



Sulfonated Pigment Yellow 12 and salts: Human health tier II assessment

12 December 2019

- Chemicals in this assessment
- Preface
- Grouping Rationale
- Import, Manufacture and Use
- Restrictions
- Existing Worker Health and Safety Controls
- Health Hazard Information
- Risk Characterisation
- NICNAS Recommendation
- References

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Benzenesulfonic acid, 4,4'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis[azo(2-acetyl-1-oxo-2,1-ethanediyl)imino]]bis-, potassium salt	84100-30-1
Benzenesulfonic acid, 4-[[2-[2-[3,3'-dichloro-4'-[2-[2-oxo-1-[(phenylamino)carbonyl]propyl]diazenyl][1,1'-biphenyl]-4-yl]diazenyl]-1,3-dioxobutyl]amino]-, compd. with 1-octadecanamine (1:1)	258280-75-0
1-Octadecanaminium, N,N-dimethyl-N-octadecyl-, salt with 4-[[2-[3,3'-dichloro-4'-[2-oxo-1-[(phenylamino)carbonyl]propyl]azo][1,1'-biphenyl]-4-yl]azo]-1,3-dioxo-butyl]amino]benzenesulfonic acid (1:1)	87553-57-9
1-Octadecanaminium, N,N,N-trimethyl-, salt with 4-[[2-[3,3'-dichloro-4'-[2-oxo-1-[(phenylamino)carbonyl]propyl]azo][1,1'-biphenyl]-4-yl]azo]-1,3-dioxo-butyl]amino]benzenesulfonic acid (1:1)	87553-58-0
Benzenesulfonic acid, 4-[[2-[3,3'-dichloro-4'-[2-oxo-1-[(phenylamino)carbonyl]propyl]azo][1,1'-biphenyl]-4-yl]azo]-1,3-dioxo-butyl]amino]-	87553-59-1

Chemical Name in the Inventory	CAS Number
Benzenesulfonic acid, 4,4'-[[3,3'-dichloro(1,1'-biphenyl)-4,4'-diyl]bis[azo(2-acetyl-1-oxo-2,1-ethanediyl)imino]]bis-	109663-65-2

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

Chemicals in this group are all sulfonated derivatives of pigment yellow (PY) 12 (CAS No. 6358-85-6). Four of the chemicals – CAS No. 84100-30-1, CAS No. 87553-58-0, CAS No. 87553-57-9 and CAS No. 258280-75-0 are salts. PY12 is a diarylide pigment based on 3,3-dichlorobenzidine (3,3-DCB; CAS No. 91-94-1).

The critical health concern for chemicals in this group is the potential for these chemicals to release 3,3'-DCB, which is reasonably anticipated to be human carcinogen (NICNASa).

These chemicals are expected to have similar physicochemical properties and bioavailability. Therefore, the chemicals are expected to have similar toxicity profiles.

Import, Manufacture and Use

Australian

No specific Australian use, import, or manufacturing information has been identified.

International

Limited data are available. The chemicals are expected to have similar uses.

The chemical, CAS No. 87553-57-9 has the following identified site-limited and commercial or domestic uses (SPIN):

- manufacture of chemicals and chemical products;
- printing and reproduction of recorded media;
- manufacture of fabricated metal products, except machinery and equipment; and
- paints, lacquers and varnishes.

Search of the patent literature online indicates that sulfonation and treatment of pigment yellow 12 with specific quaternary ammonium salts improves the performance of printing inks.

Although PY12 is used in cosmetics and tattoo inks and permanent make-up inks (NICNAS) there is no evidence of these uses for the sulfonated chemicals.

Restrictions

Australian

No known restrictions have been identified.

International

No known restrictions have been identified (Galleria Chemica).

Although azo dyes are restricted by Annex XVII to REACH Regulation for use in textiles and leather articles, azo pigments are not covered by this restriction.

Existing Worker Health and Safety Controls

Hazard Classification

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

Exposure Standards

Australian

No specific exposure standards are available.

International

No specific exposure standards are available.

Health Hazard Information

No specific hazard data are available for the chemicals in this group.

The toxicokinetics of a sulfonated water-soluble (WS) derivative of PY12 was studied in male Fischer 344 rats. Radiolabelled [¹⁴C] sulfonated WS PY12 was administered by gavage at doses of approximately 1 mg/kg bw/day. No radioactivity could be detected in the tissues examined, including blood and liver. A small amount (0.02%) was found in the urine after 1 d and the rest of the dose was excreted in the faeces. Although soluble in distilled water it was not soluble in physiological saline and precipitated in the stomach. This data indicates limited bioavailability for the sulfonated derivatives of PY12 similar to PY12 and other benzidine congener pigments (Decad, 1983; Government of Canada, 2014). The salts are expected to have similar or lower bioavailability than the parent acid.

Therefore, data on PY12 and other benzidine congener pigments are considered relevant for the chemicals in this group.

Data for PY12 and other benzidine congener pigments indicate that these chemicals were of low acute toxicity, slightly irritating to skin and eyes and not skin sensitisers. The chemicals were not considered to be genotoxic or carcinogenic. PY12 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 (NICNAS).

Accumulation of pigment particles in several areas of the lungs was observed in an inhalation study of a benzidine congener pigment. Therefore, it is possible that the chemicals, if present in the sub-micrometer-range size, may be available for systemic exposure in the particle form following inhalation exposure.

The Tier II Human Health assessment reports for the previously assessed 'Selected benzidine-congener-based pigments' which includes PY12, is available at: <https://www.nicnas.gov.au>. This report should be read in conjunction with these Tier II Human Health assessments.

Risk Characterisation

Critical Health Effects

Overall, the available data indicate that these chemicals have limited bioavailability. Generally, the systemic acute and long term toxicity of the chemicals through dermal, inhalation and oral exposure are considered low.

There is emerging evidence indicating that azo pigments can undergo photodegradation upon exposure to various sources of light, in particular solar radiation and lasers (NICNAS). However, use of the chemicals in this group in tattoos and permanent

make-up inks has not been identified.

Public Risk Characterisation

Given their limited bioavailability and the uses identified for the chemicals, these chemicals are not considered to pose an unreasonable risk to public health.

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 maintenance of 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.

Although 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, these chemicals could pose an unreasonable risk to workers unless adequate control measures to minimise inhalation exposure are implemented.

NICNAS Recommendation

Current risk management measures are considered adequate to protect public and workers' health and safety, provided that all requirements are met under workplace health and safety, and poisons legislation as adopted by the relevant state or territory. No further assessment is required.

Regulatory Control

Work Health and Safety

These chemicals are not recommended 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 these 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;
- minimising manual processes and work tasks through automating processes;
- 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 chemical has not been undertaken as part of this assessment.

References

ChemID Plus Advanced. Accessed November 2019 at <https://chem.nlm.nih.gov/chemidplus/>

Decad GM, Snyder CD Fate of water-insoluble and water-soluble dichlorobenzidine-based pigments in Fisher 344 rats. *J Toxicol Environ Health*. 1983 Mar;11(3):455-65.

Galleria Chemica. Accessed November 2019 at <http://jr.chemwatch.net/galleria/>

Globally Harmonised System of Classification and Labelling of Chemicals (GHS) United Nations 2009. Third edition. Accessed November 2019 at http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html

Government of Canada 2014. Screening Assessment Aromatic Azo and Benzidine-based Substance Grouping Certain Diarylide Yellow Pigments. Accessed November 2019 at <https://www.canada.ca/en/environment-climate-change.html>

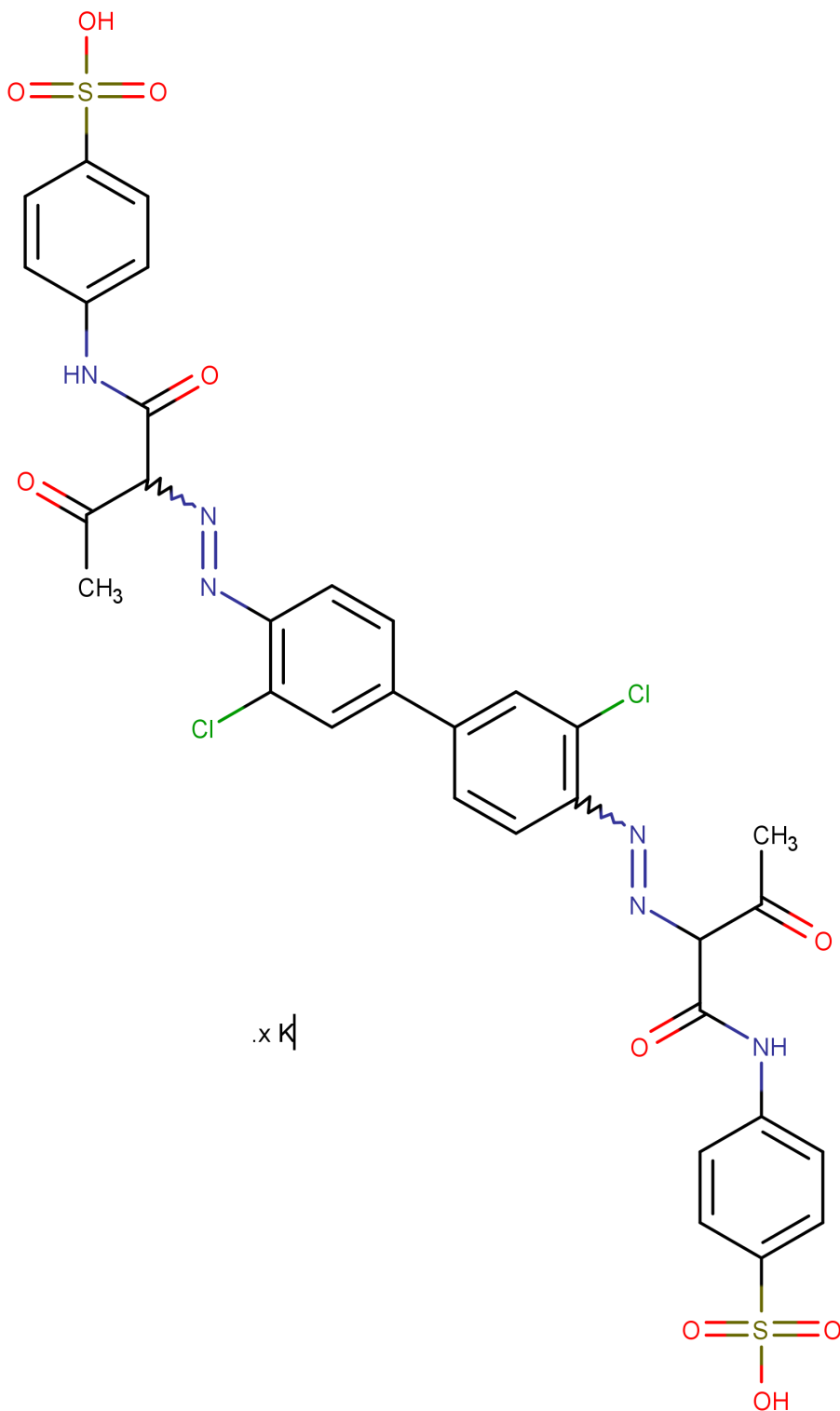
National Industrial Chemical Notification and Assessment Scheme (NICNASb). Tier II Human health assessment for Selected benzidine-congener-based pigments. Australian Government Department of Health. Accessed November 2019 at <http://www.nicnas.gov.au>

National Industrial Chemicals Notification and Assessment Scheme (NICNASa). Human health Tier II assessment for benzidine congeners. Australian Government Department of Health. Accessed November 2019 at <http://www.nicnas.gov.au>

Safe Work Australia. Hazardous Chemical Information System (HCIS). Accessed November 2019 at <http://hcis.safeworkaustralia.gov.au/>

Chemical Identities

Chemical Name in the Inventory and Synonyms	Benzenesulfonic acid, 4,4'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis[azo(2-acetyl-1-oxo-2,1-ethanediyl)imino]]bis-, potassium salt p,p'-((3,3'-dichloro(1,1'-biphenyl)-4,4'-diyl)bis(azo(2-acetyl-1-oxoethylene)imino))bis(benzenesulphonic) acid, potassium salt
CAS Number	84100-30-1
Structural Formula	



Molecular Formula	C32H26Cl2N6O10S2.xK
Molecular Weight	828.7

Chemical Name in the Inventory and Synonyms	Benzenesulfonic acid, 4-[[2-[2-[3,3'-dichloro-4'-[2-[2-oxo-1-[(phenylamino)carbonyl]propyl]diazenyl][1,1'-biphenyl]-4-yl]diazenyl]-1,3-dioxobutyl]amino]-, compd. with 1-octadecanamine (1:1) 210-92-4A
---	---

CAS Number	258280-75-0
Structural Formula	
Molecular Formula	
Molecular Weight	

Chemical Name in the Inventory and Synonyms

1-Octadecanaminium, N,N-dimethyl-N-octadecyl-, salt with 4-[[2-[[[3,3'-dichloro-4'-[[2-oxo-1-[(phenylamino)carbonyl]propyl]azo][1,1'-biphenyl]-4-yl]azo]-1,3-dioxo-butyl]amino]benzenesulfonic acid (1:1)

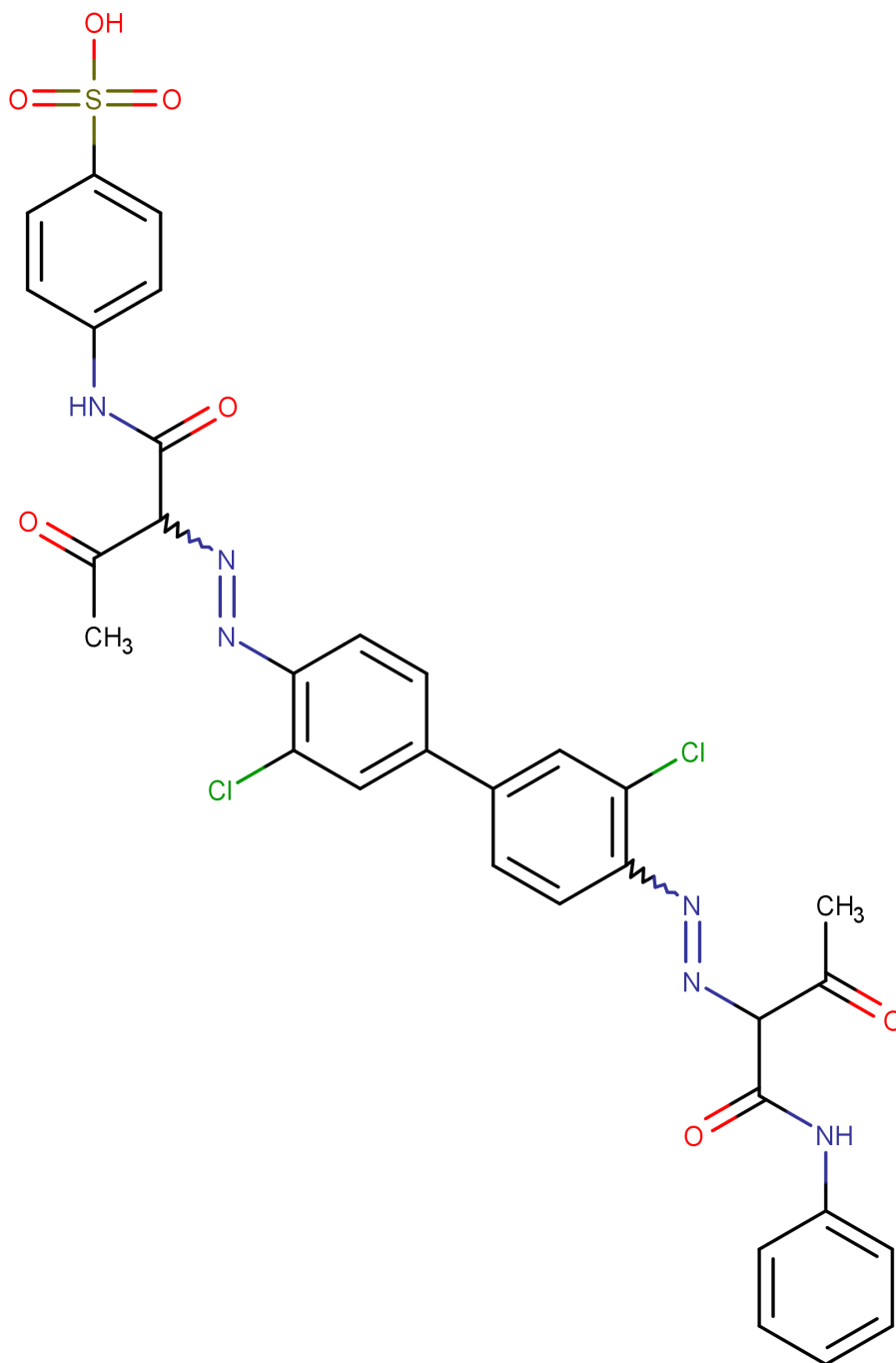
CAS Number	87553-57-9
Structural Formula	<p>The image displays the chemical structure of a complex organic salt. The cation is 1-octadecanaminium, N,N,N-trimethyl-, represented by a nitrogen atom with a positive charge and three methyl groups, and a long 17-carbon alkyl chain. The anion is a biphenyl derivative with two chlorine atoms at the 3 and 3' positions. It features a 4-phenylamino group on one phenyl ring and a 2-oxo-1-[(phenylamino)carbonyl]propyl group on the other phenyl ring, connected by an azo bridge (-N=N-). The structure is color-coded: nitrogen is blue, oxygen is red, sulfur is green, and chlorine is green.</p>
Molecular Formula	C38H80N.C32H25Cl2N6O7S
Molecular Weight	1259.6

Chemical Name in the
Inventory and Synonyms

1-Octadecanaminium, N,N,N-trimethyl-, salt with 4-[[2-[[[3,3'-dichloro-4'-[2-oxo-1-[(phenylamino)carbonyl]propyl]azo][1,1'-biphenyl]-4-]]]]

	yl]azo]-1,3-dioxo-butyl]amino]benzenesulfonic acid (1:1)
CAS Number	87553-58-0
Structural Formula	
Molecular Formula	C32H25Cl2N6O7S.C21H46N
Molecular Weight	

Chemical Name in the Inventory and Synonyms	Benzenesulfonic acid, 4-[[2-[[[3,3'-dichloro-4'-[[2-oxo-1-[(phenylamino)carbonyl]propyl]azo][1,1'-biphenyl]-4-yl]azo]-1,3-dioxo-butyl]amino]-
CAS Number	87553-59-1
Structural Formula	



Molecular Formula	C32H26Cl2N6O7S
Molecular Weight	

Chemical Name in the Inventory and Synonyms	Benzenesulfonic acid, 4,4'-[[3,3'-dichloro(1,1'-biphenyl)-4,4'-diyl]bis[azo(2-acetyl-1-oxo-2,1-ethanediyl)imino]]bis-
CAS Number	109663-65-2

Structural Formula	
Molecular Formula	C ₃₂ H ₂₆ Cl ₂ N ₆ O ₁₀ S ₂
Molecular Weight	

Share this page