Product Toxicity Summary Sheet

Form 15594 - G - PWO

Product Name	Issue Date
FLUORAD® Brand Fluorochemical Surfactant FC-95	June 5, 1992

Below is a summary of the study data giving an indication of the relative toxicity of the product. (Definitions of test procedures are found on the reverse side of this sheet.) This summary is the data for the precautionary use information provided with the product.

Relative toxicity of a material is only one factor that is important in determining the degree of hazard in handling a chemical or product. Other considerations to include are physical properties of the chemical, extent and frequency of use or exposure, intended use, and possible misuse of the product. For additional information regarding safe handling of the product, please reference the Material or Product Safety Data Sheet.

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ACUTE ORAL TOXICITY: MODERATELY TOXIC. FC-95 was found to be moderately toxic upon acute oral administration. In the study FC-95 was administered in a 20% acetone/80% corn oil suspension to 10 rats (five male and five female) per dose level. Four dose levels were used: 100, 215, 464, and 1000 mg/kg of body weight. At 1000 and 464 mg/kg all animals died. The signs before death included hypoactivity, decreased limb tone and ataxia. At 215 mg/kg 3/10 deaths were reported. At 100 mg/kg no deaths were observed. Additional pharmacotoxic signs included corneal opacity and high carriage. The combined male and female rats LD50 is 251 mg/kg (95% C.I.: 199-318 mg/kg). FC-95 is considered moderately toxic on an acute oral basis.

(International Research and Development Corp.; May 1978; 137-038)

ACUTE DERMAL TOXICITY: PRACTICALLY NONTOXIC. Ten male and ten female rabbits received a dose of FC-95 equivalent to 5000 mg/kg. The test material was dosed as a suspension in water and applied to 40% of the total body area. The rabbits were wrapped with an impervious plastic sheeting for a period of 24 hours after which time the sheeting was removed and the FC-95 washed off the skin. The animals were held for 28 days. Hyperactivity was noted in 5 of 10 males on day 6. All animals recovered by day 7 and remained asymptomatic throughout the study period. Weight gains were observed for all rabbits. No visible lesions were noted at necropsy. The acute dermal LD50 (rabbit) is greater than 5 g/kg. FC-95 is practically nontoxic dermally.

(Riker Safety Evaluation Laboratory, Inc.; March 13, 1981; 0970AB0632)

EYE IRRITATION: MILDLY IRRITATING. FC-95 was found to be mildly irritating to the eyes of albino rabbits when tested according to standard FHSA guidelines. The ocular irritation was limited to the conjunctivae in the six test animals. Irritation was noted at the 1, 24 and 48 hour post-instillation reading times. The maximum irritation score was 9.3 (highest possible score 110.0) at the 24 hour reading. By 72 hours post-instillation all readings were zero.

(WARF Institute, Inc.; November 7, 1974; WARF No. 4102871)

PRIMARY SKIN IRRITATION: NONIRRITATING. FC-95 was found to be nonirritating to the skin of albino rabbits when tested under conventional Draize procedures. No signs of dermal irritation were observed in any of the test animals at any time during the study period. The primary skin irritation score was 0.0 (highest possible score 8.0).

(WARF Institute, Inc.; November 7, 1974; WARF No. 4102871)

ACUTE INHALATION: A series of one-hour inhalation exposures to FC-95 was performed on Sprague-Dawley rats. The nominal exposure concentrations 24.09, 7.05, 6.49, 4.88, 2.86, 1.89 and 0.0 milligrams per liter. Total mortality was produced at the nominal exposure concentration of 24.09 milligrams per liter. Partial mortality was produced at nominal exposure concentrations of 7.05 (80%), 6.49 (80%), 4.88 (20%) and 2.86 (10%) milligrams per liter.

Test Descriptions

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LD_{50} - the dose lethal to 50% of the exposed animals. Dosage is expressed in grams, milligrams or milliliters per kilogram of animal body weight.

LC_{50} - the airborne concentration lethal to 50% of the exposed animals. Dosage is expressed in parts per million (ppm) by volume or milligrams per liter (mg/l) of chamber concentration for a stated period of time.

1. **Acute Oral** - refers to a test of a single dose of a product; a specified weight or volume per kilogram of body weight is administered orally to albino rabbits. There is a 14-day observation period following dosing. The product is classified for oral toxicity according to the system of Hodge and Sterner (classified on basis of oral LD_{50} in mg/kg): Extremely toxic: 1 mg or less; Highly toxic: 1 to 50 mg; Moderately toxic: 50 to 500 mg; Slightly toxic: 500 mg to 5 gms; Practically non-toxic: 5 to 15 gms; Relatively harmless: >15 gms.

2. **Acute Dermal** - refers to a test of a single dose of a product; a specified weight or volume per kilogram of body weight is administered by continuous contact for 24 hours with the bare skin of albino rabbits. There is a 14-day post-administration observation period. A descriptive rating of the dermal toxicological properties (i.e., American National Standards Institute, USA Federal Hazardous Substances Act, Hodge-Sterner or European Economic Community toxicity classification) is assigned to the product.

3. **Acute Inhalation** - refers to a test of a single continuous inhalation exposure of a specific concentration of a product for a given period of time. A descriptive rating of the inhalation toxicological properties (i.e., American National Standards Institute, USA Federal Hazardous Substances Act, Hodge-Sterner or European Economic Community toxicity classification) is assigned to the product.

4. **Primary Skin Irritation** - refers to a test of single dermal application of 0.5 gram or 0.5 milliliter of a product to albino rabbits. Either the OECD or the FHSA test guideline is employed. In the OECD test method the sample is applied to intact skin test sites of three or more animals, semi-occluded, and held in contact for 4 hours. Observations are made at 4, 24, 48 and 72 hours post-application. In the FHSA test method the sample is applied to both intact and abraded skin test sites of six animals, occluded, and held in contact for 24 hours. Observations are made at 24 and 72 hours. Scoring for dermal irritation in both test methods is according to the procedure of Draize.

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5. **Eye Irritation** - refers to a test of a single application of 0.1 gram or 0.1 milliliter of a product into the conjunctival sac of the eye of the test animals (usually albino rabbits). Either the OECD or FHSA test guideline is employed. In the OECD test method three animals are normally used with the eyes observed at 1, 24, 48 and 72 hours. In the FHSA procedure six animals are used with observations at 24 and 72 hours post-application. Additional observations or evaluation times may be added. Scoring for eye irritation in both protocols is according to the procedure of Draize.

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Other tests including dermal sensitization studies (guinea pigs), human patch tests, **in vitro** mutagenicity tests and sub-acute or chronic toxicity tests may be conducted and summarized on the Product Toxicity Summary Sheet.

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Predominate physical abnormalities observed during the exposure and post-exposure periods were labored breathing, reduced activity, excessive salivation and lacrimation, mucoid and red nasal discharge, yellow staining of the ano-genital fur, dried red material on the facial area, and general poor condition. The most frequent abnormal necropsy observations were of lung and liver discoloration. Lung discoloration was also observed in a high number of control rats and thus may not be treatment-related.

The nominally determined median lethal concentration (LC50) for a one-hour exposure to FC-95 was determined to be 5.2 milligrams per liter with approximate 95% confidence limits of 4.4 milligrams per liter and 6.4 milligrams per liter. (Bio/dynamics, Inc.; December 31, 1979; Project No. 78-7185)

90-DAY FEEDING STUDY: FC-95 was fed in the diet at levels of 30, 100, 300, 1000 and 3000 ppm to Charles River CD rats for 3 months. Five male and 5 female rats were initiated at each dosage level and in the control group.

At dosage levels of 300, 1000 and 3000 ppm, all rats died prior to scheduled termination of the study. Overt signs of toxicity included: emaciation, convulsions, altered posture, red material (right eye and/or mouth), yellow material (ano-genital region), increased sensitivity to external stimuli and reduced motor activity were evident prior to most deaths. Time of death was directly related to the dosage level with the earliest deaths seen in the 3000 ppm treatment group.

At the 30 ppm dosage level, neither male nor female rats showed any compound related changes in appearance or behavior. Mean body weights were slightly lower for the rats at the 30 ppm dosage level when compared to the controls.

At the 100 ppm dosage level at 3 months, body weight means were lowered when compared to the controls for males and for females. Food consumption means were lower (statistically significant) when compared to the controls for males and females.

Compound-related gross changes such as emaciation, areas of discoloration involving the stomach and liver were observed among treated rats that died prior to sacrifice. Similar changes were also observed in the liver of a few rats sacrificed at termination of study from the 30 and 100 ppm groups.

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Microscopically, compound-related lesions were observed among all test groups. Morphological changes consisting of centrilobular to midzonal cytoplasmic enlargement (hypertrophy) of hepatocytes were observed in the livers. Necrosis of liver cells was also present among these rats. The incidence and relative severity of the above lesions were more evident among male test rats.

In addition, especially among rats from the 30, 1000 and 3000 ppm dosage level that died prior to sacrifice, changes involving the primary (thymus, bone marrow) and secondary (spleen, mesenteric lymph nodes) lymphoid organs, stomach, intestines, muscle and skin, were observed and were all considered as compound related.

90 DAY RHESUS MONKEY FEEDING STUDY: FC-95 was administered by gavage to rhesus monkeys at dosage levels of 0 (distilled water only), 0.5, 1.5 and 4.5 mg/kg/day for 90 days. Two male and two female monkeys were initiated at each dosage level and also in the control group. The monkeys treated at the 4.5 mg/kg/day dosage level died or were sacrificed in extremis between weeks 5 and 7 of the study. These monkeys exhibited signs of toxicity in the gastrointestinal tract (anorexia, emesis, black stool and dehydration) from the first or second day of study. All the high-dose monkeys had decreased activity and before death showed marked to severe rigidity, convulsions, generalized body trembling, prostration and loss of body weight. The mean body weight decreased from 3.44 kg at the beginning of the study to 2.70 kg at week 5 of the study. At 1 month of study all monkeys at the 4.5 mg/kg/day dosage level had decreased serum cholesterol values and serum alkaline phosphatase activity.

All monkeys at the remaining dosage levels survived to the end of the study. The monkeys exhibited slightly decreased activity from the first week of the study which occasionally became moderate to marked. The animals occasionally had black stools, diarrhea, mucous in the stool and bloody stool. The 1.5 mg/kg monkeys exhibited dehydration or general body trembling at the end of study.

No gross or microscopic pathological lesions which were considered compound related were seen in tissues other than the adrenals, pancreas, and submandibular salivary glands of male and female rhesus monkeys at the 4.5 mg/kg/day dosage level.

No statistically significant variations in sex group mean weights of organs occurred between the control and experimental groups.
(International Research and Development Corp.; 1978)

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TERATOGENICITY (RAT): NOT TERATOGENTIC. FC-95, suspended in corn oil at concentrations intended to deliver 1, 5 or 10 mg/kg/day (Groups 2, 3, and 4, respectively), was administered by oral intubation to mated female Sprague-Dawley CD® rats on presumed gestation days 6-15. A fourth group (Group 1) of mated females served as the control group and received the vehicle only. There were 25 rats per dose level.

Two Group 4 females died. Treatment-related clinical observations noted in Groups 3 and 4 included thinness, hunched appearances, rough haircoats, alopecia, and anorexia. Food consumed by Groups 3 and 4 animals was significantly less than control both during treatment and throughout gestation. Compared to control (Group 1) body weight gains, significantly less body weight was gained by Groups 3 and 4 females throughout gestation. Actual loss of body weight occurred in Groups 3 and 4 animals once treatment had been initiated. Terminal body weight minus gravid uterine weight was also significantly decreased in Groups 3 and 4. Treatment-related gross pathology in Group 4 animals included incidences of gastrointestinal tract effects.

Statistical analysis revealed a positive treatment-related trend in fetal loss, attributable primarily to an increased incidence of late resorbing fetuses in litters from Group 4 dams. Mean male and female fetal body weights were significantly decreased in fetuses Groups 3 and 4 litters. Significant increases in external and visceral anomalies occurred in fetuses from Group 4 dams and included subcutaneous edema, cleft palate, and cryptorchism. Anomalies were observed primarily in fetuses from Group 4 dams exhibiting signs of severe maternal toxicity, i.e., decreased food consumption and weight loss. Fetal toxicity manifested as increased numbers of late resorbing fetuses and dead fetuses, decreased fetal body weights, and delays in skeletal system ossification occurred in litters derived from that group as well.

The specificity and frequency of these results indicate that administration of FC-95 to pregnant rats during Days 6-15 of gestation at a dose of 10 mg/kg results in maternal toxicity, fetotoxicity and an increased incidence of external and visceral anomalies and skeletal variants.

FC-95 is no teratogenic in rats at dose levels less than or equal to 5 mg/kg. FC-95 is not teratogenic at doses below maternally toxic levels.
(Hazelton Laboratories America, Inc.; December 19, 1983; 154-160)

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12234-10 Supersedes October 2, 1991

IN VITRO MUTAGENICITY TESTS: NOT MUTAGENIC. FC-95 was tested for its mutagenic potential with five Ames *Salmonella typhimurium* bacteria strains, TA1535, TA1537, TA1538, TA98 and TA100 and with the yeast *Saccharomyces cerevisiae* strain D4. Each strain was tested with and without a metabolic activation step. All tests were negative indicating FC-95 is nonmutagenic in the assays.
(Litton Bionetics, Inc.; February 1978; LBI Project No. 20838)

(105-FC95)

3M Industrial Chemical Products Division

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