

Safety data sheet

COMMISSION REGULATION (EU) No 2015/830 of 1 June 2015 amending
Annex II of Regulation (EU) No 453/2010

Issue date 12.10.2018

Date of Revision: 00

Due Date of Revision: 11.10.2020

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **Trade name:** Neelicert FD & C Red 40
- **CAS Number:**
25956-17-6
- **EC number:**
247-368-0
- **Registration number** 01-2119935928-21-0003
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Sector of Use**
SU1 Agriculture, forestry, fishery
SU5 Manufacture of textiles, leather, fur
SU6a Manufacture of wood and wood products
SU 0: Other: Surface cleaner
- **Product category**
PC3 Air care products
PC8 Biocidal products (e.g. Disinfectants, pest control)
PC9a Coatings and paints, thinners, paint removers
PC9b Fillers, putties, plasters, modelling clay
PC9c Finger paints
PC12 Fertilisers
PC14 Metal surface treatment products, including galvanic and electroplating products
PC18 Ink and toners
PC21 Laboratory chemicals
PC27 Plant protection products
PC28 Perfumes, fragrances
PC31 Polishes and wax blends
PC35 Washing and cleaning products (including solvent based products)
PC39 Cosmetics, personal care products
- **Process category**
PROC1 Use in closed process, no likelihood of exposure
PROC2 Use in closed, continuous process with occasional controlled exposure
PROC3 Use in closed batch process (synthesis or formulation)
PROC5 Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)
PROC8a Transfer of substance or preparation (charging/discharging) from/to vessels/ large containers at non-dedicated facilities
PROC8b Transfer of substance or preparation (charging/discharging) from/to vessels/ large containers at dedicated facilities
PROC9 Transfer of substance or preparation into small containers (dedicated filling line, including weighing)
PROC10 Roller application or brushing
PROC11 Non industrial spraying
PROC13 Treatment of articles by dipping and pouring
PROC14 Production of preparations or articles by tableting, compression, extrusion, pelletisation
PROC15 Use as laboratory reagent
PROC19 Hand-mixing with intimate contact and only PPE available
- **Environmental release category**
ERC2 Formulation of preparations
ERC3 Formulation in materials

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ERC4 Industrial use of processing aids in processes and products, not becoming part of articles

ERC5 Industrial use resulting in inclusion into or onto a matrix

ERC8c Wide dispersive indoor use resulting in inclusion into or onto a matrix

ERC8d Wide dispersive outdoor use of processing aids in open systems

ERC8e Wide dispersive outdoor use of reactive substances in open systems

ERC8f Wide dispersive outdoor use resulting in inclusion into or onto a matrix

· **Article category**

AC8 Paper articles

AC 02: Other (intended to be released): not specified

· **Application of the substance / the mixture**

Color additive in food, drugs, and cosmetics.

Used to color gelatins, puddings, custards, alcoholic and nonalcoholic beverages, sauces, topping, candy, sugars, frostings, fruits, juices, dairy products, bakery products, jams, jellies, condiments, meat and poultry.

· **1.3 Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Neelikon Food Dyes & Chemicals Ltd.,

D-8, D-17 Everest, 5th Floor,

Pandit Madan Mohan Malviya Marg,

Tardeo, Mumbai – 400034.

· **Further information obtainable from:**

Tel: 00 91 22 66661415(6 Hunting Lines)

Fax: 00 91 22 23523945 /66626916

Email ID: info@neelikon.com

· **1.4 Emergency telephone number:**

M/s Neelikon Food Dyes & Chemicals

Ltd., D-8, Everest, 5th Floor,

Pdt.M.M.Marg, Tardeo Circle, Mumbai 34, India

Tel.: 00 91 22 66626 874, Mobile No.:00 91 9970004002

Kind Attn. Mr. Rajeev Mathyal

SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**

· **Classification according to Regulation (EC) No 1272/2008**

The substance is not classified according to the CLP regulation.

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- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.1 Chemical characterisation: Substances**
- **CAS No. Description**
25956-17-6 disodium 6-hydroxy-5-[(2-methoxy-4-sulphonato-m-tolyl)azo]naphthalene-2-sulphonate
- **Identification number(s)**
- **EC number:** 247-368-0
- **Additional information:**
Molecular Formula: C18-H14-N2-Na2-O8-S2
Molecular Weight: 496.43
- **SVHC** The substance is not in the list of SVHC substances

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** Immediately remove any clothing soiled by the product.
- **After inhalation:**
Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.
- **After skin contact:**
Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops. Cold water may be used.
- **After eye contact:**
Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention if irritation occurs.
- **After swallowing:**
Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear.
- **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

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SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture**
In case of fire, the following can be released:
Nitrogen oxides (NO_x)
Carbon monoxide (CO)
Sulphur dioxide (SO₂)
Carbon dioxide (CO₂)
Sodium oxides
- **5.3 Advice for firefighters**
- **Protective equipment:**
Fire fighters should wear positive self-contained breathing apparatus.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:**
Do not allow product to reach sewage system or any water course.
- **6.3 Methods and material for containment and cleaning up:**
Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.
- **6.4 Reference to other sections**
Refer to section 8 and 13 for additional information on personal protection equipment and disposal methods.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Ground all equipment containing material. Avoid contact with skin and eyes. Do not breathe dust. Do not ingest.
- **Information about fire - and explosion protection:**
Keep away from heat and sources of ignition.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
Provide ventilation for receptacles.
Store in a cool, dry, well-ventilated area away from incompatible substances.
- **Information about storage in one common storage facility:**
Store away from oxidizing and reducing agents.
- **Further information about storage conditions:**
Keep container tightly sealed.
Protect containers against physical damage and check regularly for leaks.

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· **7.3 Specific end use(s)***Color additive in food, drugs, and cosmetics.**Used to color gelatins, puddings, custards, alcoholic and nonalcoholic beverages, sauces, topping, candy, sugars, frostings, fruits, juices, dairy products, bakery products, jams, jellies, condiments, meat and poultry.***SECTION 8: Exposure controls/personal protection**· **Additional information about design of technical facilities:***Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits.**If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.*· **8.1 Control parameters**· **Ingredients with limit values that require monitoring at the workplace:** Not required.· **DNELs**

Data for WORKERS

Long-term: (DNEL) 34.843 mg/m³ through Inhalation exposure

Long-term: (DNEL) 19.762 mg/kg bw/da through dermal exposure

Data for the GENERAL POPULATION

Long-term: (DNEL) 8.592 mg/m³ through inhalation exposure

Long-term: (DNEL) 9.881 mg/kg bw/day through dermal exposure

· **PNECs**

Hazard for Aquatic Organisms

Freshwater 100 µg/L (1)

Intermittent releases (freshwater) 1 mg/L

Marine water 10 µg/L (1)

Intermittent releases (marine water) -

Sewage treatment plant (STP) 899.78 µg/L

Sediment (freshwater) 46 741.98 mg/kg sediment dw

Sediment (marine water) 46 741.98 mg/kg sediment dw

· **8.2 Exposure controls**· **Personal protective equipment:**· **General protective and hygienic measures:***The usual precautionary measures are to be adhered to when handling chemicals.*· **Respiratory protection:***A self-contained breathing apparatus should be used to avoid inhalation of the product.*· **Protection of hands:**

Protective gloves

*The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.**Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.**Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation*

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· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:** Splash goggles· **Body protection:**

Protective work clothing

Boots

SECTION 9: Physical and chemical properties· **9.1 Information on basic physical and chemical properties**· **General Information**

· Appearance:	Solid
· Form:	Powder
· Colour:	Dark Red
· Odour:	Odourless
· Odour threshold:	Not available

· **pH-value (1 g/l) at 27 °C:** 6 - 9

· **Change in condition**

· **Melting point/Melting range:** 244 °C (at 966 hPa)

· **Boiling point/Boiling range:** 310 °C (at 966 hPa)

· **Flash point:** 255 °C (at 966 hPa)

· **Flammability (solid, gaseous):** Product is not flammable.

· **Self-igniting:** Product is not self-igniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

· **Oxidising properties** 164.8 Vol %

· **Vapour pressure:** Not available

· **Density at 27 °C:** 0.706 g/cm³

· **Evaporation rate** Not data available

· **Solubility in / Miscibility with water at 27 °C:**

4200 mg/l

· **Partition coefficient (n-octanol/water) at 27 °C:**

0.052 log POW (Shake flask method)

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- **Viscosity:**
- **Dynamic:** Not applicable.
- **9.2 Other information** Neelicol Allura Red was found to be stable in organic solvent dichloro methane and no degradation products were formed after 24 hours as evident from the GC-MS chromatogram obtained at 0 hours and that obtained after 24 hours.

SECTION 10: Stability and reactivity

- **10.1 Reactivity** Stable at ambient temperature and under normal conditions of use.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** Strong oxidizing and reducing agents.
- **10.6 Hazardous decomposition products:**
Nitrogen oxides (NO_x)
Sulphur oxides (SO_x)
Carbon monoxide and carbon dioxide

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values relevant for classification:**

Oral	LD50	>2000 mg/kg (mouse)
Dermal	LD 50	>10000 mg/kg bw (rabbit)

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Tests for dermal irritation on intact and abraded skin of rabbit showed no gross irritation at levels of 0.316, 1.0, 3.16 and 10 g/kg bw of Neelicol Allura Red; nonetheless a persistent skin staining did occur.
- **Serious eye damage/irritation**
Hen's egg test on the chorioallantoic membrane (HET-CAM) were performed with a 1 % aqueous dilution of Neelicol Allura Red AC. The diluted test item was applied onto the CAM of fertilized chicken eggs at day 9 of incubation and was rinsed off 30 sec after application and evaluation of the irritation parameters was performed. The 1% aqueous solution of Neelicol Allura Red AC did not cause any damaging effect on the CAM as the obtained evaluation resulted in score 0.
- **Respiratory or skin sensitisation**
In 14 days rest period study disodium 6-hydroxy-5-[(2-methoxy-4-sulphonato-m-tolyl)azo] naphthalene-2-sulphonate (NEELICOL ALLURA RED AC) when applied to human skin did not produce allergic responses during the induction phase nor contact dermatitis in the

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challenge period. Thus it is concluded that the test substance disodium 6-hydroxy-5-[(2-methoxy-4-sulphonato-m-tolyl)azo]naphthalene-2-sulphonate is not a skin sensitizer

- **Toxicokinetics, metabolism and distribution**

There was poor absorption of the Neelicol Allura Red by the dogs and no significant radioactivity could be detected in any of the organs and tissues assayed 72 hours following the last dose administered. Approximately 85% of the administered dose (75 and 95% in each case) was excreted in the feces within 24 hours suggesting low bio-accumulation potential

- **Repeated dose toxicity**

ORAL: Toxicity of Neelicol Allura Red was assessed in HaM/ICR (CD-1) mice in life time study. 50

CD1 mice per sex per dose group were fed Neelicol Allura Red in diet at dose concentration of

Males: 0.37, 1.39 or 5.19% (0, 507, 1877, 7422 mg/kg bw/day), Females: 0.37, 1.39 or 5.19% (0, 577, 2043, 8304 mg/kg bw/day), for 1 wk prior to breeding, throughout a 2- or 3-wk breeding period, and during the gestation and lactation periods. When the last litter reached 21 days of age, weanling mice were randomly selected to populate the F1 phase. No significant compound related adverse effect were observed on mortality, clinical signs, body weight, food consumption, hematology, clinical chemistry, gross and histopathology. Hence no-observable-adverse effect level in these studies was 5.19%; approximately 7300 and 8300 mg/kg body weight/day for male and female mice, respectively.

DERMAL: The LOAEL value of Neelicol Allura Red in Mice was observed at dose concentration of

50000 mg/kg. At this dose acanthosis, hyperkeratosis and dermatitis was observed.

- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**

- **Germ cell mutagenicity**

Mutagenicity: The substance was found to be non-mutagenic as per Ames test

- **Carcinogenicity** No data available

- **Reproductive toxicity** The substance is not toxic for reproduction.

- **STOT-single exposure** No data available

- **STOT-repeated exposure** No data available

- **Aspiration hazard** No data available

SECTION 12: Ecological information

- **12.1 Toxicity**

- **Aquatic toxicity:**

IGC50 (46 hrs)	8.9978 mg/L (Tetrahymen Pyriformis)
LC50 (48 hrs)	722.455 mg/L (Daphnia magna)
LC50 (96 hrs)	5439.436 mg/L (Fish)
NOEC (72 hrs)	8.3529 mg/L (Pseudokirchneriella subcapitata)

- **12.2 Persistence and degradability**

The PBT Profiler & EPI Suite has estimated that Neelicol Allura Red is expected to be found predominantly in soil and its persistence estimate is based on its transformation in this medium. Its half-life in soil, 120 days (2880 hrs.). This does not exceeds the threshold of

>120 days. Therefore, Neelicol Allura Red is estimated to be not persistent in the soil environment.

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· **12.3 Bioaccumulative potential**

The estimated BCF of the key study was obtained to be 3.2 dimensionless. This low value of BCF of Neelicol Allura Red indicates its non bioaccumulative nature as the BCF factor is less than the bio-concentration threshold of 2000.

· **12.4 Mobility in soil**

The substance has low mobility in soil.

Soil Adsorption Coefficient i.e Koc value of Neelicol Allura Red was estimated as 26880 L/kg by means of MCI method. This indicates that Neelicol Allura Red will have strong tendency of sorption to soil and sediment and therefore have negligible to slow migration potential to groundwater.

· **12.5 Results of PBT and vPvB assessment**

· **PBT:** Not PBT

· **vPvB:** Not vPvB

· **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations· **13.1 Waste treatment methods**· **Recommendation**

Recycle any unused portion of the material for its approved use or return it to the manufacturer or supplier.

Ultimate disposal of the chemical must consider: the material's impact on air quality; potential migration in soil or water; effects on animal, aquatic, and plant life; and conformance with environmental and public health regulations.

· **Uncleaned packaging:**

· **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information· **14.1 UN-Number**

· **ADR, ADN, IMDG, IATA** Not applicable

· **14.2 UN proper shipping name**

· **ADR, ADN, IMDG, IATA** Not applicable

· **14.3 Transport hazard class(es)**

· **ADR, ADN, IMDG, IATA**

· **Class** Not applicable

· **14.4 Packing group**

· **ADR, IMDG, IATA** Not applicable

· **14.5 Environmental hazards:**

· **Marine pollutant:** No

· **14.6 Special precautions for user** Not applicable.

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· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code** Not applicable.

· **UN "Model Regulation":** Not applicable

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**
- **Substances of very high concern (SVHC) according to REACH, Article 57**
The substance is not listed as SVHC.
- **15.2 Chemical safety assessment:**
Substance is not classified - chemical safety assessment is not required

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing MSDS:** Product safety department.
- **Contact:**
+91-02 194 263527 (Direct Line)
+91-02 194 263694 Ext-259
+91 9970004009
Email ID: rrmore@neelikon.com
- **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
DNEL: Derived No-Effect Level (REACH)
PNEC: Predicted No-Effect Concentration (REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
SVHC: Substances of Very High Concern
vPvB: very Persistent and very Bioaccumulative
- **Sources**
- REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on classification, labelling and packaging of substances and mixtures,

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amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending
Regulation (EC) No 1907/2006

- Data from registered dossier

<https://echa.europa.eu/registration-dossier/-/registered-dossier/12184>

· * **Data compared to the previous version altered.**

Section 3 – Composition /Information on ingredients

Section 4 - First Aid Measures

Section 5 - Fire Fighting Measures

Section 6 - Accidental Release Measures

Section 7 - Handling and Storage

Section 8 - Exposure Controls / Personal Protection

Section 9 - Physical & Chemical Properties

Section 10 – Stability and reactivity

Section 12 - Ecological Information

Section 13 - Disposal Considerations

Section 15 - Regulatory Information

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PREPARED BY	APPROVED BY	ISSUED BY	STATUS
Q.C. HEAD	QA & QC HEAD	Management Representative	