

COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No1907/2006

Issue Date: 23.08.2018

Date of Revision: 06.09.2023

Due Date of Revision : 03.04.2026

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

· 1.1 Product identifier

· **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

PC9a Coatings and paints, thinners, paint removers

PC9b Fillers, putties, plasters, modelling clay

PC9c Finger paints

PC12 Fertilisers

PC14 Metal surface treatment 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 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions.

PROC2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions

PROC3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition PROC5 Mixing or blending in batch processes

PROC8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities

PROC8b Transfer of substance or mixture (charging and discharging) at dedicated facilities

PROC9 Transfer of substance or mixture 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 *Tabletting, compression, extrusion, pelletisation, granulation*

PROC15 *Use as laboratory reagent*

PROC19 *Manual activities involving hand contact*

· **Environmental release category**

ERC2 *Formulation into mixture*

ERC3 *Formulation into solid matrix*

ERC4 *Use of non-reactive processing aid at industrial site (no inclusion into or onto article)*

ERC5 *Use at industrial site leading to inclusion into/onto article*

ERC8c *Widespread use leading to inclusion into/onto article (indoor)*

ERC8d *Widespread use of non-reactive processing aid (no inclusion into or onto article, outdoor)*

ERC8e *Widespread use of reactive processing aid (no inclusion into or onto article, outdoor)*

ERC8f *Widespread use leading to inclusion into/onto article (outdoor)*

· **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:

Windy Point Soap Making Supplies Inc.
14, 6125-12th Street SE
Calgary, AB T2H 2K1
587-318-6678

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.

- **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** *The substance has no endocrine-disrupting properties according to Regulation (EU) 2017/2100*
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

SECTION 3: Composition/information on ingredients

- **3.1 Chemical characterization: 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: C₁₈H₁₆N₂O₈S₂.2Na
Molecular Weight: 496.43
- **SVHC** *The substance is not in the SVHC list.*

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.
- **Information for doctor:** *Treat symptomatically and supportively.*
- **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.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
*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 ambient temperature and dry place, 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.

· **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

· **8.1 Control parameters**

· **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.

· **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

· **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

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:	Characteristic
· Odour threshold:	Not available

· pH-value :	6 - 9(1% Solution in Water)
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· **Change in condition**

· Melting point/freezing point:	Not applicable
· Initial boiling point and boiling range:	Not applicable

· Flash point:	The flash point is only a relevant property for liquids, thus it does not need to be done for substances that are solids or gases at room
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· Flammability (solid, gas):	Product is not flammable.
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· Auto-ignition temperature:	Product is not selfigniting.
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· Explosive properties:	Product does not present an explosion hazard.
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· **Explosion limits:**

· Upper:	
· Oxidising properties	164.8 Vol %

· Vapour pressure:	Not available
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· Bulk Density :	0.5-0.7 g/cm ³ (After tapping)
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· Evaporation rate	Not data available
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· Solubility in / Miscibility with water at 27 °C:	222.0 g/l
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· 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** Neelicert FD & C Red 40 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	>10000 mg/kg (rat)
Dermal	LD50	>10000 mg/kg bw (rabbit)

- **Primary irritant effect:**
- **Skin corrosion/irritation**
The test chemical showed no gross irritation at levels tested; also no skin staining occurred. Hence, the test chemical was considered to be not irritating to skin.
- **Serious eye damage/irritation**
Hen's egg test on the chorioallantoic membrane (HET-CAM) were performed with a 1 % aqueous dilution of Neelicert FD & C Red 40 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 Neelicert FD & C Red 40

AC did not cause any damaging effect on the CAM as the obtained evaluation resulted in score 0.

· **Respiratory or skin sensitization**

The test chemical did not produce any skin allergic reaction in the induction as well as challenge treatment. Hence, the test chemical was considered to be not sensitizing to skin .

· **Additional toxicological information:**

· **Toxicokinetics, metabolism and distribution**

There was poor absorption of the Neelicert FD & C Red 40 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 Neelicert FD & C Red 40 was assessed in HaM/ICR (CD-1) mice in life time study. 50

CD1 mice per sex per dose group were fed Neelicert FD & C Red 40 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.

· **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

· **11.2 Information on other hazards**

· **11.2.1 Endocrine disrupting properties:** The substance has no endocrine-disrupting properties according to Regulation (EU) 2017/2100

· **11.2.2 Information on other hazard:** No further information is available.

SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**

LC50 (48 hrs)	722.455 mg/L (Daphnia magna)
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LC50 (96 hrs)	5439.436 mg/L (Fish)
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· **12.2 Persistence and degradability**

The PBT Profiler & EPI Suite has estimated that Neelicert FD & C Red 40 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 exceed the threshold of

>120 days. Therefore, Neelicert FD & C Red 40 is estimated to be not persistent in the soil environment.

· **12.3 Bioaccumulative potential**

The estimated BCF of the key study was obtained to be 3.2 dimensionless. This low value of BCF of Neelicert FD & C Red 40 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 Neelicert FD & C Red 40 was estimated as 26880 L/kg by means of MCI method. This indicates that Neelicert FD & C Red 40 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 Endocrine disrupting properties:** The substance has no endocrine-disrupting properties according to Regulation (EU) 2017/2100

· **12.7 Other adverse effect:** No further information is 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 Regulated

· **14.2 UN proper shipping name**

· **ADR, ADN, IMDG, IATA**

Not Regulated

· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA	
· Class	<i>Not Regulated</i>
· 14.4 Packing group	
· ADR, IMDG, IATA	<i>Not Regulated</i>
· 14.5 Environmental hazards:	
· Marine pollutant:	<i>No</i>
· 14.6 Special precautions for user	<i>Not applicable.</i>
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	<i>Not applicable.</i>
· UN "Model Regulation":	<i>Not Regulated</i>

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*
- **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.

· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international 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, amending and repealing COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to 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 1: Identification of the substance/mixture and of the company/undertaking*

• *Section 2: Hazard Identification*

• *Section 9: Physical and Chemical properties.*

• *Section 11: Toxicological Information.*

• *Section 12: Ecological Information.*

• *Section 16: Other information*

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