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

OFFICE OF PREVENTION,
PESTICIDES, AND TOXIC SUBSTANCES

DATE: September 14, 2006

ACTION MEMORANDUM – Addendum/Correction

SUBJECT: Reassessment of Four Inert Ingredient Exemptions from the Requirement of a Tolerance – Addition of CAS Reg. No. 1300-72-7

FROM: Pauline Wagner, Chief Pauline Wagner 9/26/06
Inert Ingredient Assessment Branch
Registration Division (7505P)

TO: Lois Rossi, Director
Registration Division (7505P)

I. FQPA REASSESSMENT ACTION

Action: This memorandum adds the CAS Reg. No. 1300-72-7 to Table 1 on Page 1, and to the table in Attachment 2 on Page 6 of the document.

Table 1. on Page 1 of the document is corrected as follows:

CFR Citation				CAS Reg. No.'s
40 CFR §	**Inert Ingredients**	**Limits**	**Uses**	
180.920	Xylenesulfonic acid its ammonium calcium, magnesium, potassium, sodium, and zinc salts.	(none)	Surfactants, related adjuvants of surfactants	26447-10-9, 827-21-4, 30346-73-7, 88-61-9, 25321-41-9, 609-54-1, 30587-85-0, 827-19-0, 1300-72-7 (See Attachment 2 for 9CI names)
180.930	Xylenesulfonic acid its ammonium calcium, magnesium, potassium, sodium, and zinc salts.	(none)	Surfactants, related adjuvants of surfactants	

a. Residues listed in 40 CFR 180.920 are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops only.
b. Residues listed in 40 CFR 180.930 are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to animals.

Attachment 2 on Page 6 is corrected as follows:

Tolerance Exemption Expression and its Included Chemicals	
40 CFR §	**Tolerance Exemption Expression**
180.920 and .930	Xylenesulfonic acid and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts
CAS Reg. No.	**9CI Name**
26447-10-9	Benzenesulfonic acid, dimethyl-, ammonium salt
827-21-4	Benzenesulfonic acid, 2,4-dimethyl-, sodium salt
30346-73-7	Benzenesulfonic acid, dimethyl-, potassium salt
88-61-9	Benzenesulfonic acid, 2,4-dimethyl-
25321-41-9	Benzenesulfonic acid, dimethyl-
609-54-1	Benzenesulfonic acid, 2,5-dimethyl-
30587-85-0	Benzenesulfonic acid, 2,4(2,6 or 3,5)-dimethyl-, sodium salt
827-19-0	Benzenesulfonic acid, 2,5-dimethyl-, sodium salt
1300-72-7	Benzenesulfonic acid, dimethyl-, sodium salt

MANAGEMENT CONCURRENCE:

I concur with the addendum/corrections noted above.

Lois A. Rossi

Lois A. Rossi, Director
Registration Division

September 28, 2006
Date

cc: Debbie Edwards, SRRD
Joe Nevola, SRRD

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

OFFICE OF PREVENTION,
PESTICIDES, AND TOXIC SUBSTANCES

June 30, 2006

ACTION MEMORANDUM

SUBJECT: Reassessment of Four Inert Ingredient Exemptions from the Requirement of a Tolerance

FROM: Pauline Wagner, Chief Pauline Wagner 6/30/06
Inert Ingredient Assessment Branch
Registration Division (7505P)

TO: Lois Rossi, Director
Registration Division (7505P)

I. FQPA REASSESSMENT ACTION

Action: Reassessment of four inert ingredient exemptions from the requirement of a tolerance as listed in Table 1. below.

Table 1.

CFR Citation				CAS Reg. No.'s
40 CFR §	**Inert Ingredients**	**Limits**	**Uses**	
180.920[a]	Toluenesulfonic acid and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts	(none)	Surfactants, related adjuvants of surfactants (Please see the NOTE below)	38251-37-5, 51650-46-5, 36747-44-1, 104-15-4, 4124-42-9, 30526-22-8, 25231-46-3, 657-84-1, 12068-03-0, 617-97-0, 13438-45-4, 15046-75-0, 16106-44-8, 26447-09-6 (See Attachment 1 for 9CI names)
180.930[b]	Toluenesulfonic acid and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts	(none)	Surfactants, related adjuvants of surfactants (Please see the NOTE below)	
180.920	Xylenesulfonic acid its ammonium calcium, magnesium, potassium, sodium, and zinc salts.	(none)	Surfactants, related adjuvants of surfactants	26447-10-9, 827-21-4, 30346-73-7, 88-61-9, 25321-41-9, 609-54-1, 30587-85-0, 827-19-0 (See Attachment 2 for 9CI names)
180.930	Xylenesulfonic acid its ammonium calcium, magnesium, potassium, sodium, and zinc salts.	(none)	Surfactants, related adjuvants of surfactants	

a. Residues listed in 40 CFR 180.920 are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops only.
b. Residues listed in 40 CFR 180.930 are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to animals.

NOTE: Please note that the uses of toluenesulfonic acid, etc., under 40 CFR 180.930 will be corrected in the CFR to read "Surfactants, related adjuvants of surfactants".

Use Summary: Toluenesulfonic acid and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts are exempted from the requirement of a tolerance when used as inert ingredients in pesticide products applied to growing crops only (40 CFR 180.920) and to animals (40 CFR 180.930). Xylenesulfonic acid and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts are exempted from the requirement of a tolerance when used as inert ingredients in pesticide products applied to growing only (40 CFR 180.920) and to animals (40 CFR 180.930). These chemicals are also used in household and commercial cleaning products and personal care products.

Background

In October 2005, the Organization for Economic Cooperation and Development (OECD) released the Screening Information Data Set (SIDS) Initial Assessment Profile for the Hydrotropes Category. This document only provides a brief summary of the conclusions of the SIDS. The reader is referred to the SIDS for the full information, which can be found at http://cs3-hq.oecd.org/scripts/hpv/.

The hydrotropes category in the SIDS includes three subgroups: the methyl, dimethyl, and methylethyl benzene sulfonates, (or the toluene, xylene, and cumene sulfonates). The Agency has determined that the information contained in the SIAR is adequate for predicting the toxicity and behavior of all of the inert ingredients encompassed by the tolerance exemption chemicals listed in the table.

Special Considerations for Infants and Children

In a developmental toxicity study in rats, calcium xylene sulfonate (31% a.i.) was administered via gavage to female rats at 0, 150, 1500, or 3000 mg/kg bw/day in water days 6-15 of gestation. No treatment related effects were observed and there was no evidence of developmental toxicity. The NOAEL for maternal and fetal toxicity was 3000 mg/kg bw/day, corresponding to 936 mg a.i./kg bw/day (the highest dose tested). Based on this information, there is no concern, at this time, for increased sensitivity to infants and children to toluenesulfonic acid and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts, or to xylenesulfonic acid and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts when used as inert ingredients applied to growing crops only or to animals. For the same reason, a safety factor analysis has not been used to assess risk and, therefore, the additional tenfold safety factor for the protection of infants and children is also unnecessary.

Aggregate Exposures

In examining aggregate exposure, the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other nonoccupational exposures, including drinking water from ground water or surface

water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

For these chemicals, a qualitative assessment for all pathways of human exposure (food, drinking water, and residential) is appropriate given the use limitations and lack of human health concerns associated with exposure to these substances when used as inert ingredients in pesticide formulations.

Cumulative Exposure

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to toluenesulfonic acid and its ammonium, calcium, magnesium, sodium, and zinc salts or to xylenesulfonic acids and their ammonium, calcium, magnesium, sodium, and zinc salts and any other substances, and these chemicals do not appear to produce toxic metabolites produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that these chemicals have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

Human Health Risk Characterization

Based on the available data, these two groups of chemicals (as defined in Table 1) are of low oral, dermal, and inhalation toxicity.

Toxicity results are consistent across the toluene, xylene, and cumene sulfonates and their various salts. Acute Oral LD_{50} values in animals ranged from 1044 mg/kg bw (calcium xylene sulfonate) to 6500 mg/kg bw (sodium xylene sulfonate). The dermal LD_{50} in rabbits was >624 mg/kg bw (calcium xylene sulfonate), and the inhalation LC_{50} in rats was >557 mg/L (557 g/m^3 sodium toluene sulfonate). In a series of rabbit skin and eye irritation studies, sodium xylene sulfonate, calcium xylene sulfonate, and sodium cumene sulfonate were not skin irritants and both calcium xylene sulfonate and sodium cumene sulfonate caused slight but reversible eye irritation. There was no skin sensitization observed in animal studies.

Thirteen oral and dermal repeat-dose (subchronic and chronic) studies were conducted in rats or mice. Doses ranged from 6 to 2000 mg/kg bw/day dermally and from 1.1 up to 4092 mg/kg bw/day orally. Test durations ranged from 17 days to two years. No significant systemic toxicity was noted in the dermal studies with local effects (NOAEL 400 mg/kg bw/day, LOAEL 1300 mg/kg bw/day [epidermal hyperplasia]) noted in one of the six studies. In regard to the results of the oral studies, it was determined that the most appropriate NOAEL for systemic toxicity was 763 mg/kg bw/day based on a reduction in relative spleen weight in female rats.

The hydrotropes category was assessed for mutagenic/genotoxic potential in a variety of assays including the mouse micronucleus, Ames, mouse lymphoma, sister chromatid exchange, and chromosome aberration assays. No positive results were seen *in vitro* or *in vivo* in any of the studies. For both mice and rats dermally exposed for two years, there was no evidence of a carcinogenic potential.

There are no reproductive toxicity studies noted for this category of chemicals, however, after examination of the sex organs (such as the prostate, testes, and ovaries) from the animals in the 91- and 90-day oral feeding studies and 90-day and two year dermal studies yielded no evidence to suggest that these chemicals would have an adverse effect on the reproductive organs. In a developmental toxicity study in rats, calcium xylene sulfonate (31% a.i.) was administered via gavage to female rats at 0, 150, 1500, or 3000 mg/kg bw/day in water days 6-15 of gestation. No treatment related effects were observed and there was no evidence of developmental toxicity. The NOAEL for maternal and fetal toxicity was 3000 mg/kg bw/day, corresponding to 936 mg a.i./kg bw/day (the highest dose tested).

Dietary (food and drinking water) and residential (dermal and inhalation) exposures are possible from the use of these chemicals as inert ingredients in pesticide products. Based on the SIDS conclusions for the hydrotropes category; toluenesulfonic and xylenesulfonic acids and their ammonium, calcium, magnesium, potassium, sodium, and zinc salts (as defined in Table 1) are also predicted to be readily biodegradable according to OECD criteria, which will reduce the likelihood of residues on food. For the same reason, significant contributions to drinking water are not anticipated from the use of these chemicals as inert ingredients in pesticide products applied to growing crops or animals. These chemicals have low toxicity, and exposure to residues above toxicity levels of concern is not anticipated.

Taking into consideration available toxicity and exposure information, the Agency has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure (dietary and non-occupational sources of exposure) to toluenesulfonic and xylenesulfonic acids and their ammonium, calcium, magnesium, potassium, sodium, and zinc salts (as defined in Table 1) when used as inert ingredients in pesticide formulations applied to growing crops only or to animals. Therefore, it is recommended that the two exemptions from the requirement of a tolerance for these chemicals under 40 CFR 180.920 and the two exemptions from the requirement of a tolerance under 40 CFR 180.930 be considered reassessed as safe under section 408(q) of the Federal Food, Drug, and Cosmetic Act.

List Reclassification Determination: The current List Classification for toluenesulfonic and xylenesulfonic acids and their ammonium, calcium, magnesium, potassium, sodium, and zinc salts is 3. Because EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to these chemicals when used as inert ingredients in pesticide formulations, the List Classification for these chemicals will change from List 3 to List 4B.

II. MANAGEMENT CONCURRENCE

I concur with the reassessment of the four exemptions from the requirement of a tolerance for the inert ingredient toluenesulfonic acid and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts, and xylenesulfonic acid and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts, as well as the List reclassification determinations described above. I consider the two

exemptions established in 40 CFR 180.920 and the two exemptions established in 40 CFR 180.930 to be reassessed for purposes of FFDCA's section 408(q) as of the date of my signature, below. A Federal Register Notice regarding this tolerance exemption reassessment decision will be published in the near future.

Lois A. Rossi, Director
Registration Division

1/3/06
Date:

cc: Debbie Edwards, SRRD
Joe Nevola, SRRD

Attachment 1

Tolerance Exemption Expression and its Included Chemicals	
40 CFR §	**Tolerance Exemption Expression**
180.920 and .930	Toluenesulfonic acid and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts
Chemicals included in this exemption	
CAS Reg. No.	**9CI Name**
38251-37-5	Benzenesulfonic acid, 3-methyl-, sodium salt
51650-46-5	Benzenesulfonic acid, 4-methyl-, magnesium salt
36747-44-1	Benzenesulfonic acid, 4-methyl-, calcium salt
104-15-4	Benzenesulfonic acid, 4-methyl-
4124-42-9	Benzenesulfonic acid, 4-methyl-, ammonium salt
30526-22-8	Benzenesulfonic acid, methyl-, potassium salt
25231-46-3	Benzenesulfonic acid, methyl-
657-84-1	Benzenesulfonic acid, 4-methyl-, sodium salt
12068-03-0	Benzenesulfonic acid, methyl-, sodium salt
617-97-0	Benzenesulfonic acid, 3-methyl-
13438-45-4	Benzenesulfonic acid, 4-methyl-, zinc salt
15046-75-0	Benzenesulfonic acid, 2-methyl-, sodium salt
16106-44-8	Benzenesulfonic acid, 4-methyl-, potassium salt
26447-09-6	Benzenesulfonic acid, methyl-, ammonium salt

Attachment 2

Tolerance Exemption Expression and its Included Chemicals	
40 CFR §	**Tolerance Exemption Expression**
180.920 and .930	Xylenesulfonic acid and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts
CAS Reg. No.	**9CI Name**
26447-10-9	Benzenesulfonic acid, dimethyl-, ammonium salt
827-21-4	Benzenesulfonic acid, 2,4-dimethyl-, sodium salt
30346-73-7	Benzenesulfonic acid, dimethyl-, potassium salt
88-61-9	Benzenesulfonic acid, 2,4-dimethyl-
25321-41-9	Benzenesulfonic acid, dimethyl-
609-54-1	Benzenesulfonic acid, 2,5-dimethyl-
30587-85-0	Benzenesulfonic acid, 2,4(2,6 or 3,5)-dimethyl-, sodium salt
827-19-0	Benzenesulfonic acid, 2,5-dimethyl-, sodium salt