

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 Yellow 6

· **CAS Number:**

2783-94-0

· **EC number:**

220-491-7

· **Registration number** 01-2120734373-58-0000

· **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

SU6b Manufacture of pulp, paper and paper products

SU7 Printing and reproduction of recorded media

SU8 Manufacture of bulk, large scale chemicals (including petroleum products)

SU11 Manufacture of rubber products

SU12 Manufacture of plastics products, including compounding and conversion

SU13 Manufacture of other non-metallic mineral products, e.g. plasters, cement

SU18 Manufacture of furniture

SU19 Building and construction work

SU24 Scientific research and development

· Product category

PC1 Adhesives, sealants

PC3 Air care products

PC9c Finger paints

PC12 Fertilisers

PC13 Fuels

PC20 Processing aids such as pH-regulators, flocculants, precipitants, neutralization agents

PC23 Leather treatment products

PC24 Lubricants, greases, release products

PC26 Paper and board treatment products

PC28 Perfumes, fragrances

PC29 Pharmaceuticals

PC31 Polishes and wax blends

PC33 Semiconductors

PC34 Textile dyes, and impregnating products

PC35 Washing and cleaning products (including solvent based products)

PC39 Cosmetics, personal care products

· Process category

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

PROC4 Chemical production where opportunity for exposure arises

PROC7 Industrial spraying

PROC9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing)

PROC11 Non industrial spraying

PROC15 Use as laboratory reagent

· **Environmental release category**

ERC1 Manufacture of the substance

ERC2 Formulation into mixture

ERC3 Formulation into solid matrix

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

ERC6a Use of intermediate

ERC6b Use of reactive processing aid at industrial site (no inclusion into or onto article)

ERC6c Use of monomer in polymerisation processes at industrial site (inclusion or not into/onto article)

ERC6d Use of reactive process regulators in polymerisation processes at industrial site (inclusion or not into/onto article)

ERC7 Use of functional fluid at industrial site

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

ERC9a Widespread use of functional fluid (indoor)

ERC9b Widespread use of functional fluid (outdoor)

ERC10a Widespread use of articles with low release (outdoor)

ERC10b Widespread use of articles with high or intended release (outdoor)

ERC11a Widespread use of articles with low release (indoor)

ERC11b Widespread use of articles with high or intended release (indoor)

ERC12a Processing of articles at industrial sites with low release

ERC12b Processing of articles at industrial sites with high release

ERC12c Use of articles at industrial sites with low release

· **Article category**

AC1 Vehicles

AC4 Stone, plaster, cement, glass and ceramic articles

AC5 Fabrics, textiles and apparel

AC6 Leather articles

AC8 Paper articles

AC11 Wood articles

AC13 Plastic articles

· **Technical function** Pigment

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

*It is use in food, drugs and cosmetics, Pigment (printing inks); water soluble food colorant
Used in gelatin, frozen desserts, carbonated beverages, dry drink powders, confectionary
products, bakery products, cereals, puddings, aqueous drug solutions, tablets, capsules,
toothpaste and hair rinses.*

· **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** Not applicable

· **Hazard pictograms** No pictogram

· **Signal word** No signal word

· **Hazard statements** Not applicable

· **2.3 Other hazards**

The substance has no endocrine-disrupting properties according to Regulation (EU) 2017/2100

· **Results of PBT and vPvB assessment**

· **PBT:** The substance is not PBT.

· **vPvB:** The substance is not vPvB.

SECTION 3: Composition/information on ingredients

· **3.1 Chemical characterisation: Substances**

· **CAS No. Description**

2783-94-0 disodium 6-hydroxy-5-[(4-sulphonatophenyl)azo]naphthalene- 2-sulphonate

· **Identification number(s)**

· **EC number:** 220-491-7

· **Additional information:**

Molecular Formula: C₁₆H₁₀N₂Na₂O₇S₂

Molecular Weight: 452.36 g/mol

IUPAC Name: disodium 6-hydroxy-5-[(4-sulfonatophenyl)diazenyl]naphthalene-2-sulfonate

CAS Name: Disodium 6-hydroxy-5-[(4-sulphonatophenyl)azo]naphthalene-2-sulphonate

- **SVHC** The substance is not in the SVHC list.

SECTION 4: First aid measures

· **4.1 Description of first aid measures**

· **General information:**

Do not leave affected persons unattended.

Remove contaminated clothing and shoes.

- **After inhalation:** Move out of affected area and supply fresh air.

· **After skin contact:**

Immediately rinse with water.

Generally the product does not irritate the skin.

- **After eye contact:** Rinse opened eye for several minutes under running water.

- **After swallowing:** Clean mouth by gargling with water.

- **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:** Use DRY chemical powder, water spray, fog or 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)

Carbon dioxide (CO₂)

Sulphur dioxide (SO₂)

· **5.3 Advice for firefighters**

· **Protective equipment:**

Wear self contained breathing apparatus for fire fighting if necessary.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
*Wear protective equipment. Keep unprotected persons away.
Ensure adequate ventilation
Avoid formation of dust.*
- **6.2 Environmental precautions:**
*Do not allow product to reach sewage system or any water course.
Do not allow to enter sewers/ surface or ground water.*
- **6.3 Methods and material for containment and cleaning up:**
Pick up and arrange disposal without creating dust. Keep in suitable, closed containers for disposal.
- **6.4 Reference to other sections**
*See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.*

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
*Avoid contact with eyes and skin.
Avoid formation of dust and aerosols.
Ensure good ventilation/exhaustion at the workplace.*
- **Information about fire - and explosion protection:**
*Keep ignition sources away - Do not smoke.
Protect from heat.*
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
Store in ambient temperature and dry Place and well-ventilated area away from incompatible substances.
- **Information about storage in one common storage facility:**
Combustible materials should be stored away from extreme heat and away from strong oxidizing agents.
- **Further information about storage conditions:** *Keep container tightly sealed.*
- **7.3 Specific end use(s)**
*It is use in food, drugs and cosmetics, Pigment (printing inks); water soluble food colorant
Used in gelatin, frozen desserts, carbonated beverages, dry drink powders, confectionary products, bakery products, cereals, puddings, aqueous drug solutions, tablets, capsules, toothpaste and hair rinses.*

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

INHALATION Exposure Threshold Most sensitive study

Systemic Effects

Long-term:(DNEL) 1 469.298 mg/m³effect on fertility

Acute /short term:No hazard identified

Local Effects

Long-term:No hazard identified

Acute /short term:No hazard identified

DERMAL Exposure Threshold Most sensitive study

Systemic Effects

Long-term:(DNEL) 833.333 mg/kg bw/dayeffect on fertility

Acute /short term:No hazard identified

Local Effects

Long-term:No hazard identified

Acute /short term:No hazard identified

EYE Exposure

No hazard identified

Data for the GENERAL POPULATION

INHALATION Exposure Threshold Most sensitive study

Systemic Effects

Long-term:(DNEL) 362.319 mg/m³effect on fertility

Acute /short term:No hazard identified

Local Effects

Long-term:No hazard identified

Acute /short term:No hazard identified

DERMAL Exposure Threshold Most sensitive study

Systemic Effects

Long-term:(DNEL) 416.667 mg/kg bw/dayeffect on fertility

Acute /short term:No hazard identified

Local Effects

Long-term:No hazard identified

Acute /short term:No hazard identified

ORAL Exposure Threshold Most sensitive study

Systemic Effects

Long-term:(DNEL) 208.333 mg/kg bw/dayeffect on fertility

Acute /short term:No hazard identified

EYE Exposure

No hazard identified

· **PNECs**

Hazard for Aquatic Organisms

Freshwater 113.2 - 165 µg/L (2)

Intermittent releases (freshwater) 1.132 - 1.65 mg/L (2)

Marine water 11.32 - 16.5 µg/L (2)

Intermittent releases (marine water)-

Sewage treatment plant (STP) 1.76 mg/L (2)

Sediment (freshwater) 72 054.279 mg/kg sediment dw (2)

Sediment (marine water) 72 054.279 mg/kg sediment dw (2)

Hazard for Air

Air No hazard identified (2)

Hazard for Terrestrial Organism

Soil 34.5 g/kg soil dw (2)

Hazard for Predators

Secondary poisoning No potential for bioaccumulation (2)

· **8.2 Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

Do not eat, drink, smoke or sniff while working.

The usual precautionary measures are to be adhered to when handling chemicals.

· **Respiratory protection:** Not necessary if room is well-ventilated.

· **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

· **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:** Eye wash bottle with pure water.

· **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:	Orange Red
· Odour:	Characteristic

· pH-value:	6-8(1% Solution in Water)
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· **Change in condition**

· Melting point/freezing point:	Not applicable
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· Flammability (solid, gas):	Product is not flammable.
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· Ignition temperature:	950 °C
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· Decomposition temperature:	390 °C
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· Explosive properties:	Product does not present an explosion hazard.
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· Oxidising properties	361.1 ml KMno4 Vol %
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· Vapour pressure at 25 °C:	1.43E-22 mmHg
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· Bulk Density :	0.5-0.7 g/cm ³ (After tapping)
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· Solubility in / Miscibility with water at 20 °C:	125.0 g/l
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· Partition coefficient: n-octanol/water at 25 °C:	-1.180 log POW (HPLC method.)
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· 9.2 Other information	solubility in ethanol 5000 mg/L at 26°C
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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** Hazardous polymerisation will not occur.

· **10.4 Conditions to avoid** Avoid formation of dust.

- **10.5 Incompatible materials:** Incompatible with oxidizing materials.
- **10.6 Hazardous decomposition products:**
Hazardous decomposition products formed under fire conditions - Carbon oxides, nitrogen oxides (NOx)

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) >6000mg/kg (mouse)
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- **Primary irritant effect:**
- **Skin corrosion/irritation**
Disodium 6-hydroxy-5-[(4-sulphonatophenyl)azo]naphthalene-2-sulphonate (sunset yellow FCF) in petrolatum or in aqueous solutions was found to be not irritating to rabbit skin.
- **Serious eye damage/irritation**
Disodium 6-hydroxy-5-[(4-sulphonatophenyl)azo]naphthalene-2-sulphonate (sunset yellow FCF) was found to be minimally irritant to the rabbit eye
- **Respiratory or skin sensitisation**
Disodium 6-hydroxy-5-[(4-sulphonatophenyl)azo]naphthalene-2-sulphonate was predicted as a weak sensitizer to human skin. However, this sensitization effect was not considered adequate enough for the classification of the substance as a skin sensitisation category.
- **Additional toxicological information:**
- **Repeated dose toxicity**
Oral route
The 80 weeks chronic repeated dose study on male and female Charles River CD mouse indicated that no effects observed on body weight, organ weight, haematology and histopathology. Thus, on the basis of study results the NOAEL (no observed adverse effect level) was observed to be 16000 mg/kg diet.

Dermal route
The 90 days subchronic repeated dose dermal study on rabbit indicated that no effects observed on mortality, urinalysis, haematology and histopathology. Thus, on the basis of study results the NOAEL (no observed adverse effect level) was observed to be 10000 mg/kg.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity**
Disodium 6-hydroxy-5-[(4-sulphonatophenyl)azo]naphthalene-2-sulphonate (CAS no. 2783-94-0) did not induce gene mutations by base pair changes or frame shifts in the genome of the Salmonella typhimurium strains TA 1535, TA 1537, TA 98, TA 100 and TA 102 in the presence and absence of S9 metabolic activation system and hence it is not likely to classify as a gene mutant.

- **Carcinogenicity** No data available
- **Reproductive toxicity**
Sunset Yellow FCF was administered in the diet to 60 mice (10/sex/group) at dietary levels of 300, 600, and 1200 mg/kg bw/day the control groups (20 mice, 10/sex) were given basal diets (Nihon Clea, CE-2) to investigate for possible reproductive effect.
The NOAEL for maternal toxicity study was considered to be 300 mg/kg bw/day whereas LOAEL was considered to be 600 mg/kg bw/day in Crj: CD-1 strain mouse when Sunset Yellow FCF was administered orally by diet.
- **STOT-single exposure** No data available
- **STOT-repeated exposure** No data available
- **Aspiration hazard** No data available
- **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:**

EC50 (48 hrs)	>100 mg/L (<i>Daphnia magna</i>)
EC50 (72 hrs)	113.2 mg/L (<i>Desmodesmus subspicatus</i>)
LC50 (96 hrs)	>100 mg/L (<i>Danio rerio</i>)

· **12.2 Persistence and degradability**

28-days Closed Bottle test following the OECD guideline 301 D to determine the ready biodegradability of the test item Disodium 6 -hydroxy-5 -[(4 -sulphonatophenyl)azo] naphthalene-2 -sulphonate. The study was performed at a temperature of 20°C. The test system included control, test item and reference item. The % degradation of procedure control (reference item) was also calculated using BOD & ThOD and was determined to be 75.3%. Degradation of Sodium Benzoate exceeds 46.38 % on 7 days & 61.44 % on 14th day. The activity of the inoculum is thus verified and the test can be considered as valid. The BOD28 value of test chemical was observed to be 1.1 mgO₂/mg. ThOD was calculated as 1.2 mgO₂/mg. Accordingly, the % degradation of the test item after 28 days of incubation at 20 ± 1°C according to Closed Bottle test was determined to be 91.66%. Based on the results, the test item, under the test conditions, was considered to be readily biodegradable in nature.

· **12.3 Bioaccumulative potential** The substance is non-bioaccumulative.

· **12.4 Mobility in soil**

The substance has strong adsorption to soil and negligible migration potential to ground water

· **Additional ecological information:**

· **General notes:**

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system

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

- **PBT:** The substance is not PBT.
- **vPvB:** The substance is 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**
Dispose off waste material according to local, state and federal 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, IMDG, IATA | Not regulated |
| · 14.3 Transport hazard class(es)
· ADR, ADN, IMDG, IATA
· Class | Not regulated |
| · 14.4 Packing group
· ADR, IMDG, IATA | Not regulated |
| · 14.5 Environmental hazards:
· Marine pollutant: | No |
| · 14.6 Special precautions for user | Not regulated. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not regulated. |
| · UN "Model Regulation": | Not regulated |

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** Not applicable

- **Hazard pictograms** No pictogram
- **Signal word** No signal word
- **Hazard statements** Not applicable

- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** Substance is not listed.

- **National regulations:**

- **Other regulations, limitations and prohibitive regulations**
International Inventories
 - Australian Inventory of Industrial Chemicals (AIIC)-Listed
 - China - Chemical Inventory of Existing Chemical Substances (IECSC) - Listed
 - Danish Environmental Protection Agency (DK-EPA) - Listed
 - KEMI List of Substances on the Market-Listed
 - Korea – KE Numbers-Listed
 - New Zealand - Inventory of Chemicals (NZIoC)-Listed
 - Philippine Inventory of Chemicals and Chemical Substances (PICCS)-Listed
 - Taiwan Chemical Substance Inventory (TCSI)-listed
 - Thailand - First Existing Chemicals Inventory-Listed
 - Turkish Chemical Inventory-Listed
- **15.2 Chemical safety assessment:**
Exposure assessment not required as substance is not classified as dangerous.

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

-ECHA <https://echa.europa.eu/substance-information/-/substanceinfo/100.018.629>

-toxplanet <https://chemical-search.toxplanet.com//product-search/listexpert/ei-fts-search/cb65e822-93f1-4a84-92e7-5f044a2f9975>

-Chemidplus <https://chem.nlm.nih.gov/chemidplus/rn/startswith/2783-94-0>

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

- Section 1: Identification of the substance /preparation & of the company/ undertaking.
- Section 2: Hazard(s) identification
- 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 and Chemical properties.
- Section 10: Stability and Reactivity.
- Section 11: Toxicological Information.
- Section 12: Ecological Information.

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