

SECTION I (To be completed by Product Standards, Brand R&D)

PS Central Log No. 88-24

A. Requestor & Location Ms. Young Young 26-1 QA Mgr notified _____
 Amount and Type of Material Found MSDS on File? Severity of Problem Factory/Floor/Shift. Amount of Cut Filler/Cigarettes _____

See Attachment 1

Dept Charge No. 217 Signature/Date Detected L.E. McCallum 8/3/88
 cc: R.L. Suber J. H. Wilson R.L. Willard B.M. Wagner H.E. Guess K.W. Smith R.M. Harrington
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SECTION II (To be completed by Applied Analytical Research Division, Applied R & D)

A. Analytical Methods employed/MSDS Sheets used _____

B. Compounds identified N.A.

Signature and Date _____

SECTION III (To be completed by Scientific Affairs, Bio/Bio, R&D)

Assessment SEE ATTACHED

Signature and Date R.M. Harrington 8-4-88

SECTION IV (To be completed by Manufacturing Practices Review Committee, Sec.)

Ship Use as shorts G-7 Landfill Other Additional Testing Required?
All 613 was found to be free of contamination and suitable for use.
Engineering and analytical review indicates that foam removed from the 613
process after contact with ch. 11 water is suitable for use. This foam may
be returned to the process at the convenience of 63-1 operations personnel.
See Attached 1 Signature and Date F. V. Hill R.M. H.C. 8/25/88
 cc: Bio/Bio

SECTION V (To be completed by QA Mgr)

Action Taken Fred Bailey, plant manager of 63-1, was notified this date that
6-13 being held in quarantine could be released for shipment and that foam
currently being held in drums could be reintroduced into the system as
needed. Signature and Date Young R. Young 18-31-88

Section VI (To be completed by Plant Manager)

Corrective Action Taken First stage Condenser internal basket replaced,
foam recovery system cleaned, drained and refilled effective 8-1-88.
J.F. Elder Signature and Date 8-1-88

Copies to: J. H. Wilson R.L. Willard R.L. Suber B.M. Wagner H.E. Guess R.M. Harrington
 J.F. Elder J.F. Elder

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On Monday, August 1, 1988, a gasket in the first stage freon condenser at 63-1 ruptured allowing chilling water containing Drewguard 315, a corrosion inhibitor, and Drewguard 254, a biocide, to mix with the freon in the system. At the time the rupture was discovered, approximately 20,000 pounds of G13-23 had been produced. This product was isolated and is being held in quarantine at 63-1. The approximately 7,000 pounds of freon that were in the system at the time of the leak were pumped into drums and are being held at 63-1 awaiting disposition. After the system was purged, it was washed down following a procedure supplied by Mr. A. Eugene Stainbach and confirmed as being effective by Dr. Robert M. Harrington of R&D. The gasket was repaired, the system was recharged with freon and production was resumed.

It is estimated that approximately 4,500 pounds of chilling water came in contact with or mixed with approximately 7,000 pounds of freon in the system. Drewguard 315 is used in concentrations of 1000 ppm and Drewguard 254 is used in concentrations of 50 ppm when initially added to the system.

Two incidents which required repairs to the chilling water system and impact on these concentrations, had occurred the previous week. The first incident involved a leaking condenser and resulted in the loss of approximately one-third of the water contained in the system. The leak was repaired and the system refilled with water but no Drewguard 315 or Drewguard 254 added. The second incident involving freon loss for the system, required that approximately two-thirds of the chilling water be drained from the system to effect repairs. Again the system was refilled with water and no additional quantities of the Drewguard formulas were added.

Section III (88-24)

This potential product contamination involves two water treatment formulations, Drewguard 254 and Drewguard 315. Drewguard 254 is a 45% solution of gluteraldehyde. Drewguard 315 is composed of 25% sodium molybdate, 10% sodium hydroxide and 10% sodium tolytriazole.

According to Section I of this report, Drewguard 254 and 315 were initially present in the recirculating water system at 50 and 1000 ppm, respectively. After the two incidents which reduced the concentrations of these water treatments, the estimated concentrations of Drewguard 254 and 315 in the recirculating water would be reduced to 11 and 220 ppm, respectively. Since the recirculating water leaked into the Freon recovery system in the ratio of 4,500 pounds of chilled water to 7,000 pounds of Freon, this would further reduce the concentrations of Drewguard 254 and 315 in the Freon-water mixture to approximately 5 and 90 ppm, respectively:

Freon and water form a liquid bi-layer upon contact, therefore, a partition coefficient is established for each of these water treatment chemicals in the mixture. Since gluteraldehyde is a polar compound and sodium hydroxide, sodium molybdate and sodium tolytriazole are ionic compounds that dissociate in water, at equilibrium they would greatly favor the aqueous based layer.

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This would result in the vast majority (probably 90% - 100%) of these water treatments to remain in the aqueous layer, which is drawn off the Freon in the recycling process. Based on this, the amount of these water treatment chemicals in the Freon would probably be very low (<1 ppm).

Sodium molybdate (Na_2MoO_4) is a corrosion inhibitor. It is not acutely toxic, but rabbits ingesting a 0.1% diet of Na_2MoO_4 died after several weeks. Molybdenum is a trace element essential for good health. Excessive amounts can lead to anemia, fatty degeneration of the liver and death.

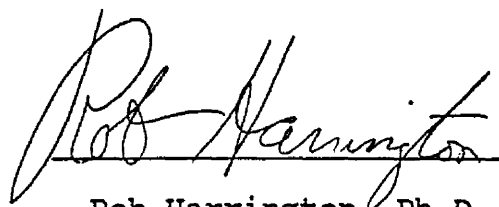
Sodium tolyltriazole is a rust inhibitor. It is of a moderate toxicity with an oral LD_{50} of 675 mg/kg in rats. No additional toxicity data are available.

Sodium hydroxide (NaOH) is a very corrosive alkaline substance. It is not volatile but aerosol mists of NaOH are very irritating to the eyes and respiratory system. Contact with strong NaOH solutions should be avoided. The American Conference of Governmental Industrial Hygienists (ACGIH) has set a threshold limit value (TLV) of 2 mg/m^3 . The concentration of NaOH in this mixture would be insignificant.

Gluteraldehyde is moderately toxic at elevated vapor concentrations. At low exposure levels it is a strong irritant to the nose and eyes and may cause skin sensitization. The LD_{50} in the rat has been measured as high as 2.4 g/kg and the four-hour LC_{50} high as

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is approximately 5000 ppm (ACGIH, Documentation of Threshold Limit Values and Biological Exposure Indices, 1986). The exposure limit is set a 0.8 mg/m^3 (0.2 ppm) by the ACGIH.

 8-4-88
Rob Harrington, Ph.D. Date

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A review of the G13 process, and the chemical treatments in the chill water indicated that there was very little potential for transference of significant amounts of chill water components to the freon.

Samples of the suspect freon from 63-1 were analyzed by Garnett Douthitt of applied R&D (results attached) and confirmed that the freon from 63-1 was not significantly affected by contact with the chill water. A review of this data indicates that the level of metals in the 63-1 freon sample was essentially the same as the 601 control sample. Both freon samples were significantly lower in concentration than the chill water sample.

8/25/88 K. W. Smith

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