Final Report

Assessment of Exposures and Risks from the Use of Pulp-Containing Medical Devices

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1. INTRODUCTION

Under the terms of the July 1988 Consent Decree between EPA, EDF, and NWF, EPA must assess risks associated with the use of medical devices since these devices are known to contain bleached wood pulp or derivatives of bleached wood pulp. This report provides the estimated exposures and risks associated with the use of medical devices containing bleached wood pulp. The scope of this assessment is limited to "patients" (nonoccupational); occupational exposures and risks were not estimated.

This assessment has been developed in cooperation with the Food and Drug Administration (FDA) Center for Devices and Radiological Health (CRDH). The Center has provided a list of medical devices that contain bleached wood pulp, numerous parameters/assumptions concerning product use and wood pulp content, and general guidance on how each product is used.

Table 1-1 provides a list of those medical devices believed to contain bleached wood pulp. Note, however, that FDA is not certain whether other medical devices may contain bleached wood pulp because manufacturers are not required to provide FDA information regarding the ultimate source of the raw materials. Therefore, the products listed in this table are FDA's best estimate on what products contain bleached wood pulp. These devices are used at medical facilities, and several may be purchased over the counter for home use.

This report is organized into three parts. Section 2 contains all the exposure and risk estimates, along with input parameters used to derive these estimates. A discussion on uncertainties is presented in Section 3, and Section 4 presents conclusions.

Table 1-1. Medical Devices for Which Exposures and Risks Were Estimated and Their Corresponding Uses

Medical device	Use
Unscented menstrual pad	To absorb menstrual discharge
Scented menstrual pad	To absorb menstrual discharge
Unscented menstrual tampon	To absorb menstrual discharge
Scented menstrual tampon	To absorb menstrual discharge
Alcohol pads	To apply alcohol or other disinfectants to the surface of the skin
Skin preparation for dressing wounds	To clean cuts or wounds before applying a permanent bandage
Absorbable hemostatic agents	A small sponge used during surgery
Wound dressings containing carboxymethyl cellulose	To cover cuts or wounds
Surgical apparel	Worn by surgeons, nurses, and patients during surgery (e.g., hoods, caps, masks, gowns, foot coverings, drapes)
Adult diapers	To absorb urine or feces uncontrollably released by adults
Medical disposal bedding	To cover mattresses
Medical absorbent fiber	Cotton-like pads used to apply medication or to absorb small amounts of fluid from a patient's body surface
Absorbent tipped applicator	To apply medications or remove specimens from a patient
Examination gown	Worn by patients during examinations
Ophthalmic sponges	Small sponges used to absorb fluids during eye surgery
Hydroxpropymethyl cellulose	To replace fluids in the eye lost during surgery
Cottonoid paddie	To absorb body fluids (i.e., a cotton ball)
Electroconductive media	Conductive creams or gels used to reduce the impedance to the electrode from the surface of the skin
Cutaneous electrode	An electrode applied directly to the skin to either record physiological signals or apply stimulation
Anesthetic conduction filter	A microporous filter used to remove particulates from anesthesia or other gases
Breathing circuit bacteria filter	To filter microbiological and particulate matter from a breathing circuit (which administers medical gases to a patient)
Heat and moisture condensers	To preserve the purity and physical state of gases used in a respirator or as an anesthesia
Isolation gowns	Worn to isolate patients at a hospital

2. ESTIMATES OF EXPOSURES AND RISKS FROM DERMAL CONTACT WITH PULP-CONTAINING MEDICAL DEVICES

2.1 Exposure Parameters

The exposure parameters used to estimate exposure and risks from dermal contact with pulp-containing medical devices are listed in Table 2-1. Unless otherwise noted, the data in this table were obtained directly from FDA (letter from Mel Stratmeyer, Food and Drug Administration, to Greg Schweer, U.S. Environmental Protection Agency, dated June 5, 1989).

In addition to the exposure parameters listed in Table 2-1, the industry average concentrations of 2,3,7,8-TCDD and 2,3,7-8-TCDF found in pulp in the 104 Mill Study were used to estimate exposures and risks for all medical devices, except those made from rayon. This was necessary because, in most cases, concentrations of 2,3,7,8-TCDD and 2,3,7,8-TCDF in pulp at individual mills could not be traced to specific medical devices. In calculating the average values, one-half the detection limit was substituted for nondetected values (see Table 2-2). However, the average concentrations were similar to average concentrations calculated without nondetected values.

For those medical devices made from rayon, the identities of those mills that produce dissolving cellulose pulp used to make rayon were identified by the American Paper Institute. The locations of the sites and the concentrations of 2,3,7,8-TCDD and 2,3,7,8-TCDF in pulp from those sites as found in the 104 Mill Study are presented in Table 2-3.

Of the devices listed in Table 2-1, the following subset belongs in the category of rayon-containing devices:

Unscented Menstrual Tampon
Scented Menstrual Tampon

Table 2-1. Exposure/Risk Parameters for Medical Devices

Device name[a]	Contact type[a]	Device mass[a] (gm)	Pulp in product[a] (%)	Pulp mass in product[a] (gm)	Exposure duration[a] (days/ lifetime)	Volume of liquid on skin/ total volume[b] (%)	Wetting factor[b] (%)	Absorbtion rate through skin[c] (%)	Partition coefficient[c] TCDD	TCDF
Unscented Menstrual Pad	Skin	10	90	9	2,400	25	10	25	14,300	5,300
Scented Menstrual Pad	Skin	10	90	9	2,400	25	10	25	14,300	5,300
Unscented Menstrual Tampon	Intact Nat. Channel	3-5	90	3.6	2,400	100	100	100	14,300	5,300
Scented Mentrual Tampon	Intact Nat. Channel	3-5	90	3.6	2,400	100	100	100	14,300	5,300
Alcohol Pads	Skin	0.5-1	100	0.75	6	100	100	25	2,000	2,000
Skin Prep. Wipe for Dressing Wounds	External, Short Term	2			NA	50	10	25	14,300	5,300
Absorbable Hemostatic Agents (e.g., SurgicelR, Oxycel)	Internal, Short Term	3-5	100	4	NA	100	100	100	14,300	5,300
Wound Dressings Containing Carboxymethyl Cellulose	Compromised Tissue	4	100		NA	50	50	100	14,300	5,300
Surgical Apparel: Hood, Cap, Masks, Gowns, Foot Cov., Drapes	External	150 (GWNS) 7-10 (MSKS)	100	150 8.5	0.17	NA	NA	0.30	NA	NA
Adult Diapers	Skin	113.5	90	102.2	730	0.017	10	25	14,300	6,300
Medical Disposable Bedding	Skin	113.5	100	113.5	1	NA	NA	0.30	NA	NA
Medical Absorbent Fiber	Skin	<0.5	100	0.5	17.7	50	100	25	14,300	5,300
Absorbent Tipped Applicator	Skin	0.25	50	0.12	17.7	100	100	25	2,000	2,000
Examination Gown	Skin	113.5	100	113.5	0.6	NA	NA	0.30	NA	NA
Ophthalmic Sponges	Surgical Aids	0.5	100	0.5	0.08	100	100	100	14,300	5,300
Hydroxypropymethyl Cellulose	Intraocular Surg Aid	<1 ml	100	1	0.08	100	100	100	14,300	5,300
Cottonoid Paddie	Compromised Tissue	2	<1	0.002	0.5	100	100	100	2,000	2,000
Electro Conductive Media	Skin Surface(Intact)	1-5	<1	0.003	2	100	100	25	2,000	2,000
Cutaneous Electrode	Skin Surface(Intact)	1-5	<1	0.003	2	100	100	25	2,000	2,000
Anesthetic Conduction Filter	No Direct Contact	2-3	100	2.5						
Breathing Circuit Bacteria Filter	No Direct Contact	2-3	100	2.5						
Heat & Moisture Condensers	No Direct Contact	2-3	100	2.5						
Isolation Gowns	External	150	100	150	0.17	NA	NA	0.30	NA	NA

NA - Not applicable

[a] Data obtained from FDA/CDRH (Stratmeyer (1989) or telephone conversations between Versar and FDA).

[b] Assumptions by Versar and FDA based on best available data and expected use patterns.

[c] Based on data obtained from Babich (1989) and Babich et al. (19 (see Chapter 9 and Appendix A of this assessment).

Table 2-2. Average Concentrations of 2,3,7,8-TCDD and 2,3,7,8-TCDF in Pulp Calculated Based on Results from the 104-Mill Data Base

	Highest conc. (pg/g)	Average conc. without nondet. (pg/g)	Average conc. with nondet. (pg/g)
2,3,7,8-TCDD	116	8.4	8.5
2,3,7,8-TCDF	2,620	84.4	84.4

Table 2-3. Concentrations of 2,3,7,8-TCDD and 2,3,7,8-TCDF in Pulp at Pulp Mills that Produce Dissolving Cellulose

Company	Mill location	2,3,7,8-TCDD conc. (pg/g)	2,3,7,8-TCDF conc. (pg/g)
Alaska Pulp Corp.	Sitka, AK	0.7 (ND)	1.4
International Paper Co.	Natchez, MS	3.6	15.0
		2.2	3.0
ITT Rayonier, Inc.	Fernandina Beach, FL	0.2 (ND)	0.5 (ND)
	Jesup, GA	0.6 (ND)	0.8 (ND)
		0.3 (ND)	0.8
		0.7 (ND)	0.6
		0.7 (ND)	0.9
	Port Angeles, WA.	0.6 (ND)	2.1
Ketchikan Pulp & Paper	Ketchikan, AK	0.3 (ND)	0.3 (ND)
Proctor & Gamble Co.	Mehoopany, PA	2.0	1.1
Weyerhaeuser Co.	Cosmopolis, WA	1.0 (ND)	6.3
		NQ	6.4
		0.3 (ND)	2.9
		0.3 (ND)	3.1
AVERAGE CONCENTRATION[a]		0.8	3.0

ND = Non-Detect.
NQ = Not Quantified.

[a] In calculating the average concentrations, ND values were assumed to be one-half the detection limit.

[a] There will be no direct contact for these products. The only potential exposure route is through inhalation of dioxin that leaves the filter or condenser and enters the indoor air. The exposure through this pathway is expected to be negligible because only a very small amount of dioxin will leave these products and enter the air, and of the amount that does enter the indoor air, very little will actually enter the lungs and be absorbed.

[b] LADDs were calculated as follows:8

$$\frac{\left(\text{Concentration } \left(\frac{pg}{g}\right) \times \text{Pulp Mass } \left(\frac{g}{day}\right) \times \text{Exposure Duration (Days)} \times \text{Volume of Liquid on Skin/Total Volume} \times \text{Wetting Factor (unitless)} \times 1/\text{Partition Coefficient (unitless)} \times \text{Absorption Rate (\%)}\right)}{\text{Body Weight (Kg)} \times \text{Lifetime (70 years)} \times 365 \text{ days/year.}}$$

There were two exceptions, however. The first exception was the method to estimate LADD for surgical apparel, medical disposable bedding, examination gowns, and isolation gowns and this was explained in footnote h in Table 8-2. The other exception was for products where FDA already estimated the total mass of the product available for exposure (skin prep. wipe for dressing wounds, absorbable hemostatic agents, and wound dressings containing carboxymethyl cellulose). In this case, LADD was estimated as follows:8

$$\frac{\left(\text{Concentration} \times \text{Total Mass Exposed} \times \text{Volume of Liquid on Skin/Total Volume} \times \text{Wetting Factor} \times 1/\text{Partition Coefficient} \times \text{Absorption Rate}\right)}{\text{Body Weight} \times 70 \text{ years} \times 365 \text{ days/year}}$$

[c] The slope factors are as follows for TCDD: EPA 1.56×10^{5} $(mg/kg\ day)^{-1}$; FDA = 1.75×10^{4} $(mg/kg\ day)^{-1}$; CPSC = 6.7×10^{4} $(mg/kg/day)^{-1}$.

[d] The slope factors are as follows for TCDF: EPA 1.56×10^{4} $(mg/kg\ day)^{-1}$; FDA = 1.75×10^{3} $(mg/kg\ day)^{-1}$; CPSC = 0.

[e] For EPA and FDA cancer slope factors, risk was estimated as follows: Risk = potency factor $(mg/kg\text{-}day)^{-1} \times 10^{-9}$ mg/pq x LADD (pq/kg-day)/0.55. However, for the CPSC cancer slope factor, risk was estimated as follows: Risk = potency factor $(mg/kg\text{-}day)^{-1} \times 10^{-9}$ mg/pg x LADD (pg/kg-day) / 0.75. The divisor is changed to 0.75 (from 0.55) because a different bioassay was used. The total risk is the sum of the risks from TCDD and TCDF.

Would Dressings Containing Carboxymethyl Cellulose
Medical Absorbent Fiber
Hydroxpropymethyl Cellulose

The exposure parameters in Table 2-1 that require further explanation are detailed below.

2.1.1 Exposure Duration

Depending on the specific situation, alcohol pads are used rarely to daily. As a worst use assumption it is assumed that each application of alcohol pads lasted 30 seconds and will be administered 365 days per year for 50 years.

Surgical apparel and isolation gowns are used only during surgery. It is assumed that surgery lasts 2 hours or 0.083 day and occurs twice over a 70-year lifetime. In addition, exposure to medical disposable bedding will occur for hours on a rare basis. It is assumed that exposure to medical disposable bedding would last 12 hours per visit and would occur twice over a 70-year lifetime. The examination gowns used by patients are worn occasionally for hours. It is assumed that the gowns are worn for 1 hour every 5 years over a 70-year lifetime.

Exposures to medical absorbent fiber and absorbent tipped applicators occur for seconds on an occasional to daily basis. As a worst-case assumption, it is assumed that these devices are used for 60 seconds at a rate of 365 days per year over 70 years.

Both ophthalmic sponges and hydroxypropymethyl cellulose are used during eye surgery. Eye surgery lasts less than 1 hour and occurs once or twice per lifetime. Therefore, it is assumed that eye surgery will last 1 hour and that it occurs twice over a 70-year lifetime.

Cottonoid paddies are used several minutes to hours on a negligible basis; therefore, it is assumed that the paddies are used once for 12 hours over a 70-year lifetime. Electro conductive media and cutaneous electrodes are used on a negligible basis for minutes to days. It is assumed that the exposure duration for these devices occur once for 2 days over a 70-year lifetime.

2.1.2 Absorption Rate

The rate of 2,3,7,8-TCDD transferred to the skin over a 24-hour period from surgical apparel, medical disposable bedding, and examination and isolation gowns is calculated as 0.012 (0.0005/hr x 24 hr) (Babich 1989). In addition, it was assumed that 25 percent of this amount will be absorbed. There is no partition coefficient since this is based on dry skin transfer. Therefore, the amount transferred and absorbed over a 24 hour period is 0.012 x 0.25 = 0.003 or 0.3%. Since there is no partition coefficient, the LADD was calculated differently than for the other products:

$$\frac{\text{Concentration (pg/g)} \times \text{Pulp Mass (g/day)} \quad \text{Exposure Duration (days)} \times \text{Transfer Rate (\%)} \times \text{Absorption Rate (\%)}}{\text{Body Weight (kg)} \times \text{Lifetime (70 years)} \times 365 \text{ days/year}}$$

For those products in contact for long periods of time with internal body fluids or in contact with compromised tissue in a wetted state, 100 percent absorption was assumed.

2.1.3 Partition Coefficient

The partition coefficients used are those reported for paper pulp using ethanol, synthetic urine, or saline solution in Babich et al. (1989). The partition coefficient used for alcohol pads is based on the ethanol results. Ethanol closely approximates the rubbing alcohol solution actually used. The transfer medium for the use of absorbent tipped applicators, cottonoid paddies, electro conductive media, and

cutaneous electrode is assumed to be analogous to the transfer medium assumed by Babich (1989) for make-up removal using facial tissues (ethanol). This assumption provides a worst-case scenario for the partition coefficient.

For all other medical devices, with the exception of diapers, saline solution was assumed to be the most representative partitioning/transfer medium. For adult diapers, the results from the urine partitioning experiment were used.

The final general point about Table 2-1 is that when no actual data were available, reasonable or reasonable worst-case assumptions were used. For example, for the "volume of liquid on skin/total volume" and the "wetting factor," reasonable worst-case assumptions were used. For partition coefficients, the most reasonable case was selected; however, if no clear choice could be made, the worst-case option was used. The estimation of the exposure duration was also based on the most "reasonable" assumptions. However, if accurate data were not available, reasonable worst-case assumptions were used.

2.2 Exposure/Risk Assessment for Medical Devices

Table 2-4 lists the exposure/risks associated with the use of the medical devices listed in Table 1-1. A few general points should be noted when reviewing this table. First, lifetime average daily dose (LADD) was estimated using three slightly different methods, depending on the way the product is used and the type of data available. The most common method was as follows:

$$\frac{(C)(PM)(ED)(V)(WF)(1/PC)(AR)}{\text{Body Weight (kg)} \times \text{Lifetime (70 years)} \times 365 \text{ Days/Year}}$$

Table 2-4. Estimates of Risks to the General Population from the Use of Pulp-Containing Medical Devices

Device name	Lifetime average daily dose (LADD)[b] (pg/kg/day) 2,3,7,8-TCDD	TEQ	Lifetime individual cancer risk[c,d,e] EPA	2,3,7,8-TCDD (%)	FDA	2,3,7,8-TCDD (%)	CPSC	2,3,7,8-TCDD (%)	Potentially exposed population
Unscented Menstrual Pad	4.49E-08	1.65E-07	4.68E-11	27	5.25E-12	27	4.01E-12	100	3.96E+07
Scented Menstrual Pad	4.49E-08	1.65E-07	4.68E-11	27	5.25E-12	27	4.01E-12	100	3.71E+07
Unscented Menstrual Tampon	2.70E-07	5.43E-07	1.54E-10	50	1.73E-11	50	2.41E-11	100	2.83E+07
Scented Menstrual Tampon	2.70E-07	5.43E-07	1.54E-10	50	1.73E-11	50	2.41E-11	100	5.20E+06
Alcohol Pad	2.67E-09	5.32E-09	1.51E-12	50	1.70E-13	50	2.39E-13	100	1.0E+06 - 1.0E+07
Skin Prep. Wipe for Dressing Wounds	2.08E-10	7.64E-10	2.17E-13	27	2.43E-14	27	1.86E-14	100	Millions
Absorbable Hemostatic Agent (e.g., Surgicel®, Oxycel)	1.66E-08	6.11E-08	1.73E-11	27	1.95E-12	27	1.48E-12	100	Millions
Wound Dressing Containing Carboxymethyl Cellulose	7.82E-12	1.57E-11	4.46E-15	50	5.01E-16	50	6.99E-16	100	Hundreds of Thousands
Surgical Apparel: Hood, Cap, Mask, Gown, Foot cov., Drape	3.64E-07	7.25E-07	2.06E-10	50	2.31E-11	50	3.25E-11	100	Millions (patients) Thousands (health care)
Adult Diaper	1.05E-10	3.43E-10	9.73E-14	31	1.09E-14	31	9.41E-15	100	1.0E+06 - 1.0E+07
Medical Disposable Bedding	1.62E-06	3.23E-06	9.15E-10	50	1.03E-10	50	1.45E-10	100	1.0E+06 - 1.0E+07
Medical Absorbent Fiber	3.46E-11	6.96E-11	1.97E-14	50	2.22E-15	50	3.09E-15	100	1.0E+06 - 1.0E+07
Absorbent-Tipped Applicator	1.26E-09	2.51E-09	7.13E-13	50	8.00E-14	50	1.13E-13	100	1.0E+06 - 1.0E+07
Examination Gown	9.71E-07	1.94E-07	5.49E-10	50	6.16E-11	50	8.67E-11	100	1.0E+06 - 1.0E+07
Ophthalmic Sponge	1.58E-11	5.15E-11	1.46E-14	31	1.64E-15	31	1.42E-15	100	
Hydroxypropymethyl Cellulose	2.50E-12	5.03E-12	1.43E-15	50	1.60E-16	50	2.24E-16	100	1.5 Million Cataract Oper./Year
Cottonoid Paddie	2.38E-12	4.74E-12	1.34E-15	50	1.51E-16	50	2.12E-16	100	Millions
Electro-Conductive Media	3.56E-12	7.10E-12	2.01E-15	50	2.26E-16	50	3.18E-16	100	Millions
Cutaneous Electrode	3.56E-12	7.10E-12	2.01E-15	50	2.26E-16	50	3.18E-16	100	Millions
Anesthetic Conduction Filter[a]									Millions
Breathing Circuit Bacteria Fltr.[a]									Millions
Heat & Moisture Condensers[a]									Millions
Isolation Gown	3.64E-07	7.25E-07	2.06E-10	50	2.31E-11	50	3.25E-11	100	Millions (patients) Thousands (health care)

Table 2-4. (continued)

[a] There will be no direct contact for these products. The only potential exposure route is through inhalation of dioxin that leaves the filter or condenser and enters the indoor air. Exposure through this pathway is expected to be negligible because only a very small amount of dioxin will leave these products and enter the air, and of the amount that does enter indoor air, very little will actually enter the lungs and be absorbed.

[b] LADDs were calculated as follows:

$$\frac{\left(\text{Concentration } \frac{(pg)}{(g)} \times \text{Pulp Mass } \frac{(g)}{(day)} \times \text{Exposure Duration (Days)} \times \text{Volume of Liquid on Skin/Total Volume} \times \text{Wetting Factor (unitless)} \times 1/\text{Partition Coefficient (unitless)} \times \text{Absorption Rate (\%)}\right)}{\text{Body Weight (Kg)} \times \text{Lifetime (70 years)} \times 365 \text{ days/year}}$$

There were two exceptions, however. The first exception was the method to estimate LADD for surgical apparel, medical disposable bedding, examination gowns, and isolation gowns, and this was explained in Equation 8-3. The other exception was for products where FDA already estimated the total mass of the product available for exposure (skin prep. wipe for dressing wounds, absorbable hemostatic agents, and wound dressings containing carboxymethyl cellulose). In this case, LADD was estimated as follows:

$$\frac{\left(\text{Concentration} \times \text{Total Mass Exposed} \times \text{Volume of Liquid on Skin/Total Volume} \times \text{Wetting Factor} \times 1/\text{Partition Coefficient} \times \text{Absorption Rate}\right)}{\text{Body Weight} \times 70 \text{ years} \times 365 \text{ days/year}}$$

[c] The slope factors are as follows for 2,3,7,8-TCDD: EPA = 1.56×10^{-4} $(pg/kg\ day)^{-1}$; FDA = 1.75×10^{-5} $(pg/kg\ day)^{-1}$; CPSC = 6.7×10^{-5} $(\mu g/kg/day)^{-1}$.

[d] The slope factors are as follows for 2,3,7,8-TCDF: EPA = 1.56×10^{-5} $(pg/kg\ day)^{-1}$; FDA = 1.75×10^{-6} $(pg/kg\ day)^{-1}$; CPSC = 0.

[e] For EPA and FDA cancer slope factors, risk was estimated as follows: Risk = potency factor $(pg/kg\text{-}day)^{-1}$ x LADD (pg/kg-day)/0.55. However, for the CPSC cancer slope factor, risk was estimated as follows: Risk = potency factor $(pg/kg\text{-}day)^{-1}$ x LADD (pg/kg-day) / 0.75. The divisor is changed to 0.75 (from 0.55) because a different bioassay was used. The total risk is the sum of the risks from TCDD and TCDF.

where:

C = Concentration (pg/g) of 2,3,7,8-TCDD or TCDF
PM = Pulp mass (g/day)
ED = Exposure duration (days/lifetime)
V = Volume of liquid on skin/total volume
WF = Wetting factor (unitless)
PC = Partition coefficient (unitless)
AR = Absorption rate (%)

This method estimates the amount of 2,3,7,8-TCDD/TCDF available on the skin surface, the transfer rate of dioxin from the medical device to the surface of the skin (partition coefficient), and the absorption rate through the skin. For several products (skin preparation for dressing wounds, absorbable hemostatic agents, and wound dressing containing carboxymethyl cellulose), FDA provided the total mass of product an individual may reasonably be exposed to over a lifetime. Therefore, this altered the way that the amount of 2,3,7,8-TCDD/TCDF available on the skin surface was estimated. For these products, LADD was estimated as follows:

$$\frac{(C)(TM)(V)(WF)(1/PC)(AR)}{\text{Body Weight (kg)} \times \text{Lifetime (70 years)} \times 365 \text{ days/year}}$$

where:

C = Concentration (pg/g)
TM = Total mass exposed
ED = Exposure duration (days/lifetime)
V = Volume of liquid on skin/total volume
WF = Wetting factor (unitless)
PC = Partition coefficient (unitless)
AR = Absorption rate (%)

For three other devices (surgical apparel, medical disposable bedding, and examination gowns), the rate of 2,3,7,8-TCDD/TCDF transferred to the skin and the absorption rate were combined. This transfer and absorption rate was used by Babich (1989), and it applies to products that will undergo dry contact with the skin surface. In these situations, LADD was estimated as follows:

$$\frac{(C)(PM)(ED)(TR)(AR)}{\text{Body Weight (kg)} \times \text{Lifetime (70 years)} \times 365 \text{ days/year}}$$

where:

C = Concentration (pg/g)
PM = Pulp mass (g/day)
ED = Exposure duration (days)
TR = Transfer rate (unitless)
AR = Absorption rate (%)

As shown in Table 2-4, LADDs for 2,3,7,8-TCDD were found to range from 2.38×10^{-12} pg/kg/day for cottonoid paddies to 1.62×10^{-6} pg/kg/day for medical disposable bedding. LADDs for 2,3,7,8-TCDF were found to range from 2.36×10^{-11} pg/kg/day for cottonoid patties to 1.61×10^{-5} pg/kg/day for medical disposable bedding. The other categories with the highest exposure levels are isolation gowns, examination gowns, surgical apparel, and tampons. Exposures for all these categories were estimated using the transfer and absorption rate of 0.3 percent because they involve dry skin contact. This method may be yielding unrealistically high estimates since it is expected that, in reality, dry skin contact would yield a lower dose.

Estimated risks were found to vary from 2.22×10^{-16} to 9.15×10^{-10} using EPA slope factors. They were found to vary from 2.49×10^{-17} to 1.03×10^{-10} using FDA slope factors and 5.07×10^{-17} to 1.45×10^{-10} using the CPSC factor (CPSC does not place the same emphasis on risks calculated by the TEQ method as it does for 2,3,7,8-TCDD itself when estimating carcinogenic potency. Therefore, Table 2-4 presents CPSC risk estimates based on 2,3,7,8-TCDD alone).

3. UNCERTAINTY ANALYSIS

The goal of an analysis of uncertainties is to provide decision makers with the complete spectrum of information concerning the quality of an assessment, including the variability in the estimated exposures and risks, the inherent variability in the input parameters, data gaps, and the effect these gaps have on the accuracy or reasonableness of the exposure and risk estimates developed. The general causes of uncertainty in an exposure/risk assessment are as follows:

- Measurement error;
- Use of indirect empirical or generic data;
- Variability;
- Use of models to estimate exposure/risk; and
- Use of professional judgment/disagreement.

For this assessment, uncertainties will occur from all of the above areas. All areas are important, with the possible exception of measurement errors. Measurement errors will occur (e.g., in determining the product mass), but compared to other errors, they will usually be insignificant. The remainder of this section discusses how the specifics of this assessment apply to the major areas of uncertainty.

Indirect or empirial data create uncertainties when the surrogate data used do not directly apply. The most important example is the partition coefficient because most partition coefficients were usually not estimated using the transfer medium in which the exposure will take place. It is anticipated that the partition coefficient can affect the results by over an order of magnitude, and this may be the single most important area of uncertainty.

Use of models to approximate the process of transfer and absorption of dioxin thru human skin introduces uncertainty into the assessment.

Uncertainty may be further compounded by the selection of the input parameters because errors associated with these parameters may be propagated by the use of these models.

Variability and professional judgment are most important in terms of the input parameters used in the exposure and risk models. All parameters are affected to some degree by these two areas of uncertainty, with exposure duration likely to have the largest effect on the results. For some categories (e.g., menstrual products), exposure duration is known within reasonable limits. In most other categories, however, a wide range of possible exposure durations is expected, and thus a high level of uncertainty will occur. Professional judgment is also particularly important for "volume of liquid on skin/total volume" and "wetting factor," since in most cases, measured data were not available.

4. CONCLUSIONS

Based on the analysis presented in this report, risks from individual medical devices are very small. The most significant risk, medical disposable bedding, was found to be 9.15×10^{-10}. It is possible that risks to health care workers could be greater than other subpopulations because this population will have significantly higher exposure durations and may be exposed to multiple medical devices. Unfortunately, this subpopulation could not be characterized with the existing data. If additional work is done on risks from dioxins and furans in medical devices, additional data should be gathered, and risks to health care workers should be characterized.

5. REFERENCES

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