

Date: September 6, 2023

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: D & C Green 8

· CAS Number:

6358-69-6

· EC number:

228-783-6

- Registration number 01-2120115886-50-0000
- 1.2 Relevant identified uses of the substance or mixture and uses advised against
- · Life cycle stages

IS Use at industrial Sites

PW Widespread use by professional workers

F Formulation or re-packing

· Sector of Use

- SU3 Industrial uses: Uses of substances as such or in preparations at industrial sites
- SU 5 Manufacture of textiles, leather, fur.
- SU 6a Manufacture of wood and wood products.
- SU 7 Printing and reproduction of recorded media.
- SU9 Manufacture of fine chemicals
- SU 10 Formulation [mixing] of preparations and/or re-packaging (excluding alloys).
- SU 22 Professional uses: Public domain (administration, education, entertainment, services, craftsmen)
- SU23 Electricity, steam, gas water supply and sewage treatment
- SU 0 Other: Preservation and sanitation agent.

Product category

- PC3 Air care products
- PC 4 Anti-freeze and de-icing products
- PC 17 Hydraulic fluids
- PC 18 Ink and toners
- PC 19 Intermediate
- PC 21 Laboratory chemicals
- PC35 Washing and cleaning products (including solvent based products)
- PC 39 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
- PROC4 Chemical production where opportunity for exposure arises
- PROC5 Mixing or blending in batch processes
- PROC 6 Calendering operations.
- PROC7 Industrial spraying



Date: September 6, 2023

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

PROC19 Manual activities involving hand contact

· Environmental release category

ERC 1 Manufacture of the substance.

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.

ERC6a Use of intermediate

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

ERC8a Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor)

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).

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

ERC10a Widespread use of articles with low release (outdoor)

ERC11a Widespread use of articles with low release (indoor)

· Article category

AC 8 Paper articles

AC 13 Plastic articles

· Application of the substance / the mixture

manufacturing of the substance.

used as a Laboratory chemical.

used in automotive care products, paints and coating or adhesives, fragrances and air fresheners, inks and toners, food packaging material, cosmetics, and personal care products. Used in water systems to detect leakages.

· 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



Date: September 6, 2023

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

6358-69-6 trisodium 8-hydroxypyrene-1,3,6-trisulphonate

- Identification number(s) EC number: 228-783-6
- · Additional information:

Molecular Formula: C16-H7-O10-S3.3Na

Molecular Weight: 524.37 g/mol

IUPAC Name: Trisodium 8-hydroxypyrene-1,3,6-trisulphonate

Synonyms: Neelink - Solvent Green 7

C.I. 59040 Pyranine



Date: September 6, 2023

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · General information:

First aid personnel should pay attention to their own safety.

Do not leave affected persons unattended.

· 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.

· After skin contact:

Generally, the product does not irritate the skin.

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

· After eye contact:

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

Rinse opened eye for several minutes under running water.

· After swallowing:

Clean mouth by gargling with water.

Do not induce vomiting

Drink plenty of 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:

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 (CO2), sulfur oxides (SOx), 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.



Date: September 6, 2023

· 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.

Wear protective equipment. Keep unprotected persons away.

6.2 Environmental precautions:

Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

If the product contaminates rivers and lakes or sewers inform respective authorities.

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 contact with eyes.

Any unavoidable deposit of dust must be regularly removed.

Do not eat, drink, or smoke while using this product.

Provide appropriate exhaust ventilation at places where dust is formed.

· 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.

Store in ambient temperature and dry Place.

Provide proper ventilation/exhaustion.

Information about storage in one common storage facility:

keep away from food materials

keep away from oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches



Date: September 6, 2023

· Further information about storage conditions:

Store in dry conditions.

Check regularly for leaks.

Caution when reopening receptacles with broken seal.

· 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.

· DNELs

Data for WORKERS INHALATION Exposure

Systemic Effects Long-term: (DNEL) 16.4 mg/m³ developmental toxicity / teratogenicity

DERMAL Exposure

Systemic Effects Long-term: (DNEL) 30 µg/kg bw/day repeated dose toxicity

Data for the GENERAL POPULATION

INHALATION Exposure

Systemic Effects Long-term: (DNEL) 2.9 mg/m³ developmental toxicity / teratogenicity

DERMAL Exposure

Systemic Effects Long-term: (DNEL) 3.57 µg/kg bw/day repeated dose toxicity

ORAL Exposure

Systemic Effects Long-term: (DNEL) 1.67 mg/kg bw/day developmental toxicity /

teratogenicity

PNECs

Hazard for Aquatic Organisms

Freshwater: 100 µg/L

Intermittent releases (freshwater): 1 mg/L

Marine water: 10 µg/L

Intermittent releases (marine water): 100 µg/L Sewage treatment plant (STP): No hazard identified Sediment (freshwater): 2.06 mg/kg sediment dw Sediment (marine water): 206 µg/kg sediment dw

Hazard for Terrestrial Organism

Soil: 353 µg/kg soil 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:

Use suitable respiratory protective device in case of insufficient ventilation.



Date: September 6, 2023

· Protection of hands:



Protective gloves

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

Safety glasses

· 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: Greenish Yellow
Odour: Characteristic
Odour threshold: Not applicable

• **pH-value**: 5 - 7 (1% Solution in Water)

· Change in condition

Melting point/freezing point: 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

temperature.



Date: September 6, 2023

Flammability (solid, gas):	Product is not flammable.
Decomposition temperature:	252 -258.5 °C
Explosive properties:	Product does not present an explosion hazard
Explosion limits:	
Lower:	Not applicable
Upper:	Not applicable
Oxidising properties	non oxidising
· Vapour pressure:	Vapour pressure value could not be
•	determined as the substance decomposes
Bulk Density:	0.5 - 0.8 g/cm³(After tapping)
· Evaporation rate	Not applicable
Solubility in / Miscibility with	
water at 31 °C:	100.0 g/l
· Partition coefficient: n-octanol/water	at 25
°C:	-3.97 log POW
9.2 Other information	Particle size distribution (Granulometry): The particle size distribution was determined to be in the range of 150 micron to 25 micron.

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

Under normal conditions of storage and use, hazardous reactions will not occur.

- · 10.4 Conditions to avoid contact with incompatible materials.
- 10.5 Incompatible materials: oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches
- · 10.6 Hazardous decomposition products: carbon monoxide (CO), carbon dioxide (CO2), sulfur oxides (SOx), other pyrolysis products typical of burning organic material.



Date: September 6, 2023

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 >15000 mg/kg bw (rat (Wistar)male) (OECD TG 401)

Dermal LD50 >2000 mg/kg bw (rat (Sprague-Dawley)male/female) (OECD TG 402)

- Primary irritant effect:
- · Skin corrosion/irritation

A study was performed to evaluate the dermal irritation potential of the test chemical in rabbits. 6 rabbits were used for the study. The animals were conventionally kept in single cages and were given an appropriate diet and tap water ad libitum. Only animals with uninjured skin were used. Each animal was given approximately 0.5 g of the test sample diluted with water on a plaster bandage fixed on the shaved back skin. The back skin not treated with the test chemical served as a control. After removing the dressing, the exposed areas of the skin were washed with soap and water. The exposure time was 24 h. The follow-up time was 7 days. The findings were collected 24 and 72 hours after the end of exposure, even after 7 days. The extent of erythema or edema formation according to DRAIZE and all other conspicuous findings were recorded. The mean erythema and edema scores were 0,0 respectively. The test chemical was considered not irritating to rabbit skin.

Serious eye damage/irritation

The eye potential of the test chemical was evaluated in rabbits. Following application of the neat test material, all animals showed slight conjunctival redness which in five of 6 animals was completely reversible within 72 hours, and in one animal within 7 days. In two animals, very slight tear flow occurred after application which also was completely reversible within 48 hours. Following application of a 30% aqueous solution of the test material, all animals showed slight conjunctival redness (max. score 1) one hour after application which was completely reversible within 24 hours. Following application of a 3% aqueous solution, three animals showed slight conjunctival redness (max. score 1) at 24 hours after application which was completely reversible within 48 hours. Since the observed effects were reversible by 7 days, the test chemical can considered to be not irritating to rabbit eyes.

Respiratory or skin sensitisation

Skin sensitisation:

The sensitization potential of D&C Green 8 was determined by performing patch tests on humans.

The dye was applied in Finn Chambers and read first at 2 or (more commonly) 3 days and again at 4–7 days. The reactions of the patients were graded as '?+ ', '+' and '++' categories. 9 patients were tested with the dye. No reactions were reported by all the patients D&C Green 8 can be considered as a non- sensitizer in humans.

- · Additional toxicological information:
- · Repeated dose toxicity

Repeated dose toxicity: Oral

90 days toxicity study was conducted in rats with test substance fed at dietary levels of 50,500 and 5000mg/kg/day. (100, 1000, 10000 ppm) Therefore No Observed Adverse Effect



Date: September 6, 2023

Level (NOAEL) for repeated oral administration of test substance in rats was considered to be 500mg/kg bw for 90 days by oral feed.

Repeated dose toxicity: dermal

In a two-year study 60 mice were applied once a week with 3.5 mg substance (0.05 ml of a 7% solution) for 2 years. The No Observed Adverse Effect Level (NOAEL) for repeated dermal exposure to test substance in 60 mice for 2 years is 3.5 mg (0.05 ml of a 7% solution)

Result: Based on the data for the test chemical, Solvent Green 7 is not likely to exhibit repeated dose toxicity.

· CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)

· Germ cell mutagenicity

In vitro mammalian chromosome aberration test for 7-amino-4-hydroxynaphthalene-2-sulphonic acid in chinese hamster lung cells was found to be negative.

In-vitro bacterial reverse mutation assay test for 7-amino-4-hydroxynaphthalene-2-sulphonic acid on Salmonella typhimurium strains TA 100; TA 1535; TA 1537; TA; TA 97; without S9 metabolic activation does not exhibit positive gene mutation effect.

· Carcinogenicity No further relevant information available.

Reproductive toxicity

Reproductive toxicity study

NOAEL was considred to be 500mg/kg bw/day for F0, F1 and F2 generation. When male and female Charles River CD rats were treated with test material orally. no treatment-related effects were reported on survival. No treatment-related changes were reported at gross necropsy. There were no substance related effects on fertility, gestation, pup viability or lactation indices, on reproductive organs of females, or on organ weights among parents and offspring.

There was no toxicity to either the F1 or F2 generation.

STOT-single exposure

Oral:

No symptoms were observed after single doses of 5000 and 15000 mg/kg. Growth was not delayed in either treatment group.

Dermal:

Administration of the test item at 2000 mg/kg did not result in any signs of toxicity and mortality during the study period of 14 days. Animals exhibited normal body weight gain through the study period.

Gross pathological examination did not reveal any abnormalities attributable to the treatment.

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

· Aspiration hazard

The particle size distribution of test substance was determined to be in the range of 150 micron to 25 microns. Thus, it is concluded that the majority of the particle size of the chemical is is not in the inhalable size which is less than 10 microns.

exposure to humans via inhalation route is not likely taking into account due to the low vapour pressure of the test chemical.



Date: September 6, 2023

Based on available data, test chemical is unlikely to cause aspiration hazard.

- 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 hazards: No further information is available

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:

48h-EC50 | 500.3 mg/L (Daphnia magna) (OECD TG 202)

96h-LC50 | >100 mg/L (Danio rerio) (OECD TG 203)

12.2 Persistence and degradability

Biodegradation in water: screening tests

The test chemical undergoes 38.59 % biodegradation after 28 days in the test condition.

Thus, the test item was considered to be primary inherently biodegradable.

· 12.3 Bioaccumulative potential

Bioaccumulation endpoint can also be considered for waiver as per in accordance with column 2 of Annex IX of the REACH regulation, testing for this endpoint is scientifically not necessary and does not need to be conducted since the test chemical has a low potential for bioaccumulation based on $\log Kow \le 3$.

· 12.4 Mobility in soil

The sorption of test chemical on natural sediment was evaluated by a series of batch experiments on solution of different salinities. Percent adsorption of test chemical was 29–53% (0.01 DSW), 38–59% (0.5 DSW) and 64–88% (DSW), except for sample B3 (41%, 83% and 98%, 0.01 DSW, 0.5 DSW and DSW, respectively). On the basis of this, test chemical has low to moderate sorption on sediments and therefore have moderate to slow migration potential to groundwater.

- 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 effects :** No further relevant information available.

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

· Recommendation

Consult state, local or national regulations to ensure proper disposal. Smaller quantities can be disposed of with household waste.



Date: September 6, 2023

- · Uncleaned packaging:
- Recommendation:

Dispose of packaging according to regulations on the disposal of packaging.

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: Marine pollutant:	No
14.6 Special precautions for user	Not applicable.
14.7 Transport in bulk according to Ai II of Marpol and the IBC Code	nnex Not applicable.
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 Not applicable
- Signal word Not applicable
- Hazard statements Not applicable
- Precautionary statements Not applicable
- · Other regulations, limitations, and prohibitive regulations

Australia-AIIC: Listed China-IECSC: Listed Canada-DSL: Listed US-EPA STCA: Listed



Date: September 6, 2023

Taiwan-TCSI: Listed EU-EINECS: Listed ECHA-Annex III: Listed Philippine-PICCS: Listed New Zealand-NZIoC: Listed Korea-KE Number: KE-08552

Thailand-First Existing Chemicals Inventory: Listed Vietnam National Chemical Inventory (Draft): Listed EU - Cosmetic Ingredients and Fragrance Inventory: Listed Mexico-National Inventory of Chemical Substances: Listed

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:

Chemical Safety Report not required as the substance is not classified.

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:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organisation

ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)

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



Date: September 6, 2023

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

- Data from ECHA Dossier for CAS 6358-69-6:

https://echa.europa.eu/registration-dossier/-/registered-dossier/17360/1/1

- Data from ToxPlanet:

https://chemical-search.toxplanet.com//product-search/chem-id/ei-fts-search/cfcc2d4d-d7ad-4e3c-83d3-8092b2dfaa60

- Data compared to the previous version altered.
- Section 1: Identification of substance and company
- Section 2: Hazards classification
- Section 3: Composition /information on ingredient
- 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.
- Section 13: Disposal consideration.
- Section 14: Transport information
- Section 15: Regulatory Information
- Section 16: Other information

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