ENVIRONMENTAL PROTECTION AGENCY

[PF–827; FRL–6023–6]

Rohm and Haas Company; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on food contact paper and paperboard.

DATES: Comments, identified by the docket control number PF–734, must be received on or before October 23, 1998.

ADDRESSES: By mail submit written comments to: Information and Records Integrity Branch, Public Information and Services Divison (7502C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under ''SUPPLEMENTARY INFORMATION.'' No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Marshall Swindell, PM 33, Antimicrobial Division (7510W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 6B, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA 22202, (703) 308–6341; e-mail: swindell.marshall@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemical in or on food contact paper and paperboard under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF–827] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number (PF–827) and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 1, 1998.

Frank Sanders,

Director, Antimicrobial Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the views of the petitioner. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Rohm and Haas Company

PP 8F4977

EPA has received a pesticide petition 8F4977 from Rohm and Haas Company, 100 Independence Mall West, Philadelphia, PA 19106-2399, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for 4,5-Dichloro-2-n-octyl-3(2*H*)-isothiazolone (CASRN 64359-81-5), in or on food contact paper and paperboard. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

Alternatively, this petition is proposing, pursuant to section 409 of the FFDCA, 21 U.S.C. 348, to amend 21 CFR 176.170 and 176.300, to establish a regulation for the use of 4,5-Dichloro-2-n-octyl-3(2*H*)-isothiazolone in or on food contact paper and paperboard. Regulatory authority for the rule proposed by this petition currently resides with EPA. EPA intends to transfer this regulatory authority to FDA, by rulemaking, pursuant to section 201(q)(3) of the FFDCA, 21 U.S.C. 321(q)(3). Any final regulation based on this petition will be determined by the status of the rulemaking at the time of the petition's final disposition.

Rohm and Haas Company's summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by Rohm and Haas Company and represents the views of Rohm and Haas Company. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

A. Residue Chemistry

This petition is not for residues in or on raw agricultural commodities. It is for residues in or on food contact paper

and paperboard. Accordingly, the residue chemistry data submitted are solely for the residues remaining in food contact paper and paperboard and coatings on food contact paper and paperboard when the subject slimicide (4,5-dichloro-2-n-octyl-3(2*H*)-isothiazolone, CASRN 64359-81-5, hereafter referred to as RH-287) is used in the following applications: for addition to pulp and paper mill process water to control slime-forming microorganisms, for addition to coatings that will be used on paper and paperboard to preserve the paper, for application to wet lap at pulp mills prior to manufacture of paper, and for addition to dispersed pigments that will be used in the manufacture of paper and paperboard. Each of these applications is discussed separately below.

1. *Residues in paper and paperboard from treatment of process water.* Gas chromatography with mass spectral detection was used to analyze paper from a field trial where the maximum use concentration (4 part per million (ppm) in the slurry water, 0.033 lb. RH-287 per ton of paper) was added to the process water. Paper from this trial had a concentration of RH-287 that ranged from 6.9 to 35.4 ppm based on the weight of the paper. Samples of paper that had 25 ppm RH-287 were extracted with food simulants using standard FDA protocols for determining food additive extractables from food contact materials. Samples were extracted for 24 hours with the appropriate aqueous and fatty food simulants for uncoated paper. The concentration of RH-287 in the food simulants was 0.68 µg RH-287/inch^2 of paper in the aqueous simulant and <0.22 µg RH-287/inch^2 of paper in the fatty food simulant.

2. *Residues from coated paper and paperboard.* Samples of paper were coated with either a latex-based coating or a starch-based coating. The concentration of RH-287 in the latex-coated paper was 100 ppm of RH-287 based on the weight of paper, whereas the concentration in the starch-coated paper was 145 ppm based on the weight of paper. These papers were then extracted with food simulating solvents using standard FDA methods for 24 hours. The concentration of RH-287 found in the aqueous food simulant was 1.23 µg/inch^2 in the latex-coated paper and 2.64 µg/inch^2 in the starch-coated paper. The concentration of RH-287 found in the fatty food simulant was 4.78 µg/inch^2 in the latex-coated paper and 5.02 µg/inch^2 in the starch-coated paper.

3. *Residues in paper from wet lap treated with RH-287.* The maximum use level for treatment of wet lap is 100 ppm of RH-287 based on the dry weight of the fiber. Laboratory-made paper containing 108 ppm of RH-287 was repulped in a manner consistent with the actual repulping of wet lap. From this experiment it was found that the final paper contained 15 ppm of RH-287. Using standard FDA assumptions, this concentration is equivalent to 0.70 µg RH-287/inch^2 of paper.

4. *Residues from dispersed pigments in paper and paperboard.* The allowable concentration of RH-287 in dispersed pigments is between 10 and 50 ppm. Since dispersed pigments will be a component of latex or starch-type coatings, the coated paper migration study encompassed these uses. As a result, no separate migration studies were conducted with paper prepared from dispersed pigments that were treated with RH-287. The dietary contribution of RH-287 from dispersed pigments is expected to be at most 21% of the dietary contribution for the coated paper.

5. *Analytical method.* This is a tolerance exemption petition and, accordingly, no enforcement analytical method is proposed.

B. Toxocological Profile

1. *Acute toxicity.* RH-287 Technical (96.9% active ingredient) is slightly to moderately toxic by the oral route, with an acute oral LD_{50} in rats of 1636 milligram/kilogram (mg/kg) (MRID 42977701) and in mice of 567 mg/kg (MRID 43471601). RH-287 is considered corrosive to the skin and eyes. A formulation of RH-287 in xylene produced skin sensitization in guinea pigs (MRID 126793). RH-287 is irritating to the respiratory tract via inhalation exposure; the 4 hr inhalation LC_{50} in rats was 0.26 mg/liter (MRID 43471602).

Acute toxicity studies conducted on an end-use product containing 4.25% RH-287 with surfactants in water indicated that the product was practically non-toxic by either the oral or dermal routes; the oral and dermal LD_{50} in rats was > 5,000 and > 2,000 mg/kg product, respectively (MRID 44259302 and 44259303, respectively). The 4.25% product was slightly irritating to the skin (MRID 44259306) but was corrosive to the eyes (MRID 44259305). The 4 hr inhalation LC_{50} for the use product in rats was 1.3 mg/liter product (MRID 44259304).

2. *Genotoxicity.* RH-287 Technical was negative (non-mutagenic) in the Ames *Salmonella* gene mutation assay (MRID 43471605), negative in a gene mutation assay in Chinese hamster ovary (CHO) cells (MRID 43471606), negative in *in vitro* chromosomal aberration assay in CHO cells (MRID 43471607), and negative in a mouse *in vivo* micronucleus assay (MRIDs 43471601, 43471608, and 43901901). RH-287 is judged to be non-genotoxic.

3. *Subchronic toxicity.* RH-287 Technical (98.8% active ingredient) was administered in the diet to groups (10/sex/group) of Crl:CD® BR rats for three months at dietary concentrations of 0, 100, 500, 1,000, and 4,000 ppm (MRID 43471603). No treatment-related mortality was observed. Significant reductions in body weight and body weight gain were observed at 1,000 ppm in females and at 4,000 ppm in both sexes. Food consumption was transiently reduced at 1,000 ppm in females. Food and water consumption were reduced throughout the treatment period at 4,000 ppm in both sexes. Serum triglyceride levels were decreased at 1,000 ppm in females; several other clinical chemistry parameters were affected in both sexes at 4,000 ppm. Histological findings indicative of gastric irritation were limited to the forestomach and were observed at 1,000 and 4,000 ppm in both sexes. The no-observed effect level (NOEL) for RH-287 when administered in the diet to rats for three months was 500 ppm (equivalent to 32.5 and 36.7 mg/kg/day in males and females, respectively).

4. *Chronic toxicity/oncogenicity.* Chronic toxicity and oncogenicity studies have not been conducted with RH-287 since these studies were not required for the FIFRA registration of RH-287 Technical. Chronic toxicity and oncogenicity studies are judged not to be warranted for RH-287 based on the primary toxicity of gastric irritation observed in the RH-287 three-month dietary toxicity study described above, its non-mutagenic potential, and its negligible dietary exposure (see below).

5. *Developmental toxicity.* RH-287 Technical was administered to pregnant rats by daily oral gavage on days 6-15 of gestation at 0, 10, 30, 100, and 300 mg/kg/day, and dams were killed on day 20 for cesarean sectioning (MRID 43471604). Significant mortality was observed at 300 mg/kg/day, and this group was terminated prior to day 20. Maternal body weight change was reduced at 100 mg/kg/day. Feed consumption was reduced throughout the treatment period at 100 mg/kg/day but was increased in this group following the treatment period. An increased number of litters from rats dosed with 100 mg/kg/day had fetuses with wavy ribs, a skeletal variation. There were no treatment-related effects on the numbers of early or late resorptions, live fetuses per litter, fetal body weight or sex ratio, external, soft-

tissue, or head abnormalities, or skeletal malformations. The NOELs for maternal and fetal toxicity in this study were 10 and 30 mg/kg/day, respectively. RH-287 was not teratogenic in rats.

6. *Pharmacokinetics*. The absorption, distribution, and excretion of oral administration of 20 and 250 mg/kg ^{14}C-RH-287 were investigated in male and female Crl:CD® BR rats (MRID 43471609 and 43901901). ^{14}C-RH-287 was moderately rapidly absorbed; peak plasma concentrations were achieved between 6 and 24 hr. ^{14}C-RH-287 was rapidly excreted mostly within two days after dosing and primarily in the feces. Tissues and residual carcasses contained negligible amounts of ^{14}C-label four days after dosing indicating that ^{14}C-RH-287 does not bioaccumulate.

7. *Reference dose (RfD)*. EPA has not previously set an RfD for RH-287 since at the time of registration review for RH-287 microbicide (EPA Reg. No. 707-224) Rohm and Haas did not request use in food contact materials. Based on the subchronic NOEL of 32.5 mg/kg/day and an uncertainty factor of 100, Rohm and Haas Company proposes an RfD for RH-287 of 0.325 mg/kg/day (based on minimal gastric irritation and decreased body weight and food consumption). An RfD of 0.325 mg/kg/day leads to the following allowable daily intakes (ADI) for adult males and females and for children and infants:

Adult male (70 kg), ADI = 22.8 mg/day;

Adult female (60 kg), ADI = 19.5 mg/day;

Child (20 kg), ADI = 6.5 mg/day; and

Infant (8 kg), ADI = 2.6 mg/day.

Since the RfD for RH-287 is based primarily on the physico-chemical effect of gastric irritation, a wide difference in the susceptibility between children/infants and adults would not be anticipated. The gastric irritation effects are likely a function of the concentration of RH-287 in the stomach, which is a function of the amount of RH-287 per unit of body weight. Thus, exposure to a given mg/kg/day dose of RH-287 is expected to yield similar gastric concentrations of RH-287 among infants, children, and adults. An RfD of 0.325 mg/kg/day is judged to be an appropriate safe maximum ingestion dose for RH-287.

C. Aggregate Exposure

1. *Dietary exposure*— i. *Food in contact with paper or paperboard made in process water containing RH-287*. Analysis of paper samples manufactured in a papermill which used RH-287 amended slurry water by gas chromatography with mass spectral detection revealed levels of RH-287 in the paper ranging from 6.9 to 35.4 ppm. Samples of paper that had 25 ppm were extracted with food simulating solvents using standard FDA protocols for determining food additive extractables for 24 hours. The levels of RH-287 recovered were 0.68 µg/inch^2 of paper in the aqueous food simulant and less than 0.22 µg/inch^2 of paper in the fatty food simulant. The standard FDA assumption is that 10 g of food is in contact with one inch^2 of paper. Therefore, the corresponding food concentrations are 68 ppb of RH-287 in aqueous food and 22 ppb of RH-287 in fatty foods. Using a standard equation provided by the FDA for estimating dietary exposure to an indirect food additive migrating from food packaging, the hypothetical worst case potential for dietary exposure to RH-287 as a result of RH-287 migration into foods in contact with paper and paperboard made in process water containing RH-287 is:

$<M_{slimicide}> = f_{aqueous\ and\ acidic}(M_{10\ percent\ ethanol}) + f_{alcohol\ and\ fatty}(M_{fatty})$

The food type distribution factors ($f_{foodtype}$) are:

$f_{aqueous\ and\ acidic}$ 0.57 + 0.01 = 0.58

$f_{alcohol\ and\ fatty}$ 0.01 + 0.41 = 0.42

and <M> is the concentration of residues in food.

$<M_{slimicide}> = 0.58(68\ ppb) + 0.42(22\ ppb)$

$<M_{slimicide}> = 48$ ppb

The above value of $<M_{slimicide}>$ was obtained from paper that contained 25 ppm of RH-287. In the paper mill trial, the concentration of RH-287 ranged from 6.9 to 35.4 ppm. To ensure that the dietary concentration is conservatively estimated, the value for $<M_{slimicide}>$ is adjusted upward by multiplying by 1.4 (35/25) to give a concentration of 67 ppb. This value is then converted into a dietary concentration by taking into consideration the consumption factor for uncoated paper and paperboard, which is 10% for this type of packaging material. As a result, the maximum dietary concentration of RH-287 resulting from its use in slimicide applications is 6.7 ppb ($Diet_{slimicide}$).

ii. *Food in contact with paper or paperboard prepared with coatings containing RH-287*. Two different coatings were prepared. One was a latex-based coating, and the other was a starch-based coating. The latex coating was applied to paper at the maximum use level of 100 ppm (based on the weight of paper). The concentration found in the aqueous food simulant from the latex-based coating was 123 ppb and in the fatty food simulant was 478 ppb. However, the starch-based coating was 145 ppm, approximately 50% higher. The starch values, 264 ppb for the aqueous food simulant and 502 ppb in the fatty food simulant, can be normalized to the maximum use level of 100 ppm of RH-287 by multiplication by 0.69 (100/145) to give food concentrations of 182 ppb for the aqueous food simulant and 346 ppb for the fatty food simulant. Worst case calculations are based on using the concentration in the aqueous food simulant from the starch coating and the concentration in the fatty food simulant from the latex coating. This calculation takes into account the rather rare possibility that starch coatings containing RH-287 would be used exclusively with aqueous foods while latex coatings would be used exclusively with fatty foods.

$<M_{coatings}> = f_{aqueous\ and\ acidic}(M_{10\ percent\ ethanol}) + f_{alcohol\ and\ fatty}(M_{fatty})$

$<M_{coatings}> = 0.58(0.182) + 0.42(0.478)$

$<M_{coatings}> = 0.310$ µg RH-287/g of food = 310 ppb RH-287

The $<M_{coating}>$ is converted into a dietary concentration by utilizing a 10% consumption factor. The contribution to the diet from paper prepared from latex and starch based coatings is 31 ppb ($Diet_{coating}$).

iii. *Food in contact with paper or paperboard made from wet lap treated with RH-287*. The maximum use level permitted for RH-287 on wet lap is 100 ppm based on the dry weight of fiber. Wet lap consists of approximately 50% fiber and 50% water and never contacts food directly. It is a pulp product that requires further processing before paper can be made from it. During the manufacture of paper from wet lap, the wet lap is repulped in water. This slurry is approximately 0.5% to 1% fiber. Laboratory experiments demonstrated that paper made from wet lap contains only 14% of the RH-287 active material originally present in the wet lap, indicating that most of the RH-287 is lost during the repulping process.

Paper manufactured from wet lap represents only 3% of all paper made in North America. If we assume the worst case that all of the RH-287 in the paper made from repulped wet lap migrates into food, then the maximum RH-287 residues in food would be:

$<M_{wet\ lap}>$ = (100 µg/g of paper)(0.14)(0.05g of paper/inch^2 of paper)(1 inch^2 of paper/10 g of food) = 0.07 µg/g = 70 ppb

The above worst case value of RH-287 residues in food ($<M_{wet\ lap}>$) can then be converted to the dietary contribution ($Diet_{wet\ lap}$) by multiplication by the consumption factor. The consumption factor for uncoated paper is 0.1, and since wet lap represents only 3% of all paper made in North America, the overall consumption factor for wet lap

paper is 0.003. The worst case overall amount of RH-287 in the diet contributed from wet lap would be (70 ppb) (0.003) = 0.21 ppb.

iv. *Food in contact with paper or paperboard made with dispersed pigments containing RH-287.* As described above, the maximum level of RH-287 in paper coatings contributed from dispersed pigments is 21% of the value determined for the latex-coated paper. We can, therefore, calculate the amount of RH-287 that dispersed pigments would contribute to the diet by multiplying 31 ppb ($Diet_{coating}$) by 0.21 = 6.5 ppb ($Diet_{dispersed\ pigment}$).

v. *Summation of dietary exposure.* The sum of the dietary contributions of RH-287 from the different applications is shown below:

$Diet_{slimicide}$	6.7 ppb
$Diet_{coating}$	31.0 ppb
$Diet_{wet\ lap}$	0.21 ppb
$Diet_{dispersed\ pigment}$	6.5 ppb
$Diet_{sum}$	44.4 ppb

2. *Drinking water.* The use of RH-287 as a slimicide for pulp and paper mills does not provide for entry of RH-287 into drinking water sources. Spent process water from such sites is treated as waste water, typically on-site, prior to release into surface waters. There is no provision for RH-287 to enter groundwater systems since RH-287 is not registered for use directly on raw agricultural commodities.

3. *Non-dietary exposure.* RH-287 is an industrial-use microbicide whose only other registered water-treatment uses (i.e., other than use in pulp and paper manufacturing) is as a slimicide control agent in recirculating cooling water, air washer systems, recirculating closed loop water cooling systems, decorative fountains, and can warmer and brewery pasteurizers. All of the uses of RH-287 involve only occupational exposures. There are no registrations and no intended uses in residential scenarios.

4. *Estimated total daily intake.* The daily diet for adults is 3 kg/day. The worst case estimated daily intake (EDI) of RH-287 for adults from possible residuals in food contact paper and paperboard is:

EDI_{adult} = 3.0 kg of food/day x 44.4 ppb = 133 µg/day

The daily diet differs in quantity for children of different ages. At 6 months of age, the daily diet is 1.1 kg, and the mean body weight for a 6 month old infant is 8 kg. In the age interval 4 to 6 years of age, the daily diet is 2 kg/day, and the mean body weight of a child this age is 20 kg. The EDI's for infants and children are based on these total diet amounts and are:

EDI_{infant} = 1.1 kg of food/day x 44.4 ppb = 49 µg/day

EDI_{child} = 2.0 kg of food/day x 44.4 ppb = 89 µg/day

Thus for a 6 month old infant (8 kg), a 4 to 6 year old child (20 kg), an adult woman (60 kg), and an adult man (70 kg), the daily intakes of RH-287 associated with the above EDIs, expressed as µg/kg/day and as percent of RfD utilization (RfD = 0.325 mg/kg/day = 325 µg/kg/day) are:

	Dietary exposure	Percent RfD utilized
Infant	6.1 µg/kg/day	1.9
Child	4.5 µg/kg/day	1.4
Woman	2.2 µg/kg/day	0.7
Man	1.9 µg/kg/day	0.6

Rohm and Haas Company notes that in 40 CFR 180.1 (l) EPA has defined that a ''negligible residue ordinarily will add to the diet an amount which will be less than 1/2000th of the amount that has been demonstrated to have no effect from feeding studies on the most sensitive animal species tested.'' Thus, for a 100-fold uncertainty factor based RfD, this means an RfD utilization of 5% or less. Rohm and Haas considers, therefore, that under the hypothetical worst case dietary exposure assessment, RH-287 residues are clearly negligible residues.

D. Cumulative Effects

RH-287 has the intrinsic toxicological potential to produce irritation at the site of contact at relatively high concentrations. This chemico-physico (non-systemic) property is consistent with other compounds which cause irritation effects at the site of application. We have evaluated this effect in the context of the extremely low dietary exposure to RH-287 in the subject indirect food additive application and do not believe there is any evidence for a cumulative risk concern.

E. Safety Determination

1. *U.S. population.* Since the use of RH-287 as a slimicide in pulp and papermills is, under hypothetical worst case conditions, expected to lead to at most only negligible indirect dietary exposures in adults [i.e., not greater than 0.6 to 0.7% of the RfD for adults which is less than the negligible criteria of 5% of RfD defined in 40 CFR 180.1(1)], it is Rohm and Haas Company's judgment that there is a reasonable certainty that no harm will come to adults from dietary exposure to RH-287 residues which could occur in food contact paper and paperboard produced in pulp and paper mills utilizing RH-287 for slime control, and for paper coatings, wet lap, and dispersed pigment preservation in accordance with its FIFRA labeling.

2. *Infants and children.* Since the use of RH-287 as a slimicide in pulp and papermills is, under hypothetical worst case conditions, expected to lead to at most only negligible indirect dietary exposures in infants and children [i.e., not greater than 1.4-1.9% of the RfD for infants and children which is less than the negligible criteria of 5% of RfD defined in 40 CFR 180.1(1)], it is Rohm and Haas Company's judgment that there is a reasonable certainty that no harm will come to infants and children from dietary exposure to RH-287 residues which could occur in food contact paper and paperboard produced in pulp and paper mills utilizing RH-287 for slime control, and for paper coatings, wet lap, and dispersed pigment preservation in accordance with its FIFRA labeling.

3. *Sensitive individuals.* Since the RfD for RH-287 is based primarily on the physico-chemical effect of gastric irritation, wide differences in susceptibility to RH-287 based on metabolic differences among individuals would not be anticipated. Because of this, and because of the relatively large margins of safety for exposure to RH-287 from food in contact with paper products (i.e., 5,300 to 17,000), it is Rohm and Haas Company's judgment that there is a reasonable certainty that no harm will come to individuals with pre-existing gastro-intestinal tract conditions, such as ulcers, colitis, and similar pathologies, from dietary exposure to RH-287 residues which could occur in food contact paper and paperboard produced

in pulp and paper mills utilizing RH-287 for slime control, and for paper coatings, wet lap, and dispersed pigment preservation in accordance with its FIFRA labeling.

F. International Tolerances

There are no Codex maximum residue levels (MRLs) established for residues of RH-287.

G. Estrogenic Effects

RH-287 is judged not to be an estrogenic material for the following reasons:

1. RH-287 is not structurally related to any known estrogenic materials. Although RH-287 contains two chlorine atoms, these chlorine atoms are readily released as chloride ions upon environmental degradation;

2. An extensive toxicology database on RH-287 and other isothiazolones indicates that these materials do not cause direct systemic toxicity. Relatively high concentrations of these materials are only toxic to the site of application;

3. Histopathologic examination in our RH-287 three-month dietary study summarized above indicated no toxicity to reproductive organs; and

4. Our developmental toxicity study summarized above indicated no reproductive toxicity.

Thus, based on structure activity analysis and on toxicology studies conducted with RH-287, there is no scientific evidence that indicates, or even suggests, that RH-287 is estrogenic. (Karen Levy)

[FR Doc. 98–25448 Filed 9–22–98; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL MARITIME COMMISSION

[Docket No. 98–16]

Eastern Mediterranean Shipping Corp. d/b/a Atlantic Ocean Line and Anil K. Sharma Possible Violations of Sections 10(a)(1), 10(b)(1) and 10(d)(1) of the Shipping Act of 1984; Order of Investigation and Hearing

Eastern Mediterranean Shipping Corp. (''Eastern''), also doing business as Atlantic Ocean Line,[1] is a tariffed and bonded NVOCC located at 990 Avenue of the Americas, Suite 6E, New York, NY 10018. Eastern holds itself out as an NVOCC pursuant to its ATFI tariff FMC No. 013236–001, effective December 12, 1995. Eastern currently maintains an NVOCC bond, No. 8941330, in the amount of $50,000 with the Washington International Insurance Company, located in Schaumburg, Illinois.

Eastern was incorporated in 1994, and Anil (a.k.a. ''Andy'') K. Sharma, who owns 100% of the company stock, is the President and Chief Executive Officer. Sharma currently manages Eastern, and is actively involved in the company's day to day operations as an NVOCC.

Section 10(a)(1) of the Shipping Act of 1984 (''1984 Act''), 46 U.S.C. app. § 1709(a)(1), prohibits any person knowingly and willfully, directly or indirectly, by means of false billings, false classification, false weighing, false report of weight, false measurement, or by any other unjust or unfair device or means, to obtain or attempt to obtain ocean transportation for property at less than the rates or charges that would otherwise be applicable. It appears that Eastern has knowingly and willfully misdeclared cargo shipments in order to obtain favorable rates under a service contract entered into with Zim Israel Navigation Co. Ltd. (''Zim''). For the shipments at issue, Eastern's house bills of lading properly declared the commodity being shipped. However, the master bills of lading issued by the carrier show that Eastern declared a different commodity for the same shipment. Zim rated the commodities in accordance with the inaccurate description furnished by Eastern. In each instance, Eastern changed the declaration from a commodity not listed in the service contract, to a commodity that was contained therein. Eastern was named as shipper on all of Zim's bills of lading, and therefore had knowledge of the actual commodity for which transportation was obtained. Other documentation, such as invoices, rate quotes, booking confirmations and shipper's export declarations reflect that Eastern and its principals were apparently cognizant that the shipments actually consisted of commodities different from those listed on Zim's bills of landing.

Section 10(b)(1), 46 U.S.C. app. § 1709(b)(1), prohibits a common carrier from charging, collecting or receiving greater, less or different compensation for the transportation of property than the rates and charges set forth in its tariff. It appears that Eastern did not charge the rates set forth in its tariff on numerous shipments, filed tariff amendments subsequent to the shipment taking place, and in other instances failed to file a commodity rate at all. Eastern also filed commodity rates under the wrong commodity description, making them inapplicable to the shipments involved. It further appears Eastern also improperly assessed surcharges not filed in its tariff.

Section 10(d)(1), 46 U.S.C. app. § 1709(d)(1), states that no common carrier may fail to establish, observe and enforce just and reasonable regulations and practices relating to or connected with receiving, handling, storing, or delivering property. It appears Eastern has failed to establish and observe reasonable practices in receiving and delivering property entrusted to it by its customers. The Commission's Office of Informal Inquiries and Complaints and Informal Dockets, has received over 40 complaints in the last two years from shippers and freight forwarders who have dealt with Eastern. The complaints include instances such as Eastern failing to pay ocean freight to the ocean common carrier, failing to respond to requests for information about shipments, as well as failing to release bills of lading once freight has been paid. Furthermore, it appears that Eastern repeatedly fails to notify shippers regarding sailing schedules and vessel names, provides deceptive information about the location of cargo and fails to deliver cargo as promised. As a direct result of Eastern's failure to perform its duties as an NVOCC, shippers experience frustration and anxiety over losing their business reputation as well as lost revenue in correcting the problems caused by Eastern.

Under section 13 of the 1984 Act, 46 U.S.C. app. § 1712, a person is subject to a civil penalty of not more than $25,000 for each violation knowingly and willfully committed, and not more than $5,000 for other violations.[2] Section 13 further provides that a common carrier's tariff may be suspended for violations of section 10(b)(1) for a period not to exceed one year, while section 23 of the 1984 Act, 46 U.S.C. app. § 1721 provides for a similar suspension in the case of violations of section 10(a)(1) of the 1984 Act.

Now therefore, it is ordered, That pursuant to sections 10, 11, 13, and 23 of the 1984 Act, 46 U.S.C. app. §§ 1709, 1710, 1712 and 1721, an investigation is instituted to determine:

(1) Whether Eastern Mediterranean Shipping Corp. and/or Anil K. Sharma violated section 10(a)(1) of the 1984 Act by directly or indirectly obtaining

[1] Although Eastern currently uses Atlantic Ocean Line as a d/b/a, the principal of Eastern started Atlantic Ocean Line Corp., ATFI org. number 014201, in 1996 as a separately tariffed and bonded NVOCC. It appears that Atlantic Ocean Line Corp. operated, until recently, from the same office as Eastern.

[2] The maximum penalties are raised by 10 percent for violations occurring after November 7, 1996. See Inflation Adjustment of Civil Monetary Penalties, 276 S.R.R. 809 (1996).