Risk Management Approach

for

Solvent Violet 13

Chemical Abstracts Service Registry Numbers (CAS RN):

81-48-1

Environment and Climate Change Canada

Health Canada

July 2021

Summary of Proposed Risk Management

This document outlines the proposed risk management actions under consideration for Solvent Violet 13, which has been found harmful to human health.

In particular, the Government of Canada is proposing:

- Measures to reduce exposures to Solvent Violet 13 from certain cosmetics by describing it as a prohibited or restricted ingredient on the Health Canada Cosmetic Ingredient Hotlist. The Hotlist is used to communicate that certain substances may not be compliant with requirements of the *Food and Drugs Act* or provisions of the *Cosmetic Regulations*.

The risk management actions outlined in this Risk Management Approach document may evolve through consideration of assessments and risk management options published for other Chemicals Management Plan (CMP) substances as required to ensure effective, coordinated, and consistent risk management decision-making.

Note: The proposed risk management actions may evolve through consideration of additional information obtained from the public comment period, literature and other sources.

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1. Context

The *Canadian Environmental Protection Act, 1999* (CEPA) (Canada 1999) provides the authority for the Minister of Environment and the Minister of Health (the ministers) to conduct assessments to determine if substances are toxic to the environment and/or harmful to human health as set out in section 64 of CEPA[1,2], and if so, to manage the associated risks.

The seven substances, listed in Annex A and referred to throughout this document as Solvent Violet 13, Pigment Blue 60, Solvent Violet 59, Solvent Blue 36, Disperse Red 60, Acid Blue 239 and CAS RN 74499-36-8, are included in the screening assessment of the Anthraquinones Group (ECCC, HC, 2021).

2. Issue

Health Canada and Environment and Climate Change Canada conducted a joint scientific assessment of Solvent Violet 13 as part of the Anthraquinones Group. A notice summarizing the scientific considerations of the screening assessment for the substances in this group was published in the *Canada Gazette*, Part 1, on July, 17, 2021. For further information, refer to Screening Assessment Report for the Anthraquinones Group.

2.1 Screening Assessment Conclusion

On the basis of the information available, the screening assessment concludes that Solvent Violet 13 in the Anthraquinones Group, meets the criteria under paragraph 64 *(c)* of CEPA because it is entering the environment in a quantity or

[1] Section 64 [of CEPA]: *For the purposes of* [Parts 5 and 6 of CEPA]*, except where the expression "inherently toxic" appears, a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that*

- *(a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;*
- *(b) constitute or may constitute a danger to the environment on which life depends; or*
- *(c) constitute or may constitute a danger in Canada to human life or health.*

[2] A determination of whether one or more of the criteria of section 64 of CEPA are met is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs, and products available to consumers. A conclusion under CEPA is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the *Hazardous Products Regulations*, which are part of the regulatory framework for the Workplace Hazardous Materials Information System for products intended for workplace use. Similarly, a conclusion based on the criteria contained in section 64 of CEPA does not preclude actions being taken under other sections of CEPA or other Acts.

concentration or under conditions that constitute or may constitute a danger in Canada to human life or health (Canada 2021). The exposures and sources of concern identified in the screening assessment are oral and dermal exposure to Solvent Violet 13 in certain cosmetics (body creams, lipsticks/lip balms, permanent hair dyes, spray perfumes and face paints). As such, this document will focus on these exposure sources (refer to section 5).

It is concluded that Solvent Violet 13 is not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity, or that constitute or may constitute a danger to the environment on which life depends under paragraphs 64*(a)* and *(b)* of CEPA, respectively.

The screening assessment also concludes that the other substances in the Anthraquinones Group, namely Pigment Blue 60, Solvent Violet 59, Solvent Blue 36, Disperse Red 60, Acid Blue 239, and CAS RN 74499-36-8, do not meet the criteria under section 64 of CEPA (Canada 2021).

Although a risk to human health or the environment has not been identified at current levels of exposure, there may be a concern if exposure to Solvent Violet 59, Solvent Blue 36, Disperse Red 60, Acid Blue 239, and CAS RN 74499-36 were to increase. As a result, these substances may be considered in future initiatives to track their commercial status or identify new uses.

The screening assessment also concludes that Solvent Violet 13 meets the persistence criteria but not the bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations* made under CEPA (Canada 2000).

2.2 Recommendation under CEPA

On the basis of the findings of the screening assessment conducted under CEPA, the Ministers recommend that Solvent Violet 13 be added to the List of Toxic Substances in Schedule 1 of the Act[3].

The Ministers have taken into consideration comments made by stakeholders during the 60-day public comment period on the draft screening assessment for the Anthraquinones Group and its associated Risk Management Scope for Solvent Violet 13.

As the Ministers finalize the recommendation to add Solvent Violet 13 to Schedule 1, risk management instruments will be proposed and finalized within

[3] When a substance is found to meet one or more of the criteria under section 64 of CEPA, the ministers can propose to take no further action with respect to the substances, add the substance to the Priority Substances List for further assessment, or recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of the Act.

24 months from the date on which the Ministers recommend that Solvent Violet 13 be added to Schedule 1 of CEPA, and finalized within 18 months from the date on which the risk management instruments are proposed, as outlined in sections 91 and 92 of CEPA (refer to section 8 for publication timelines applicable to this group of substances).

2.3 Public Comment Period on the draft Screening Assessment Report and the Risk Management Scope

The draft screening assessment for the Anthraquinones Group (ECCC, HC, 2018a) and the associated Risk Management Scope document for Solvent Violet 13 (ECCC, HC, 2018b) summarizing the proposed risk management options under consideration at the time, were published on November 3, 2018. Industry and other interested stakeholders were invited to submit comments on both documents during a 60-day public comment period.

Comments received on the draft screening assessment report and the Risk Management Scope were taken into consideration in the development of this document. A summary of responses to the public comments received is available.

3. Proposed Risk Management

3.1 Proposed Human Health Objectives

Proposed human health objectives are quantitative or qualitative statements of what should be achieved to address human health concerns.

The proposed human health objective for Solvent Violet 13 is focused on addressing the exposure sources of concern outlined in section 5 of this document. As such, the proposed human health objective is to reduce exposure of the general population to Solvent Violet 13 to levels that are protective of human health.

3.2 Proposed Risk Management Objectives

Proposed risk management objectives set quantitative or qualitative targets to be achieved by the implementation of risk management regulations, instrument(s) and/or tool(s) for a given substance or substances.

The proposed risk management objective for Solvent Violet 13 is:

- to reduce dermal and oral exposure to Solvent Violet 13 from certain cosmetics.

3.3 Proposed Risk Management Actions under Consideration

To achieve the proposed risk management objective and to work towards achieving the proposed human health objective, the proposed risk management action for Solvent Violet 13 under consideration is:

(1) Measures to reduce exposures to Solvent Violet 13 from certain cosmetics by describing Solvent Violet 13 as a prohibited or restricted ingredient on the Health Canada Cosmetic Ingredient Hotlist[4]. The Hotlist is used to communicate that certain substances may not be compliant with requirements of the *Food and Drugs Act* or provisions of the *Cosmetic Regulations*.

Following the publication of this Risk Management Approach document, additional information obtained from the public comment period and from other sources will be considered, along with the information presented in this document, in the instrument selection and development process[5]. The risk management actions outlined in this document may evolve through consideration of assessments and risk management options published for other CMP substances to ensure effective, coordinated, and consistent risk management decision-making.

3.4 Performance Measurement and Evaluation

Performance measurement evaluates the ongoing effectiveness and relevance of the actions taken to manage risks from toxic substances[6]. The aim is to

[4] Health Canada's Cosmetic Ingredient Hotlist is an administrative tool that Health Canada uses to communicate to manufacturers and others that certain substances may contravene the general prohibition found in section 16 of the *Food and Drugs Act* (F&DA), or may contravene one or more provisions of the *Cosmetic Regulations*. Section 16 of the F&DA states that "No person shall sell any cosmetic that has in or on it any substance that may cause injury to the health of the user". In addition, the Cosmetic Ingredient Hotlist includes certain substances that may make it unlikely for a product to be classified as a cosmetic under the F&DA. Compliance with the provisions of section 16 are monitored, in part, through the mandatory notification provisions of section 30 of the *Cosmetic Regulations* of the F&DA, which requires that all manufacturers and importers provide a list of the cosmetic's ingredients to Health Canada.

[5] The proposed risk management regulation(s), instrument(s) or tool(s) will be selected using a thorough, consistent and efficient approach and take into consideration available information in line with the Government of Canada's Cabinet Directive on Regulatory Management (TBS 2012a), Red Tape Reduction Action Plan (TBS 2012b) and the *Red Tape Reduction Act* (Canada 2015).

[6] Performance measurement can be performed at two levels:

- Instrument-based performance measurement evaluates the effectiveness of an individual instrument in meeting the specific risk management objectives that were set out when the risk management tool was designed. The results of performance measurement will help determine if additional risk management is needed (*i.e.*, evaluate whether risk management objectives have been met); and

determine whether the human health objectives have been met and whether there is a need to revisit the risk management approach for that substance to ensure that risks are managed effectively over time.

The Government of Canada plans to measure the effectiveness of the risk management actions by collecting and analyzing data including data on Solvent Violet 13 in certain cosmetics in order to measure progress towards meeting the risk management objectives.

The results of performance measurement and evaluation will be used to inform whether further risk management action is warranted and will be made available to Canadians along with recommendations for further action, if applicable.

4. Background

4.1 General Information on Solvent Violet 13

Solvent Violet 13 is an organic substance which is part of the Anthraquinones Group. The analogue anthraquinone (CAS RN 84-65-1) is the common structural backbone shared among all the substances in the Anthraquinones Group.

4.2 Current Uses and Identified Sectors

Solvent Violet 13 was included in a survey issued pursuant to section 71 of CEPA (Canada 2012). Total reported imports of Solvent Violet 13 for 2011 ranged from 1000 to 10 000 kg and no manufacturing activities were reported above the reporting threshold of 100 kg. The major use reported in Canada for Solvent Violet 13 according to the above mentioned survey is for the manufacture of candles (Environment Canada 2013).

Solvent Violet 13 is also identified as being used in cosmetics, based on notifications submitted under the *Cosmetic Regulations* to Health Canada, specifically for a variety of cosmetics, including body creams, bath products, lipsticks/lip balms, make-up, nail products, shampoos and conditioners, hair styling products, perfumes and face painting products (personal communication, emails from the Consumer and Hazardous Products Safety Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated February 1, 2016, 2019; unreferenced). Solvent Violet 13 may also be used as a component in food packaging materials; however, exposure is expected to be negligible. The substance may also be used as a component in

- Substance-based performance measurement considers performance of all final risk management instruments applied to a chemical substance and relevant data or indicators of exposure to the environment or human health (*i.e.*, evaluate whether human health and/or environmental objectives have been met).

incidental additives such as hand sanitizers and cleaners, and used in food processing establishments, with no expected food contact (personal communication, e-mail from the Food Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated April 24, 2017; unreferenced).

Solvent Violet 13 is also listed in the Natural Health Products Ingredients Database with a non-medicinal role for external use only as colour additive. It is also listed in the Licensed Natural Health Products Database as being present a non-medicinal ingredient in a limited number of currently licensed topical natural health products, such as acne therapy products, anti-dandruff products, and antiseptic skin cleansers (LNHPD [modified 2016], NHPID [modified 2017]). Given its presence in a limited number of natural health products combined with limited information regarding product concentrations, exposure from natural health products has not been identified as a concern at this time.

Solvent Violet 13 is listed on the Health Canada Pest Management Regulatory Agency (PMRA) List of Formulants (personal communication, email from the PMRA, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada (ESRAB), dated 2016; unreferenced).

Additional consumer uses for Solvent Violet 13 identified in Canada from publicly available sources include pet shampoos (MSDS 2007a,b; 2015a,b).

Globally, Solvent Violet 13 was also identified as a colourant in non-plastic toys (Danish EPA 2015) and in other products including textiles, paper, and plastics (ECHA c2007-2019a).

5. Exposure Sources and Identified Risks

Solvent Violet 13 was not identified or measured in any environmental media in Canada or elsewhere. Exposure from environmental media that could impact human health of the general population is considered to be minimal.

Direct exposures from use of products available to consumers were evaluated in the screening assessment. Estimates of potential exposure to Solvent Violet 13 were derived from the use of cosmetics.

Given limited substance-specific hazard data for chronic toxicity and carcinogenicity endpoints, a read-across approach based on health effects information for the substance anthraquinone, was used to inform this part of the hazard assessment.

The critical health effects associated with Solvent Violet 13 identified in the screening assessment (Canada 2019) are carcinogenicity based on the analogue

anthraquinone and non-cancer systemic effects (kidney, liver, spleen, and bone marrow toxicity) based on the analogue anthraquinone. In the assessment, exposure of Canadians to Solvent Violet 13 in the following scenarios were identified as a potential concern:

Non-cancer systemic effects:

- Dermal exposure of adults through use of body creams and spray perfumes.

Cancer effects:

- Oral exposure of all age groups through use of lipsticks or lip balms; and
- Dermal exposure of various age groups though the use of body creams, permanent hair dyes, spray perfumes and face paints.

Margins of exposure (MOEs) between levels of exposure of the general population from daily use of Solvent Violet 13 in certain cosmetics (body cream, spray perfume) and levels associated with non-cancer health effects were considered potentially inadequate to address uncertainties in the health effects and exposure databases. MOEs between levels of exposure of the general population from daily use of Solvent Violet 13 in certain cosmetics (lip balm, lipstick, body cream, permanent hair dye, spray perfume and face paint) and cancer effects were also considered potentially inadequate. MOEs were, however, considered adequate for other uses of Solvent Violet 13 (Canada 2019).

No sources of exposure other than cosmetics were identified as a concern in the screening assessment (ECCC, HC, 2021).

6. Risk Management Considerations

6.1 Alternatives and Alternate Technologies

There are alternative substances available that may serve the same function as Solvent Violet 13 (e.g., as colorants or dyes); however, their feasibility as replacements for specific cosmetic products is unknown.

6.2 Socio-economic and Technical Considerations

Socio-economic factors will be considered in the selection process for a regulation and/or instrument respecting preventive or control actions, and in the development of the risk management objectives(s) as per the guidance provided in the Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action* (Treasury Board of Canada Secretariat TBS,

2007). In addition, socio-economic factors will also be considered in the development of regulations, instrument(s) and/or tool(s) to address risk management objective(s) as identified in the *Cabinet Directive on Regulatory Management* (TBS 2018), Red Tape Reduction Action Plan (TBS 2012) and the *Red Tape Reduction Act* (Canada 2015).

7. Overview of Existing Risk Management

7.1 Related Canadian Risk Management Context

Domestically, the pertinent risk management actions are as follows:

***Food and Drugs Act* (F&DA)**

Food: The safety of chemicals used in food packaging materials and incidental additives is subject to the provisions of section 4(1)(a) of the F&DA, and food packaging materials are also subject to the provisions in Division 23 of the *Food and Drug Regulations*. Solvent Violet 13 is not currently included on Health Canada's Lists of Permitted Food Additives; therefore, it is not an approved food additive in foods sold in Canada.

Cosmetics: Solvent Violet 13 is present in cosmetics based on notifications submitted under the *Cosmetic Regulations*; it is not currently included on Health Canada's Cosmetic Ingredient Hotlist.

Drugs: In Canada, Solvent Violet 13 is listed under the *Food and Drugs Regulations as* a colouring agent permitted in drugs for external use (Canada, 2017).

Natural Health Products (NHPs): NHPs are regulated under the *Natural Health Products Regulations.* Solvent Violet 13 is listed with a non-medicinal role for external use only as a colour additive in natural health products (NHPID, 2017).

***Pest Control Products Act* (PCPA)**

Solvent Violet 13 is listed on the Pest Management Regulatory Agency (PMRA) List of Formulants (personal communication, 2016 email from the PMRA, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada; unreferenced).

7.2 Pertinent International Risk Management Context

Internationally, the pertinent risk management actions are as follows:

United States:

- *Food and Drug Act*, Title 21 of the Code of Federal Regulation (CFR):
    - Part 74 – Listing of Color Additives Subject to Certification. Solvent Violet 13 is listed as a color additive that is subject to certification and permitted for use in cosmetics for external use only, and not allowed for eye area or generally (including lipsticks). It is also allowed for use in externally applied drugs and in medical devices not to exceed (NTE) 0.1-0.3% by weight in various absorbable sutures; in amounts NTE the minimum reasonably required to accomplish the intended coloring effect in contact lenses; NTE 0.2% of intraocular lens haptics, NTE 0.15% by weight of meniscal tracks (US eCFR, 2017a).
    - Part 82, Listings of Certified Provisionally Listed Colors and Specifications (drugs and cosmetics) (US eCFR, 2017b); and Part 81, General Specification and General Restrictions for Provisional Color Additives for Use in Foods, Drugs and Cosmetics where it is restricted from use in the manufacture of ingested drugs or cosmetics subject to ingestion (US eCFR, 2017c).Threshold for Regulation (TOR) Exemption (TOR No. 1998-015), with use limitations, at levels not to exceed 0.2 ppm in polystyrene food-contact articles. Threshold of Regulation Exemptions are generally applicable and are effective for the food contact substance (FCS).
    - Inventory of Effective FCS Notifications - The database lists effective premarket notification for food contact substances that have been demonstrated to be safe for their intended use. Solvent Violet 13 is listed as a colourant in food-contact polystyrene, at levels not to exceed 0.70 ppm, for all food types except for use in contact with infant formula and breast milk. It is also listed as a component in epoxy resin coatings for repeat use in contact with beer, at a maximum level of 1 percent by weight of the cured epoxy coating (US FDA, 2017).

- Additionally, FCS Notifications are effective for the manufacturer or supplier identified in the notification.

- *Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA), Environmental Protection Agency (EPA) Regulations. Solvent Violet 13 is classified as List 4B - an inert ingredient in pesticides based upon the ‘reasonable certainty of no harm’ safety finding. It is cleared for use in food and non-food as a dye. This inert ingredient is used pre-harvest with

exemptions from the requirement of a tolerance when used in accordance with good agricultural practice. To be exempt from the requirement of a tolerance, it must be limited to not more than 0.005% of the pesticide formulation. It is also an inert ingredient applied to animals (with exemption from the requirement of a tolerance) (US EPA, 2005; US eCFR 2017d).

European Union:

While Solvent Violet 13 is included in Annex IV, List of Colorants Allowed in Cosmetic Products, of European Commission Regulation No 1223/2009 (EC, 2009), it is also listed in Annex II of the List of Substances Prohibited in Cosmetic Products, as per Commission Implementing Regulation No 344/2013 (EC, 2013), specifically when used as a substance in hair dye products.

Other:

- New Zealand - Cosmetic Products Group Standard Solvent Violet - listed in schedule 4, components cosmetic product must not contain when used as a substance in hair dye products (New Zealand, 2006).

- Australia - Australian Government Regulation of Cosmetics (website) - listed as a colouring for use as excipients in medicines for topical use only and does not require evaluation of toxicology data (Australia, 2016).

8. Next Steps

8.1 Public Comment Period

Industry and other interested stakeholders are invited to submit comments on the content of this Risk Management Approach or other information that would help to inform decision-making (such as outlined in section 3.2). Please submit additional information and comments prior to September 15, 2021.

Comments and information submissions on the Risk Management Approach should be submitted to the address provided below:

Environment and Climate Change Canada
Chemicals Management Division
Gatineau Quebec K1A 0H3

Tel: 1-800-567-1999 | 819- 938-3232
Fax: 819-938-5212
Email: eccc.substances.eccc@canada.ca

Companies who have a business interest in Solvent Violet 13 are encouraged to identify themselves as stakeholders. Stakeholders will be informed of future decisions regarding Solvent Violet 13 and may be contacted for further information.

Following the public comment period on the Risk Management Approach document, the Government of Canada will initiate the development of the specific risk management instrument(s), where necessary. Comments received on the Risk Management Approach document will be taken into consideration in the selection or development of these instrument(s). Consultation will also take place as instrument(s) are developed.

8.2 Timing of Actions

Electronic consultation on the Risk Management Approach: July 17, 2021 to September 15, 2021.

Publication of responses to public comments on the Risk Management Approach document: Concurrent to the publication of the proposed instrument(s).

Publication of the proposed instrument(s): At the latest, 24 months from the date on which the Ministers recommended that Solvent Violet 13 be added to Schedule 1 of CEPA.

Consultation on the proposed instrument(s): 60-day public comment period, starting upon publication of the proposed instrument.

Publication of the final instrument(s): At the latest, 18 months from the publication of the proposed instrument.

These are planned timelines and are subject to change. Please consult the schedule of risk management activities and consultations for updated information on timelines.

9. References

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[US eCFR]. United States Code of Federal Regulations. 2017a. Title 21, Part 74 (Listing of Color Additives Subject to Certification).

[US eCFR] United States Code of Federal Regulations. 2017b. Title 21, Part 82 (Listing of Certified Provisionally Listed Colors and Specifications) Subpart 82.1602.

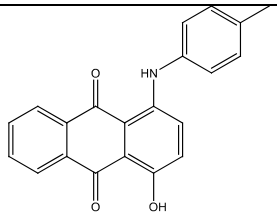
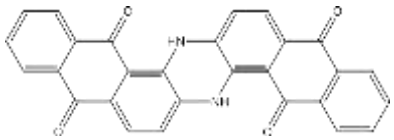
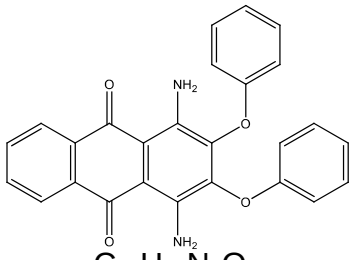
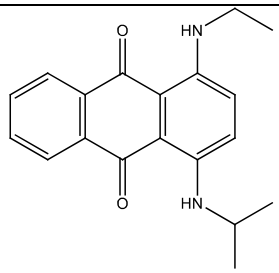
[US eCFR] United States Code of Federal Regulations. 2017c. Title 21, Part 81 (General Specifications and General Restrictions for Provisional Color Additives for Use In Foods, Drugs, and Cosmetics), Subpart 81.30.

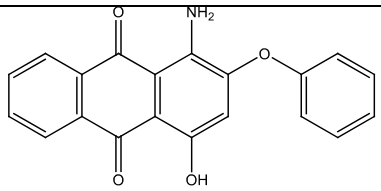
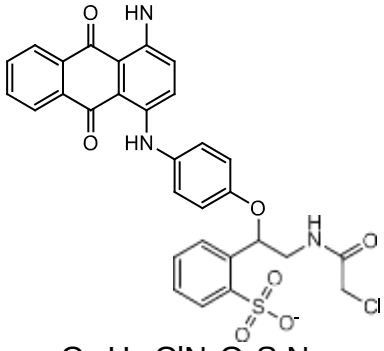
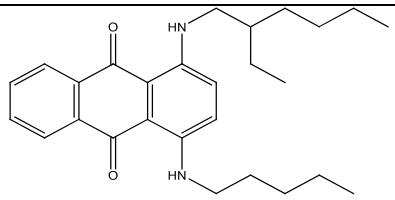
[US eCFR]. United States Code of Federal Regulations. 2017d. Title 40, Part 180: Tolerances and Exemptions for Pesticide Chemical Residues in Food.

[US EPA]. United States Environmental Protection Agency. 2005. Memorandum: May 20, 2005 [pdf].

[US FDA]. United States Food and Drug Administration. 2017. Inventory of Effective Food Contact Substance (FCS) Notifications.

ANNEX A

CAS RN	DSL name (common name; (acronyms; other names)	Chemical structure and molecular formula	Molecular weight (g/mol)
81-48-1	9,10-Anthracenedione, 1-hydroxy-4-[(4-methylphenyl)amino]- (Solvent Violet 13; also called Disperse Blue 72)	 $C_{21}H_{15}NO_3$	329.35
81-77-6	5,9,14,18-Anthrazinetetrone, 6,15-dihydro- (Pigment Blue 60)	 $C_{28}H_{14}N_2O_4$	442.43
6408-72-6	9,10-Anthracenedione, 1,4-diamino-2,3-diphenoxy- (Solvent Violet 59; also called Disperse Violet 31 and Disperse Violet 26)	 $C_{26}H_{18}N_2O_4$	422.44
14233-37-5	9,10-Anthracenedione, 1,4-bis[(1-methylethyl)amino]- (Solvent Blue 36	 $C_{20}H_{22}N_2O_2$	322.41

17418-58-5	9,10-Anthracenedione, 1-amino-4-hydroxy-2-phenoxy- (Disperse Red 60)	 $C_{20}H_{13}NO_4$	331.33
72391-24-3	Benzenesulfonic acid, [[(chloroacetyl)amino]methyl][4-[[4-(cyclohexylamino)-9,10-dihydro-9,10-dioxo-1-anthracenyl]amino]phenoxy] methyl-, monosodium salt (Acid Blue 239)	 $C_{36}H_{34}ClN_3O_7S.Na$	710.18
74499-36-8	9,10-Anthracenedione, 1,4-diamino-, N,N'-mixed 2-ethylhexyl and Me and pentyl derivs. (NA)	 $C_{27}H_{36}N_2O_2$	420.60