Selected benzidine-congener-based pigments: Human health tier II assessment

29 June 2018

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Acetoacetanilide, 2,2'-[(3,3'-dichloro-4,4'-biphenylylene)bis(azo)]bis[2',5'-dimethoxy-	15110-84-6
3H-Pyrazol-3-one, 4,4'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[2,4-dihydro-5-methyl-2-phenyl-	3520-72-7
Butanamide, 2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2-methoxyphenyl)-3-oxo-	4531-49-1
Butanamide, 2,2'-[[3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl]bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo-	5102-83-0
Butanamide, 2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2-methylphenyl)-3-oxo-	5468-75-7
Butanamide, 2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxo-	5567-15-7

Chemical Name in the Inventory	CAS Number
Butanamide, 2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(4-methylphenyl)-3-oxo-	6358-37-8
Butanamide, 2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-N-phenyl-	6358-85-6
1H-Pyrazole-3-carboxylic acid, 4,4'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[4,5-dihydro-5-oxo-1-phenyl-, diethyl ester	6358-87-8
Butanamide, 2,2'-[(3,3'-dimethoxy[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-N-phenyl-	6505-28-8
3H-Pyrazol-3-one, 4,4'-[(3,3'-dimethoxy[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[2,4-dihydro-5-methyl-2-phenyl-	6505-29-9
3H-Pyrazol-3-one, 4,4'-[(3,3'-dimethoxy[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[2,4-dihydro-5-methyl-2-(4-methylphenyl)-	6883-91-6
Butanamide, 2,2'-[(3,3'-dimethoxy[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2-methylphenyl)-3-oxo-	7147-42-4
Butanamide, 2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2-chlorophenyl)-3-oxo-	14569-54-1
3H-Pyrazol-3-one, 4,4'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[2,4-dihydro-5-methyl-2-(4-methylphenyl)-	15793-73-4
p-Acetoacetophenetidide, 2,2''-[(3,3'-dichloro-4,4'-biphenylylene)bis(azo)]bis-	31775-20-9
Butanamide, 2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-, N,N'-bis(o-anisyl and 2,4-xylyl) derivatives	68610-86-6
Butanamide, 2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-, N,N'-bis(phenyl and p-tolyl) derivatives	68610-87-7
Butanamide, 2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-, N,N'-bis(phenyl and 2,4-xylyl) derivatives	72207-62-6

Chemical Name in the Inventory	CAS Number
Butanamide, 2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-, N,N'-bis(o-anisyl and phenyl) derivatives	76822-91-8
Butanamide, 2-[[3,3'-dichloro-4'-[[1-[[(2,4-dimethylphenyl)amino]carbonyl]-2-oxopropyl]azo][1,1'-biphenyl]-4-yl]azo]-N-(2-methylphenyl)-3-oxo-	78952-72-4
Butanamide, 2-[[3,3'-dichloro-4'-[[4,5-dihydro-3-methyl-1-(4-methylphenyl)-5-oxo-1H-pyrazol-4-yl]azo][1,1'-biphenyl]-4-yl]azo]-N-(2,4-dimethylphenyl)-3-oxo-	79665-33-1
Butanamide, 2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-, N,N'-bis(p-anisyl and phenyl) derivatives	90268-23-8
Butanamide, 2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-, N,N'-bis(4-chloro-2,5-dimethoxyphenyl and 2,4-xylyl) derivatives	90268-24-9
Benzenesulfonic acid, 3-[4-[[3,3'-dichloro-4'-[[1-[[(2,4-dimethylphenyl)amino]carbonyl]-2-oxopropyl]azo][1,1'-biphenyl]-4-yl]azo]-4,5-dihydro-3-methyl-5-oxo-1H-pyrazol-1-yl]-, calcium salt (2:1)	113010-48-3

Preface

This assessment was carried out by staff of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) using the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.

The IMAP framework addresses the human health and environmental impacts of previously unassessed industrial chemicals listed on the Australian Inventory of Chemical Substances (the Inventory).

The framework was developed with significant input from stakeholders and provides a more rapid, flexible and transparent approach for the assessment of chemicals listed on the Inventory.

Stage One of the implementation of this framework, which lasted four years from 1 July 2012, examined 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This included chemicals for which NICNAS already held exposure information, chemicals identified as a concern or for which regulatory action had been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

Stage Two of IMAP began in July 2016. We are continuing to assess chemicals on the Inventory, including chemicals identified as a concern for which action has been taken overseas and chemicals that can be rapidly identified and assessed by using Stage One information. We are also continuing to publish information for chemicals on the Inventory that pose a low risk to human health or the environment or both. This work provides efficiencies and enables us to identify higher risk chemicals requiring assessment.

The IMAP framework is a science and risk-based model designed to align the assessment effort with the human health and environmental impacts of chemicals. It has three tiers of assessment, with the assessment effort increasing with each tier. The Tier I assessment is a high throughput approach using tabulated electronic data. The Tier II assessment is an evaluation of risk

on a substance-by-substance or chemical category-by-category basis. Tier III assessments are conducted to address specific concerns that could not be resolved during the Tier II assessment.

These assessments are carried out by staff employed by the Australian Government Department of Health and the Australian Government Department of the Environment and Energy. The human health and environment risk assessments are conducted and published separately, using information available at the time, and may be undertaken at different tiers.

This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

For more detail on this program please visit:**www.nicnas.gov.au**

Disclaimer

NICNAS has made every effort to assure the quality of information available in this report. However, before relying on it for a specific purpose, users should obtain advice relevant to their particular circumstances. This report has been prepared by NICNAS using a range of sources, including information from databases maintained by third parties, which include data supplied by industry. NICNAS has not verified and cannot guarantee the correctness of all information obtained from those databases. Reproduction or further distribution of this information may be subject to copyright protection. Use of this information without obtaining the permission from the owner(s) of the respective information might violate the rights of the owner. NICNAS does not take any responsibility whatsoever for any copyright or other infringements that may be caused by using this information.

ACRONYMS & ABBREVIATIONS

Grouping Rationale

All the chemicals in this group are 3,3'-disubstituted benzidine-congener-based pigments, which have the characteristic diazotised 3,3'-benzidine-congener structure. Although the other chemical groups attached at the diazo linkages differ, the linkage for all members of this group is through an acetoacetanilide group or pyrazole based group.

These chemicals have similar physical-chemical properties and therefore are expected to have similar bioavailability. Therefore, the chemicals are expected to have similar toxicity profiles. These chemicals have similar uses including inks in tattoos and permanent makeup.

Import, Manufacture and Use

Australian

The chemical Pigment Yellow (PY) 13 (CAS No. 5102-83-0) is listed on the 2006 High Volume Industrial Chemicals List (HVICL) with a total reported volume of 1000–9999 tonnes. It has a reported use as a colouring agent in the paper and pulp industry.

The chemicals PY12 (CAS No. 6358-85-6) and PY174 (CAS No. 78952-72-4) were reported to be used as colouring agents under previous mandatory and/or voluntary calls for information. The total volume introduced into Australia, reported under previous mandatory and/or voluntary calls for information, for both of these chemicals, was 100–1000 tonnes.

The chemicals Pigment Orange (PO) 34 (CAS No. 15793-73-4), PO 13 (CAS No. 3520-72-7), PY 14 (CAS No. 5468-75-7), PY 83 (CAS No. 5567-15-7) and PO 16 (CAS No. 6506-28-8) were identified as present in tattoo inks available in Australia (NICNAS, 2016).

International

The following international uses have been identified through European Union Registration, Evaluation and Authorisation of Chemicals (EU REACH) dossiers; the Organisation for Economic Cooperation and Development Screening information data set International Assessment Report (OECD SIAR); Galleria Chemica; Substances and Preparations in the Nordic countries (SPIN)

database; the European Commission Cosmetic Ingredients and Substances (CosIng) database; United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary; and eChemPortal: OECD High Production Volume chemical program (OECD HPV), the US Environmental Protection Agency's Aggregated Computer Toxicology Resource (ACToR), and the US National Library of Medicine's Hazardous Substances Data Bank (HSDB).

The chemicals PY12, PY13, PY17 (CAS No. 4531-49-1) and PY83 have reported cosmetic use. The identified cosmetic products include:

- bath salts for infants, face makeup, hair dye, mascara, nail polish, and batch showering products (PY12); and
- foundation, hair dye, hair grooming products, lipstick, mascara, and nail polish (PY83) (Government of Canada, 2014).

The chemicals PY12, PY13, PY14, PY55 (CAS No. 6358-37-8), PY83, PY87 (CAS No. 15110-84-6), PO 13 (CAS No. 3520-72-7), PO16 and PO34 (CAS No. 15793-73-4) are reported to be used as tattoo inks and permanent make-up inks (Government of Canada, 2014; JRC, 2015).

The chemicals in this group also have reported use in the following:

- inks, toners and colourants;
- paints and coatings;
- alkyd resin enamel;
- reprographic agent (PY17, PY 176 (CAS No. 90268-24-9));
- reproduction of recorded media (PY12, PY13, PY 17, PY83 and PY176);
- polymer preparations and compounds (PY 17, PY 152 (CAS No. 31775-20-9), Pigment Red (PR) 38 (CAS No 6358-87-8);
- paint removers and thinners (PY 17, PY 152);
- fillers and putties (PY 17, PY 152); and
- chalks, modelling clays and synthetic resin lacquers (PO13).

The chemicals have reported site-limited uses as colourant in manufacture of plastic and rubber materials, textile, fabric and leather articles, and wood products (PY 17).

Restrictions

Australian

No known restrictions have been identified.

International

The chemicals are listed on the following (Galleria Chemica).

The chemicals PY12 and PY13 are listed in the:

- European Union (EU) Cosmetics Regulation 1223/2009 Annex II—List of substances prohibited in cosmetic products. The chemicals are not permitted to be used in hair dye.
- New Zealand Cosmetic Products Group Standard—Schedule 4: Components cosmetic products must not contain. These chemicals are not permitted to be used in hair dye.

- Association of Southeast Asian Nations (ASEAN) Cosmetic Directive Annex II Part 1: List of substances which must not form part of the composition of cosmetic products.
- China List of Banned Substances for Use in Cosmetics

The chemical PY 83 is listed in the European Union (EU) Cosmetics Regulation 1223/2009 Annex IV (list of colorants allowed in cosmetic products) for use in rinse-off products only.

The chemical PY174 is listed in the United Arab Emirates Restricted Chemicals.

The Resolution ResAP(2008)1 on requirements and criteria for the safety of tattoos and permanent make-up (Council of Europe, 2008) lists the benzidine congeners (3,3'-dichlorobenzidine, 3,3'-dimethoxybenzidine, 3,3'-dimethylbenzidine) under the aromatic amines which should not be present or released from tattoos and permanent make-up products in concentrations that are technically avoidable according to good manufacturing procedures. Chemicals that contain substances that are listed in the EU Directive 76/768/EEC Annex II and IV (with restrictions) are also not permitted. These requirements have been imbedded by several European countries into their domestic legislative framework (European Commission JRC, 2015).

In addition, a proposal for a restriction of substances in tattoo inks and permanent make up was published in October 2017: This restriction proposal included the following assessed benzidine-congener-based pigments (with a proposed concentration limit of 0.1 %): PY 87 (CAS No. 15110-84-6), PO 13 (CAS No. 3520-72-7), PY 14 (CAS No. 5468-75-7), (PY 83 (CAS No. 5567-15-7), PY 55 (CAS No. 6358-37-8), PY 12 (CAS No. 6358-85-6), PO 16 (CAS No. 6505-28-8), PO 34 (CAS No. 15793-73-4) (ECHA Annex XV Restriction Report, 2017).

Existing Worker Health and Safety Controls

Hazard Classification

The chemicals are not listed on the Hazardous Substances Information System (HCIS) (Safe Work Australia).

Exposure Standards

Australian

No specific exposure standards are available. However, the permissible exposure limits (as the time weighted average (TWA) for dusts may apply (10 mg/mg/m^3 measured as inspirable dust).

International

No specific exposure standards are available, although in many countries a generic TWA exposure limit in the range of 1–10 mg/m^3 for respirable dust or particles (insoluble) not otherwise classified appears to apply (Galleria Chemica).

Health Hazard Information

Toxicokinetics

Overall, the available data indicate that these chemicals have limited bioavailability. This would be expected given their large molecular size and low water solubility. Limited uptake of the chemicals in particle form cannot be ruled out.

In the majority of oral metabolism and absorption studies, there was no evidence of absorption or azo bond cleavage for the chemicals. Results from an inhalation study with PY17 and from a dermal study with PY12 did not show evidence of azo bond cleavage or absorption of these substances. Low levels of 3,3'-dichlorobenzidine (3,3'-DCB) in urine and some detectable 3,3'-DCB adducts in haemoglobin and liver deoxyribonucleic acid (DNA) were reported in some studies in rabbits and rats following oral exposure and intratracheal instillations. However, these findings are equivocal and are considered possibly due to the presence of soluble 3,3'-DCB-containing impurities (OECD, 2003; US EPA, 2010; Government of Canada, 2014; REACHc; REACHj; REACHk).

Whilst discolouration of organs has been observed in repeated oral toxicity studies, which could indicate bioavailability, contamination during necropsy could not be excluded (see **Repeated dose toxicity: Oral** section).

Accumulation of pigment particles in several areas of the lungs was observed in an inhalation study of PY13 (see **Repeated dose toxicity: Inhalation**). 'Low levels of uptake and systemic distribution to local lymph nodes and other distal tissues have been described for other insoluble microparticles and nanoparticles administered to the lungs and gastrointestinal tract' (Government of Canada, 2014). Therefore, it is possible that the chemicals, if present in the sub-micrometer-range size, may be absorbed systemically in the particle form following oral and inhalation exposure. The fraction of the total administered dose that could be absorbed in this way is expected to be low.

Acute Toxicity

Oral

Based on acute toxicity tests in rats following oral exposure, the chemicals are expected to have low acute oral toxicity.

Acute dose toxicity of several of the chemicals have been investigated in various rat strains, with median lethal dose (LD50) values >2000 mg/kg bw.

In an acute oral toxicity study, CD rats received (oral gavage) a single dose of 11000 or 17000 mg/kg bw/day of PY 12 in a peanut oil suspension. Treatment resulted in pigmentation in the faeces. There was no incidence of death in any dosed group.

In other studies, Sprague Dawley (SD) and Wistar rats received (oral gavage) single doses of 1750–15 000 mg/kg bw of PY 13 and PY 83. In these studies, the only chemical-induced effects were the discolouration of the faeces after 24 hours of exposure or ruffled fur and crouched posture. No mortalities were observed (OECD, 2003; US EPA, 2010).

Male and female RAI rats were treated by gavage at the limit dose of 10 mL/kg bw (corresponding to about 3500 mg/kg bw). No animals died (REACHb).

Numerous acute oral animal studies were reported in the REACH dossiers for various pigments. While it was difficult in most cases to identify the particular pigment tested, the results were consistent with low acute toxicity (REACHa–m).

Dermal

The data for acute dermal toxicity of the chemicals are limited.

In a study with PY 13, no clinical signs of toxicity or deaths were observed following the treatment of SD rats with 400 mg/L of PY 13 in polyethylene glycol/water (50:50). The reported LD50 was >3000 mg/kg bw (test substance), equivalent to 1700 mg/kg bw pure PY 13) (OECD, 2003; REACHb). In a study reported to be according to OECD Test Guideline (TG) 402, a pigment (possibly PR 38) had low acute toxicity (LD50 >2000 mg/kg bw). No mortality or signs of toxicity were observed (REACHh). Given the low acute toxicity following oral exposure and limited absorption through the skin, the dermal acute toxicity for all chemicals is expected to be low.

Inhalation

The chemicals are expected to have low acute inhalation toxicity.

The chemical PY 13 had low acute toxicity in rats following inhalation exposure, with no mortalities or toxic effects observed. The median lethal concentration (LC50) was >4448 mg/m^3 (OECD, 2003).

A single acute inhalation study was reported in the REACH dossiers for PY 17, PY 126, PY 127, PY 152 and PY 188 (CAS No. 72207-62-6). The particular pigment tested could not be clearly identified from the summary. In the reported nose only acute inhalation study, inhalation exposure of rats to an aerosol at up to 4250 mg/m^3 over 4 hours did not result in the death of animals during a 14-day observation period, nor any macroscopically visible changes upon necropsy. The LC50 was >4250 mg/m^3 (REACHb; REACHf; REACHi; REACHl; REACHm).

Exposure of male and female Wistar rats to 230 mg/m^3 PY 17 for 4 hours did not result in the death of the animals during a 14 day observation period (Government of Canada, 2014).

Similar effects are expected for all the chemicals in the group.

Corrosion / Irritation

Skin Irritation

The chemicals are expected to, at the most, slightly irritate the skin. Following repeated dermal exposure in New Zealand White (NZW) rabbit skin under occlusive (full or partial) conditions, skin erythema was noted. The effects are not sufficient to warrant hazard classification (REACHa–m).

Eye Irritation

Limited data is available for the chemicals. Based on the available data, the chemicals may slightly irritate the eye, but the overall effects are not sufficient to warrant hazard classification.

In an OECD TG 405 eye irritation study, NZW rabbits were treated with 100 mg of PY 12 as a paste with 0.13 mL of polyethylene glycol 400 in the eye. The eye was washed with warm saline at 24 hours after application. Corneal opacity was observed in 1 out of 3 animals and was fully reversible within 24 hours. Iridial effects were noted in all three rabbits up to 24 hours after application. Conjunctival redness and chemosis were observed in all rabbits for up to 72 hours after application. These effects were fully reversible by seven days (REACHa).

Slight eye irritation was reported in Chbb:NZW rabbits following exposure to PY 87. No further details were provided (US EPA, 2010).

Numerous eye irritation studies in rabbits were reported in the REACH dossiers for various pigments. Whilst it was difficult in most cases to identify the particular pigment tested, in general reported effects were slight eye reactions such as conjunctival redness and chemosis. All reactions were reversible within 7 days or earlier (REACHa–m).

Sensitisation

Skin Sensitisation

The negative results observed for chemicals in several skin sensitisation animal studies (Buehler test, guinea pig maximisation test and LLNA) support a conclusion that the chemicals are not skin sensitisers.

Several studies have been conducted to evaluate the skin sensitisation potential of the chemicals of this group. Female Dunkin/Hartley guinea pigs were induced (epicutaneous), using Buehler test method, with 60 % weight/volume (w/v) PY 12 suspended in corn oil under occlusive conditions for 0, 7 and 14 days. At day 28, the animals were challenged with 3, 10, 30 and 60 % w/v PY 12 and reactions were monitored at 24 and 48 hours following the challenge exposure. Histopathological

assessments of the challenge sites, together with the appropriate controls, were conducted using light microscopy. The results demonstrated only minimal skin irritation in animals from all treated groups. Appropriate skin reaction was observed in the positive control group. In comparison to the controls, the effects in the treated groups were not statistically significant. The result indicated that PY 12 did not induce sensitisation in guinea pigs. There was also no evidence of sensitisation in two similar studies with PY 13 (OECD, 2003; US EPA, 2010).

Similar results were obtained from a guinea pig maximisation test which was compliant with the OECD TG 406. In this study, intradermal induction of 1 % of the chemical PY 176 in hydroxyethyl-cellulose (1 % in water) was conducted in female Dunkin/Hartley guinea pigs. Dermal induction and challenge exposures were performed under occlusive condition using 25 % of the chemical in the same vehicle. Changes in the skin of the treated and control animals were observed at 24 and 48 hours. The results showed that PY 176 did not induce skin sensitisation at the tested concentration (REACHk).

Several LLNA studies (OECD TG 429) were reported in the REACH dossiers for various pigments. The test substance was tested up to a concentration of 25 %. A variety of solvents were used in these studies. While it was difficult in most cases to identify the particular pigment tested, no clinical signs of sensitisation were reported (REACHa–m).

Observation in humans

Whilst some positive case studies have been reported for PY 12, the chemical (2 % in yellow petrolatum) was negative in patch tests in 32 patients (20 women, 12 men) with allergic contact dermatitis (OECD, 2003; Government of Canada, 2014).

Repeated Dose Toxicity

Oral

Considering the no observed adverse effect levels (NOAELs) for systemic toxicity available from 4- to 104-week studies in rats and in mice (1000–6500 mg/kg bw/day), and based on the treatment-related effects reported in various oral repeated dose toxicity studies, the chemicals are not considered to cause serious damage to health from repeated oral exposure.

In a 28 day gavage study, Crj:CD(SD)IGS rats were treated with PO 16 up to 1000 mg/kg bw/day. No chemical-related mortalities and no pathological abnormalities were seen at any doses tested (Government of Canada, 2014). NOAELs of 1000 mg/kg bw/day were established for PY 12 and PO 34 in two separate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (see **Reproductive and developmental toxicity** section).

Similar findings were reported from 78- and 104-week chronic oral toxicity studies with PY 12 and/or PY 83 in Fischer 344 (F344) and SD rats. In the 78-week investigation, male F344 rats were orally exposed to 1000 mg/kg bw/day and 2000 mg/kg bw/day, whereas females were given 1250 mg/kg bw/day and 2500 mg/kg bw/day of PY 12. The animals were allowed to recover for 28 weeks. Findings from this study showed that compared with the controls, there were no significant differences in the mortality rates in the animals from all dose groups. However, in the liver of the treated animals, basophilic changes of the cytoplasm were observed. In addition, all treated rats displayed yellowness of their exterior, most organs and on the surfaces of the internal mucosa. The authors noted that contamination during necropsy cannot be excluded in relation to this particular observation. The reported lowest observed effect level (LOEL) in this study was 1250 mg/kg bw/day based on basophilic hepatocellular changes. In the 104-week study, exposure to a diet containing 0, 68, 205 or 630 mg/kg bw/day of PY 12 or PY 83 did not result in deaths or any pathological abnormalities in SD rats. Similarly, negative findings were also observed in a 78-week study in B6C3F1 mice (NOAEL of 6500 mg/kg bw/day) (OECD, 2003; US EPA, 2010; Government of Canada, 2014).

Overall, the available data indicate limited treatment-related changes observed in the parameters tested including organ weights, survival, urine, haematology and histopathology.

Dermal

No data are available.

Inhalation

The available information on repeated dose inhalation toxicity of the chemicals is limited.

In a 21-day repeated dose inhalation toxicity study in rats, the no observed adverse effect concentration (NOAEC) for the chemical PY 13 was 157 mg/m^3. In this test guideline comparable inhalation study, RAI fSPF (RA25) rats were exposed (nose only) to 0, 52, 157, 401 mg/m^3 of PY 13 for 6 hours a day, 5 days a week for 21 days. Although no deaths were observed in any group at the termination of exposure, treatment-related changes in rats from the highest-dose group (401 mg/m^3) were observed. The males in this group showed significant reduction in bodyweight. Weight increases (absolute and relative) and yellow colouration were detected in the lungs of high dose group. These changes persisted even after the 21-day recovery period. Compared with the controls, the highest-dose group showed a higher percentage of polymorphonuclear neutrophils and a lower percentage of lymphocytes. In addition, focal accumulation of brown/yellow particles in several areas of the lungs and foamy pneumonocytes in the alveoli were also observed in this group. Although pigment deposition was observed at all doses, inflammatory immune responses were only observed at the highest concentration tested (US EPA, 2010; Government of Canada, 2014; REACHc; REACHk).

Genotoxicity

Based on the weight of evidence from the available in vitro and in vivo genotoxicity studies, the chemicals are not considered genotoxic.

In vitro studies

The chemicals PY 12, PY 13, PY 83 and PY 176, tested negative in bacterial reverse mutation assays in *Salmonella typhimurium* strains TA98, TA100, TA102, TA1535 and TA1537, with or without metabolic activation. No cytotoxic or genotoxic effects were observed (OECD, 2003; US EPA, 2010; Government of Canada, 2014). BPAOPB (CAS No. 7147-42-4) and PO 16 were also not mutagenic in modified Ames assays (Government of Canada, 2014).

A pigment, possibly PR 38, tested negative in the plate incorporation assay in *S. typhimurium* strains TA 98, TA 100, TA 1535, and TA 1537, and the *E. coli* strain WP2 uvrA, with and without metabolic activation. In the pre-incubation test, the chemical induced gene mutations by frameshift in the genome of the strain *S. typhimurium* TA98 only in the presence of metabolic activation. It was not mutagenic in all other strains tested (REACHh).

PY 12 was considered overall to be negative in a gene mutation mouse lymphoma assay. PY 12 did not induce chromosomal aberration and sister chromatid exchange (SCE) in Chinese hamster ovary (CHO) cells. PO 16 tested negative in a chromosome aberration test in vitro (OECD, 2003; US EPA, 2010; Government of Canada 2014).

In vivo studies

Results from a 4-week in vivo study in rats treated via diet with diarylide azo pigments (PY 13 or PY 17) showed very low levels (only slightly above detection limits) of 3,3'-DCB adducts (potential azo bond cleavage metabolite) for PY 13. No adducts were found in rats treated with PY17. The authors reasoned that the detected 3,3'-DCB adducts were results of contamination and concluded that the chemicals were not genotoxic (Sagelsdorff et al., 1996).

Negative results were reported for the following in vivo studies in the REACH dossiers for various pigments (REACHa–m). It was difficult to identify the particular pigment tested.

In an vivo micronucleus assay using ICR (Institute of Cancer Research) mice were treated with a single dose of 0, 1250, 2500 and 5000 mg/kg bw of a pigment. There were no significant increases in the incidences of micronucleated polychromatic erythrocytes (PCE) in any dose group when compared to the control group. The ratio of PCE to normochromatic erythrocytes was not affected in these studies.

In a study conducted in accordance with OECD TG 486, an inadequately characterised pigment was assessed for its potential to induce DNA repair in the hepatocytes of male Wistar rats treated orally at1000 and 2000 mg/kg bw of the pigment. The

chemical did not induce biologically relevant levels of unscheduled DNA synthesis in the hepatocytes of treated animals when compared to control animals.

Carcinogenicity

There is no evidence of carcinogenic potential for the chemicals in this group.

The chemical PY 12 produced no treatment-related increase in the incidence of neoplasms or non-neoplastic lesions in National Toxicology Program (NTP) carcinogenicity studies in rats and mice. There was also no evidence of carcinogenicity in rats exposed to PY 83 for 104 weeks (see **Repeated dose toxicity** section for details of studies) (US EPA 2010; Government of Canada, 2014).

However, emerging evidence indicates that these chemicals can undergo photodegradation upon the exposure to various sources of light, in particular solar radiation and lasers (Wang et al., 2005; Poon et al., 2008; Government of Canada, 2014; European Commission JRC, 2015). This process has been suggested to result in the chemicals breaking down into carcinogenic aromatic amines as observed in experimental models (Cui et al., 2004; Engel et al., 2009). In particular, following exposure to irradiation with different light sources or laser irradiation), diarylide pigments in tattoos, PY 14, PY 83, PO 13, PO 16 and PO 34, were degraded into amines including the related benzidine congener on which the pigment is based (Hauri, 2011; European Commission JRC, 2015). Furthermore, the chemicals have been shown to undergo thermal cleavage into carcinogenic amines upon exposure to a range of high temperatures (240–300 °C) (Az et al., 1990).

The potential breakdown products 3,3'-DCB and 3,3’-DMOB are reasonably anticipated to be human carcinogens (NICNAS).

Reproductive and Developmental Toxicity

Based on the available data, it can be concluded that the chemicals are not expected to have adverse reproductive or developmental effects.

The reproductive and developmental toxicity of the chemical PY 12 was evaluated in Wistar rats in accordance with the OECD TG 422 standards. In this study, rats were exposed to the chemical daily through oral gavage at doses 0, 50, 200 and 1000 mg/kg bw/day for 4 weeks in males and 6–7 weeks in females. The results showed no significant treatment-related changes in relation to mortality, bodyweight, feed consumption and indices of reproduction and offspring viability. A NOAEL of 1000 mg/kg bw was reported in this study (REACHa).

In a guideline study (OECD TG422) PO 34 was administered Wistar rats, at doses of 0, 100, 300 or 1000 mg/kg bw/day (males for 28 days and females for up to 54 days). No treatment-related effects were observed in parents or offspring. A NOAEL of 1000 mg/kg bw was reported in this study (REACHj).

Risk Characterisation

Critical Health Effects

Overall, the available data indicate that these chemicals have limited bioavailability. Limited uptake of the chemicals in particle form cannot be ruled out. Generally, the systemic acute and long-term toxicity of the chemicals through dermal, inhalation and oral exposure are considered low. However, emerging evidence indicate that these chemicals can undergo photodegradation upon exposure to various sources of light, in particular solar radiation and lasers. The potential breakdown products 3,3'-DCB and 3,3'-DMOB are reasonably anticipated to be human carcinogens (NICNAS).

Public Risk Characterisation

Although use in cosmetic products in Australia is not known, some of the chemicals are reported to be used in cosmetic products overseas. Given their limited bioavailability, these chemicals are not considered to pose an unreasonable risk to public

health for the majority of cosmetic applications.

The chemicals PY 14, PY 83, PO 13, PO 16 and PO 34 have been identified as present in tattoo inks available in Australia. Additional chemicals have been reported in tattoo inks overseas. The intradermal injection of these chemicals as inks in permanent makeup and tattoos is likely to be a potential hazard. The decomposition or breakdown of pigments in tattoo inks following the exposure to a variety of light sources, such as lasers during tattoo removals, natural sunlight, and ultraviolet light results in the pigments breaking down into carcinogenic aromatic amines (see Carcinogenicity section). In addition, tattoo inks are reported to contain pigment particles in the sub-micrometre range which could increase the bioavailability of these chemicals (Danish EPA, 2012; Government of Canada, 2014).

Considering the potential breakdown products, 3,3'-DCB and 3,3'-DMOB, are reasonably anticipated to be human carcinogens, the chemicals may pose an unreasonable risks to consumers if used in tattoo inks and permanent make-up.

Given the potential prolonged exposure to permanent hair dyes, there is also uncertainty with the risk associated with the product. A number of the chemicals are banned for use in hair dyes overseas (see International restrictions section).

A Tier III assessment to further investigate the risk of photodegradation of these dyes should be undertaken.

Occupational Risk Characterisation

During product formulation, dermal, ocular and inhalation exposure of workers to the chemical may occur, particularly where manual or open processes are used. These may include transfer and blending activities, quality control analysis, and cleaning and maintaining equipment. Worker exposure to the chemical at lower concentrations may also occur while using formulated products containing the chemical. The level and route of exposure will vary depending on the method of application and work practices employed.

Whilst the available data indicates that these chemicals have limited bioavailability, limited uptake of the chemicals in particle form cannot be ruled out; accumulation of particles in the lungs has been observed in animal studies. Therefore the chemicals could pose an unreasonable risk to workers unless adequate control measures to minimise inhalation exposure are implemented.

NICNAS Recommendation

Given the limited information on the photodegradation of pigments in tattoo inks and permanent makeup into carcinogenic substances, the chemicals are recommended for Tier III assessment.

Formulators and importers of tattoo inks should consider substituting products which contain the pigments in this group.

All other risks are considered to have been sufficiently assessed at the Tier II level, subject to implementing any risk management recommendations, and provided that all requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Regulatory Control

Public Health

The need for further regulatory control for public health will be determined as part of the Tier III assessment.

Work Health and Safety

The chemicals are not recommended at this stage for classification and labelling aligned with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). This assessment does not consider classification of physical hazards and environmental hazards.

Advice for industry

Control measures

Control measures to minimise the risk from inhalation exposure to the chemicals should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate or minimise risk arising from storing, handling and using a hazardous chemical depend on the physical form and the manner in which the chemical is used. Examples of control measures which may minimise the risk include, but are not limited to:

- using local exhaust ventilation to prevent the chemical from entering the breathing zone of any worker;
- work procedures that minimise splashes and spills;
- regularly cleaning equipment and work areas; and
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemical.

Guidance on managing risks from hazardous chemicals are provided in the *Managing risks of hazardous chemicals in the workplace—Code of practice* available on the Safe Work Australia website.

Personal protective equipment should not solely be relied upon to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk. Guidance in selecting personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

Obligations under workplace health and safety legislation

Information in this report should be taken into account to assist with meeting obligations under workplace health and safety legislation as adopted by the relevant state or territory. This includes, but is not limited to:

- ensuring that hazardous chemicals are correctly classified and labelled;
- ensuring that (material) safety data sheets ((m)SDS) containing accurate information about the hazards (relating to both health hazards and physicochemical (physical) hazards) of the chemical are prepared; and
- managing risks arising from storing, handling and using a hazardous chemical.

Your work health and safety regulator should be contacted for information on the work health and safety laws in your jurisdiction.

Information on how to prepare an (m)SDS and how to label containers of hazardous chemicals are provided in relevant codes of practice such as the *Preparation of safety data sheets for hazardous chemicals—Code of practice* and *Labelling of workplace hazardous chemicals—Code of practice*, respectively. These codes of practice are available from the Safe Work Australia website.

A review of the physical hazards of the chemicals has not been undertaken as part of this assessment.

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Last Update 29 June 2018

Chemical Identities

Chemical Name in the Inventory and Synonyms	**Acetoacetanilide, 2,2'-[(3,3'-dichloro-4,4'-biphenylylene)bis(azo)]bis[2',5'-dimethoxy-** butanamide, 2,2-[(3,3-dichloro[1,1-biphenyl C.I. Pigment Yellow 87 (PY 87) Diarylide Yellow 2,2'-((3,3'-dichloro-1,1'-biphenyl-4,4'-diyl)bis(azo))bis(N-(2,5-

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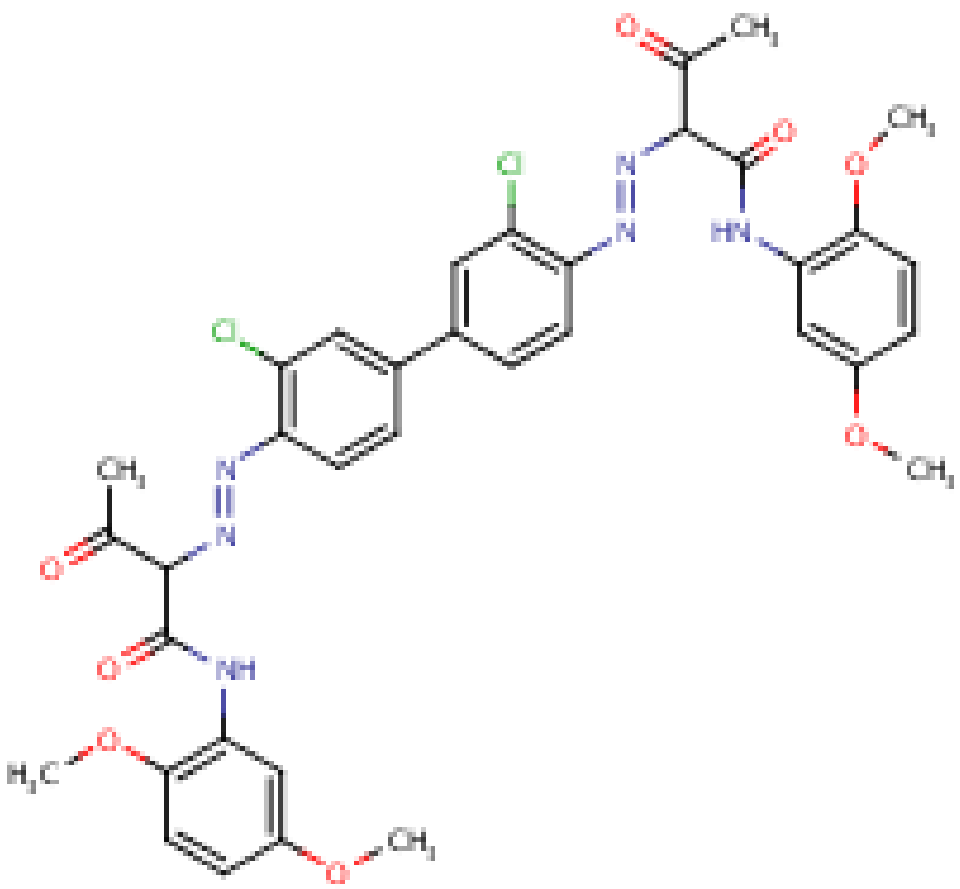
Structural Formula	
Molecular Formula	C36H34Cl2N6O8
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Chemical Name in the Inventory and Synonyms	**3H-Pyrazol-3-one, 4,4'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[2,4-dihydro-5-methyl-2-phenyl-** C.I. Pigment Orange 13 (PO 13) Benzidine Orange Atul Vulcan Fast Pigment Orange G C.I. 21110 Diarylide Orange
CAS Number	3520-72-7
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	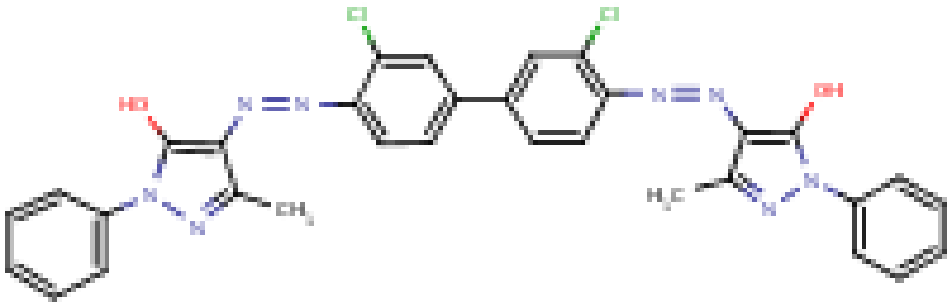
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	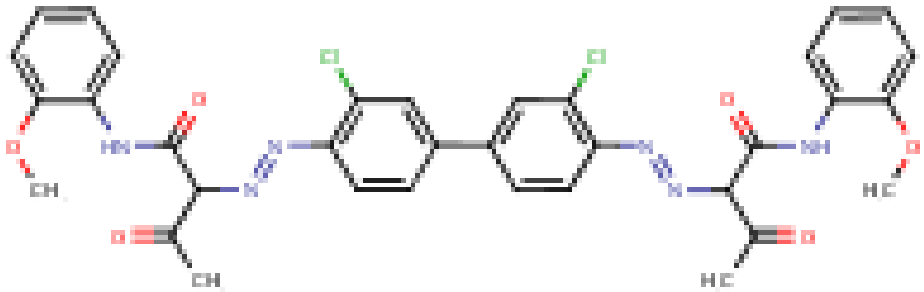
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	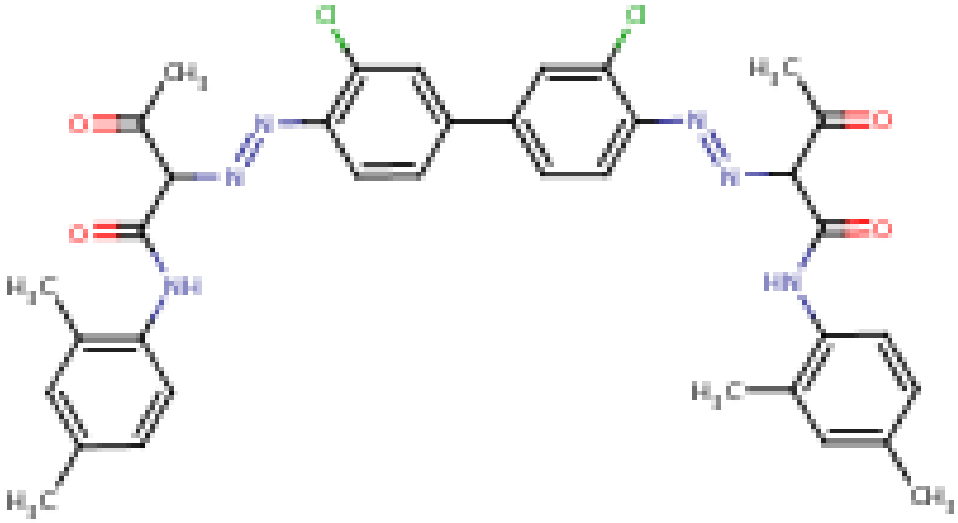
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	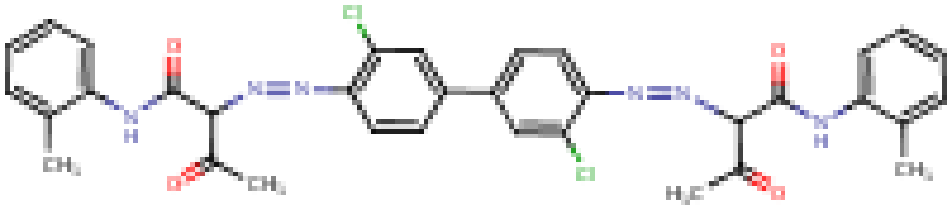
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	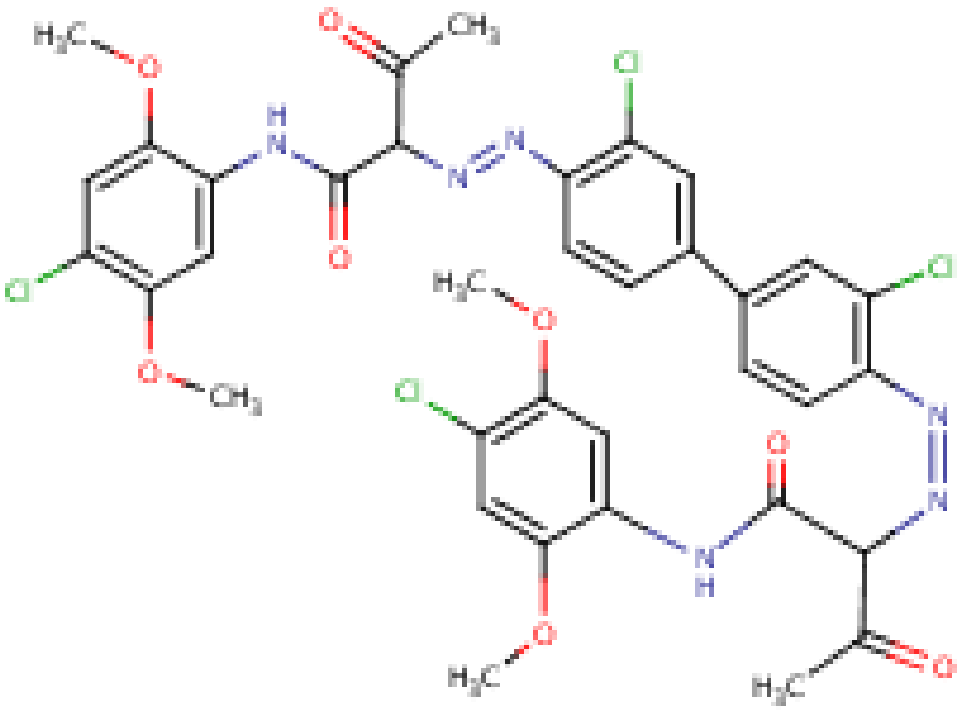
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	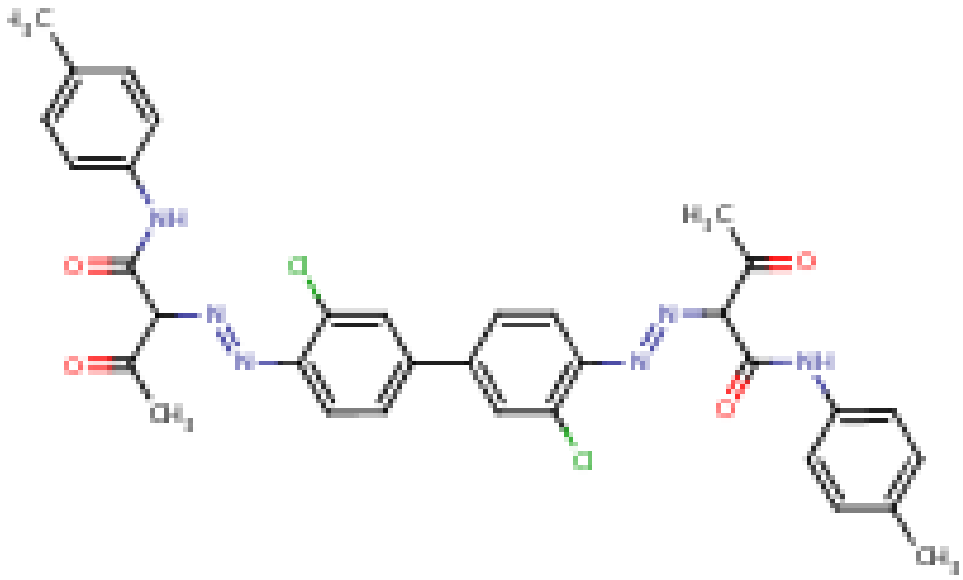
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Chemical Name in the Inventory and Synonyms	**Butanamide, 2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-N-phenyl-** C.I. Pigment Yellow 12 (PY 12) CI 21090 2,2'-((3,3'-dichloro(1,1'-biphenyl)-4,4'-diyl)bis(azo))bis(3-oxo-N-phenylbutanamide) Amazon Yellow X2485 Benzidine Yellow G
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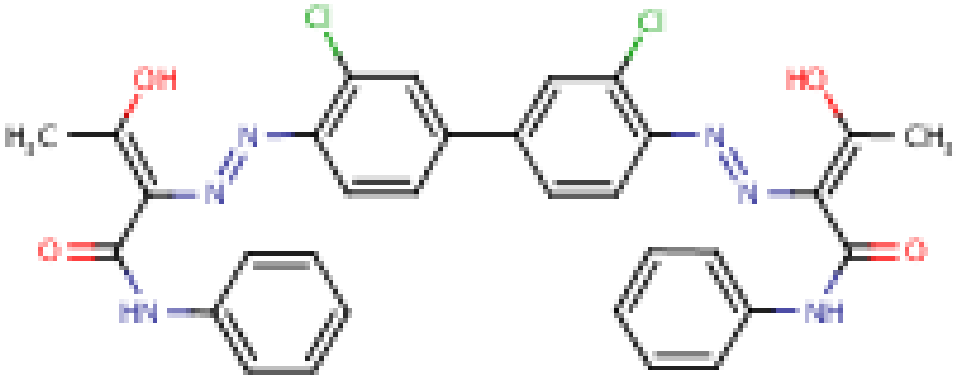

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	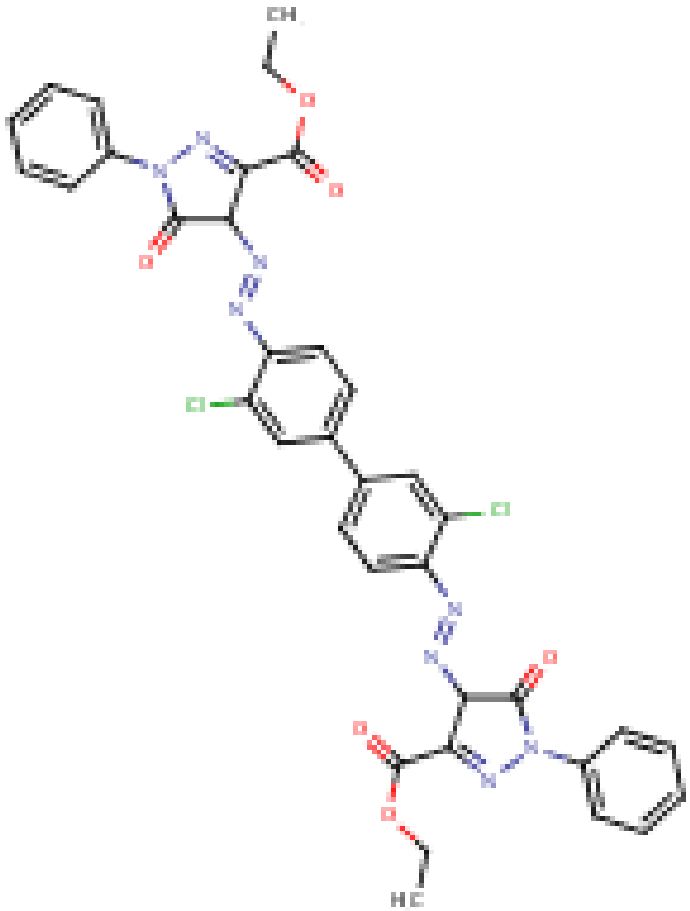
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	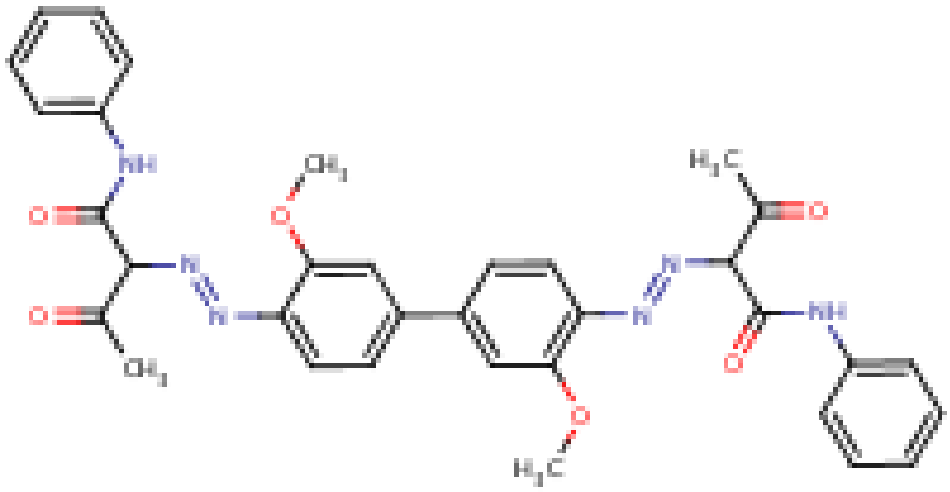
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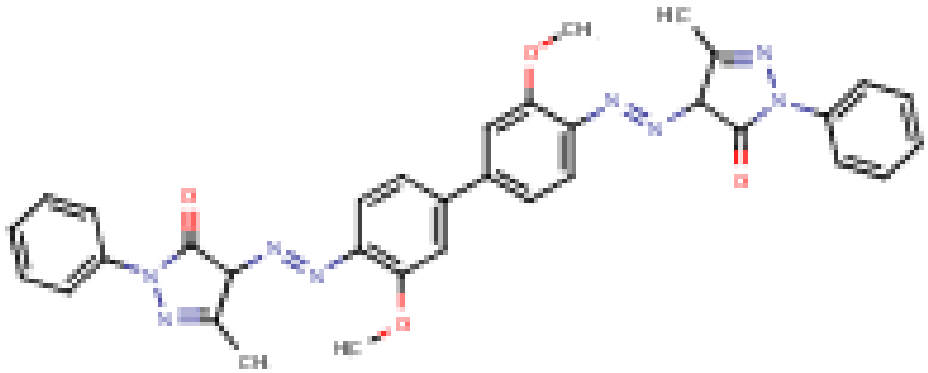
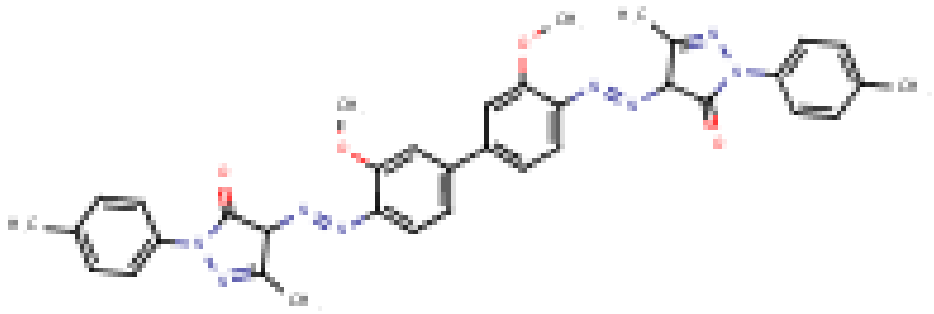
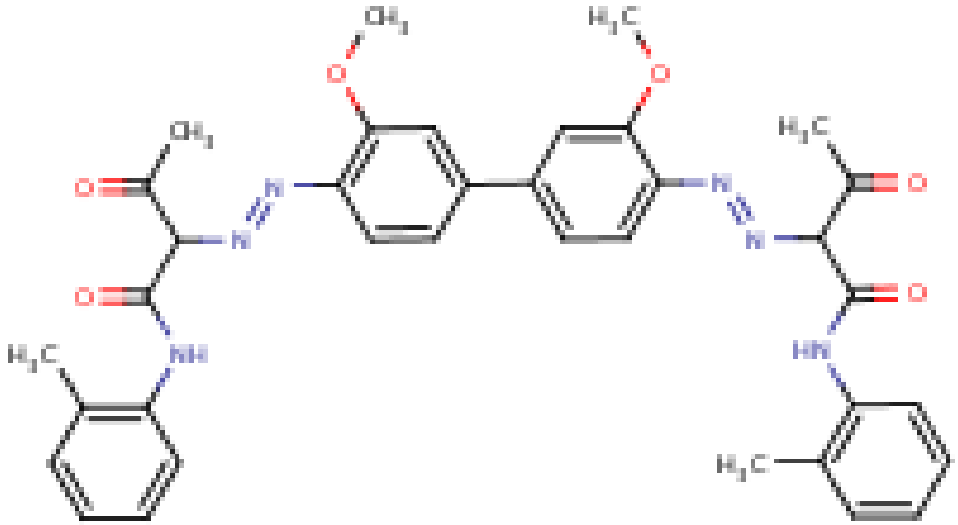
	
Molecular Formula	C34H30N8O4
Molecular Weight	614.66

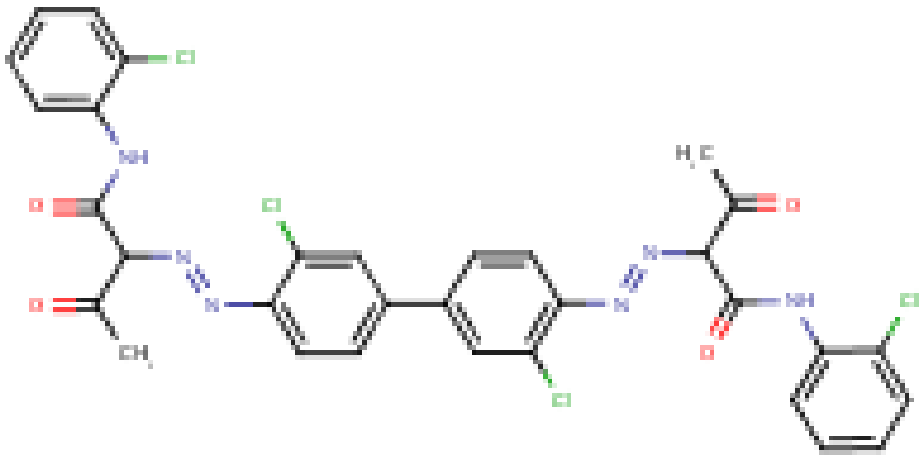
Chemical Name in the Inventory and Synonyms	**3H-Pyrazol-3-one, 4,4'-[(3,3'-dimethoxy[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[2,4-dihydro-5-methyl-2-(4-methylphenyl)-** C.I. Pigment Red 37 (PR 37)
CAS Number	6883-91-6
Structural Formula	

	
Molecular Formula	C36H34N8O4
Molecular Weight	642.72

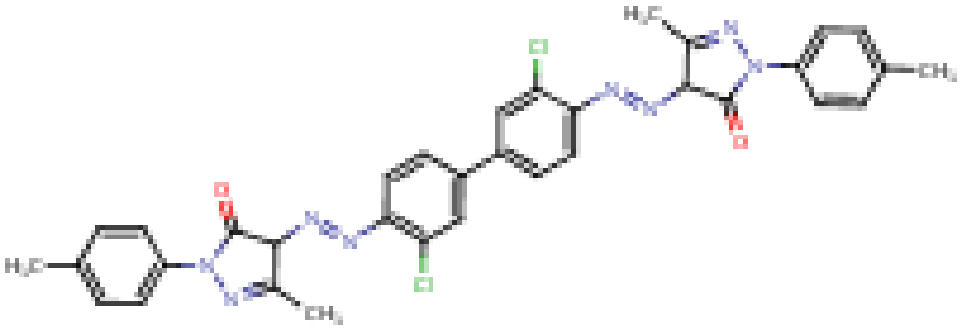
Chemical Name in the Inventory and Synonyms	**Butanamide, 2,2'-[(3,3'-dimethoxy[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2-methylphenyl)-3-oxo-** 2,2'-((3,3'-dimethoxy(1,1'-biphenyl)-4,4'-diyl)bis(azo))bis(N-(2-methylphenyl)-3-oxobutyramide) BPAOPB
CAS Number	7147-42-4
Structural Formula	

	
Molecular Formula	C36H36N6O6
Molecular Weight	648.71

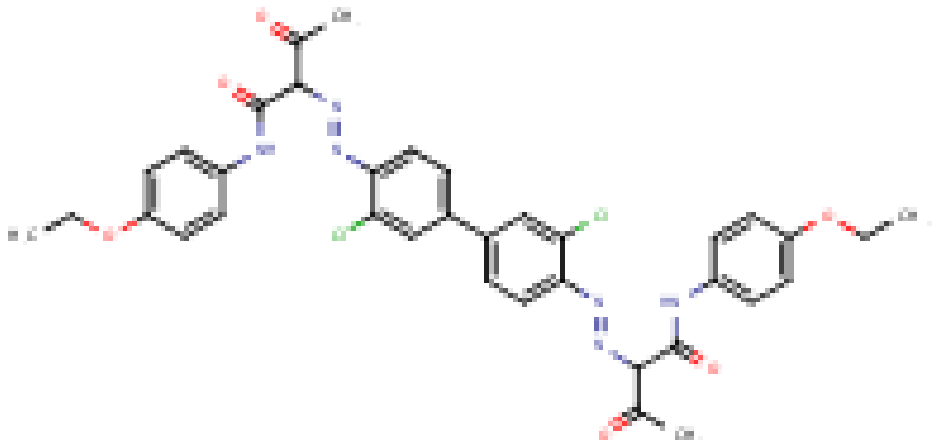
Chemical Name in the Inventory and Synonyms	**Butanamide, 2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2-chlorophenyl)-3-oxo-** C.I. Pigment Yellow 121 (PY 121) C.I. Pigment Yellow 63 2,2'-((3,3'-dichloro(1,1'-biphenyl)-4,4'-diyl)bis(azo))bis(N-(2-chlorophenyl)-3-oxobutyramide) butanamide, 2,2'-((3,3'-dichloro(1,1'-biphenyl)-4,4'-diyl)bis(2,1-diazenediyl))bis(N-(2-chlorophenyl)-3-oxo- butanamide, 2,2'-((3,3'-dichloro(1,1'-biphenyl)-4,4'-diyl)bis(azo))bis(N-(2-chlorophenyl)-3-oxo-
CAS Number	14569-54-1
Structural Formula	

	
Molecular Formula	C32H24Cl4N6O4
Molecular Weight	698.39

Chemical Name in the Inventory and Synonyms	**3H-Pyrazol-3-one, 4,4'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[2,4-dihydro-5-methyl-2-(4-methylphenyl)-** 4,4-[(3,3-dichloro-4,4-biphenylene)bis(azo) Irgalite orange F2G C.I. Pigment Orange 34 (PO 34) Roma Orange B 112700 C.I. 21115
CAS Number	15793-73-4
Structural Formula	

	
Molecular Formula	C34H28Cl2N8O2
Molecular Weight	651.56

Chemical Name in the Inventory and Synonyms	**p-Acetoacetophenetidide, 2,2''-[(3,3'-dichloro-4,4'-biphenylylene)bis(azo)]bis-** C.I. Pigment Yellow 152 (PY 152) 2,2'-((3,3'-dichloro(1,1'-biphenyl)-4,4'-diyl)bis(azo))bis(N-(4-ethoxyphenyl)-3-oxobutyramide) butanamide, 2,2'-((3,3'-dichloro(1,1'-biphenyl)-4,4'-diyl)bis(2,1-diazenediyl))bis(N-(4-ethoxyphenyl)-3-oxo- butanamide, 2,2'-((3,3'-dichloro(1,1'-biphenyl)-4,4'-diyl)bis(azo))bis(N-(4-ethoxyphenyl)-3-oxo-
CAS Number	31775-20-9
Structural Formula	

	
Molecular Formula	C36H34Cl2N6O6
Molecular Weight	717.61

Chemical Name in the Inventory and Synonyms	**Butanamide, 2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-, N,N'-bis(o-anisyl and 2,4-xylyl) derivatives** C.I. Pigment Yellow 127 (PY 127) butanamide, 2,2'-((3,3'-dichloro(1,1'-biphenyl)-4,4'-diyl)bis(azo))bis(3-oxo-, N,N'-bis(o-anisyl and 2,4-xylyl) derivs
CAS Number	68610-86-6
Structural Formula	

	No Structural Diagram Available
Molecular Formula	Unspecified
Molecular Weight	Unspecified

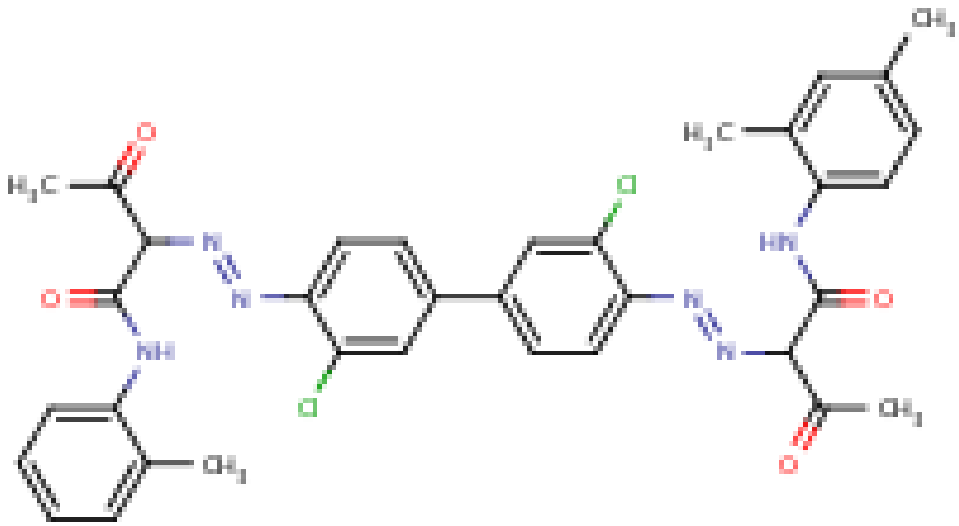
Chemical Name in the Inventory and Synonyms	**Butanamide, 2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-, N,N'-bis(phenyl and p-tolyl) derivatives** C.I. Pigment Yellow 114 (PY 114) butanamide, 2,2'-((3,3'-dichloro(1,1'-biphenyl)-4,4'-diyl)bis(azo))bis(3-oxo-, N,N'-bis(phenyl and p-tolyl) derivs
CAS Number	68610-87-7
Structural Formula	No Structural Diagram Available
Molecular Formula	Unspecified
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	**Butanamide, 2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-, N,N'-bis(phenyl and 2,4-xylyl) derivatives** C.I. Pigment Yellow 188 (PY 188)

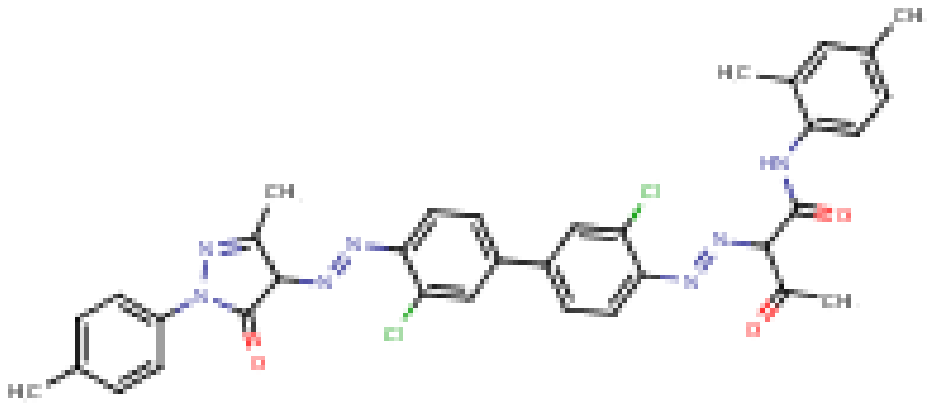
	butanamide, 2,2'-((3,3'-dichloro(1,1'-biphenyl)-4,4'-diyl)bis(2,1-diazenediyl))bis(3-oxo-, N,N'-bis(phenyl and 2,4-xylyl) derivs butanamide, 2,2'-((3,3'-dichloro(1,1'-biphenyl)-4,4'-diyl)bis(azo))bis(3-oxo-, N,N'-bis(phenyl and 2,4-xylyl) derivs
CAS Number	72207-62-6
Structural Formula	**No Structural Diagram Available**
Molecular Formula	Unspecified
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	**Butanamide, 2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-, N,N'-bis(o-anisyl and phenyl) derivatives** butanamide, 2,2'-((3,3'-dichloro(1,1'-biphenyl)-4,4'-diyl)bis(azo))bis(3-oxo-, N,N'-bis(o-anisyl and phenyl) derivs
CAS Number	76822-91-8
Structural Formula	**No Structural Diagram Available**
Molecular Formula	Unspecified

Molecular Weight	Unspecified

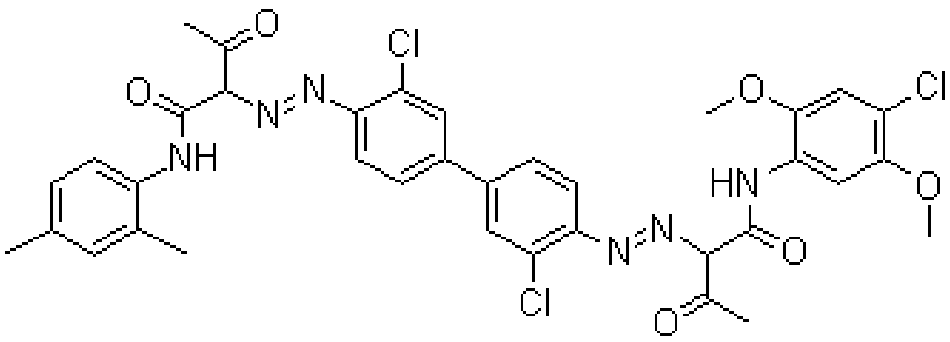
Chemical Name in the Inventory and Synonyms	**Butanamide, 2-[[3,3'-dichloro-4'-[[1-[[(2,4-dimethylphenyl)amino]carbonyl]-2-oxopropyl]azo][1,1'-biphenyl]-4-yl]azo]-N-(2-methylphenyl)-3-oxo-** C.I. Pigment Yellow 174 (PY 174) Irgalite Yellow LBT 2-((3,3'-dichloro-4'-((1-(((2,4-dimethylphenyl)amino)carbonyl)-2-oxopropyl)azo)(1,1'-biphenyl)-4-yl)azo)-3-oxo-N-(o-tolyl)butyramid
CAS Number	78952-72-4
Structural Formula	
Molecular Formula	C35H32Cl2N6O4
Molecular Weight	671.58

Chemical Name in the Inventory and Synonyms	**Butanamide, 2-[[3,3'-dichloro-4'-[[4,5-dihydro-3-methyl-1-(4-methylphenyl)-5-oxo-1H-pyrazol-4-yl]azo][1,1'-biphenyl]-4-yl]azo]-N-(2,4-dimethylphenyl)-3-oxo-** 2-((3,3'-dichloro-4'-((4,5-dihydro-3-methyl-1-(4-methylphenyl)-5-oxo-1H-pyrazol-4-yl)azo)(1,1'-biphenyl)-4-yl)azo)-N-(2,4-dimethylphenyl)-3-oxo- 2-((3,3'-dichloro-4'-((4,5-dihydro-3-methyl-5-oxo-1-(p-tolyl)-1H-pyrazol-4-

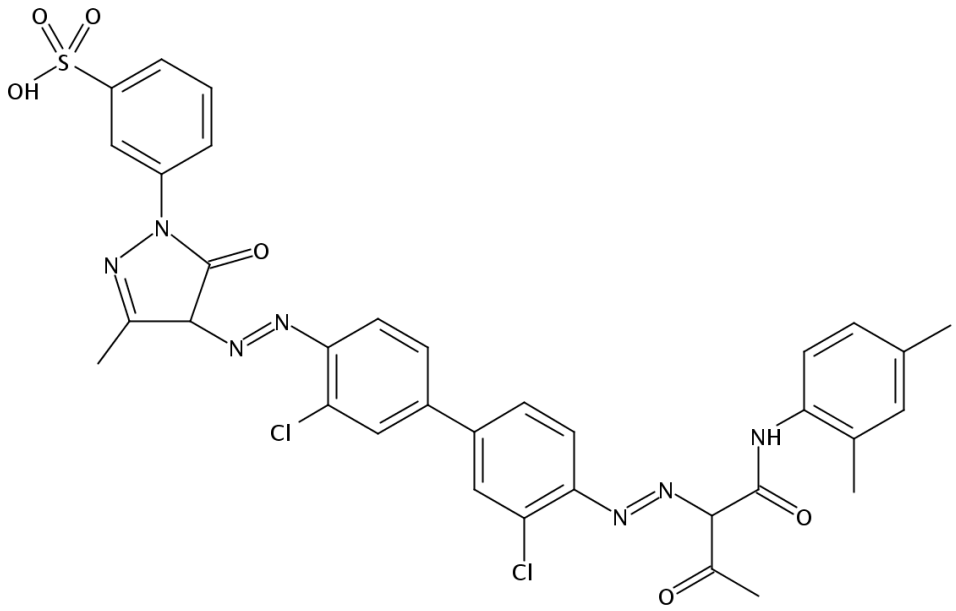
	yl)azo)(1,1'-biphenyl)-4-yl)azo)-N-(2,4-dimethylphenyl)-3-oxobutyramide
CAS Number	79665-33-1
Structural Formula	
Molecular Formula	C35H31Cl2N7O3
Molecular Weight	668.58

Chemical Name in the Inventory and Synonyms	**Butanamide, 2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-, N,N'-bis(p-anisyl and phenyl) derivatives** C.I. Pigment Yellow 126 butanamide, 2,2'-((3,3'-dichloro(1,1'-biphenyl)-4,4'-diyl)bis(azo))bis(3-oxo-, N,N'-bis(p-anisyl and Ph) derivs
CAS Number	90268-23-8
Structural Formula	

	No Structural Diagram Available
Molecular Formula	Unspecified
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	**Butanamide, 2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-, N,N'-bis(4-chloro-2,5-dimethoxyphenyl and 2,4-xylyl) derivatives** C.I. Pigment Yellow 176 (PY 176) Flexoprint Yellow GRX C.I.21103
CAS Number	90268-24-9
Structural Formula	
Molecular Formula	Unspecified
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	**Benzenesulfonic acid, 3-[4-[[3,3'-dichloro-4'-[[1-[[(2,4-dimethylphenyl)amino]carbonyl]-2-oxopropyl]azo][1,1'-biphenyl]-4-yl]azo]-4,5-dihydro-3-methyl-5-oxo-1H-pyrazol-1-yl]-, calcium salt (2:1)** benzenesulfonic acid, 3-[4-[[3,3'-dichloro-4'-[[1-[[(2,4-dimethylphenyl)amino]carbonyl]-2-oxopropyl]azo][1,1'-biphenyl]-4-yl]azo]-4,5-dihydro-3-methyl-5-oxo-1H-pyrazol-1-yl]-, calcium salt (2:1) (9CI)

CAS Number	113010-48-3
Structural Formula	 • 1/2 Ca
Molecular Formula	C34H29Cl2N7O6S.1/2Ca
Molecular Weight	Unspecified

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