APPENDIX D

Review of Confidential Business Information Memo

MEMORANDUM

To:	Mark Gerath, ENSR	**Date:**	November 2, 2004
From:	Karl Ford, BLM		
RE:	Review of Confidential Business Information on Inert Ingredients Herbicides Proposed for Use on BLM Lands		

Pesticide products contain both "active" and "inert" ingredients. The terms "active ingredient" (a.i.) and "inert ingredient" have been defined by Federal law, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), since 1947. An a.i. is one that prevents, destroys, repels, or mitigates a pest, or is a plant regulator, defoliant, desiccant, or nitrogen stabilizer. By law, the a.i. must be identified by name on the label together with its percentage by weight. An inert ingredient is simply any ingredient in the product that is not intended to affect a target pest. For example, isopropyl alcohol may be an a.i. and antimicrobial pesticide in some products; however, in other products, it is used as a solvent and may be considered an inert ingredient. The law does not require inert ingredients to be identified by name and percentage on the label, but the total percentage of such ingredients must be declared.

In September 1997, the U.S. Environmental Protection Agency (USEPA) issued **Pesticide Regulation Notice 97-6** which encourages manufacturers, formulators, producers, and registrants of pesticide products to voluntarily substitute the term "other ingredients" as a heading for the "inert" ingredients in the ingredient statement. The USEPA made this change after learning the results of a consumer survey on the use of household pesticides. Many comments from the public and the consumer interviews prompted USEPA to discontinue the use of the term "inert." Many consumers are misled by the term "inert ingredient," believing it to mean "harmless." Since neither the federal law nor the regulations define the term "inert" on the basis of toxicity, hazard or risk to humans, non-target species, or the environment, it should not be assumed that all inert ingredients are non-toxic.

The Bureau of Land Management (BLM) scientists received clearance from USEPA to review Confidential Business Information (CBI) on inert compounds identified in products containing the following ten a.i.:

- Sulfometuron methyl
- Fluridone
- Dicamba (as an a.i. in the herbicide Overdrive)
- Diquat
- Diflufenzopyr
- Imazapic
- Diuron
- Bromacil
- Chlorsulfuron
- Tebuthiuron

The information received listed the inert ingredients, their chemical abstract number, supplier, USEPA registration number, percentage of the formulation, and purpose in the formulation. Because this information is confidential, this information, including the name of the ingredients may not be disclosed.

The USEPA has a listing of regulated inert ingredients at http://www.epa.gov/opprd001/inerts/index.html. This listing categorizes inert ingredients into four categories. The listing of categories and the number of inert ingredients found among the ingredients listed for the herbicides are shown below:

- Inert Ingredients of Toxicological Concern. None.
- Potentially Toxic Inert Ingredients. None.
- Inerts of Unknown Toxicity. 12.
- Inerts of Minimal Toxicity. Over 50.
- Nine inerts were not found on USEPA's lists.

Toxicity information was also searched via the following sources:

- TOMES (a proprietary toxicological database including USEPA's Integrated Risk Information System [IRIS], the Hazardous Substance Data Bank [HSDB], the Registry of Toxic Effects of Chemical Substances (RTECS)
- USEPA's ECOTOX database which includes AQUIRE
- TOXLINE, a literature searching tool
- Material Safety Data Sheets (MSDSs) from suppliers
- Other sources, such as the Farm Chemicals Handbook
- Other cited literature sources.

Relatively little toxicity information was found. A few acute studies on aquatic or terrestrial species were reported. Little chronic data, no cumulative effects data, and almost no indirect effects data (food chain species) were found.

A number of the List 4 compounds are naturally-occurring earthen materials (e.g., clay materials or simple salts) that would produce no toxicity at applied concentrations. However, some of the inerts, particularly the List 3 inert compounds and unlisted compounds, may have moderate to high potential toxicity to aquatic species based on MSDSs or published data.

As a tool to evaluate List 3 and unlisted inerts in the ecological risk assessment, the exposure concentration of the inert compound was calculated and compared to toxicity information. Toxicity information from the above sources was used in addition to the work of Dorn et al. (1997), Wong et al. (1997), Lewis (1991), and Muller (1980) concerning aquatic toxicity of surfactants. These sources generally suggested that acute toxicity to aquatic life for surfactants and anti-foam agents ranged from 1-10 mg/L, and that chronic toxicity ranged to as low as 0.1 mg/L.

Exposure concentrations were computed using Groundwater Loading Effects of Agricultural Management Systems (GLEAMS). Inert compounds incorporated into the herbicide mixture are generally considered to be very stable compounds and tend to be highly mobile in the environment, primarily because of their inability to react with other materials or compounds. However, while these inert compounds are very mobile and relatively inactive they can potentially be toxic to aquatic organisms. To quantify the potential toxicity of inert compounds to aquatic organisms, the concentration of an inert compound in a river or pond adjacent to an herbicide application area was predicted using the GLEAMS model. The GLEAMS model was set up to simulate the effects of a generalized inert

compound in the previously described "base-case" watershed with a sand soil type. The chemical characteristics of the generalized inert compound were set at extremely high/low environmental fate values to describe it as a very mobile and stable compound; the application rate of the inert compound was fixed at 1 pound (lb) a.i./acre. The watershed characteristics were that of a typical sand watershed with atmospheric conditions representative of Medford, Oregon. The annual precipitation rate used in the inert compound simulation was 50 in/year, distributed in the same fashion as during a representative precipitation year in Medford, Oregon. The simulation was run to quasi-steady state conditions and the daily-predicted inert compound export rates from a single steady-state year of the simulation were used to calculate the annual average (chronic) and annual maximum 3-day average river and pond inert compound concentrations. The following table indicates the predicted river and pond concentrations for the inert compound resulting from an application rate of 1 lb a.i./acre. The concentrations per 1 lb a.i./acre application rate for each of eight herbicides simulated by GLEAMS, using the same watershed type, atmospheric conditions, and precipitation rate, is also listed for comparison.

Ratio of Concentration to Herbicide Application Rate (mg/L per lb a.i./acre)				
Herbicide	Average Annual River	Maximum 3 Day Average River	Average Annual Pond	Maximum 3 Day Average Pond
Diflufenzopyr	5.39E-06	3.33E-04	8.38E-04	7.52E-03
Imazapic	3.64E-04	8.19E-03	2.64E-02	5.45E-02
Sulfometuron	1.87E-04	5.81E-03	1.19E-02	3.77E-02
Tebuthiuron	4.68E-04	1.68E-02	4.33E-02	2.04E-01
Diuron	2.74E-04	4.67E-03	2.27E-02	3.35E-02
Bromacil	5.73E-04	1.72E-02	4.18E-02	1.27E-01
Chlorsulfuron	1.27E-04	2.31E-03	1.79E-02	5.31E-02
Dicamba	3.25E-04	1.30E-02	2.03E-02	1.72E-01
Inert Compound	**1.20E-03**	**3.80E-02**	**3.20E-01**	**6.90E-01**

The results of the GLEAMS simulations from the table above indicate that the ratio of river or pond concentration to application rate is highest for the inert compound. This was expected because of the extent that the chemical parameters were adjusted to represent a highly mobile and stable compound. In the case of the river, the concentrations were largely the result of characteristics related to the inert compound's mobility but in the pond the stability of the compound was also important. The inert compound concentrations were predicted to be higher than the concentrations of each herbicide in all cases, albeit to varying degrees, and the extent of these higher concentrations was similar between each of the four statistical measures.

The exposure concentration was estimated by multiplying the percentage of the inert in the formulation times the application rate in pounds/acre times the dilution rates shown in the above table. Due to the constraints of the CBI process, the inerts of potential interest can not be disclosed but the following observations were made. Low application rates for sulfometuron methyl, fluridone, diquat, dicamba, diflufenzopyr, and imazapic resulted in low exposure concentrations of inerts of much less than 1 mg/L in all cases including the worst case (maximum 3-day pond) scenario. Higher application rates for diuron and bromacil yielded higher exposure concentrations of surfactant inerts, exceeding 1 mg/L for the maximum pond scenario. These results suggest that the inert compounds of diuron and bromacil may contribute acute toxicity to aquatic organisms if they reach the aquatic environment. Inerts did not seem to be an issue with chlorsulfuron and tebuthiuron.

This approach to estimating the exposure concentration will have relatively little uncertainty for several exposure scenarios such as spills where subsequent fate processes are relatively unimportant. Considerably more uncertainty will occur in scenarios that account for the physical-chemical properties of the constituent (e.g., the GLEAMS-dependent scenarios). The exposure concentration models are very conservative, e.g. if there is uncertainty, the exposure concentrations are likely to be overestimated, not underestimated. Considerable uncertainty also exists with the toxicity information as many of these substances had no specific toxicity information and toxicity information for surfactants was used as a surrogate.

References

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