petition will result in little or no introduction of rosin derivatives into the environment because the food additive is almost completely incorporated into chewing gum and remains with the gum until it is disposed of. Moreover, the action requested in this Petition seeks no change in use and is merely an amendment to the softening point specifications for the rosin esters already cleared for use in chewing gum base under section 172.615. This amendment to the regulation is not expected to affect the demand for rosin esters within the chewing gum industry and will therefore not affect the use of rosin esters in chewing gum or the environmental impact thereof.

c. Environmental Impact as a Result of Disposal

The proposed amendment is intended to permit gum rosins originating from new geographical sources, such as China, which may contain a lower level of neutral components and have a higher softening point. These new rosins are expected to compete with and replace similar rosin derivatives that differ only with respect to the amounts of acid and neutral components present. Rosin consists primarily of C₂₀ monocarboxylic diterpene resin acids. Gum rosin originating in the United States and China contains the following resin acids in the following typical proportions.

Common Name	CAS Registry Number	Typical % in acid fraction of U.S. gum rosin	Typical % in acid fraction of Chinese gum rosin
Abietic Acid	514-10-3	22	44
Levopimaric acid and Palustric acid	79-54-9		
	1945-53-5	25	22
Neoabietic acid	471-77-2	20	15
Dehydroabietic acid	1740-19-8	5.7	4.3
Isopimaric acid	5835-26-7	17	1.5
Sandaracopimaric acid	471-74-9	1.8	2.7
Pimaric acid	127-27-5	5.1	9.2
Communic acid	1231-35-2	2.8	0

This information is taken from the book: Naval Stores, Production, Chemistry and Utilization, Duane F. Zinkel and James Russell, Editors, published by the Pulp Chemicals Association, New York, New York, 1989, page 277.

Consequently, there will be no measurable change in the amounts of substances entering the environment and the proposed action is not expected to threaten a violation of applicable laws and regulations governing disposal, e.g., the Environmental Protection Agency's regulations in 40 C.F.R. Parts 60 (combustion) and 258 (landfilling).

7. Mitigation Measures

No adverse environmental effects have been identified as likely to result from the action requested in this Petition. Hence, no alternatives or mitigation measures have been considered.

8. Alternatives to the Proposed Action

Again, no adverse environmental effects have been identified as likely to result from the action requested in this Petition. Hence, no alternatives or mitigation measures have been considered. The action requested in this Petition is not expected to affect the demand for the subject rosin esters within the chewing gum industry.

9. List of Preparers

1. David R. Joy, attorney, Keller and Heckman LLP, 1001 G Street, N.W., Washington, D.C. 20009.
2. Gary L. McCallister, Corporate Manager, Regulatory Affairs & Toxicology, Hercules Inc., Hercules Plaza, 1313 Market Street, Wilmington, Delaware 19894.

10. Certification

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Hercules Inc.

June 8, 1999
(Date)

(Signature of Responsible Official)



Gary L. McCallister
Corporate Manager,
Regulatory Affairs & Toxicology