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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DATE: November 22, 2005

ACTION MEMORANDUM

SUBJECT: Inert Reassessment – Carbon Black, CAS Reg. No. 1333-86-4

FROM: Pauline Wagner, Chief Pauline Wagner 1/22/05
Inert Ingredient Assessment Branch

TO: Lois A. Rossi, Director
Registration Division

I. FQPA REASSESSMENT ACTION

Action: Reassessment of one inert exemption from the requirement of a tolerance.

Chemical: Carbon Black
CFR: 40 CFR part 180.930 [formerly 40 CFR180.1001(e)]
CAS Reg. No: 1333-86-4

Use Summary: The major use of carbon black is in the manufacture of rubber products, particularly in tires and other automotive components. Carbon black is also used as a pigment or colorant in inks, paints, leather dyes, ceramics, and coatings; as well as in plastics. It is also has limited use as an inert ingredient in pesticide products as a colorant/pigment in animal ear-tag.

List Reclassification Determination: Based on the low risk finding, this inert ingredient can be reclassified from List 3 to 4B.

II. MANAGEMENT CONCURRENCE

I concur with the reassessment of one exemption from the requirement of a tolerance for the inert ingredient carbon black CAS Reg. No. 1333-86-4, and with the

List reclassification determination(s), as described above. I consider one exemption established in 40 CFR part 180.930 [formerly 40 CFR180.1001©] 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.

Donald R Stubbs

Lois A. Rossi, Director
Registration Division

Date: 11/22/05

CC: Debbie Edwards, SRRD
Joe Nevola, SRRD

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OFFICE OF PREVENTION,
PESTICIDES, AND TOXIC
SUBSTANCES

November 21, 2005

MEMORANDUM

SUBJECT: Reassessment of one Exemption from the Requirement of a Tolerance for Carbon Black

FROM: Bipin Gandhi
Inert Ingredient Assessment Branch (IIAB)
Registration Division (7505C)

TO: Pauline Wagner, Chief
Inert Ingredient Assessment Branch (IIAB)
Registration Division (7505C)

Background

Attached is the science assessment for carbon black. Carbon black has one exemption from the requirement of a tolerance under 40 CFR §180.930 as pigment/colorant in animal tags as listed in Table 1 under use information. This assessment summarizes available information on the use, physical/chemical properties, toxicological effects, exposure profile, environmental fate, and ecotoxicity of carbon black. The purpose of this document is to reassess the existing exemption from the requirement of a tolerance for residues of carbon black when used as an inert ingredient in pesticide formulations as required under the Food Quality Protection Act (FQPA).

Executive Summary

The only use for which carbon black is approved as an inert ingredient in pesticide formulations under 40 CFR 180.930 as colorant/pigment in animal ear-tag. All the toxicity studies reported in the literature and discussed below are for carbon black particles and not relevant to its use as colorant/pigment in (plastic) animal tag. Therefore, the toxicity is low, the exposure is low and so the risk is low. There is no expected residues of concern in food, water, or residential exposure. In summary, the aggregate exposure is low. There is a safe history of carbon black when used in tires, plastics, automobile components, inks, adhesives, paints, dyes and ceramics.

Taking into consideration all available information on carbon black, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to carbon black when used as inert ingredient in pesticide formulations when considering the dietary exposure and all other non-occupational sources of pesticide exposure for which there is reliable information. Therefore, it is recommended that one exemption from the requirement of a

tolerance established for residues of carbon black be maintained and considered reassessed as safe under section 408(q) of the FFDCA.

I. Introduction

This report provides a qualitative assessment for carbon black, a pesticide inert ingredient in pesticide formulations when used as colorant/pigment in animal tags. This chemical has an exemption from the requirement of a tolerance under 40 CFR §180.930.

Carbon blacks are commercially produced by the partial combustion or thermal decomposition of gaseous or liquid hydrocarbons. Depending on the manufacturing process used, industrial carbon blacks are known as acetylene black, channel black, lamp black, furnace black, or thermal black. Other synonyms include Pigment Black 7, Pigment Black 6, impingement black, gas-furnace black, oil-furnace black, or therma-atomic black (BIBRA, 1990; IARC, 1996). Food grade carbon blacks are produced by the carbonization of plant materials such as peat, and are known as "vegetable blacks." Modern carbon blacks are largely (>90%) furnace blacks (IARC, 1996). The various carbon blacks exhibit a range of particle sizes and differences in degree of particle aggregation, but are similar in that they all possess low ash content and high surface area/unit mass (IARC, 1996).

II. Use Information

A. Pesticide Uses

At present, carbon black is exempted from tolerance requirements in pesticide formulations applied to animals when used as colorant/pigment in animal tags (40CFR §180.930) as shown table 1 below.

Table 1. Pesticide Uses

CFR Citation				CAS Reg. No. /Name
40 CFR §	Inert Ingredients	Limits	Uses	
180.930*	Carbon Black	(none)	Colorant/ Pigment in animal tag	1333-86-4 Carbon Black

*Residues listed in 40 CFR §180.930 are exempt 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.

B. Other Uses

The other uses include indirect contact with food (as adhesive component, as colorant in coatings, etc.) is permitted (21 CFR 175.105; 177.1650; 177.2400; 177.2410). Carbon black manufactured by the channel process cannot be directly used in food, drugs or cosmetics (21 CFR 81.10). In 1993, worldwide production of carbon black approximated 6 million tons (IARC, 1996).

The major use of carbon black is as a reinforcing and abrasion-resistant material in the manufacture of rubber products, particularly in tires and other automotive components. Carbon

black is also used as a pigment or colorant in inks, paints, leather dyes, ceramics, and coatings; as well as in plastics (to which it imparts weathering resistance, electrical conductivity, and antistatic properties) (IARC, 1996).

III. Physical and Chemical Properties

Table 2. Physical and Chemical Properties[1]

Parameter	Value
Structure	C
Molecular formula	C
Physical Form/color	Finely divided black solid particles; elemental amorphous carbon powder
Odor	Odorless
Density	1.8 – 2.1
pH	3 – 9.5 (depending on manufacturing process)
Molecular Wt.	12
Melting Point	3550° C
Boiling Point	4827 ° C
Sublimation Point	3367 ° C
Solubility	Insoluble in all commercial solvents; insoluble in water
Vapor Pressure	negligible
Vapor Density	NA
Henry's Law Constant	NA
Dissociation constants	NA
Log K_{ow}	NA
Average Particle Diameter	17 – 500 mm (depending on manufacturing process)
Surface Area	6 – 200 m^2/g

[1] IARC, 1996

IV. Hazard Assessment

Carbon black is not expected to pose a hazard when used in ear tags. Much of the toxicity data on carbon black has been generated via the inhalation route due to concerns over adverse effects on the respiratory tract. These data show that high levels of particulate carbon cause respiratory damage via a mechanism known as "lung overload". Oral ingestion of carbon has not been shown to cause adverse effects even at doses of one gram or greater over a two year period. As a solid, carbon black is not expected to be absorbed through the skin

A. Hazard Profile

The information for this profile was derived from studies identified in searches of major bibliographic data bases, and reliable secondary references. A very large body of data on carbon black toxicity exists in the literature. Therefore, toxicity information for carbon black presented here

is primarily from reviews published by IARC (1996), BIBRA International Ltd (1990), WHO (1988), NCI (1985),IPCS (2001) and RTECS (2004).

Because these documents have undergone several levels of technical review, it is assumed for the purposes of the present report that any referenced toxicity data cited within them are also reliable.

B. Toxicological Data

Acute Toxicity: The literature contains very little information on the acute or short-term toxicity of carbon black, and considers carbon black to be a non-specific respiratory irritant and nuisance dust as free particles). In general, data indicate that acute effects of carbon black exposures are the same as those observed for other insoluble particulates. As a consequence, the bulk of the toxicity studies for this material have been designed to determine tumorigenicity after long-term exposure, or after a lengthy latency period following exposure to overload concentrations.

The few acute experimental studies available indicate low mammalian toxicity: rat oral LD_{50} >15,400 mg/kg, rabbit dermal LD_{50} >3000 mg/kg (ATDAE1, as cited in RTECS).

Numerous intratracheal instillation exposures to mice and rats indicate that high acute doses elicit a specific inflammatory response which is thought to be related to the large surface area presented by the instilled carbon black particles (Bowden and Adamson, 1978, 1982; Adamson and Bowden, 1978, 1980, 1982a, b; all as cited in IARC, 1996). Similar findings were noted for inhalation exposures in rats.

Subchronic/Chronic toxicity. Subchronic and chronic inhalation exposure studies have been performed in rats and mice for a range of concentrations (1.1-52.8 mg/m^3) and exposure durations (multiple hours/day at 5 days/wk for 13 wks-24 months) (Heinrich et al., Dungworth et al., Nolte et al.1994, Driscoll et al.; all as cited in IARC 1996). IARC (1996) considers that the body of evidence contained in these studies indicate that "once a certain lung burden has been achieved, inhalation of carbon black in rats results in significant [pulmonary] inflammatory responses." This study was based on free particles.

RTECS posts a 90-day intermittent inhalation "lowest published toxic concentration" of 50 mg/m^3 for 6 hr/day (TOXID9, as cited in RTECS) for respiratory tract changes in the rat, and an intermittent 4-week dermal "lowest published toxic dose" of 11 g/kg for weight loss or decreased weight gain in the rat (as free particles) (NTIS OTS0534753, as cited in RTECS).

Long-term dietary studies of laboratory rodents fed large concentrations of carbon black in the diet (free particles)(e g., 1 g/g body wt/yr; approximately 2 g/kg feed) did not provide any indication of pathological effects in rodent GI tracts (Buddingh et al., Pence and Buddingh, 1985, 1987; all as cited in IARC, 1996). Other studies indicate that carbon black is relatively innocuous by the ingestion route (Nau et al., 1976, and Steiner; both as cited in IARC, 1996; Von Hamm et al., as cited in Robertson and Smith).

Developmental Toxicity No developmental studies with the free or bound carbon black were identified, but no effects on reproductive organs of either male or female rats were reported in long term studies.

Mutagenicity. Assays have been performed on multiple commercial carbon blacks, as well as organic extracts of several. IARC (1996) has determined that "most assays for mutagenicity are negative for carbon black

Carcinogenicity. Carbon black has been evaluated for carcinogenicity by a number of IARC Working Groups (1984, 1987, 1996). Since occupational exposure levels in the carbon black production industry have historically been high, workers in this industry have been the subject of many epidemiological studies. Nine such studies of workers in the US, UK, Sweden and Canada were examined in detail by IARC (1996), which "considered the whole body of evidence rather weak and the results conflicting."

The majority of carcinogenicity studies of carbon black are by the inhalation route. These studies have shown conflicting results. One study in female mice was negative for respiratory track tumors, while two other studies using both male and female rats also showed benign and malignant tumors in the females. The particle size and form may impact the toxicity of the respiratory system.

Nau et al. (as cited in IARC, 1996) determined that repeated and prolonged painting of various carbon black suspensions onto the skin of mice demonstrated no dermal carcinogenic effect. However, tumors (some in other organs) resulted if benzene extracts of the same carbon blacks were applied to the skin of mice.

Some recent reviews point out that current evaluations of carbon black carcinogenicity are heavily dependent upon the results of rat exposure studies, and may thus not be fully applicable to the response of human lung tissue under similar exposure conditions (Brockmann et al., 1998; Levy, 1996). Brockmann et al. (1998) and Levy (1996) recommend improvements in cancer study design and techniques, and greater precision in the nomenclature used to describe observed neoplastic lesions.

D. Special Consideration for Infants and Children

Carbon black has low subchronic and chronic toxicities. Although no developmental or reproductive studies, *per se*, were identified, long term studies have not demonstrated any effects on the reproductive organs of male or female rats. Additionally, the poor to nil absorption of carbon black as demonstrated by the lack of significant adverse effects by the oral route even at high doses would mitigate any concerns. Carbon black is used in small amounts in insecticidal animal ear tags that are firmly attached to the animals. The chemical is expected to remain incorporated in the ear tag and not disperse onto the animal during movement. In the worse-case scenario, residues from use of the ear tags are expected to be in micrograms per kilogram of animal weight (through the licking of the ear tags by other animals). Dietary exposure to carbon black in meats and meat products is expected to be several orders of magnitude less than levels in the animal, therefore, far below levels of concern. Based on the available exposure and toxicity information, safe history of similar uses, a safety factor analysis has not been used to assess the risks resulting from the inert

pesticidal use of carbon black, and therefore, an additional tenfold safety factor for the protection of infants and children is unnecessary.

V. Environmental Fate Characterization/Drinking Water Considerations

Carbon black can be released into the environment from various industrial sources. However, the release from the pesticidal uses are negligible because its use is limited to composition of pigments and dyes and as a component of plastic ear tags for animals. It is not soluble in water or any other commercial solvents. Carbon black is not subject to degradation per se because it is not expected to photolyze, hydrolyze, or subject to metabolic degradation. It will not enter into the environment because it is incorporated into plastic ear tags and plastics in general do not degrade. It is an inert material and does not harm water or the environment. It is adsorb to the soil and does not harm soil or the crops grown on such soils.

Based on all of the above information and the physical/chemical properties of carbon black, concentrations of this chemical in drinking water (from runoff), are not expected from their use as colorant/pigment in animal tags in pesticide products.

Exposure Assessment

The only pesticide inert ingredient use of carbon black is as pigment in animal tag. Animal ear tags are small in size (9.5 to 14.5 g), and the amount of inert ingredient that is used as pigment in animal tag is small compare to total weight of the tag. Residential exposures (inhalation and dermal) to carbon black are not expected to occur because the carbon black as pigment which is incorporated into animal ear tags that are firmly attached to the animal. For the same reason, dietary exposures (food and drinking water) to this chemical are unlikely and there are no other food or feed crop uses for this chemical. In a worst case scenario, maximum exposure to carbon black would be in micrograms per kilogram of animal, which is well below levels of concern. Wildlife exposure and exposure to aquatic organism will be much less because of the incorporation of carbon black into plastic animal ear tag. In addition, carbon black is innocuous in nature, so no harm is expected from its use as pigment in animal ear tag.

Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in garden, lawns, or buildings (residential and other indoor uses). As stated above under 'Exposure Assessment' there will not be any exposure through food, water or residential uses.

Cumulative Exposure

Section 408(b)(2)(D)(v) of the 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 or toxicity, EPA has not made a common mechanism of toxicity safety finding as to carbon black, and any other substances, and carbon black do not appear to produce toxic metabolites produced by other substances. For the purpose of these tolerance actions, therefore, EPA has not assumed that carbon black has 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/.

IX. Human Health Risk Characterization

The only use for which carbon black is approved as an inert ingredient in pesticide formulations is under 40 CFR 180.930 as colorant/pigment in animal ear-tag. The majority of toxicity studies reported in the literature and discussed above are inhalation studies for carbon black particles and are not relevant to its use as colorant/pigment in (plastic) animal tag. One long term oral study in rats did not produce any adverse effects at doses of 1000 mg/kg. Therefore, the toxicity is low, the exposure is low and so the risk is low. There are no expected residues of concern in food, water, or residential exposure. There is a safe history of carbon black when used in tires, plastics, automobile components, inks, adhesives, paints, dyes and ceramics.

Taking into consideration all available information on carbon black, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to carbon black when used as inert ingredient in pesticide formulations when considering the dietary exposure and all other non-occupational sources of pesticide exposure for which there is reliable information. Therefore, it is recommended that the one exemption from the requirement of a tolerance established for residues of carbon black be maintained and considered reassessed as safe under section 408(q) of the FFDCA.

X. Ecotoxicity and Ecological Risk Characterization

Carbon is not soluble in water or any commercially available solvents and it is innocuous in nature, therefore, no ecological risk is expected. Following are the ecosar predicted calculations in table 3.

Table 3. Ecosar predicted data

Organism	Duration	End Pt	Predicted mg/L (ppm)
Fish	14-day	LC50	248.833
Fish	96-hr	LC50	166.759
Daphnid	48-hr	LC50	164.244
Green Algae	96-hr	EC50	95.717
Fish	30-day	Chv	17.648
Daphnid	16-day	EC50	4.940

Green Algae	96-hr	Chv	4.729
Fish	96-hr	LC50	21.718
Mysid Shrimp	96-hr	LC50	114.892
Earthworm	14-day	LC50	234.892 (dry wt soil)

* ECOSAR Run

XI. References:

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