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H. Environmental Assessment

This environmental assessment has been prepared in accordance with 21 C.F.R. § 25.31a, using the abbreviated format described in (b) (1) [50 FR 16662].

H.1 - Date: June 3, 1996

H.2 - Petitioner: Ciba-Geigy Corporation

H.3 - Address: 335 Water Street
Newport, DE 19804

H.4 - Description of the Proposed Action:

It is proposed that 21 C.F.R. § 178.3297, Colorants for Polymers, be amended to allow for the use of

2,9-dichloro-5,12-dihydroquinone[2,3-b]acridine-7,14-dione (C.I. Pigment Red 202)

marketed as Magenta RT-235-D, as a pigment for all food contact polymers. The maximum use level of this pigment will be 1.0% by weight of the polymer.

This pigment is manufactured by Ciba-Geigy at one facility only which is located at Newport, Delaware.

The use and disposal of food-packaging material containing this pigment will be widely dispersed throughout the United States in patterns corresponding to the national population density, with about 80% of these materials ultimately being deposited in land disposal sites, 10% incinerated and 10% recycled. Landfill disposal is not expected to impact watersheds or groundwater as the migration study conducted for this petition has demonstrated no migration. Incineration of articles containing this pigment result in the formation of carbon monoxide, carbon dioxide, nitrogen oxides and hydrochloric acid (absorbed by the scrubbers). Incremental increase of emission generated by, use of the pigment in polymers at levels less than 1% will be trivial compared to emission from existing waste.

HDPE and PET are considered polymers which are currently the most highly recycled plastics.

This pigment is intended for the same uses as other colorants already in use. Therefore, it is reasonable to expect that the subject additive will replace other colorants currently in use, so that approval of this petition is not likely to result in a significant increase in the number of colored containers in the municipal waste

stream. Even if there is some increase in the number of colored containers, this increase will not affect the recycling of HDPE containers because mixed color HDPE containers are currently being recycled.

It is unlikely that this pigment will penetrate the market for transparent PET bottles..

Based on the above, we believe that this product will not interfere significantly with current or future recycling of HDPE or PET.

H.5 - Identification

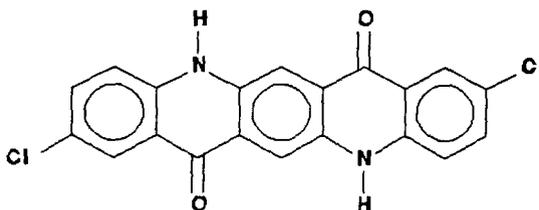
CAS Name: 2,9-dichloro-5,12-dihydroquinone[2,3-b]acridine-7,14-dione

CAS #: 3089-17-6

Molecular Formula: $C_{20}H_{10}Cl_2N_2O_2$

Molecular Weight: 472

Structural Formula:



2,9-dichloro-5,12-dihydroquinone[2,3-b]acridine-7,14-dione

Physical Description:

Bluish red, crystalline powder; insoluble in water and common organic solvents; practically no volatility at 25°C; melting point > 300°C

H.6 - Introduction of Substances into the Environment

This product (C.I. Pigment Red 202) is manufactured in the U.S. at one location. All emissions and discharges are in compliance with the applicable regulations at the production site. Potential increases in production after approval of this petition will not affect our compliance situation.

H.6.1 - Emissions

Emissions associated with the manufacture of the Product are limited to discharges of treated wastewater and air emissions in the form of product dust and minimal fugitive alcohols. These are further described below.

Wastewater

Discharges from the filtration and washing process contain traces of unreacted raw materials, sodium chloride, and traces of the Product. These materials are treated in the New Castle County Publicly Owned Treatment Works (POTW), water treatment plant. Final discharges to surface waters contain permitted levels of inorganic salts and organics expressed as BOD (Biological Oxygen Demand) and COD (Chemical Oxygen Demand).

Air Emissions

Air emissions from the manufacture of the Product are limited to Product dust during and after drying, pulverizing, and final packaging. Emission controls are through appropriate dust containment including automated packaging, air exhausts combined with filtering units. Ambient dust levels do not exceed 1 mg/m³, a level well below the OSHA recommended PEL for inert or nuisance dust. In addition, less than 1 lb/day of both methanol and ethanol may become air fugitive emissions. About 5,800 lb/yr of methanol and 8,300 lb/yr of ethanol are recycled and reused; thus, these quantities are not released to the atmosphere.

The emissions expected per 3,600 kg of RT-235-D produced in plant runs are further summarized in Table 1.

Table 1

Increased emissions (3,600 kg/year)	Air point	Air fugitive	Water	Offsite Disposal	Offsite recycle/energy recovery
Ethanol	0	222	1,232	35	8,339
p-cl-Aniline	0	1	291	37	0
Biphenyl	2	10	156	126	217
Methanol	41	304	5,940	49	5,813
Tar Wastes	0	0	0	0	1,231
Total	43	538	7,619	247	15,600

As indicated above, all discharges to water undergo biological treatment at the New Castle County POTW before discharge to a surface water body. The expected

increase in BOD loading to the POTW due to the increased production of RT-235-D is 6,636 kg/year; the increase in TSS loading is estimated to be 2,091 kg/year. Both BOD and TSS are effectively removed by the POTW.

H.6.2 - Compliance with applicable environmental and occupational safety requirements

Wastewater

Discharges of wastewater from our industrial operations are governed by the following regulations:

Waste Water Discharge Permit No: WDP 84-057 issued by the New Castle County Dept. of Public Works

NPDES Permit No.: DE0000400

Ciba-Geigy is in compliance with these regulations. Potential increases of production after this petition will not affect the company's compliance situation.

Air Emissions

Air emissions from the manufacture of the Product as described above (H.6.1) are subject to the following regulations:

OSHA air contaminants and hazard communication standard, rules (29 CFR 1910.1000 and 29 CFR 1910.1200 Respectively).

Air permit, Newport Plant, - Issued by the Delaware Natural Resources & Environmental Control Department, Division of Air & Waste Management

APC-92/437 - Thermal Oxidation Unit

APC-81/679 - Quinacridone Tar Out Scrubber

APC-90/194 and 90/195 - LUWA driers #1 and #2

Raw material exposure limits

Dimethylsuccinate (CAS # 106-65-0) - Irritant to eye, skin, and by inhalation [No established limits]

Sodium methylate (CAS # 124-41-4) - Corrosive to eye, skin, and by inhalation. [No established limits]

Sodium chloride (CAS # 7647-14-5) - Irritant to eye and skin. [No established limits]

Para-chloraniline (CAS # 106-47-8) - Severe eye irritant. If absorbed through skin, or inhaled, it can cause cyanosis. DuPont 0.5 mg/m³ TWA 8 hr.

Sodium hydroxide (CAS # 1310-73-2) - Severe burns to eyes, corrosive by inhalation and by ingestion. PEL 2 g/m³

Meta-nitrobenzene sulfonic acid, sodium salt (CAS # 127-68-4) - Eye irritant. [No established limits]

Trifluoroacetic acid (CAS # 76-05-1) - Corrosive to skin, eye, by ingestion and by inhalation. Lethal dose in rat = 10 g/m³. [No established limits]

Ciba-Geigy is in compliance with the permits and regulations cited above. Potential increases of production after approval of this petition will not affect the company's compliance situation.

I certify that we will manufacture this additive in compliance with the above regulatory requirements, including occupational exposure requirements. The regulation of this additive for the uses proposed in this petition will have no impact on the compliance with these regulatory requirements. Less than 10 percent of the total production of this pigment will go into the food packaging applications which are the subject of this petition. We have estimated the total volume of this pigment going into food packaging as 3,600 kg per year.

Based upon efficient transfer operations at users' sites, and the lack of volatility of this additive, we estimate that essentially 100 percent of this additive will become a component of polypropylene and polyethylene food packaging, with insignificant amounts lost as fugitive dust. As a result, we do not expect that this additive will enter the environment at users' sites.

H.6.3 - Market estimate

As stated above, the estimated incremental market volume to be sold into food contact polymers is kg/year.

H.7 - Fate of Emitted Substances in the Environment

This format item does not normally require documentation for food additives that are present as functional components of finished food-packaging material at a level of 5% or less. This is the case with this proposed action.

H.8 - Environmental Effects of Released Substances

This format item does not normally require documentation for food additives that are present as functional components of finished food-packaging material at a level of 5% or less. This is the case with this proposed action.

H.9 - Use of Resources and Energy:

This pigment (the proposed food additive) is intended for the same use as other colorants already in use which may be listed in 21 C.F.R. § 178.3297. These include, for example, C.I. Pigment Red 177 and C.I. Pigment Red 220. This pigment will not materially change the potential uses of the polymers to which it will be added.

H.10 - Mitigation Measures:

Documentation for this item is not required for the proposed action.

H.11 - Alternatives to the Proposed Action:

Documentation for this item is not required for the proposed action.

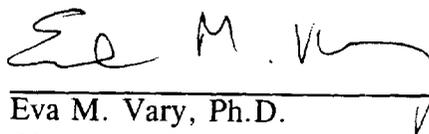
H.12 - List of Preparers:

Eva M. Vary, Ph.D.
Director of Product Safety
Ciba-Geigy Corporation
Pigments Division
335 Water St.
Newport, DE 19804

H.13 - Certification

The undersigned certifies that the information presented is true, accurate and complete to the best of the knowledge of Ciba-Geigy Corporation.

Date: June 3, 1996



Eva M. Vary, Ph.D.
Director of Product Safety
Ciba Pigments