



Environmental Assessment in support of FCN 142

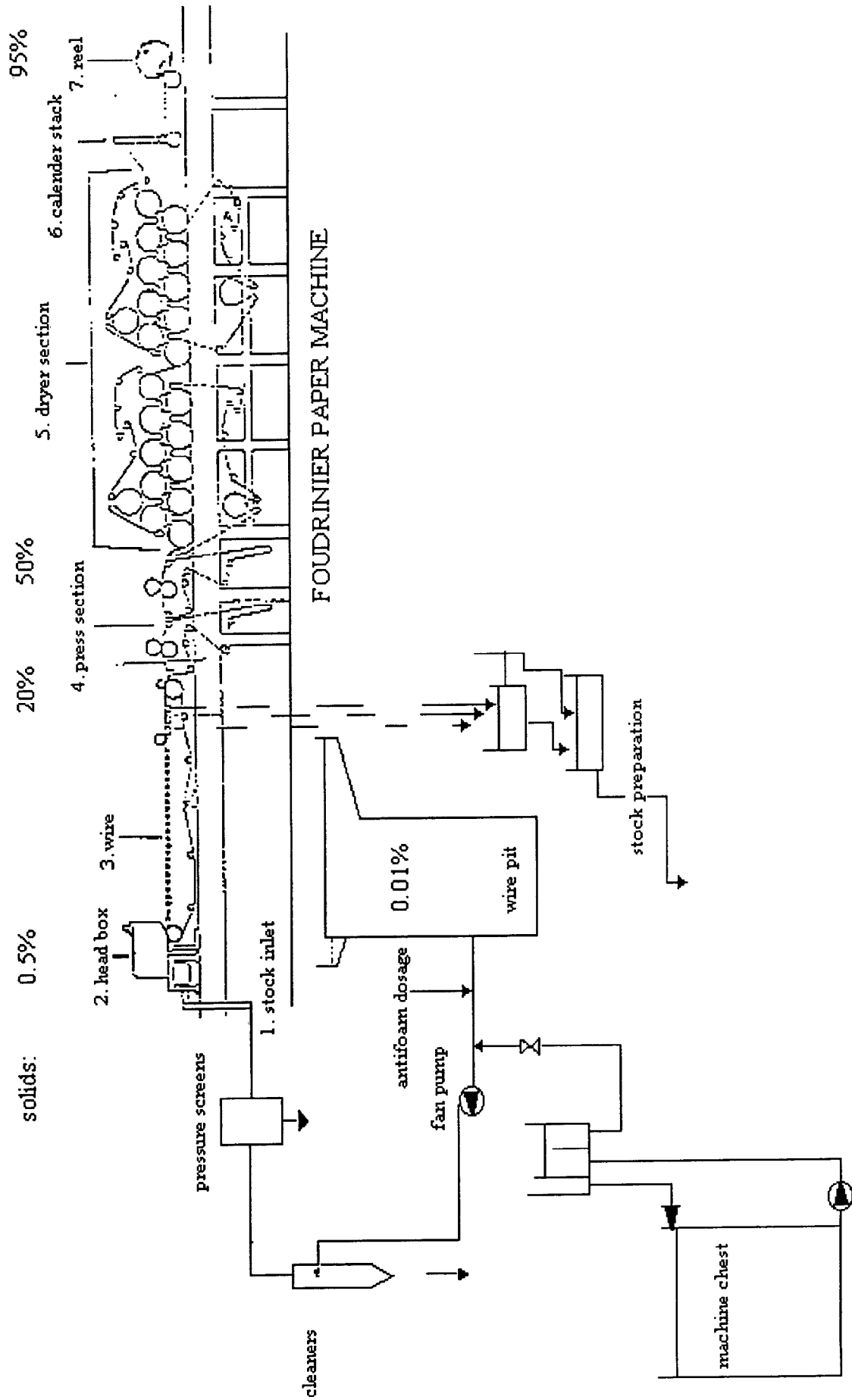
- 1) **Date:** 04/30/01
- 2) **Submitter:** Dow Corning Corporation
- 3) **Address:** P.O. Box 994
Midland, MI 48686-0994
- 4) **Description of Proposed Action**
 - a. **Requested action:** To allow the use of Silicones and siloxanes, dimethyl, methylhydrogen, reaction products with polyethylene glycol monoallyl ether acetate as a component of a defoamer used in the manufacture of paper and paperboard in accordance with 21 CFR 176.210(d)(3). This is from a general class of materials called Polyethermethylsiloxane (PEMS). This material will be used as an ingredient in making an emulsion to be used for defoaming.
 - b. **Need for Action:** The addition of the additive in the defoamer formulation will enhance paper making by reducing foam in the headbox process to allow more energy efficient circulation of the mill liquors.
 - c. **Locations of use /disposal:** The antifoam emulsion which the subject additive is part of will be used in the paper making process. Dow Corning manufactures the PEMS additive that is the subject of this FCN at its manufacturing plant in Midland, Michigan. This site is a large chemical complex located within an urban setting. All wastes generated in the production of the PEMS additive are collected and taken off site of incineration by a licensed waste disposal company.

The PEMS additive is then sold to formulators who produce fatty alcohol emulsions with a solid content of 30%. The PEMS product would replace 1/3 of the fatty alcohol to improve performance of the defoamer. The formulation would then consist of 10% of PEMS, 20% fatty alcohol and 70% water. These formulators are located throughout the world and must follow all local and national environmental and safety regulations. Current sales are in Europe only.

The Emulsion is then used as antifoam in the paper making process within paper mills located around the world. The emulsion is added at 0.02 to 0.09% as regards to the fibers into the paper making process. Figure 1 is a typical paper making machine. This means that the amount of the PEMS added is up to 0.009% based on the dry weight of the fibers.

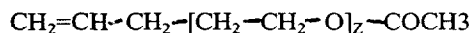
Based on a mass balance around the paper making process 55% of the PEMS product will be disposed off at the paper mill. All of this will be treated in waste water treatment. Of this most of the PEMS will end up being disposed off in the sludge via landfill or incineration. These calculations are described in section 6.B.

000046



000047

- 5) **Identification of substances that the subject of the proposed action:** The subject of this Food Contact Notification is the reaction products of Polyethylene glycol monoallyl ether acetate, (reactant A) which is represented below:



The resultant mixture is a clear to cloudy amber liquid.

- 6) **Introduction of substances into the Environment**
- a. **Introduction of substance into the environment as a result of manufacture:**
No extraordinary circumstances apply to the manufacture of this processing aid additive. The proposed manufacturing currently takes place for the same material in non food use and is compliant with all applicable emission and occupational safety requirements.
- b. **Intorduction of substances into the environment as a result of use/disposal.**
- i) **Projected Sales of the PEMS processing aid:**
- ii) A mass balance of the PEMS additive can be made with the following assumptions:
- 1,200 liters of waste water is sent for treatment for each metric ton of processed pulp based on dry weight of pulp. (2642 lbs) ⁽¹⁾
 - 0.009% of the PEMS is added to the process based on dry weight of the pulp.
 - Paper enter the driers is at 50% solids
 - All the PEMS that enters the drier stays with the paper based on the negligible vapor pressure of the PEMS.

Basis: 1 metric ton of dry fiber produced.

PEMS added to the process = 2200 lbs. of fiber X 0.00009 lbs of PEMS/ lbs. of fiber = 0.2 lbs.

000048

Ratio of water going into drier vs. Effluent to waste treatment = 2200 lbs/2642 lbs = 0.83

% of PEMS add that stays with paper = $0.83/1.83 \times 100 = 45\%$

% of PEMS that is discharged to treatment with the effluent = $1.0/1.83 = 55\%$

Therefore based on year sales of the PEMS processing Aid will go to waste processing at the paper mill

iii) Mode of introduction into the Environment:

The waste effluent from the paper making process goes to waste water treatment on a continuous basis. Of the amount going to treatment it is predicted the 97% of this will bound to the sludge and removed with the solids and either land filled or burned.⁽²⁾ The remaining 3% will discharge with the treated waste water to the environment.

iv) Material Safety Data Sheets

See Attachment.

7) Fate of Substances released in the Environment:

For information on the fate of the PEMS see *The Handbook of Environmental Chemistry Vol 3-H Organosilicon Materials*, Grish Chandra Ed., Chapter 8.

8) Environmental effects of released substances:

For information on the Environmental effects of the PEMS see *The Handbook of Environmental Chemistry Vol 3-H Organosilicon Materials*, Grish Chandra Ed., Chapter 8. The product in question is similar to the "PEMS 3 fiber finish" product discussed in the referenced chapter.

9) Use of resources and energy:

The proposed PEMS process aid is intended to replace a like portion of fatty alcohol in the antifoam emulsion. Therefore there should be no essentially no effect on the use of natural resources and energy.

10) Mitigation Measures:

No adverse environmental effects have been identified therefore there is no need to discuss mitigation measures.

11) Alternatives to the proposed action:

No adverse environmental effects have been identified therefore there is no need to discuss alternatives to the proposed action.

12) List of preparers:

Name: Charles A. McCourt
Title: FDA Regulatory Specialist
Degree: B.S. Chemical Engineering – University of Wisconsin - Madison

Name: Dr. Christina Northfleet
Title: AETS specialist
Degree: PhD. Chemistry

000049

13) **Certification:**

"The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Dow Corning Corporation."

April 30, 2001
(Date)

[Redacted Signature Box]

(Signature of Responsible Official)
Charles A. McCourt,
FDA Regulatory Compliance Specialist

14) **References:**

- 1) Phone conversation with Dr. Northfleet
- 2) G. Chandra Ed. , *The Handbook of environmental Chemistry Vol. 3 part H Organsilicon Materials*, Springer-Verlag, 1997. Pages 187, 233.

15) **Attachments:**

- MSDS for Paper Aid 40
- MSDS for Polyglycol Ester AE 11677

000050