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

OCT 5 1998

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: **Human Exposure Data Considerations:**
Review of Indoor Surface Residue Dissipation Data Submitted in Support of Product Registration for **CLEANING MAGIC I** Containing a New Active Ingredient Chemical: **Alkyl (C_{10-16}) Dimethyl Amine Oxide (Amine Oxide)**.

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DP Barcode: D244309 (S538885)

Pesticide Chemical No.: 000439

A.I. Chemical Name: Alkyl (C_{10-16}) Dimethyl Amine Oxide

Registrant: The Procter & Gamble Company

EPA File Symbol No.: 3573-LO

MRID No.: 444349-10

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SUMMARY:

An exposure study titled "Human Exposure Calculations for Dodecyl Dimethylamine Oxide (DDAO)" by R.L.Campbell dated June 30, 1982, was submitted by the Procter & Gamble Company in support of the registration of a new active ingredient (a.i.): Alkyl (C_{10-16}) Dimethyl Amine Oxide (Amine Oxide), intended for use in four proposed antibacterial dishwashing detergents to be registered under the product names: CLEANING CARE I & II, and CLEANING MAGIC I & II.

AD's Regulatory Management Branch I, Product Management Team 31, requested that AD/RASSB review the submitted data (MRID# 444349-10) in support of new product registration for CLEANING MAGIC I, EPA File Symbol No. 3573-LO. The review comments provided are specific to only this product. No evaluation was done for the other three products noted above since no labeling or other supporting documentation was provided for review.

The purpose of the exposure assessment and residue study was to present a "realistic" estimation of chronic consumer exposure to Dodecyl Dimethylamine Oxide (DDAO) that occurs using light duty liquid (LDL) detergent products. The Agency assumed that the study was submitted to address the new Human Exposure Post Application Data Requirement for an Indoor Surface Residue Dissipation Study (FIFRA data guideline 875.2300, *Series 875-Occupational and Residential Exposure Test Guidelines)* and it was reviewed for acceptability and adherence to current EPA guidelines for conduct of such studies.

In summary, the "study" (both the exposure assessment and residue data portions) was found to be unacceptable and did not meet certain requirements under EPA's Series 875.2000 Guidelines for conducting post application exposure studies, including not meeting requirements for conducting an Indoor Surface Residue Dissipation Study (guideline 875.2300). Also, the data was not acceptable for evaluatiing potential risks to children under FQPA. The overall data gaps with respect to both the DDAO exposure assessment and residue data portions of the study are summarized in the conclusion section.

Aside from an evaluation of the submitted data on DDAO, this AD/RASSB review also provides an overview of all pertinent Human Exposure Data Requirements which may be imposed by the regulatory management for the registration of the proposed product, CLEANING MAGIC I, once the toxicity profile of Amine Oxide is assessed by the Agency.

USE PATTERN:

The proposed product, CLEANING MAGIC I concentrated dishwashing detergent, contains 4.81% Amine Oxide as the antibacterial active ingredient. The draft product labeling indicates that the product is intended for handwashing of dishes, dishware, cutlery, utensils, and cutting boards, and provides directions for both general dishwashing use and to kill germs on dishware (dishes/utensils). To kill germs, the product is to be applied manually as a concentrate directly onto dishware, spread over the surface and allowed to stand 5 minutes before rinsing.

Based on the dishwashing detergent use pattern, CLEANING MAGIC I is intended for use in household, institutional, and commercial settings for terrestrial, indoor, non-food sites. The Antimicrobial Use Categories for this product are:

II. Food Handling/Storage Establishments Premises and Equipment (*Non-Food Contact);

III. Commercial/Institutional/Industrial Premises and Equipment; and

IV. Residential/Public Access Premises.

*NOTE: To be categorized as "Non-Food Contact" the registered product labeling for antimicrobial dishwashing liquids containing Amine Oxide, must state in the use directions that all treated surfaces (e.g., dishes/utensils, and cutting boards) must be rinsed with potable water prior to any contact with food.

STUDY OVERVIEW:

This exposure study submitted by the Procter & Gamble Company was assessed for regulatory and technical merit. The Agency review (1) summarizes the human exposure calculations for DDAO in detergents; (2) provides the tables used for the estimation of exposure to DDAO in detergents; (3) identifies data gaps in the exposure assessment; (4) summarizes the DDAO residue studies; (5) identifies pertinent data gaps critical to the regulatory and technical acceptability with respect to guideline requirements for an Indoor Surface Residue Dissipation Study (FIFRA data guideline 875.2300) specified in *Series 875- Occupational and Residential Exposure Test Guidelines; Group B- Postapplication Exposure Monitoring Test Guidelines*; and (6) provides a conclusion.

The study identified three possible routes of exposure to DDAO in detergent products. The routes include:

(1) Ingestion of DDAO residues present from dinnerware onto food substances;

(2) Ingestion of drinking water that contains low levels of DDAO; and

(3) Dermal exposure (e.g. percutaneous absorption) through incidental contact or foreseeable misuse of the product.

Summary of Human Exposure Assessment Calculations for DDAO in Detergents

The study suggested three possible exposure routes of DDAO in LDL products as identified above. The study used measured results for DDAO residues deposited on dinnerware to calculate exposure route (1). However, different scientific references were used to examine drinking water exposure concentrations for exposure route (2), (Games, 1979). For dermal exposure route (3), assumptions were used to estimate concentrations of DDAO in dishwashing, handwashing, and hand laundering with shampoo.

The Agency has summarized results from the Procter & Gamble (P & G) Study in Tables 1 - 4 below. A summary of the exposure doses are identified in Table 1. Table 2 identifies the exposure algorithms used to estimate the ingestion of DDAO residues present on food after exposure to DDAO contaminated dishware. Table 3 identifies the exposure algorithms used to estimate the ingestion of DDAO present in drinking water. Table 4 identifies the dermal (e.g. percutaneous) exposure through incidental contact or foreseeable misuse of the product.

Table 1: Summary of Exposure Doses

Exposure Route	Intended Uses[a] (µg/kg/day)	Intended Uses and/or Foreseeable Misuses[b] (µg/kg/day)
1) Ingestion from deposits on dinnerware	4.70	26.8[c]
2) Ingestion from drinking water	0.0029	0.0029
3) Percutaneous- Absorption during product use	0.0044	0.0157[d]

Legend:

[a] Intended uses are dishwashing and hand laundering.

[b] Foreseeable misuses are bathing, shampooing, hand washing, and dishwashing without rinse of dishes.

[c] Number represents misuse only.

[d] Number represents sum of intended use and foreseeable misuse exposures.

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Table 2: Oral Exposure to DDAO from Deposits on Dinnerware Washed in an LDL

Product Use	Dinnerware Substrate[a]	Maximum DDAO Residue Deposits[b] ($\mu g/cm^2$)	Area of Dinnerware Used[c] (cm^2/day)	Total Daily Exposure[d] (μg/day)	Total Dose[e] (μg/kg/day)
Intended Use (rinsed dinnerware)	Glass	0.007[f]	697	4.88	0.0697
	Dishes	0.12[f]	1,641	197	2.81
	Stainless Steel	0.063[f]	2,046	129	1.84
	Total				4.7
Foreseeable Misuse (unrinsed dinnerware)	Glass	0.17	697	118	1.69
	Dishes	0.50	1,641	821	11.7
	Stainless Steel	0.46	2,046	941	13.4
	Total				26.8

Legend:

[a] Dinnerware is chosen as follows: glass represents glassware, dishes represents dishes made of melamine substrates, and stainless steel represents cutlery, flatware, cookware, pots and pans.

[b] References include Miller and Domeyer, 1981 and Lampe, 1980 (MRID 444349-10).

[c] Area of dinnerware estimates are included in Appendix 1. Part A and B of the report (MRID 444349-10).

[d] Daily exposure= amount extracted into food-simulating solvents ($\mu g/cm^2$) x area if dinnerware (cm^2)/ person/day.

[e] Total daily exposure / body weight (70 kg).

[f] Averages of 10 and 60 second rinses.

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Table 3: Oral Exposure to Drinking Water

Concentration of DDAO in Drinking Water[a] (g/mL)	Volume of Water Consumed[b] (mL/day)	Total Daily Exposure[c] (g/day)	Total Dose[d] (µg/kg/day)
1.0E-10	2000	2.0E-07	0.0029

Legend:

[a] Reference is from Games, L.M..

[b] Reference is from Midwest Research Institute Report to EPA, 1979, Contract No. 68-013896, Potential Exposure to NTA in Detergents.

[c] Total Daily Exposure = Concentration DDAO in H_2O (g/mL) x Vol. H_2O (mL/day).

[d] Total Daily Dose = Total Daily Exposure/ Body Weight (70 kg).

Table 4: Percutaneous Exposure to DDAO Through Intended Use and Foreseeable Misuse

Product Use	Exposure Conc. of DDAO[a] (µg/ml)	Permeability Constant[b] (K_p) (cm/hr)	Steady State Flux[c] (µg/cm²/hr)	Duration of Exposure[d] (hrs/day)	Area of Contact[e] (cm²)	Total Daily Exposure[f] (µg/day)	Total Dose[g] (µg/kg/day)
Intended Uses							
Dishwashing	145	2.3E-06	3.3E-04	0.45	1,800	2.7E-01	0.0039
Hand Laundering	145	2.3E-06	3.3E-04	0.06	1,800	3.6E-02	0.0005
						Total	0.0044
Foreseeable Misuses							
Bath	13	2.3E-06	2.99E-05	0.18	16,000	8.61E-02	0.0012
Shampoo	5,000	2.3E-06	1.15E-02	0.004	1,900	8.74E-02	0.0012
Handwashing	50,000	2.3E-06	1.15E-01	0.006	900	6.21E-01	0.0089
						Total	0.0113
						Total (Both Pathways)	0.0157

Legend:

[a] Concentrations were derived as follows: dishwashing 0.29%, hand laundering 0.29%, bath 0.026%, shampoo 10%, and hand washing 100%. Density was not given in study.

[b] K_p calculated from Rice, 1977. Calculated from the equation K_p= flux/concentration. Where flux across human skin is <0.046 µg/hr/cm^2 and concentration is 20 mg/ml (e.g, 2E+4 µg/ml).

[c] Flux= K_p x conc.

[d] The duration of exposure assumptions are as follows: dishwashing (based on 12.7 dishwashing per week and 15 min. washing); hand laundry (10 min/use and 3.1 times/week); bath (17 min and 4.4 times/week); shampoo (1 min and 1.7 times/week); and handwashing (20 seconds).

[e] Area of contact (hands and arms) is 10% of total body surface area of 18,000 cm^2 for dishwashing and hand laundering. Reference for bath, shampoo, and handwashing is not given.

[f] Total daily exposure= steady state flux (µg/cm^2/hr) x use time (hr/day) x surface area of contact (cm^2).

[g] Total dose = daily exposure (µg/day)/ body weight (kg).

Review of the Permeability Constant Reported in the Study

Note that the reported permeability constant (K_p) of 2.3E-06 cm/hr, shown in Table 4, was calculated by the registrant from the flux reported in the Rice (1977) study. The (K_p) appeared to be much lower than expected for an organic chemical such as DDAO. Note that DDAO is a non-polar hydrophobic organic compound with a 12 carbon chain, a dimethyl group, and an amine. The structure of DDAO is shown below:

The following bulleted list shows the permeability constants (K_p's) based on the addition of carbon chains for alcohols, which have similar structures. These values have published coefficents (EPA, 1991).

- methanol, Kp= 5.0E-04 cm/hr
- butanol, Kp= 2.5E-03 cm/hr
- hexanol, Kp= 3.2E-02 cm/hr
- octanol, Kp= 5.2E-02 cm/hr
- decanol, Kp= 7.9E-02 cm/hr.

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From the above list it appears that the K_p is proportional to the length of the carbon chain; the longer the chain the higher the K_p value. Therefore, it is assumed that DDAO would be most similar to decanol which has the highest K_p of 7.9E-02 cm/hr. However, "if a molecule is big enough-if an alcohol, say has a chain of 16 to 20 carbons or more-hydrophobic and lipophillic parts display their individual solubility properties" (Morrison and Boyd, 1987). Since the compound is in a detergent matrix, it may be large enough so that dissociation occurs. The hydrophillic part (N=0) may dissolve in a polar substance such as water and the hydrophobic group (e.g, 12 carbon chain and dimethyl group) may dissolve in organic substances such as the skin.

Nevertheless, the K_p of 2.3E-06 cm/hr listed in the study (Rice, 1977) seemed extremely low. In fact, the K_p was lower than a polar compound such as water 5.0E-04 cm/hr (EPA, 1991). Since the K_p value appeared to be erroneous, a new K_p value was estimated from the following equation:

$$\log K_p = -2.72 + 0.71 \log K_{ow} - 0.0061 \text{ MW (EPA 1992)}$$

Where:

MW= 229.41
$\log K_{ow}$ = 6.273 estimated from EPIWIN database (Syracuse Research Corporation, 1996).

Using $\log K_{ow}$ values from the EPIWIN database, the Agency estimated the new K_p value for DDAO to be 2.14 cm/hr. Because of the discrepancy between the reported K_p and estimated K_p for DDAO, the Rice, 1977 study was reevaluated for technical merit.

The Rice (1977) study used in vivo percutaneous absorption data to compute a flux rate of <0.2, 6.0, 1.7, and 6.7 nmole/hr/cm^2 for man, rat, mouse, and rabbit. For measuring the dermal absorption in humans, an area measuring 4 x 15 cm of hairless skin on the outer surface of the forearm was used. Approximately 0.5 ml of an aqueous solvent containing 10 mg DDAO was applied on this patch of skin (e.g., 20 mg/ml or 20,000 µg/cm^3). The absorption of the radio-labeled DDAO that was absorbed into the human body was calculated by measuring the DDAO concentration in urine, fecal samples, and expired air. The amount of radio-labeled DDAO remaining on the skin was recovered by repeatedly (10 x) removing it using gauze pads. The actual calculation of the flux was described in the following formula.

Flux (nmole/cm^2/hr) = [Dose (nmole/cm^2) x (% absorption)/ (time of exposure)]

Note that only 0.01 and 0.23% of the administered radio-labeled compound was recovered in the excretion products (urine, fecal samples, and expired air) of man. About 92 % of the applied dose was recovered by swabbing with a moist gauze. The only recovered finding of radio-labeled DDAO was a detectable concentration of 0.23% in the urine of one sample. Approximately 0.2% DDAO was recovered on the skin. The other 7.5% was not recovered. Since no tissue samples (e.g., kidney, liver, and blood) were identified, the actual absorption was unknown.

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The study also examined percutaneous absorption in rats, mice, and rabbits. A similar procedure was used to dermally dose the animals; however, better results were obtained. Note that for the rat, mice, and rabbits approximately 35, 36, and 51% of DDAO was identified in the tissue samples and total excrement (urine, feces, and CO_2). The percent recovered in the tissue was actually 16, 17, and 5%, making up almost half of the actual absorption in rats and mice, and only about 10% of the total absorption for rabbits.

The registrant used only the flux rate reported from the Rice (1977) study in man. The K_p used in the study was computed using Ficks law (K_p=Flux/Conc.). The registrant used the flux rate of <0.2 nmole/hr/cm^2 reported in man and converted it to <0.046 µg/hr/cm^2 (Molecular weight 229.41) and divided this by the reported concentration of 20,000 ug/cm^3. Using their data, a K_p of 2.3E-06 cm/hr was calculated. Note that the K_p's for a rat, mouse, and rabbit were an order of magnitude greater at 7.0E-05, 7.5E-05, and 3.9E-05 cm/hr using only excrement recoveries. If the total absorption included tissue samples as well as excrement, the K_p values would be: 1.3E-04, 8.0E-05, and 8.5E-05 cm/hr.

In the conclusion of the Rice (1977) study, Rice mentioned that there existed an exposure length of 8 hours for man, and a length of exposure of 72 hours for rats, mice, and rabbits. This may account for the significant difference between man and the test animal species. However, the major problem with the Rice (1997) study was that the % absorption of DDAO was measured using unreliable estimates from a radioisotope assay. In the case of identifying the radioisotopes in man, the absorption of the isotope was measured based on comparing nondetectable amounts of the radioisotopes found in the urine versus the concentration initially applied on the skin. Since the radioisotopes were not detected in the urine, the detection limits were used as an estimate to calculate absorption, and thus the flux. These estimates did not appear to be valid.

Other problems in the study were that the flux was calculated using only the total excretion products. In the animal studies, approximately half of the radio-labeled DDAO was recovered in tissue samples. In summary, the animal studies would have been a more reliable and conservative estimate of the K_p. Since the studies estimated the amount of radio-labeled DDAO in the total excretion and tissue samples for animals, the most conservative K_p of 1.3E-04 cm/hr from the rat study would be a more accurate estimate of the overall absorption. This value was used in Table 5 to calculate the dermal dose.

Table 5: Percutaneous Exposure to DDAO Using a More Conservative K_p

Product Use	Exposure Conc. of DDAO[a] (µg/ml)	Permeability Constant[b] (K_p) (cm/hr)	Steady State Flux[c] (µg/cm²/hr)	Duration of Exposure[d] (hrs/day)	Area of Contact[e] (cm²)	Total Daily Exposure[f] (µg/day)	Total Dose (µg/kg/day)
Intended Uses							
Dishwashing	145	1.3E-04	1.9E-02	0.45	1,800	15	0.21
Hand Laundering	145	1.3E-04	1.9E-02	0.06	1,800	2	0.029
						Total	0.24
Foreseeable Misuses							
Bath	13	1.3E-04	1.7E-03	0.18	16,000	4.9	0.07
Shampoo	5,000	1.3E-04	0.65	0.004	1,900	4.9	0.07
Handwashing	50,000	1.3E-04	6.5	0.006	900	35.1	0.5
						Total	0.64
						Total (Both Pathways)	0.88

Legend:

[a] Concentrations were derived as follows: dishwashing 0.29%, hand laundering 0.29%, bath 0.026%, shampoo 10%, and hand washing 100%. Density was not given in study.

[b] K_p calculated from Rice, 1977. Calculated from the equation K_p= flux/concentration. Where flux across human skin is <0.046 µg/hr/cm² and concentration is 20 mg/ml (e.g, 2E+4 µg/ml).

[c] Flux= K_p x conc.

[d] The duration of exposure assumptions are as follows: dishwashing (based on 12.7 dishwashing per week and 15 min. washing); hand laundry (10 min/use and 3.1 times/week); bath (17 min and 4.4 times/week); shampoo (1 min and 1.7 times/week); and handwashing (20 seconds).

[e] Area of contact (hands and arms) is 10% of total body surface area of 18,000 cm² for dishwashing and hand laundering. Reference for bath, shampoo, and handwashing is not given.

[f] Total daily exposure= steady state flux (µg/cm²/hr) x use time (hr/day) x surface area of contact (cm²).

[g] Total dose = daily exposure (µg/day)/ body weight (kg).

Assessment of Data Gaps in Exposure Assessment

The following items are data gaps critical to the scientific validity and regulatory acceptability of this DDAO study in support of CLEANING MAGIC I registration:

- The overall quality of the exposure study write up was inadequate. The exposure study does not provide detailed text to explain or describe the many assumptions used to generate the P & G data tables. References are cited without a separate page identifying the literature citations. The many references cited are provided from primary studies rather than peer reviewed EPA guidance documents for risk assessments.

- The study used to support registration of this chemical was written in 1982. Many policy changes and human exposure assumptions have been changed since the P & G assessment was completed. It may be prudent to use a more current study to register the chemical and/or update the exposure factors used in this assessment.

- The submitted study examines human exposure calculations for Dodecyl Dimethylamine Oxide (DDAO) and is being used to register a different a.i.: Alkyl (C10-16) Dimethylamine Oxide (Amine Oxide). The toxicities may be similar; however, no toxicity data was provided to confirm or deny this similarity.

- No toxicity data was provided to calculate a margin of exposure (MOE) or carcinogenic risk. Without an MOE or carcinogenic risk, health risks due to exposure to DDAO could not be identified and used to extrapolate risk from Amine Oxide exposure.

- Exposure concentration references were not consistent (Games, 1979). Oral ingestion was calculated using measured DDAO residues from dishes; however, drinking water ingestion cited a difference source for exposure concentrations. Dermal exposure concentrations were also from a different source (references for the exact dermal concentrations were unclear).

- The study assesses only exposures to adults not children. With the passage of the Food Quality Protection Act of 1996 (FQPA), the Agency is required to examine potential exposure risks to children. Since the body weights of children (22 Kg) are much smaller than adults (70 Kg), it is critical to assess risks among children separately from adults. Children also have a higher surface area to body weight ratio, have increased ingestion rates due to frequent hand-to-mouth contact, and have limited knowledge of safety precautions associated with use of household products.

- The exposure pathways examined in the study did not include (as foreseeable misuse of the product) an additional exposure pathway that examines direct oral ingestion of dishwashing detergent by children.

- It is recommended that the registrant use more up to date EPA peer reviewed references to examine exposure scenarios. Among the references suggested include: *Risk Assessment Guidance for Superfund Volume I. Human Health Evaluation Manual (Parts A through D)* (EPA, 1989) and *Exposure Factors Handbook* (EPA, 1997).

- Exposure assumptions seem to be consistent with more recent EPA guidance for the following scenarios: (1) ingestion of DDAO deposits from dinnerware by food and (2) ingestion of drinking water that contains low levels of DDAO. However many questions and concerns (listed in the next 3 bulleted items) exist over exposure factors used in the last scenario: (3) dermal exposure (e.g. percutaneous absorption) through incidental contact or foreseeable misuse of the product.

- Included among the exposure factors in question for scenario (3) is the surface area of contact. Guidance from the *Exposure Factors Handbook* (EPA, 1997) indicates that total body area can vary from 17,000 cm^2 to 23,000 cm^2 and the mean is reported as 20,000 cm^2. The DDAO exposure assessment reports the entire body surface are as 18,000 cm^2. In addition, the mean surface area of hands and forearms are reported in the *Exposure Factors Handbook* as 0.198 m^2 (1,980 cm^2) and the DDAO exposure assessment reports a value of 1,800 cm^2. The DDAO exposure assessment also reports the surface area of skin available for contact in the bathing, shampooing, and handwash as 16,000, 1,900, and 900 cm^2, respectively. It does not include a reference or an explanation of the body parts available for contact. Using the *Exposure Factors Handbook*, it would seem reasonable that for bathing a total body surface area of 20,000 cm^2 should be used. For shampooing the body contact would include at the least hands, forearms, and head exposure, which would equate to a body surface area of 3,160 cm^2. Finally, for handwashing the original scenario of hands and forearm exposure of 1,980 cm^2 might be a more conservative estimate of the body surface area.

- The permeability constant (K_p) listed in scenario (3) is also of question. The study reports a K_p of 2.3E-06 cm/hr, and provides a reference to a human study examining flux of the chemical across the human skin (Rice, 1977). The value listed as the K_p is very low compared to other measured K_p's listed in EPA guidance. In addition, this guidance also provides an equation for estimation of the permeability coefficient:

  $$\log K_p = -2.72 + 0.71 \log K_{ow} - 0.0061 \text{ MW (EPA 1992)}$$

  Where:

  MW= 229.41
  $\log K_{ow}$ = 6.273 estimated from EPIWIN database (Syracuse Research Corp., 1996)

  Using values from the EPIWIN database, an estimated K_p of 2.14 cm/hr was obtained for DDAO. This value was considered too high to use as an estimate of dose. Instead the Rice, 1977 study was reevaluated.

  The major problem with the Rice, 1977 study was that the % absorption of DDAO was measured using unreliable (e.g., non-detectable concentrations) estimates from a radioisotope assay. In the case of identifying the radioisotopes in man, the absorption of the isotope was measured based on comparing nondetectable amount of the radioisotopes found in the urine versus the concentration initially applied on the skin. The actual % absorption from this method was 0.23%. The partition coefficients for rats in the Rice, 1977 study

appeared to be the most conservative. Since the initial K_p was calculated only using the % absorption after total excretion (18%), the partition coefficient was recalculated using the % absorption after total excretion and tissue sampling analysis (35%). The calculated K_p was 1.3E-04 cm/hr.

- Some questions also exist over the duration of exposure listed in scenario (3). For example, the average shampoo times per week is listed as 1.7 times in the DDAO exposure assessment. It would seem reasonable to adjust this assumption to at least 3-5 times per week. Another questionable assumption listed in the DDAO exposure includes a 20 second handwashing duration per day. It would seem that a more conservative estimate would be a 20 second handwashing duration including at least 3 events per day before meal times.

- The exact calculation of the mean exposure concentration identified in Table 2 was unclear and could not be verified.

Summary of the Removal of DDAO Residues from Dinnerware

The study report entitled "Human Exposure Calculations for Dodecyl Dimethylamine Oxide (DDAO)" included attachment of the following reports as supportive evidence of techniques and sampling strategies that were used to characterize the amount of DDAO residues found in dishware after use of a light duty liquid (LDL) detergent:

- "Protocol to Measure the Amount of Dodecyldimethylamine Oxide Removed from Dinnerware by Food-Simulating Solvents" (Lampe, 1980);

- "Removal of D^{14} DAO (Dodecyl Dimethylamine)" (Lampe, 1980); and

- "Test Standards for Dinnerware Deposition Studies - Experimental Summary" by L.D. Miller and B.E. Domeyer (Miller and Domeyer, 1981).

[Note: The protocol detailed the procedures and methods used for the removal of DDAO from food simulating solvents. The report entitled "Removal of D^{14} DAO (Dodecyl Dimethylamine)" (Lampe, 1980) described the results of the experiment performed. The report entitled "Test Standards for Dinnerware Deposition Studies - Experimental Summary" (Miller and Domeyer, 1981) defined the conditions commonly used in consumer handwashing studies by citing specific references.]

The purpose of the study was to determine the amount of DDAO residues that were removed by food-simulating solvents from commonly used dinnerware washed in standard light duty liquid (LDL) solutions radio-tagged with added D^{14}DAO, and either rinsed or not rinsed after washing. The equipment selected for the experiment included factory composites of the Joy and Ivory dishwashing detergents spiked with D^{14}DAO; about 50 pieces of dinnerware (i.e, china and earthenware dinner plates, glass tumblers, stainless steel pans, plastic containers) commonly used in the home; and food simulating solvents recommended in FDA's 21 CFR 175.300 (demineralized distilled water, 8% v/v ethanol in water, and heptane).