

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

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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 5

· **CAS Number:**

1934-21-0

· **EC number:**

217-699-5

· **Registration number** 01-2120116875-52-0006

· **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

SU12 Manufacture of plastics products, including compounding and conversion

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

SU19 Building and construction work

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

SU11 Manufacture of rubber products

SU18 Manufacture of furniture

SU24 Scientific research and development

· Product category

PC1 Adhesives, sealants

PC3 Air care products

PC9c Finger paints

PC12 Fertilisers

PC13 Fuels

PC18 Ink and toners

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

PROC7 Industrial spraying

PROC4 Chemical production where opportunity for exposure arises

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

PROC15 Use as laboratory reagent

PROC11 Non industrial spraying

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

· **Environmental release category**

ERC 6a Industrial use resulting in manufacture of another substance (use of intermediates)

ERC 6d: Industrial use of process regulators for polymerisation processes in production of resins, rubbers, polymers

ERC3 Formulation into solid matrix

ERC12b Processing of articles at industrial sites with high release

ERC12c Use of articles at industrial sites with low release

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

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

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

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

ERC9a Widespread use of functional fluid (indoor)

ERC9b Widespread use of functional fluid (outdoor)

ERC12a Processing of articles at industrial sites with low release

ERC1 Manufacture of the substance

ERC2 Formulation into mixture

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

ERC7 Use of functional fluid at industrial site

ERC11a Widespread use of articles with low release (indoor)

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

· **Article category**

AC1 Vehicles

AC10a: Rubber articles: Large surface area articles

AC5 Fabrics, textiles and apparel

AC13 Plastic articles

AC8 Paper articles

AC11 Wood articles

AC4 Stone, plaster, cement, glass and ceramic articles

AC6 Leather articles

· **Technical function** Pigment

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

It is used as a dye in accordance with good agricultural practices as inert (or occasionally active) ingredients in pesticide formulations.

As a dye for wool and silks; as colorant in food, drugs and cosmetics. In biochemistry as an adsorption-elution indicator for chloride estimations.

· **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**
1934-21-0 trisodium 5-hydroxy-1-(4-sulphophenyl)-4-(4-sulphophenylazo)pyrazole-3-carboxylate
- **Identification number(s)**
- **EC number:** 217-699-5
- **Additional information:**
Molecular Formula: C₁₆H₁₂N₄O₉S₂.3Na
Molecular Weight: 534.4 g/mol
- **SVHC** The substance is not in the SVHC list.

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
 - **General information:** Seek medical assistance if discomfort continues
 - **After inhalation:**
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.
 - **After skin contact:**
In case of contact, flush skin with plenty of water. Remove contaminated clothing and shoes.
 - **After eye contact:**
In case of contact, immediately flush eyes with plenty of water for a t least 15 minutes.
 - **After swallowing:**
Rinse mouth with water. Never give anything by mouth to an unconscious person. if any symptoms happen
 - **Information for doctor:** Treat symptomatically and supportively.
 - **4.2 Most important symptoms and effects, both acute and delayed**
- Eye:** May cause mild eye irritation. This product contains an anionic dye. Similar dyes have not caused injury to the cornea or conjunctiva in documented exposure cases with human or rabbit eyes.
- Skin:** May cause skin irritation. FD&C Yellow 5 has been found to cause an allergic reaction in certain susceptible people.
- Ingestion:** May cause irritation of the digestive tract. May cause gastric disturbances and electrolytic imbalance. The toxicological properties of this substance have not been fully investigated. May cause changes in teeth and supporting structures.
- Inhalation:** The toxicological properties of this substance have not been fully investigated. Inhalation of dust may cause respiratory tract irritation.

- **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 water spray, alcohol-resistant foam, dry chemical or carbon dioxide
- **5.2 Special hazards arising from the substance or mixture**
In case of fire, the following can be released:
Nitrogen oxides (NOx)
Carbon monoxide (CO)
Carbon dioxide (CO2)
- **5.3 Advice for firefighters**
- **Protective equipment:** *Use self contained breathing apparatus and protective clothing.*

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
use breathing equipment if fumes or powders are released into the air. These indications apply for both processing staff and those involved in emergency procedures.
- **6.2 Environmental precautions:**
Do not allow to enter sewers/ surface or ground water.
The product must not penetrate into the sewer system or come into contact with surface water or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Confine using earth or inert material. Collect as much material as possible and eliminate the rest using jets of water.
- **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**
Before handling the product, consult all the other sections of this material safety data sheet.
Avoid leakage of the product into the environment. Do not eat, drink or smoke during use.
Wash thoroughly after handling. Remove contaminated clothing and wash before reuse.
Avoid contact with eyes, skin, and clothing. Avoid ingestion and inhalation

· **Information about fire - and explosion protection:**

Protect from heat.

Keep ignition sources away - Do not smoke.

· **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. Keep container close while not in use.

· **Information about storage in one common storage facility:**

Keep container tightly closed in a dry and well-ventilated place.

· **Further information about storage conditions:**

keep the product in clearly labelled containers. Keep containers away from any incompatible materials, see section Stability and reactivity for details. Keep container tightly sealed.

· **7.3 Specific end use(s)**

It is used as a dye in accordance with good agricultural practices as inert (or occasionally active) ingredients in pesticide formulations.

As a dye for wool and silks; as colorant in food, drugs and cosmetics. In biochemistry as an adsorption-elution indicator for chloride estimations.

SECTION 8: Exposure controls/personal protection

· **8.1 Control parameters**

During the risk assessment process, it is essential to take into consideration the ACGIH occupational exposure levels for inert particulate otherwise classified (PNOC respirable fraction: 3 mg/m³; PNOC inhalable fraction: 10 mg/m³). For values above these limits, use a P type filter, whose class (1, 2 or 3) must be chosen according to the outcome of risk assessment.

TLV of solvent mixture: 10 mg/m³.

· **Additional information about design of technical facilities:** No further data; see item 7.

· **Ingredients with limit values that require monitoring at the workplace:** Not required.

· **DNELs**

Data for Workers

-Hazard via inhalation route

Long-term: (DNEL) 372.52 mg/m³ developmental toxicity / teratogenicity

-Hazard via dermal route

Long-term: (DNEL) 52.82 mg/kg bw/day developmental toxicity / teratogenicity through dermal exposure

Data for General Population

- Hazard via inhalation route

Long-term: (DNEL) 91.86 mg/m³ developmental toxicity / teratogenicity

- Hazard via dermal route

Long-term: (DNEL) 26.41 mg/kg bw/day developmental toxicity / teratogenicity

- Hazard via oral route

Long-term: (DNEL) 26.41 mg/kg bw/day developmental toxicity / teratogenicity

· **PNECs**

Hazard for Aquatic Organisms

Freshwater 120 µg/L

Intermittent releases (freshwater) 1.2 mg/L

Marine water 12 µg/L (1)

Intermittent releases (marine water) -

Sewage treatment plant (STP) 10 mg/L

Sediment (freshwater) 469.92 µg/kg sediment dw

Sediment (marine water) 46.992 µg/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:** *Not necessary if room is well-ventilated.*

· **Protection of hands:**

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

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:** *If contact is likely, safety glasses with side shields are recommended.*

· **Body protection:** *Protective work clothing*

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form:

Solid

Powder

Colour:

Light Orange Powder

· **Odour:**

Characteristic

· **Odour threshold:**

Not available

· **Change in condition**

Melting point/freezing point:

Not Applicable

Initial boiling point and boiling range:	909.54 °C (RA data)
· Flash point:	Flash point is a property of liquid or solids with a very high vapour pressure. The substance is a solid with very low vapour pressure
· Flammability (solid, gas):	non flammable
· Decomposition temperature:	> 314 - < 391 °C (RA data)
· Explosive properties:	The tested substance could be considered as a not-explosive substance
· Explosion limits:	
· Upper:	
· Oxidising properties	No oxidizing properties.
· Vapour pressure at 25 °C:	7.94E-021 Pa.(RA data)
· Bulk Density:	0.5-0.7 g/cm ³ (After tapping)
· Solubility in / Miscibility with water at 25 °C:	200.0 g/l
· Partition coefficient: n-octanol/water at 20 °C:	-1.572 (Shake flask method)
· 9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

· 10.1 Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

· **10.2 Chemical stability** The product is stable in normal conditions of use and storage.

· **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**

none in particular, however, the usual precautions used for chemical products should be respected

· **10.5 Incompatible materials:** information not available.

· **10.6 Hazardous decomposition products:**

Nitrogen oxides

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	LD 50	> 2000 mg/kg bw (Mouse)
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· **Primary irritant effect:**

· **Skin corrosion/irritation**

The results show no irritation on human skin therefore the tested item is to be considered as non-irritant to skin under CLP classification.

· **Serious eye damage/irritation**

All animals were free of significant signs of ocular irritation other than slight conjunctival redness (score of 1) or discharge (score of 1 or 2) seen sporadically in the eyes of both test and control animals throughout the study.

The tested substance is considered to be not irritant for the rabbits eyes based on the results under Regulation 1272/2008.

· **Respiratory or skin sensitisation**

The purpose of this skin sensitization study was to assess the allergenic potential of test chemical when administered to the skin of CBA mice following OECD 429, murine local lymph assay.

Based on the results, the tested item should not be considered as skin sensitizer under defined experimental conditions in the two vehicles tested.

· **Additional toxicological information:**

· **Toxicokinetics, metabolism and distribution**

Based on the data available, test chemical undergoes to a metabolic degradation into metabolites which are excreted by urine and faeces and therefore test chemical can be considered as not-bioaccumulative.

· **Repeated dose toxicity**

There were no consistent, biologically significant compound or dose-related effects on behaviour, morbidity, mortality, haematology, or general physical observations in repeated dose toxicity study.

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

· **Germ cell mutagenicity**

Under the experimental conditions, the test item did not show mutagenicity activity in the bacterial reverse mutation test with *Salmonella typhimurium* and *Escherichia coli* test chemical could be considered not mutagenic.

· **Carcinogenicity**

Six carcinogenicity studies reviewed by JEFCA are reported in Efsa report on Acid Yellow 23 but there are more recent studies reviewed in 2002.

The publication of Maekawa et al (1987) and Borzelleca and Hallagan (1988) were evaluated for the assessment of the carcinogenicity.

No evidence of carcinogenicity was observed in all of the studies.

Test Chemical does not have a potential to induce benign or malignant neoplasias.

· **Reproductive toxicity**

Lifetime exposure of rats to the tested substance as a dietary admixture at levels up to 5.0% did not demonstrate toxic effects.

· **STOT-single exposure** Based on available data, the classification criteria are not met.

· **STOT-repeated exposure** Based on available data, the classification criteria are not met.

· **Aspiration hazard** Based on available data, the classification criteria are not met.

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:**

EC 50 (48 hrs)

125 mg/L (*Daphnia Magna*)

EC50 (72 hrs)

125 mg/L (*Algae*) (*Desmodesmus subspicatus*)

LC 50 (96 hrs) (static)

> 120 mg/L (*Danio rerio*)(RA data)

· **12.2 Persistence and degradability**

Ready biodegradability was tested on similar substance following OECD 301 B. The biodegradation resulted to be between 30 and 40 % in the CO₂ evolution test and this values correspond to the results: "not readily biodegradable".

This results were confirmed by the estimation of ready biodegradability on test chemical. Based on the above considerations, test chemical could be considered as not readily biodegradable.

· **12.3 Bioaccumulative potential** No further relevant information available.

· **12.4 Mobility in soil**

Based on the estimated value and the low value of Log Kow, the tested substance should not be absorbed to the substrate. [LogKoc: -4.228]

· **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**

The disposal must be made in conformity with actual rules, in authorized dump or thermodistructions plant. Do not empty into waters or drains.

· **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** *Not Regulated*

· **14.4 Packing group**

· **ADR, IMDG, IATA** *Not Regulated*

· **14.5 Environmental hazards:**

Not Regulated.

· **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*

· **Precautionary statements** *Not applicable*

· **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
- Mexico - National Inventory of Chemical Substances-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

· **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

-ECHA <https://echa.europa.eu/substance-information/-/substanceinfo/100.016.091>
-Toxplanet <https://chemical-search.toxplanet.com//product-search/listexpert/ei-fts-search/9a145883-dc76-4e73-a398-21142f8e4941>
· **Data compared to the previous version altered.**

- *Section 3: Composition /Information on Ingredients*
- *Section 9: Physical and Chemical properties.*
- *Section 11: Toxicological Information.*
- *Section 12: Ecological Information.*

Disclaimer & Caution

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