

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

January 24, 2008

MEMORANDUM

SUBJECT: Product Chemistry Chapter for the Paraformaldehyde

Reregistration Eligibility Decision (RED) Document

FROM: Srinivas Gowda, Microbiologist/Chemist

Risk Assessment and Science Support Branch (RASSB)

Antimicrobials Division (7510P)

TO: Mark Hartman, Branch Chief

Diane Isbell, Team Leader

ShaRon Carlisle, Chemical Review Manager

Regulatory Management Branch II Antimicrobials Division (7510P)

Timothy McMahon, Risk Assessor Antimicrobials Division (7510P)

THRU: Siroos Mostaghimi, Team Leader, Team one

Risk Assessment and Science Support Branch (RASSB)

Antimicrobials Division (7510P)

Norman Cook, Branch Chief

Risk Assessment and Science Support Branch (RASSB)

Antimicrobials Division (7510P)

Attached is the Product Chemistry Chapter for the Paraformaldehyde RED Document.

PARAFORMALDEHYDE REREGISTRATION ELIGIBILITY DECISION

PRODUCT CHEMISTY CHAPTER

PC Code: 043002; Case No. 0556

REGULATORY HISTORY

Paraformaldehyde is a white crystalline solid formed by polymerization of formaldehyde. In 1964, under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), paraformaldehyde was first registered as a sanitizer and fungicide for use on barber and beauty shop equipment. Since then, paraformaldehyde has been registered as a disinfectant, sanitizer, fungicide, and microbiocide. Sites for which this chemical was registered include household and domestic dwellings; ships and ship holds; bedding and clothing; and nonfood/nonfeed-transporting trucks. Until 1991, paraformaldehyde was also registered for decontamination of laboratories and experimental animal facilities. However, all registrations for this use and many of the other uses described above were canceled due to nonpayment of registration maintenance fees by the manufacturer. Subsequently, only two products remain registered. Presently there are 2 active products under a single PC Code 043002, which are listed in Table 1 under the Appendix. Steri-DriTMFumigant is used as bacteriostat, fungicide, and sanitizer in hair/beauty salons and barber shops, and Sun Pac is used as mildewcide for closets, cupboards, dresser drawers, trunks, suitcases, lockers, golf bags, trailers, bathroom and kitchens. There are no inerts for this chemical. EPA issued a Registration Standard for paraformaldehyde in May 31, 1988.

CHEMICAL IDENTIFICATION

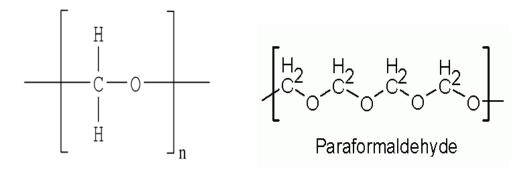


Figure 1. Molecular Structures of Paraformaldehyde

Common Name: Paraformaldehyde

Chemical Name: Paraformaldehyde

Other Name(s): Paraformaldehyde

CAS Registry Number: 30525-89-4

OPP Chemical Code: 043002

Case Number: 0556

Empirical Formula: $HO(CH_2O)_nH$ (n = 6 - 100)

Molecular Weight: (30.03)n g/mole

Manufacturers: Protexall Products Inc

Noble Pine Products Co.

Highest Percent of

Active Ingredient: 95%

Formulation Types

Registered: Technical Grade Active Ingredients (TGAI):

None.

Manufacturing Use Products (MP):

None.

End Use Products (EP):

Crystalline

Chemical Properties: Paraformaldehyde is a white crystalline solid with an irritating odor. It is the polymerized form of formaldehyde. It has a melting point of 120 to 170°C, density of 1.46 g/ml at 15°C, bulk density of 750 to 850 kg/m3, and sp gr. of 1.4. Solubility in water is partial and is dependent on pH, temperature and molecular weight. It is insoluble in most organic solvents and very soluble in dilute alkali and acids. It has a vapor pressure of 1.45 mm Hg at 25°C and 1 mm Hg at 30°C. It has a pH of 3.5- 4.5 and is moderately corrosive.

PRODUCT CHEMISTRY DATA REQUIREMENTS FOR REREGISTRATION OF PARAFORMALDEHYDE:

Product chemistry data requirements and results are summarized in Tables 2 and 3 under, "APPENDIX".

FINDINGS/CONCLUSIONS:

All product chemistry data requirements have been fulfilled for the active ingredient paraformaldehyde. See Tables 2 and 3 under, "APPENDIX". RASSB has no objections to the reregistration of paraformaldehyde with respect to product chemistry data requirements.

APPENDIX:

Table 1. Registered Active Products of Paraformaldehyde

EPA Reg. No.	Formulation Type	Percent Active Ingredient	Registrant
397-6	EP Crystalline	62.3%	Noble Pine Products Co.
4972-43	EP Crystalline	95.0%	Protexall Products, Inc.

Table 2: Manufacturing and Impurity Data for Paraformaldehyde

Product Identity, Composition, and Analysis

OPP Guideline No.	OPPTS Guideline No.	Requirement	MRID	Status ¹	Details or Deficiency
61-1	830.1550	Product identity and composition	43987201 43983801	A	Refer to Chemical Identification on page 2
61-2a	830.1600	Description of materials used to produce the product	43987201 43983801	A	СВІ
61-2a	830.1620	Description of production process	43987201 43983801	A	СВІ
61-2a	830.1650	Description of formulation process	43987201 43983801	A	СВІ
61-2b	830.1670	Discussion of formation of impurities	43987201 43983801	A	СВІ
62-1	830.1700	Preliminary analysis	43987201 43983802 43983801	A	СВІ
62-2	830.1750	Certified limits	43987201	A	СВІ
62-3	830.1800	Enforcement analytical method	43987201 43983801	A	Sulfite Method -Potentiometric Titration
64-1	830.1900	Submittal of samples		N/A	

 $^{^{1}}A = Acceptable; N/A = Not Applicable.$

 Table 3: Physical and Chemical Properties for Paraformaldehyde

OPP Guideline No.	OPPTS Guideline No.	Requirement	MRID	Status ¹	Results or Deficiency
63-2	830.6302	Color	43987201 43983801 57014 57022 57024 76242	A	White prill white crystalline solid White solid flakes
63-3	830.6303	Physical state	43987201 43983801 57014 57022 57024 76242	A	Solid, flakes, powder
63-4	830.6304	Odor	43987201 43983801 57014 57022 57024 76242	A	Pungent formaldehyde odor
63-5	830.7200	Melting Point	43987201 43983801 57014 57024 76242	A	120 to 170°C closed tube
63-6	830.7220	Boiling Point	43987201 43983801 124869	N/A	Solid at ambient temperature Slowly sublimes to formaldehyde gas. 760 mm Hg Sublimes at 150°C
63-7	830.7300	Density, Bulk Density, or Specific Gravity	43987201 43983801 124869 57014 57024 76242	A	750 to 850 kg/m3 Density: 1.46 g/ml @ 15°C Density varies with particle size and degree of compaction. Free flowing: approx. 37 lbs/cu ft Packed: approx. 42 lbs/cu ft Sp Gr. 1.40
63-8	830-xxxx	Solubility in organic solvents at 25°C (g/100 ml)	57014 57024 76242	A	Acetone: Soluble to insoluble Dilute Alkali: Very Soluble Dilute Acid: Very Soluble Insoluble in alcohol, ether. Insoluble in most organic solvents. (TOXNET).

OPP Guideline No.	OPPTS Guideline No.	Requirement	MRID	Status ¹	Results or Deficiency
					Solubility (Room Temperature): • Ethanol 2.37% • Methanol 4.71% • Hexane 5.10 ppm • Ether 108 ppm • 1.0 N NaOH 22.9% • 0.1N NaOH 22.8%
63-8	830.7840	Water solubility	43987201 43983801 44268001 57014 57024 76242 124869	A	>90% in water at pH 9.0 Slightly soluble in cold water. Difficulty Soluble. Partial – dependent on pH, temperature and molecular weight. The higher polymers are insoluble in water. The rate at which paraformaldehyde dissolves (hydrolyzes) in water is at a minimum at pH 3-5; it increases rapidly at lower or higher pHs. (TOXNET) Dissolves slowly in cold water, more rapidly in hot water, hydrolyzing and depolymerizing as it dissolves.
63-9	830.7950	Vapor Pressure Vapor Density	43987201 43983801 124869 57014 57024 76242	A	1.45 pCH ₂ (mm) depolymerization pressure at 25°C 1 mm Hg @ 30°C 1.4 mm Hg @25°C 1.55 mm Hg @ 30°C mm Hg Dry Air 1; Dew point 3 @ 60°C mm Hg Dry Air 5; Dew point 15 10.5 mm Hg @ 25°C (TOXNET) 1.03 (Air=1)
63-10	830.7370	Dissociation constants	43987201	A	1.6 x 10E-13 aqueous formaldehyde no formic acid
		in water	43983801		1.8 x 10E-4 for formic acid

OPP Guideline No.	OPPTS Guideline No.	Requirement	MRID	Status ¹	Results or Deficiency
					pKa = 15.50 @ 25°C (TOXNET)
63-11	830.7550	Partition coefficient (n-octanol / water)	43987201 43983801	A	-0.65 (calculated)
63-12	830.7000	рН	43987201 43983801	A	3.5 – 4.5 (In aqueous solution) A 5% suspension in water is neutral to litmus (TOXNET).
63-13	830.6313	Stability to normal and elevated temperatures. Stability to metals. Stability to metal ions.	43987201 43983801 44268001 57014 57024 124869	A	Paraformaldehyde is stable on exposure to sunlight, elevated temperatures (54°C) and elemental metals, copper, iron and aluminum. Stable under ordinary conditions of use and storage. Releases formaldehyde gas slowly as it sublimes at room temperatures. (Slowly sublimes to formaldehyde). High temperature causes liberation of formaldehyde gas. Stable for up to 12 months when stored at ambient temperatures.
63-15	830.6315	Flammability	43987201 43983801 57022 124869	A	~71°C tag closed cup; 93°C Flash point: 70°C 158F Tag Closed Cup (TCC) 200F Tag Open Cup (TOC) Flash Points: Closed Cup: 70°C (158°F). 158F Tag Closed Cup (TCC) 200F Tag Open Cup (TOC)
63-17		Storage stability	43987201 43983801	A	Stable for up to 12 months when stored at ambient temperatures. Product must be store at temperatures not higher than 25°C.
63-16	830.6316	Explodability	43987201 43983801	A	Upper~70%; Lower~7% Explosion limits: 7.0 – 73% Autoignition temp: 300°C (572°F)
63-18	830.7100	Viscosity	43987201	A	N/A Product is solid at 25°C

OPP Guideline No.	OPPTS Guideline No.	Requirement	MRID	Status ¹	Results or Deficiency
			43983801		
63-19		Miscibility	43987201 43983801	A	~90% in water at pH 9.0
63-20	830.6320	Corrosion Characteristic	43987201 43983801	A	Moderate
63-21	830.6321	Dielectric Breakdown Voltage	43987201 43983801	A	~450e @20°C
63-14	830.6314	Oxidation/Reduction: Chemical Incompatibility	43987201 43983801 57022	A	Oxidation: 2HCHO + H202 + 2NaOH > 2HCOONa + 2H20 + H2 HCH0+1/2 O2 > HCOOH HCHO + 02 > C02 + H20 [Requires very high temp - >300°C] 2HCHO +02 > 2C0 + 2H20 Reduction: HCHO + H2 < > CH3OH Incompatibility: Incompatible with strong acids, organic acids, strong oxidizing agents, oxides, alkalies, strong bases, amines. Combustible. Dust may form an explosive mixture with air. Liberates poisonous gases on combustion. Incompatibilities:
			124869		Caustics, strong alkalis, isocyanates, anhydrides, oxides and inorganic acids. Paraformaldehyde or concentrated formalin solutions may react violently with strong oxidizing agents, ammonia, strong alkalis, isocyanates, peracids, anhydrides and inorganic acids.
					Hazardous Polymerization: Will not occur.
Other Ch	emical/Ph	ysical Properties			
		Classification			Aldehyde

 $^{^{1}}A = Acceptable; N/A = Not applicable.$

Bibliography

MRID	Citation Reference
57014	Celanese Chemical Company (19??) Identity: Paraformaldehyde Flake, Hi Assayl. (Unpublished study received Nov 4, 1977 under 11558- 4; CDL:232281-A)
57022	Celanese Chemical Company (1975) Material Safety Data Sheet: Para- form. Rev. (Unpublished study received Nov 4, 1977 under 11558-4; CDL:232281-I)
57024	Celanese Chemical Company (19??) Identity: Paraformaldehyde Flake. (Unpublished study received Nov 4, 1977 under 11558-6; CDL:232283-A)
76242	Hallemite Lehn & Fink (19??) Study: Chemistry of Paraformaldehyde Flake. (Unpublished study received Jan 11, 1977 under 10000-4; CDL:229293-C)
124869	Dane Chemco, Inc. (1966) Chemical StudyParaform. (Compilation; unpublished study received Jan 24, 1983 under 45341-1; CDL:249359-A)
43983801	Sibinovic, K. (1996) Product ChemistryDi-Gas Mildewcide: Lab Project Number: FYD-DI-GAS-01-95. Unpublished study prepared by Shaldra, Inc. 54 p.
43983802	Willis, C. (1995) Formol y Derivados Paraformaldehyde: Preliminary Analysis: Final Report: Lab Project Number: 1220-01. Unpublished study prepared by Case Consulting Labs, Inc. 19 p.
43987201	Sibinovic, K. (1996) Product ChemistryVP Paraformaldehyde: Lab Project Number: FYD-DI-GAS-01-95. Unpublished study prepared by Shaldra, Inc. 54 p.
44268001	Willis, C. (1997) Physical and Chemical Characteristics of VP Paraformaldehyde: Stability and Solubility: Final Report: Lab Project Number: 1220-03. Unpublished study prepared by Case Consulting Laboratories, Inc. 10 p. {OPPTS 830.6313, 830.7840}.
44892801	Sibinovic, K. (1999) Product ChemistryDiGas/Mildewcide (Paraformaldehyde Prill): Lab Project Number: DI-GAS-01-99. Unpublished study prepared by Shaldra, Inc. 16 p.

Sign-off Date : 01/24/08 DP Barcode No. : D348487