



**COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006**

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

· **1.1 Product identifier**

· **Trade name:** Neelicert FD&C Blue 2

· **CAS Number:**

860-22-0

· **EC number:**

212-728-8

· **1.2 Relevant identified uses of the substance or mixture and uses advised against**

· **Product category**

PC 3 Air care products

PC 28 Perfumes, fragrances

PC 31 Polishes and wax blends

PC 35 Washing and cleaning products

PC 39 Cosmetics, personal care products

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

\*Cosmetics and personal care products

\*Air care products

\*Coating products

\*Inks and toners

\*Perfumes and fragrances

\*Polishes and waxes

· **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

**Trade name: Neelicert FD&C Blue 2**

## SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



*Skin Sens. 1 H317 May cause an allergic skin reaction.*

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
*The substance is classified and labelled according to the CLP regulation.*
- **Hazard pictograms**



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- **Signal word** *Warning*
- **Hazard statements**  
*H317 May cause an allergic skin reaction.*
- **Precautionary statements**  
*P261 Avoid breathing dust/fume/gas/mist/vapours/spray.*  
*P280 Wear protective gloves.*  
*P362+P364 Take off contaminated clothing and wash it before reuse.*  
*P333+P313 If skin irritation or rash occurs: Get medical advice/attention.*  
*P321 Specific treatment (see on this label).*  
*P501 Dispose of contents/container in accordance with local/regional/national/international regulations.*
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** *No further relevant information available.*
- **vPvB:** *No further relevant information available.*

## SECTION 3: Composition/information on ingredients

- **3.1 Chemical characterisation: Substances**
- **CAS No. Description**  
*860-22-0 Indigo Carmine*
- **Identification number(s)**
- **EC number:** *212-728-8*

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· **Additional information:**

*Molecular formula: C<sub>16</sub>H<sub>8</sub>N<sub>2</sub>Na<sub>2</sub>O<sub>8</sub>S<sub>2</sub>*

*Molecular Weight: 466.36*

*IUPAC: 1H-Indole-5-sulfonic acid, 2-(1,3-dihydro-3-oxo-5-sulfo-2H-indol-2-ylidene)-2,3-dihydro-3-oxo-, disodium salt*

*Synonym: Disodium 5,5'-(2-(1,3-dihydro-3-oxo-2H-indazol-2-ylidene)-1,2-dihydro-3H-indol-3-one) disulphonate,*

*3,3'-dioxo-2,2'-bis-indolyden-5,5'-disulfonic acid disodium salt*

· **SVHC** the substance is not listed in current SVHC list.

## **SECTION 4: First aid measures**

· **4.1 Description of first aid measures**

· **General information:**

*Do not leave affected persons unattended.*

*First aid personnel should pay attention to their own safety.*

*Move out of dangerous area*

· **After inhalation:**

*After inhalation of greater quantities of dust, take affected person to fresh air.*

*Encourage patient to blow nose to ensure clear passage of breathing.*

*Maintain an open airway.*

· **After skin contact:**

*Generally, the product does not irritate the skin.*

*If skin irritation or rash occurs: Get medical advice/attention.*

*In case of contact with skin, clean with soap and water.*

*Remove contaminated clothing.*

· **After eye contact:**

*Check and remove contact lenses, if present and easy to do.*

*Eyelids should be held away from the eyeball to ensure thorough rinsing.*

*Wash eye under running water for several minutes.*

· **After swallowing:**

*Keep person warm and at rest.*

*Do not induce vomiting*

*Get medical attention if any discomfort continues.*

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

· **4.2 Most important symptoms and effects, both acute and delayed**

*May cause allergic skin reaction.*

· **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:**  
*powder or water spray.*  
*Fight larger fires with water spray or alcohol resistant foam.*
- **For safety reasons unsuitable extinguishing agents:** *Water with full jet*
- **5.2 Special hazards arising from the substance or mixture**  
*carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>), sulfur oxides (SO<sub>x</sub>), other pyrolysis products typical of burning organic material.*
- **5.3 Advice for firefighters**  
*Use standard fire fighting procedures.*  
*If safe to do so, remove containers from path of fire.*  
*Use water delivered as a fine spray to control fire and cool adjacent area.*
- **Protective equipment:**  
*Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus.*

### **SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures**  
*Ensure adequate ventilation*  
*Avoid formation of dust.*  
*Avoid inhalation of dusts.*  
*Wear protective equipment.*  
*Keep unprotected persons away.*
- **6.2 Environmental precautions:**  
*If the product contaminates rivers and lakes or sewers inform respective authorities.*  
*Do not allow to enter sewers/ surface or ground water.*
- **6.3 Methods and material for containment and cleaning up:**  
*Sweep up, shovel up or vacuum up (consider explosion-proof machines designed to be grounded during storage and use).*  
*Place spilled material in clean, dry, sealable, labeled container.*
- **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 direct contact with the substance.*  
*Ensure good ventilation/exhaustion at the workplace.*

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Prevent formation of dust.  
Avoid contact with eyes and skin.

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- **Information about fire - and explosion protection:**  
Normal measures for preventive fire protection.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**  
Check all containers are clearly labelled and free from leaks.  
Keep containers securely sealed  
Store in ambient temperature and dry Place. Keep container close while not in use.
- **Information about storage in one common storage facility:**  
keep away from food materials  
Isolate from incompatible material.  
Maintain an ambient temperature ,dry,ventilated conditions for storage. Should be periodically inspected.
- **Further information about storage conditions:**  
To maintain product quality, do not store in heat or direct sunlight.  
Keep away from oxidizing agents i.e., nitrates, oxidizing acids, chlorine bleaches
- **7.3 Specific end use(s)** No further relevant information available.

**SECTION 8: Exposure controls/personal protection**

- **8.1 Control parameters**
- **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.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.  
Good personal hygiene practices should be followed.  
Contaminated clothing should be thoroughly cleaned.  
Keep away from foodstuffs, beverages, and feed.  
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:**  
Use suitable respiratory protective device in case of insufficient ventilation.
- **Protection of hands:**



Protective gloves

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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:**



Tightly sealed goggles

Chemical safety goggles

· **Body protection:** Standard work wear and safety boots for normal handling and use.

## SECTION 9: Physical and chemical properties

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

· **General Information**

**Appearance:**

Solid

· **Form:**

Powder

· **Colour:**

Dark blue

· **Odour:**

Odourless

· **pH-value :**

5 – 7.5

· **Change in condition**

**Melting point/freezing point:**

Not applicable

**Initial boiling point and boiling range:**

Not applicable

· **Flash point:**

>250 °C (closed cup (ISO 2719))

· **Flammability (solid, gas):**

Product is not flammable.

· **Decomposition temperature:**

> 340 °C

· **Auto-ignition temperature:**

Product is not selfigniting.

· **Explosive properties:**

Product does not present an explosion hazard.

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· <b>Explosion limits:</b>	
· <b>Upper:</b>	
<b>Oxidising properties</b>	No oxidizing properties.
· <b>Vapour pressure at 25 °C:</b>	3.16E-022 mmHg
· <b>Bulk Density :</b>	0.6-0.95 g/cm <sup>3</sup> (After tapping)
· <b>Solubility in / Miscibility with water at 26 °C:</b>	14.0 g/l
· <b>Partition coefficient: n-octanol/water at 25 °C:</b>	-3.57 log POW
· <b>9.2 Other information</b>	The mean pour density and tapped density of the test item was found to be 0.666 g/cm <sup>3</sup> and 0.714 g/cm <sup>3</sup> at 29.05 °C and 965.05 hPa.

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability** Stable at ambient temperature and under normal conditions of use.
- **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**  
Avoid contact with incompatible materials.  
contact with incompatible materials.
- **10.5 Incompatible materials:**  
oxidizing agents i.e., nitrates, oxidizing acids, chlorine bleaches.
- **10.6 Hazardous decomposition products:**  
Carbon dioxide  
Sulphur oxides (SO<sub>x</sub>)  
Carbon monoxide

### 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	2500 mg/Kg (mouse)
		> 3000 mg/kg (rat)



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- **Primary irritant effect:**
- **Skin corrosion/irritation** No irritating effect
- **Serious eye damage/irritation** No irritating effect
- **Respiratory or skin sensitisation**

May cause an allergic skin reaction.

The indigo carmine compound was patch tested for the allergy in the 204 (191 male and 13 female) workers from 15 Italian feed mills. 1% test substance in petrolatum was applied on back of workers using Scanpor tape for 48 hr. Reactions were read at 48 and 96 h according to the ICDRG scale. Indigo carmine shows positive reaction in two cases. 3 workers (workers with cutaneous complaints (contact dermatitis or pruritus sine materia)) show positive reaction and 2 workers (workers without cutaneous complaints) shows positive reaction. Hence, the substance indigo carmine is reported to be skin sensitizing to human.

- **Additional toxicological information:**
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity**

The substance is considered to be not mutagenic in *Salmonella typhimurium* strain TA1535, TA1537, TA1538, TA98 and TA100 with and without metabolic activation.

- **Carcinogenicity** No Further relevant information available.
- **Reproductive toxicity**  
NOAEL: 1 282 mg/kg bw/day (male)  
NOAEL: 1 592 mg/kg bw/day (female)  
No effect on survival, body weight, food consumption, ophthalmoscopic examinations, hematology, clinical chemistry, urine-analysis, organ weights, gross pathology and histopathology
- **STOT-single exposure** No Further relevant information available.
- **STOT-repeated exposure** No Further relevant information available.
- **Aspiration hazard** No Further relevant information available.

## SECTION 12: Ecological information

### · 12.1 Toxicity

#### · **Aquatic toxicity:**

Justification for non-classification: The substance is not classified for aquatic toxicity, as it is found to be readily biodegradable.

48h-EC50	2 383.851mg/L ( <i>Daphnia magna</i> ) (estimated (Q)SAR)
72h-EC50	2.079 mg/L ( <i>Chlorella vulgaris</i> ) (OECD TG 201)

- **12.2 Persistence and degradability** the substance is readily biodegradable
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.



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- **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:** No further relevant information available
- **vPvB:** No further relevant information available.
- **12.6 Other adverse effects** No further relevant information 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:**  
Packagings that may not be cleansed are to be disposed of in the same manner as the product.  
Dispose of packaging according to regulations on the disposal of packaging.

### SECTION 14: Transport information

- |                                                                                  |                 |
|----------------------------------------------------------------------------------|-----------------|
| · <b>14.1 UN-Number</b>                                                          |                 |
| · <b>ADR, ADN, IMDG, IATA</b>                                                    | Not regulated   |
| · <b>14.2 UN proper shipping name</b>                                            |                 |
| · <b>ADR, ADN, IMDG, IATA</b>                                                    | Not regulated   |
| · <b>14.3 Transport hazard class(es)</b>                                         |                 |
| · <b>ADR, ADN, IMDG, IATA</b>                                                    |                 |
| · <b>Class</b>                                                                   | Not regulated   |
| · <b>14.4 Packing group</b>                                                      |                 |
| · <b>ADR, IMDG, IATA</b>                                                         | Not regulated   |
| · <b>14.5 Environmental hazards:</b>                                             |                 |
| · <b>Marine pollutant:</b>                                                       | No              |
| · <b>14.6 Special precautions for user</b>                                       | Not applicable. |
| · <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable. |

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· **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**  
The substance is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard statements**  
H317 May cause an allergic skin reaction.
- **Precautionary statements**  
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
P280 Wear protective gloves.  
P362+P364 Take off contaminated clothing and wash it before reuse.  
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.  
P321 Specific treatment (see on this label).  
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**  
Australia-AIIC: Listed  
China-IECSC: Listed  
Danish DK-EPA: Listed  
Canada-DSL: Listed  
US-EPA TSCA: Listed  
EU-EINECS: Listed  
Japan Food Sanitation Law - List of Designated Additives: Listed  
KEMI List of Substances on the Market: Listed  
Korea – KE Number: KE-10733  
Mexico - National Inventory of Chemical Substances: Listed  
New Zealand-NZIoC: Listed  
Philippine-PICCS: Listed  
Taiwan-TCSI: Listed

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- **Substances of very high concern (SVHC) according to REACH, Article 57**  
The substance is not listed in current SVHC List.
- **15.2 Chemical safety assessment:**  
A Chemical Safety Assessment has not been carried out.

### 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)

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

Skin Sens. 1: Skin sensitisation – Category 1

#### • **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 ECHA Dossier:

<https://echa.europa.eu/registration-dossier/-/registered-dossier/17362/>

- Data from Toxplanet:

<https://chemical-search.toxplanet.com//product-search/listexpert/ei-fts-search/f33be1e6-12e7-4946-9352-f901ff179c15>

#### • **\* Data compared to the previous version altered.**

- Section 1: Identification of the substance/mixture and of the company/undertaking
- Section 2: Hazard Identification
- 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.

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- *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*
- *Section 13: Disposal consideration*
- *Section 14: Transport information*
- *Section 15: Regulatory information*
- *Section 16: Other information*

**Disclaimer & Caution**

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