



## Azo Dyes that Cleave to Aromatic Amines of Potential Toxicological Concern: Human health tier II assessment

01 July 2016

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### Chemicals in this assessment

| Chemical Name in the Inventory  | CAS Number |
|---|------------|
| <b>Benzenamine, 4-[(4-nitrophenyl)azo]-</b>   | 730-40-5   |
| <b>2-Naphthalenol, 1-[(2,4-dimethylphenyl)azo]-</b>   | 3118-97-6  |
| <b>2-Naphthalenol, 1-(phenylazo)-</b>   | 842-07-9   |
| <b>Benzenesulfonic acid, 4-[[3-[(dimethylphenyl)azo]-2,4-dihydroxyphenyl]azo]-, monosodium salt</b>   | 1320-07-6  |
| <b>2-Naphthalenesulfonic acid, 3-[[4-(acetylamino)phenyl]azo]-4-hydroxy-7-[[[5-hydroxy-6-(phenylazo)-7-sulfo-2-naphthalenyl]amino]carbonyl]amino]-, disodium salt</b> | 3441-14-3  |
| <b>2,7-Naphthalenedisulfonic acid, 4-[(2,4-dimethylphenyl)azo]-3-hydroxy-, disodium salt</b>  | 3761-53-3  |
| <b>1,3-Benzenediamine, 4-methyl-6-(phenylazo)-, monohydrochloride</b>   | 4438-16-8  |
| <b>3H-Pyrazol-3-one, 4-[(2,4-dimethylphenyl)azo]-2,4-dihydro-5-methyl-2-phenyl-</b>   | 6407-78-9  |
| <b>Phenol, 4-[[4-(phenylazo)-1-naphthalenyl]azo]-</b>   | 6253-10-7  |
| <b>Propanenitrile, 3-[ethyl[3-methyl-4-[2-(6-nitro-2-benzothiazolyl)diazanyl]phenyl]amino]-</b>   | 16586-42-8 |
| <b>Phenol, 4-[[2-methoxy-4-[(4-nitrophenyl)azo]phenyl]azo]-</b>   | 19800-42-1 |
| <b>Resorcinol, bis(xylylazo)-</b>   | 28514-75-2 |
| <b>Benzamide, N-[5-[bis[2-(acetyloxy)ethyl]amino]-2-[(4-nitrophenyl)azo]phenyl]-</b>  | 29765-00-2 |
| <b>3-Pyridinecarbonitrile, 6-amino-4-methyl-5-[(4-nitrophenyl)azo]-2-[[3-(2-phenoxyethoxy)propyl]amino]-</b>  | 85409-74-1 |

### 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](http://www.nicnas.gov.au)

#### Disclaimer

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#### ACRONYMS & ABBREVIATIONS

## Grouping Rationale

All the chemicals in this group are azo compounds that share a similar molecular structure (R—N=N—R). The chemicals in this group could contain one or more azo linkages, in which the attached functional groups differ for each chemical.

The significance of azo-reduction in the mutagenicity and carcinogenicity of azo dyes is well established. The chemicals in this group have the potential to undergo reductive cleavage to form one or more of the following aromatic amines, which have been identified as having potential carcinogenic and/or genotoxic concerns based on a recent study by Bruschiweiler et al. (2014):

- benzenamine (CAS No. 62-53-3);
- benzenamine, 2,4-dimethyl- (CAS No. 95-68-1);
- benzenamine, 4-nitro- (CAS No. 100-01-6);
- phenol, 4-amino- (CAS No. 123-30-8); and
- 2-benzothiazolamine, 6-nitro- (CAS No. 6285-57-0; not on AICS).

The critical concern for these chemicals relates to potential carcinogenicity. Due to the range of functional groups present in the chemicals being assessed, they are not considered to be toxicologically similar for local toxicity effects, including sensitisation, and there is a lack of data to assess these effects. However, these local effects are not a high priority for assessment compared with the concerns about carcinogenicity, which, if validated, would be expected to determine appropriate risk management measures.

## Import, Manufacture and Use

### Australian

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

### International

The following international uses have been identified through: Galleria Chemica; the Substances and Preparations in the Nordic countries (SPIN) database; the European Commission Cosmetic Ingredients and Substances (CosIng) database; the United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary; the US Environmental Protection Agency's Aggregated Computer Toxicology Resource (ACToR); and the Canadian assessments of aromatic azo and benzidine based dyes (Government of Canada, 2013a; Government of Canada, 2013b; Government of Canada, 2014).

Some of the chemicals are listed in the US Personal Care Product Council INCI dictionary with the following identified functions:

- as colourant (CAS Nos. 1320-07-6, 3118-97-6, 3761-53-3, and 6407-78-9); and
- as hair colourant (CAS Nos. 730-40-5, 1320-07-6, 3441-14-3, and 4438-16-8).

All of the chemicals in this group have reported commercial use as synthetic dyes in textiles, although the introduction of these dyes for domestic dyeing use cannot be excluded.

Resorcinol, bis(xyllylazo)- also has reported non-industrial use as a pesticide (US EPA, 2011).

The majority of the chemicals in this group have been pre-registered, but have not undergone the full registration process, specified under the European Union (EU) Registration, Evaluation and Authorisation of Chemicals (REACH) legislation (European Chemicals Agency).

## Restrictions

### Australian

No known restrictions have been identified.

### International

The chemicals identified by the CAS Nos. 730-40-5, 842-07-9, 1320-07-6, 3118-97-6, 3441-14-3, and 4438-16-8 are listed on one or more of the following lists (Galleria Chemica):

- Association of South East Asian Nations (ASEAN) Cosmetic Directive Annex II Part 1: List of substances which must not form part of the composition of cosmetic products;
- EU Cosmetics Regulation 1223/2009 Annex II—List of substances prohibited in cosmetic products;
- New Zealand Cosmetic Products Group Standard—Schedule 4: Components cosmetic products must not contain; and
- Health Canada List of prohibited and restricted cosmetic ingredients (The Cosmetic Ingredient 'Hotlist').

## Existing Worker Health and Safety Controls

### Hazard Classification

The chemical 2-naphthalenol, 1-(phenylazo)- (CAS No. 842-07-9) is classified as hazardous, with the following risk phrases for human health in the Hazardous Substances Information System (HSIS) (Safe Work Australia):

- Xi; R43 (sensitisation);
- R68 Mut. Cat 3 (mutagenicity); and
- R40 Carc. Cat 3 (carcinogenicity).

All the other chemicals are not listed on HSIS (Safe Work Australia).

### Exposure Standards

#### Australian

No specific exposure standards are available for the chemicals.

#### International

No specific exposure standards are available for the chemicals.

## Health Hazard Information

Based on a review of publicly available hazard information in accordance with the IMAP Framework (NICNAS, 2013), limited toxicological data were identified for the majority of the chemicals in this group.

The toxicokinetics of this group is expected to be influenced by varying molecular weight and polarity (Bafana et al., 2011; Government of Canada, 2014). The chemicals in this group belong to one of the following types of dyes: disperse, direct, reactive, solvent, basic and acidic dyes. Whilst the reported levels of solubility and bioavailability of the dye molecules appear to vary, available data on similar chemicals and empirical data suggest a potential for azo reduction to bioavailable amines (SCCNFP, 2002; SCCP, 2005; SCCS, 2011; Government of Canada, 2011; Government of Canada, 2013a; Government of Canada, 2013b; Government of Canada, 2014).

Azo bond reduction and cleavage occurs by an enzyme-mediated metabolism in the liver, skin and intestines. In the liver, metabolism is facilitated by cytosolic and microsomal enzymes (Platzek et al., 1999), including NADH cytochrome P450 reductase, NAD(P)H quinone oxidoreductase, and cytochrome P450s (OEHHA, 2012). Bacterial strains in human faeces have been shown to cleave azo dyes, suggesting an important role of intestinal microflora in azo reduction (Platzek et al., 1999).

Although azo reduction occurs favourably in anaerobic conditions, several *in vitro* and *in vivo* studies indicated that this process could also occur aerobically when azo dyes are applied to the skin (SCCP, 2005). *In vitro*, the skin microflora of mice, guinea pigs and humans caused reductive cleavage of the azo dyes, followed by percutaneous absorption of the resulting amines (SCCNFP, 2002). In addition, non-biological processes, such as thermal and photochemical degradation, have also been reported to break azo linkages (Engel et al., 2009).

The critical concern for this group of chemicals relates to potential carcinogenic effects following exposure. Sudan I (CAS No. 842-07-9) and Sudan II (CAS No. 3118-97-6) are considered to have genotoxic and carcinogenic potential (Government of Canada, 2013a). Ponceau MX (CAS No. 3761-53-3) and Sudan I (CAS No. 842-07-9) have been evaluated by the International Agency for Research on Cancer (IARC) and classified the chemicals as Group 2B (possibly carcinogenic to humans) and 3 (not classifiable as to its carcinogenicity to humans), respectively (IARC, 1975).

The chemicals in this group have the potential to undergo reductive cleavage of the azo linkage that would likely result in the formation of potential carcinogenic and/or genotoxic aromatic amines (see **Grouping Rationale**). The carcinogenicity and/or genotoxicity of three of these amines have been assessed by NICNAS for the following chemicals:

- benzenamine, 2,4-dimethyl- (CAS No. 95-68-1) (NICNASb);
- benzenamine (CAS No. 62-53-3) (NICNASa); and
- phenol, 4-amino- (CAS No. 123-30-8) (NICNASc).

These aromatic amine cleavage products are expected to have greater absorption than the dye from which they are derived (Platzek et al., 1999).

## Risk Characterisation

### Critical Health Effects

The critical health effects for risk characterisation of these chemicals are genotoxicity and carcinogenicity following breakdown of these chemicals to genotoxic and/or carcinogenic aromatic amines.

### Public Risk Characterisation

*Cosmetic and domestic*

The chemicals identified by the CAS Nos. 730-40-5, 1320-07-6, 3118-97-6, 3441-14-3, 3761-53-3, 4438-16-8, and 6407-78-9 have been identified as having potential cosmetic use. Several of the chemicals are banned or restricted internationally, particularly for use in cosmetics (see **Restrictions: International**). The Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) (2002) concluded that 'azo dyes which may release one or more carcinogenic aromatic amines, poses a risk to the health of the consumer'.

All of the chemicals have potential use as synthetic dyes. Based on the available data, widespread domestic use is not expected; however, the introduction of these dyes for home use cannot be excluded. The margins between the upper-bounding estimates of exposure of the chemicals identified by the CAS Nos. 842-07-9 and 6407-78-9 from their use in consumer products and their critical health effect levels were estimated by the Government of Canada (2013a). Whilst quantitative risk calculations for these chemicals were considered adequate, in the absence of Australian specific use data, it is not possible to extrapolate this finding for Australia.

Overall, there is sufficient uncertainty regarding the safety of these chemicals in cosmetic and domestic products and therefore, a Tier III assessment is required (see **NICNAS Recommendation**).

#### **Dyed textiles and leather**

The public could also be exposed to potential carcinogenic aromatic amines as impurities, or through the release of these aromatic amines derived from the chemicals in this group through:

- prolonged exposure to articles of clothing and leathers containing the dyes; and
- young children exposed by sucking the materials containing the dye.

The Australian Competition and Consumer Commission (ACCC) has published guidance on the safe concentrations of particular chemicals in consumer goods (ACCC, 2014b). The guidance prescribes concentrations of chemicals in clothing, textiles and leather articles in direct and prolonged contact with the human skin or oral cavity, below which a safety concern does not exist. It also includes a list of hazardous aromatic amines classified as carcinogens in the EU and identified in the REACH list of 22 aromatic amines in Annex XVII Appendix 8 (European Commission, 2006).

In considering the NICNAS recommendation for previously assessed azo dyes, the ACCC conducted a market survey to determine if any dyes of concern had been used in manufacturing consumer goods supplied in Australia. The ACCC has negotiated several recalls of products based on the results of the surveys (ACCC, 2014a). The ACCC is considering mechanisms to restrict the supply of textiles and leather articles that could come into direct and prolonged contact with the human skin that might plausibly result in human exposure to certain aromatic amines at unacceptable levels. Although the ACCC is only considering restriction mechanisms for azo dyes that cleave to the 22 carcinogenic aromatic amines (European Commission, 2006), the options identified may also be relevant for the chemicals in this group.

Further assessment at Tier III is required to determine whether there are similar concerns to those associated with the 22 carcinogenic aromatic amines (see **NICNAS Recommendation**).

### **Occupational Risk Characterisation**

During product formulation, oral, 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.

Overall, there is sufficient uncertainty regarding the hazards of these chemicals in the workplace, and therefore, a Tier III assessment is required (see **NICNAS Recommendation**) to determine the appropriate occupational controls.

### **NICNAS Recommendation**

The chemicals in this group and their potentially genotoxic and/or carcinogenic amine cleavage products are recommended for Tier III assessment to determine whether:

- risk management controls for domestic and cosmetic use are required;
- similar concerns to those associated with the 22 amines subject to restrictions in textiles in Europe exist; and
- there are additional azo dye chemicals in the Australian Inventory of Chemical Substances (AICS) which may break down to aromatic amines identified as potentially carcinogenic and/or genotoxic by Bruschiweiler et al. (2014) that may require further assessment.

### **Regulatory Control**

### **References**

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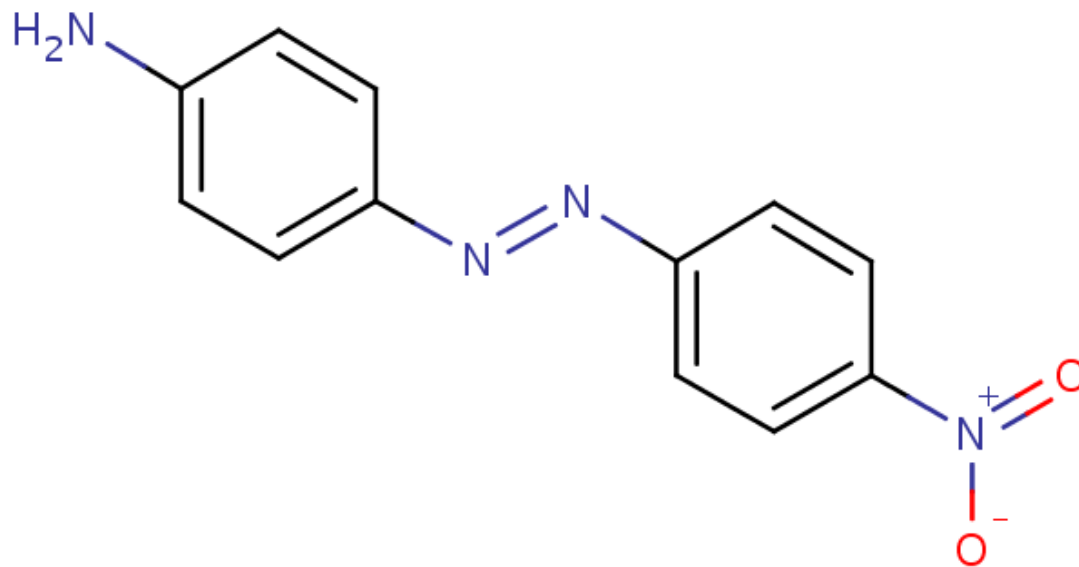
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Last Update 01 July 2016

## Chemical Identities

|   |  |
|---|--|
| Chemical Name in the Inventory and Synonyms | <b>Benzenamine, 4-[(4-nitrophenyl)azo]-</b><br>C.I. 11005<br>Solvent Orange 9<br>Disperse Orange 3 |
| CAS Number                                  | 730-40-5   |
| Structural Formula                          |  |



Molecular Formula

C<sub>12</sub>H<sub>10</sub>N<sub>4</sub>O<sub>2</sub>

Molecular Weight

242.23

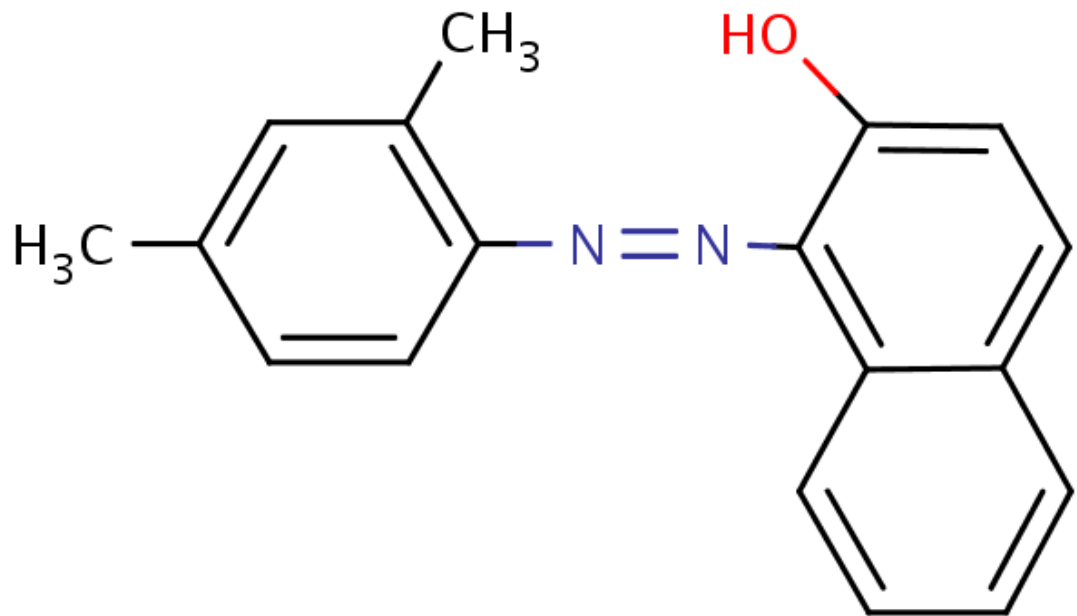
Chemical Name in the  
Inventory and Synonyms

**2-Naphthalenol, 1-[(2,4-dimethylphenyl)azo]-**  
C.I. Solvent Orange 7  
Sudan II  
C.I. 12140

CAS Number

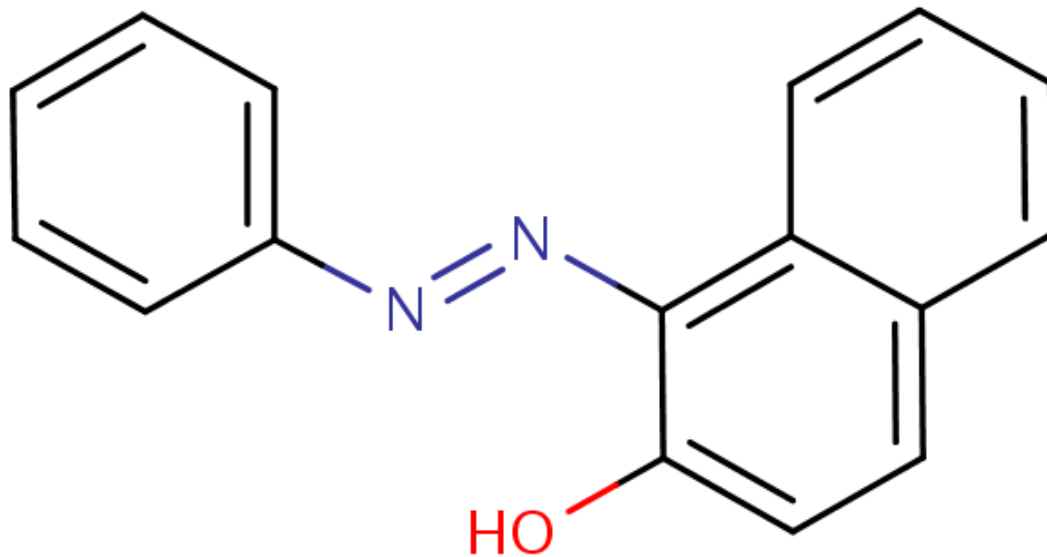
3118-97-6

Structural Formula



|                   |  |
|-------------------|--|
| Molecular Formula | C <sub>18</sub> H <sub>16</sub> N <sub>2</sub> O |
| Molecular Weight  | 276.33   |

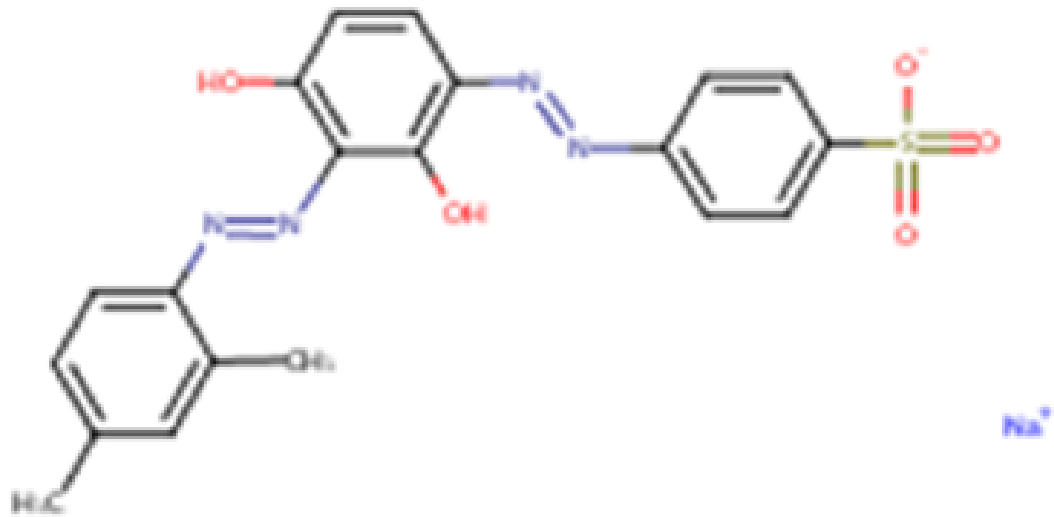
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| Chemical Name in the Inventory and Synonyms | <b>2-Naphthalenol, 1-(phenylazo)-</b><br>C.I. Solvent Yellow 14<br>C.I. 12055<br>Disperse yellow 97<br>Sudan I |
| CAS Number                                  | 842-07-9   |
| Structural Formula                          |  |



|                   |  |
|-------------------|--|
| Molecular Formula | C <sub>16</sub> H <sub>12</sub> N <sub>2</sub> O |
| Molecular Weight  | 248.28   |

|   |  |
|---|--|
| Chemical Name in the Inventory and Synonyms | <b>Benzenesulfonic acid, 4-[[3-[(dimethylphenyl)azo]-2,4-dihydroxyphenyl]azo]-, monosodium salt</b><br>D and C Brown No. 1<br>CI Acid Orange 24<br>CI 20170<br>4-[[3-[(2,4-dimethylphenyl)azo]-2,4-dihydroxyphenyl]azo]benzenesulfonic acid, 4-[[3-[(2,4-dimethylphenyl)azo]-2,4-dihydroxyphenyl]azo]benzenesulfonic acid, Monosodium Salt |
| CAS Number                                  | 1320-07-6  |
| Structural Formula                          |  |





Molecular Formula

C<sub>20</sub>H<sub>18</sub>N<sub>4</sub>O<sub>5</sub>.Na

Molecular Weight

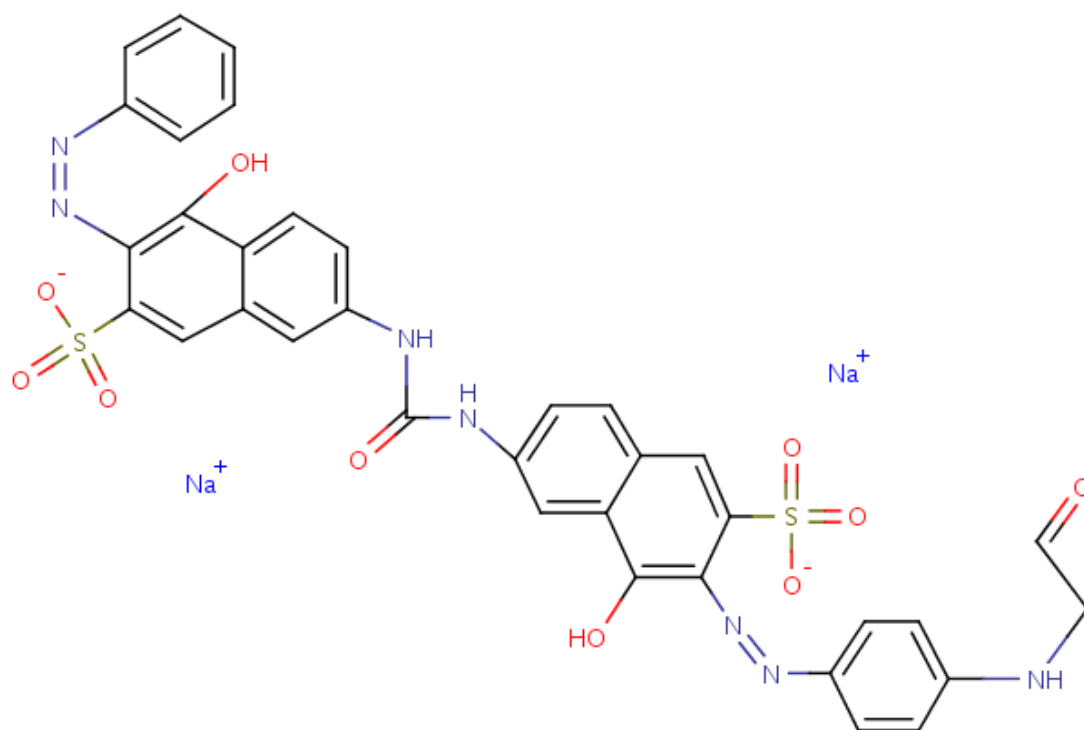
Chemical Name in the Inventory and Synonyms

**2-Naphthalenesulfonic acid, 3-[[4-(acetylamino)phenyl]azo]-4-hydroxy-7-[[[5-hydroxy-6-(phenylazo)-7-sulfo-2-naphthalenyl]amino]carbonyl]amino]-, disodium salt**  
 C.I. Direct Red 23  
 C.I. 29160

CAS Number

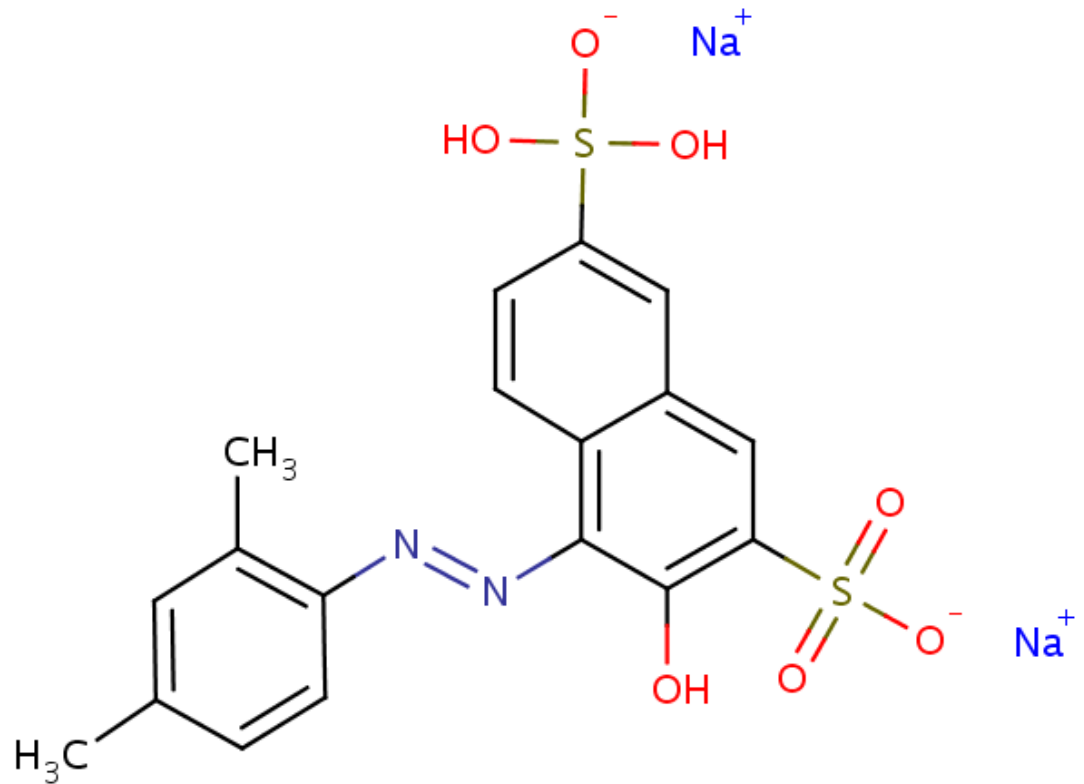
3441-14-3

Structural Formula



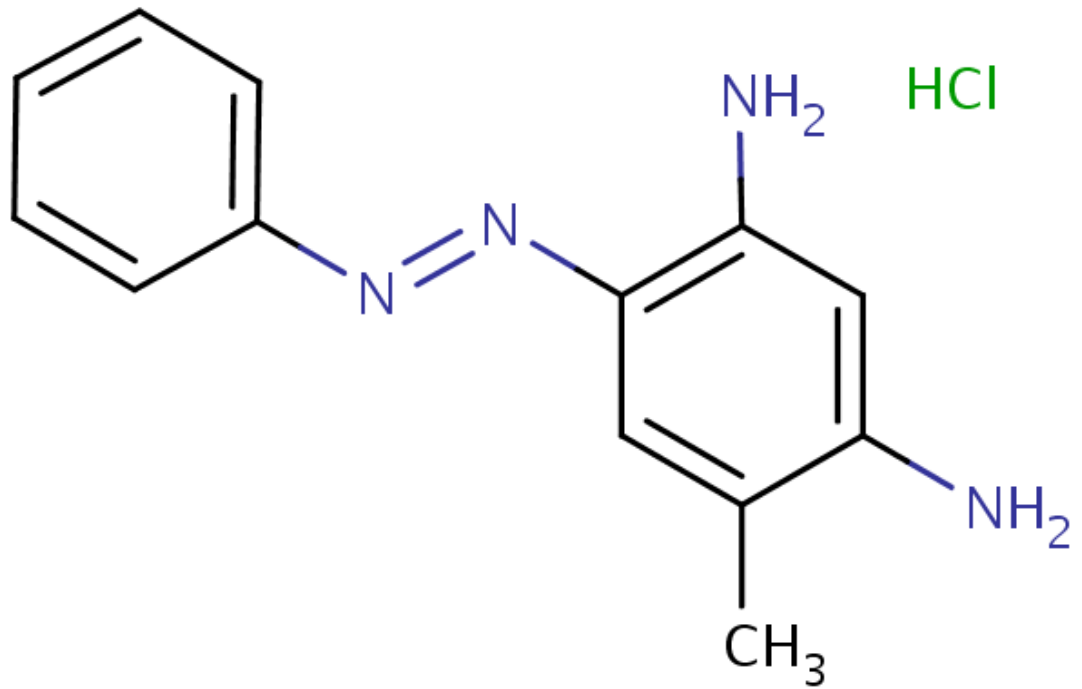
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| Molecular Formula | C35H27N7O10S2.2Na |
| Molecular Weight  |                   |

|   |   |
|---|---|
| Chemical Name in the Inventory and Synonyms | <b>2,7-Naphthalenedisulfonic acid, 4-[(2,4-dimethylphenyl)azo]-3-hydroxy-, disodium salt</b><br>C.I. Acid Red 26<br>Ponceau MX<br>C.I. Food Red 5 |
| CAS Number                                  | 3761-53-3   |
| Structural Formula                          |   |



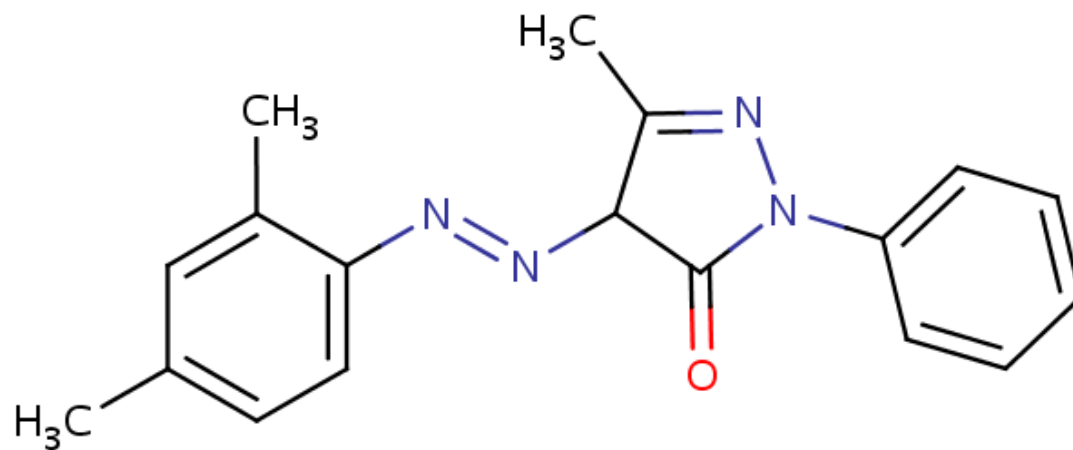
|                   |   |
|-------------------|---|
| Molecular Formula | C <sub>18</sub> H <sub>16</sub> N <sub>2</sub> O <sub>7</sub> S <sub>2</sub> .2Na |
| Molecular Weight  | 480.42  |

|   |   |
|---|---|
| Chemical Name in the Inventory and Synonyms | <b>1,3-Benzenediamine, 4-methyl-6-(phenylazo)-, monohydrochloride</b><br>C.I. Basic Orange 1<br>C.I. 11320<br>Chrysoidine R |
| CAS Number                                  | 4438-16-8   |
| Structural Formula                          |   |



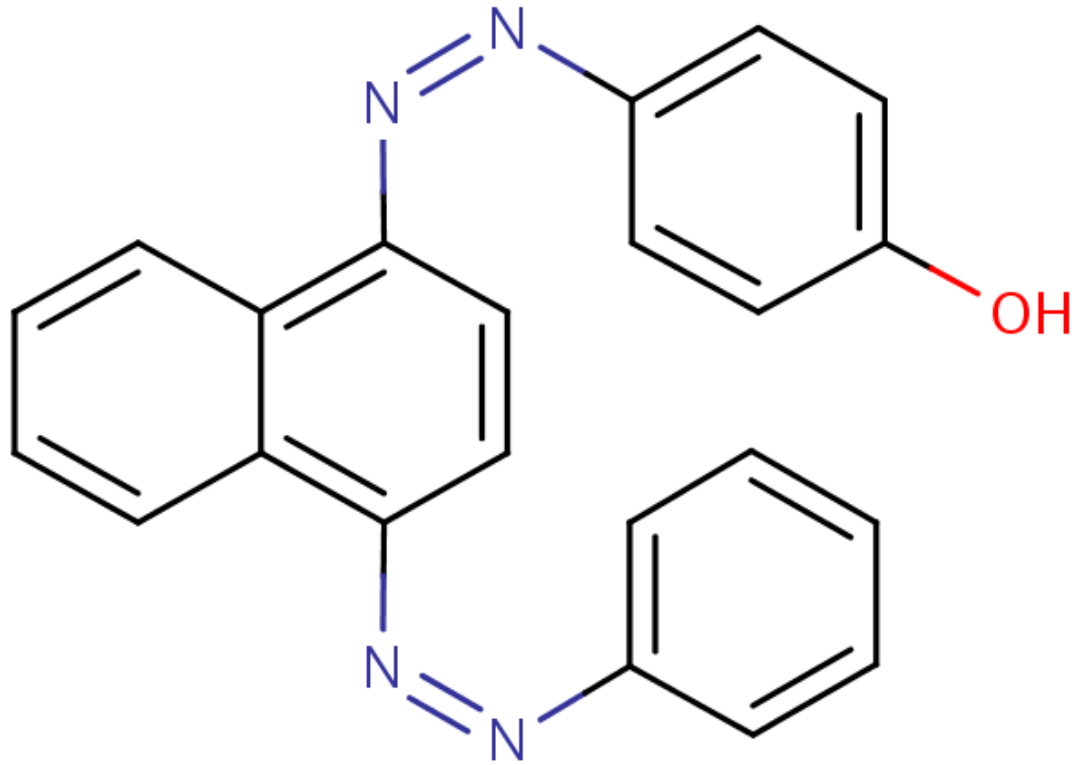
|                   |   |
|-------------------|---|
| Molecular Formula | C <sub>13</sub> H <sub>14</sub> N <sub>4</sub> .ClH |
| Molecular Weight  | 262.74  |

|   |   |
|---|---|
| Chemical Name in the Inventory and Synonyms | <b>3H-Pyrazol-3-one, 4-[(2,4-dimethylphenyl)azo]-2,4-dihydro-5-methyl-2-phenyl-</b><br>C.I. Solvent Yellow 18<br>C.I. 12740 |
| CAS Number                                  | 6407-78-9   |
| Structural Formula                          |   |



|                   |  |
|-------------------|--|
| Molecular Formula | C <sub>18</sub> H <sub>18</sub> N <sub>4</sub> O |
| Molecular Weight  |  |

|   |  |
|---|--|
| Chemical Name in the Inventory and Synonyms | <b>Phenol, 4-[[4-(phenylazo)-1-naphthalenyl]azo]-</b><br>C.I. Disperse Orange 13<br>C.I. 26080 |
| CAS Number                                  | 6253-10-7  |
| Structural Formula                          |  |



Molecular Formula

C<sub>22</sub>H<sub>16</sub>N<sub>4</sub>O

Molecular Weight

352.39

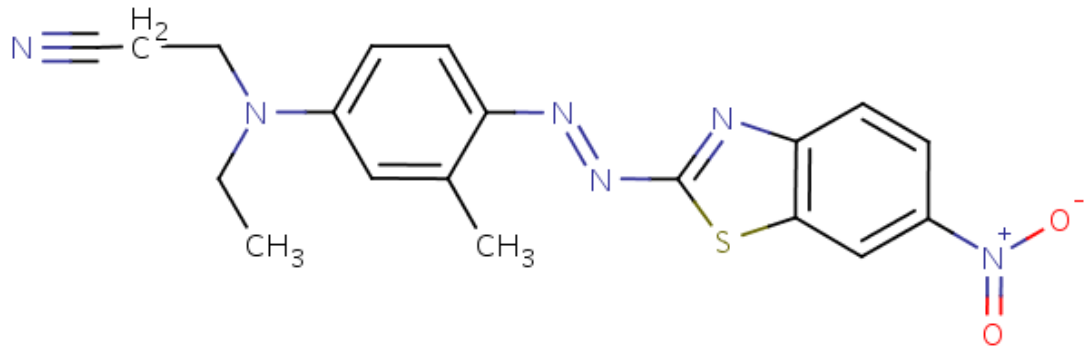
Chemical Name in the Inventory and Synonyms

**Propanenitrile, 3-[ethyl[3-methyl-4-[2-(6-nitro-2-benzothiazolyl)diazenyl]phenyl]amino]-**  
 3-[N-ethyl-4-[(6-nitro-2-benzothiazolyl)azo  
 C.I. Disperse Red 179  
 C.I. 112290

CAS Number

16586-42-8

Structural Formula



Molecular Formula

C<sub>19</sub>H<sub>18</sub>N<sub>6</sub>O<sub>2</sub>S

Molecular Weight

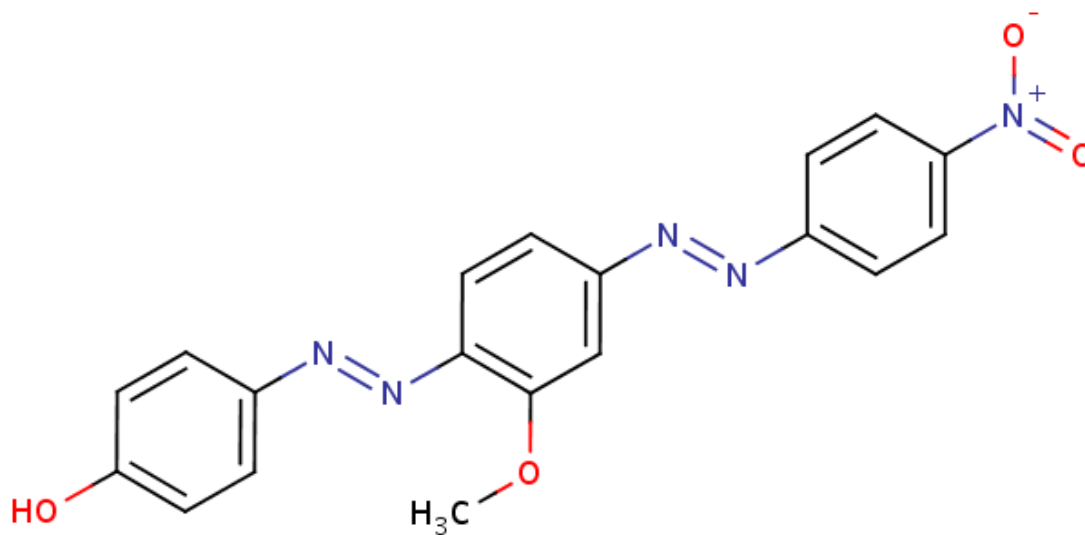
Chemical Name in the Inventory and Synonyms

**Phenol, 4-[[2-methoxy-4-[(4-nitrophenyl)azo]phenyl]azo]-4-[[2-methoxy-4-[(4-nitrophenyl)azo]phenyl]azo]-**

CAS Number

19800-42-1

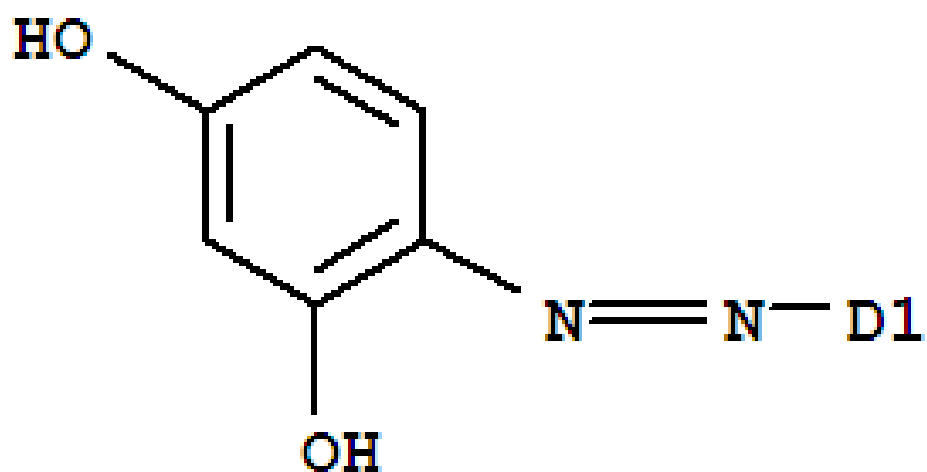
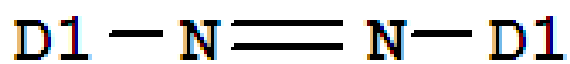
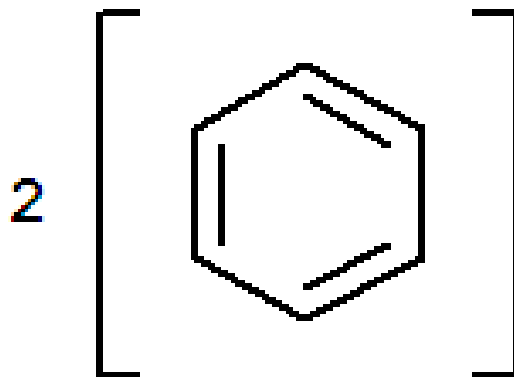
Structural Formula



|                   |   |
|-------------------|---|
| Molecular Formula | C <sub>19</sub> H <sub>15</sub> N <sub>5</sub> O <sub>4</sub> |
| Molecular Weight  |   |

|   |  |
|---|--|
| Chemical Name in the Inventory and Synonyms | <b>Resorcinol, bis(xyllylazo)-bis(xyllylazo)resorcinol</b> |
| CAS Number                                  | 28514-75-2   |
| Structural Formula                          |  |





Molecular Formula

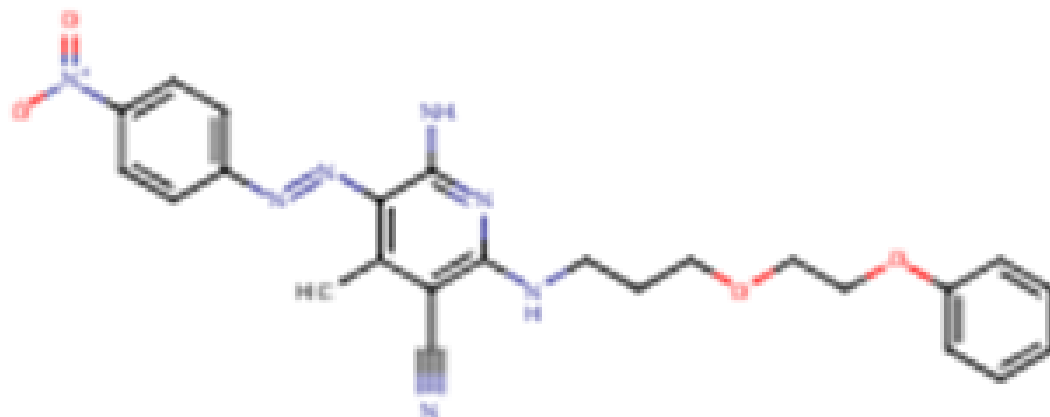
C<sub>22</sub>H<sub>22</sub>N<sub>4</sub>O<sub>2</sub>

Molecular Weight

374.48

|   |  |
|---|--|
| Chemical Name in the Inventory and Synonyms | <b>Benzamide, N-[5-[bis(2-(acetyloxy)ethyl)amino]-2-[(4-nitrophenyl)azo]phenyl]-5'-[bis(2-hydroxymethyl)amino]-2'-[(p-nitrophenyl)azo]benzanilide, diacetate</b> |
| CAS Number                                  | 29765-00-2   |
| Structural Formula                          |  |
| Molecular Formula                           | C <sub>27</sub> H <sub>27</sub> N <sub>5</sub> O <sub>7</sub>  |
| Molecular Weight                            |  |

|   |   |
|---|---|
| Chemical Name in the Inventory and Synonyms | <b>3-Pyridinecarbonitrile, 6-amino-4-methyl-5-[(4-nitrophenyl)azo]-2-[[3-(2-phenoxyethoxy)propyl]amino]-6-amino-4-methyl-5-[(4-nitrophenyl)azo]-2-[[3-(2-phenoxyethoxy)propyl]amino]nicotinonitrile</b> |
| CAS Number                                  | 85409-74-1  |
| Structural Formula                          |   |



|                   |   |
|-------------------|---|
| Molecular Formula | C <sub>24</sub> H <sub>25</sub> N <sub>7</sub> O <sub>4</sub> |
| Molecular Weight  |   |

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