NEELIKON FOOD DYES & CHEMICALSLTD.
Safety data sheet
COMMISSION REGULATION (EU) No 2015/830 of 1 June 2015 amending Annex II of Regulation (EU) No 453/2010

Issue date 30.04.2018 *Date of Revision: 01.09.2018* *Due Date of Revision: 31.08.2020*

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

· **Trade name: Neelicert FD & C Blue 1 Lake.**
· **CAS Number:**
68921-42-6
· **EC number:**
272-939-6
· **Registration number 01-2119937767-21-0001.**
· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
· **Sector of Use**
SU0 Other
SU6b Manufacture of pulp, paper and paper products
SU24 Scientific research and development
SU5 Manufacture of textiles, leather, fur
SU19 Building and construction work
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
SU1 Agriculture, forestry, fishery
SU4 Manufacture of food products
· **Product category**
PC1 Adhesives, sealants
PC3 Air care products
PC8 Biocidal products (e.g. Disinfectants, pest control)
PC9a Coatings and paints, thinners, paint removers
PC9b Fillers, putties, plasters, modelling clay
PC9c Finger paints
PC12 Fertilisers
PC18 Ink and toners
PC21 Laboratory chemicals
PC27 Plant protection products
PC28 Perfumes, fragrances
PC31 Polishes and wax blends
PC35 Washing and cleaning products (including solvent based products)
PC0 Other
PC39 Cosmetics, personal care products
· **Process category**
PROC7 Industrial spraying
PROC11 Non industrial spraying
PROC14 Production of preparations or articles by tabletting, compression, extrusion, pelletisation
PROC15 Use as laboratory reagent
PROC1 Use in closed process, no likelihood of exposure
PROC2 Use in closed, continuous process with occasional controlled exposure
PROC3 Use in closed batch process (synthesis or formulation)

(Contd. on page 2)

NEELIKON FOOD DYES & CHEMICALSLTD.
Safety data sheet
COMMISSION REGULATION (EU) No 2015/830 of 1 June 2015 amending Annex II of Regulation (EU) No 453/2010

Issue date 30.04.2018 *Date of Revision: 01.09.2018* *Due Date of Revision: 31.08.2020*

Trade name: Neelicert FD & C Blue 1 Lake.

(Contd. of page 1)

PROC4 Use in batch and other process (synthesis) where opportunity for exposure arises
PROC5 Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)
PROC8a Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities
PROC8b Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities
PROC9 Transfer of substance or preparation into small containers (dedicated filling line, including weighing)
PROC21 Low energy manipulation of substances bound in materials and/or articles

· **Environmental release category**

ERC8c Wide dispersive indoor use resulting in inclusion into or onto a matrix
ERC8d Wide dispersive outdoor use of processing aids in open systems
ERC8e Wide dispersive outdoor use of reactive substances in open systems
ERC8f Wide dispersive outdoor use resulting in inclusion into or onto a matrix
ERC7 Industrial use of substances in closed systems
ERC5 Industrial use resulting in inclusion into or onto a matrix
ERC6b Industrial use of reactive processing aids
ERC3 Formulation in materials
ERC2 Formulation of preparations
ERC8a Wide dispersive indoor use of processing aids in open systems
ERC11b Wide dispersive indoor use of long-life articles and materials with high or intended release (including abrasive processing)

· **Article category**

AC8c Paper articles: Packaging (excluding food packaging)
AC1 Vehicles
AC4 Stone, plaster, cement, glass and ceramic articles
AC5 Fabrics, textiles and apparel
AC6 Leather articles
AC10 Rubber articles
AC11 Wood articles
AC13 Plastic articles
AC8a: Paper articles: Large surface area articles
AC 0: Other:
AC8 Paper articles

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

(Contd. on page 3)

NEELIKON FOOD DYES & CHEMICALSLTD.
Safety data sheet
COMMISSION REGULATION (EU) No 2015/830 of 1 June 2015 amending Annex II of Regulation (EU) No 453/2010

Issue date 30.04.2018 Date of Revision: 01.09.2018 Due Date of Revision: 31.08.2020

Trade name: Neelicert FD & C Blue 1 Lake.

(Contd. of page 2)

FOOD USES: Bakery Products: Icings, fillings, sugar decorations and oil based coatings. Confectionery: Candy and confectionery coatings and chewing gums. Dairy Products: Ice creams, yoghurts, and wax coatings for cheese. Dessert Products: Gelatins, puddings and beverage bases. Seasoning Products: Snack food coatings and mixes, spice mixes.
PHARMACEUTICAL USES: Coated and compressed tablets, gelatin (soft and hard) capsules.
NON FOOD USES: Personal Care: Lipsticks, blushers, creams, lotions, and cosmetic powders.
PACKAGING: Plastic films and wax coated packagings, Can linings. (Medium and high strength are recommended for these applications)
INKS: Flexographic and Lithographic. (High strength lakes are recommended for use in Inks)

· **1.3 Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Neelikon Food Dyes & Chemicals Ltd.,
D-8, D-17 Everest, 5th Floor,
Pandit Madan Mohan Malviya Marg,
Tardeo, Mumbai – 400034.

· **Further information obtainable from:**
Tel: 00 91 22 66661415(6 Hunting Lines)
Fax: 00 91 22 23523945 /66626916
Email ID: info@neelikon.com
· **1.4 Emergency telephone number:**
M/s Neelikon Food Dyes & Chemicals
Ltd., D-8,Everst,5th Floor,
Pdt.M.M.Marg,Tardeo Circle,Mumbai 34,India.
Tel.: 00 91 22 66626 874, Mobile No.:00 91 9970004002
Kind Attn. Mr. Rajeev Mathyal

SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**
The substance is not classified according to the CLP regulation.

· **2.2 Label elements**
· **Labelling according to Regulation (EC) No 1272/2008** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **2.3 Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.

(Contd. on page 4)

· **vPvB:** Not applicable.

(Contd. of page 3)

SECTION 3: Composition/information on ingredients

· **3.1 Chemical characterisation: Substances**
· **CAS No. Description**
68921-42-6 dihydrogen (ethyl)[4-[[4-[ethyl(3-sulphonatobenzyl)amino]phenyl](2-sulphonatophenyl)methylene]cyclohexa-2,5-dien-1-ylidene](3-sulphonatobenzyl)ammonium, aluminium salt
· **Identification number(s)**
· **EC number:** 272-939-6
· **Additional information:**
Molecular Formula : C37H36N2O9S3.xAl
Molecular weight : 748.884705 Da
· **SVHC** The substance is not in the list of SVHC substances

SECTION 4: First aid measures

· **4.1 Description of first aid measures**
· **General information:**
Remove breathing equipment only after contaminated clothing have been completely removed.
· **After inhalation:**
Move victim to fresh air. Call emergency medical service. Give artificial respiration if victim is not breathing. Administer oxygen if breathing is difficult. Keep victim warm and quiet. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
· **After skin contact:**
Remove and isolate contaminated clothing and shoes. In case of contact with substance, immediately flush skin with running water for at least 20 minutes. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
· **After eye contact:**
Move victim to fresh air. Check for and remove any contact lenses. In case of contact with substance, immediately flush eyes with running water for at least 20 minutes. Keep victim warm and quiet. Treat symptomatically and supportively. Effects of exposure to substance may be delayed. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
· **After swallowing:**

(Contd. on page 5)

(Contd. of page 4)

If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth. Keep victim warm and quiet. Loosen tight clothing such as a collar, tie, belt or waistband. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves. Effects of exposure (ingestion) to substance may be delayed.

· ***4.2 Most important symptoms and effects, both acute and delayed***
Effects of Overexposure : May cause mechanical irritation to eyes.
Medical Conditions Aggravated by Exposure : Persons with respiratory conditions may be at increased risk.
Primary Route(s) of Entry : Inhalation, Ingestion and eyes.
· ***Information for doctor:*** *Treat symptomatically and supportively.*
· ***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:***
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
· ***5.2 Special hazards arising from the substance or mixture***
FIREFIGHTERS SHOULD BE EQUIPPED WITH SELF-CONTAINED BREATHING APPARATUS TO GUARD AGAINST POTENTIALLY TOXIC AND IRRITATING FUMES. AVOID DUSTING. DUST CAN FORM EXPLOSIVE MIXTURES WITH AIR.
· ***5.3 Advice for firefighters***
· ***Protective equipment:*** *Self-contained breathing apparatus and protective clothing.*

SECTION 6: Accidental release measures

· ***6.1 Personal precautions, protective equipment and emergency procedures***
Avoid eye contact and excessive skin contact.
Use appropriate NIOHS/MSHA approved respirator. Wear chemical gloves goggles, and lab coat.
· ***6.2 Environmental precautions:***
Prevent material from contaminating soil or entering sewerage and drainage systems.
· ***6.3 Methods and material for containment and cleaning up:***
Carefully contain spilled material . Deposit spilled material in appropriate waste containers for disposal.
· ***6.4 Reference to other sections***
Refer to section 8 and 13 for additional information on personal protection equipment and disposal methods.

(Contd. on page 6)

NEELIKON FOOD DYES & CHEMICALSLTD.
Safety data sheet
COMMISSION REGULATION (EU) No 2015/830 of 1 June 2015 amending Annex II of Regulation (EU) No 453/2010

Issue date 30.04.2018 Date of Revision: 01.09.2018 Due Date of Revision: 31.08.2020

Trade name: Neelicert FD & C Blue 1 Lake.

(Contd. of page 5)

SECTION 7: Handling and storage

· **7.1 Precautions for safe handling**
Use with adequate ventilation. Avoid contact with eyes. Wash thoroughly after handling and before mealtimes.
· **Information about fire - and explosion protection:**
Prevent the accumulation of air borne dust/dust cloud. The potential of a dust cloud explosion exists.
Follow normal measures for preventive fire protection.

· **7.2 Conditions for safe storage, including any incompatibilities**
· **Storage:**
· **Requirements to be met by storerooms and receptacles:**
Provide adequate general mechanical exhaust to keep airborne levels low if user operations generate dust.
Recommended decontamination facilities: eye bath, washing facilities.
· **Information about storage in one common storage facility:**
Store away from oxidizing materials and strong caustic materials.
· **Further information about storage conditions:**
Store containers closed in ambient location away for all possible combustion sources and incompatibles.
· **7.3 Specific end use(s)**
FOOD USES: Bakery Products: Icings, fillings, sugar decorations and oil based coatings. Confectionery: Candy and confectionery coatings and chewing gums. Dairy Products: Ice creams, yoghurts, and wax coatings for cheese. Dessert Products: Gelatins, puddings and beverage bases. Seasoning Products: Snack food coatings and mixes, spice mixes.
PHARMACEUTICAL USES: Coated and compressed tablets, gelatin (soft and hard) capsules.
NON FOOD USES: Personal Care: Lipsticks, blushers, creams, lotions, and cosmetic powders.
PACKAGING: Plastic films and wax coated packagings, Can linings. (Medium and high strength are recommended for these applications)
INKS: Flexographic and Lithographic. (High strength lakes are recommended for use in Inks)

SECTION 8: Exposure controls/personal protection

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

· **8.1 Control parameters**
· **Ingredients with limit values that require monitoring at the workplace:** Not required.
· **DNELs**
Workers
Systemic effects - Long-term
Inhalation: 112.9176692 mg/m³
Dermal: 64.04285714 mg/kg bw/day

(Contd. on page 7)

NEELIKON FOOD DYES & CHEMICALSLTD.
Safety data sheet
COMMISSION REGULATION (EU) No 2015/830 of 1 June 2015 amending Annex II of Regulation (EU) No 453/2010

Issue date 30.04.2018 *Date of Revision: 01.09.2018* *Due Date of Revision: 31.08.2020*

Trade name: Neelicert FD & C Blue 1 Lake.

(Contd. of page 6)

General population
Systemic effects - Long-term
Inhalation: 27.8447205 mg/m³
Dermal: 32.02142857 mg/kg bw/day
Oral: 16.01071429 mg/kg bw/day

· ***PNECs***
1) Water
PNEC aqua (freshwater): 0.03148 mg/L PNEC aqua (marine water): 0.003148 mg/L PNEC aqua (intermittent releases): 0.3148 mg/L

2) Sediment
PNEC sediment (freshwater): 54637957 mg/kg sediment dw
PNEC sediment (marine water): 54637957 mg/kg sediment dw

3) PNEC soil: 261859337 mg/kg soil dw
4) PNEC STP: 100 mg/L

· ***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 NIOSH/MSHA approved air purifying respirator as needed to control exposure.
· ***Protection of hands:***

Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
· ***Material of gloves*** *Rubber gloves*
· ***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:*** *Safety glasses with side shields or goggles.*
· ***Body protection:*** *Protective work clothing*

(Contd. on page 8)

NEELIKON FOOD DYES & CHEMICALSLTD.
Safety data sheet
COMMISSION REGULATION (EU) No 2015/830 of 1 June 2015 amending Annex II of Regulation (EU) No 453/2010

Issue date 30.04.2018 Date of Revision: 01.09.2018 Due Date of Revision: 31.08.2020

Trade name: Neelicert FD & C Blue 1 Lake.

(Contd. of page 7)

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Fine powder.
Colour:	Fine Blue Powder.
· **Odour:**	Odourless
· **pH-value at 26 ℃:**	4 – 5.5
· **Change in condition**	
Melting point/Melting range:	>300 ℃ (at 966 hPa)
Boiling point/Boiling range:	Data waiving (boiling point is not required for solids which melt above 300 ℃)
· **Flash point:**	In the experimental determination of flash point by the closed cup method, Brilliant Blue FCF Lake was reported to be non flammable at 966hPa since no flash was obtained after heating.
· **Flammability (solid, gaseous):**	Product is not flammable.
· **Self-igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Explosion limits:**	
Oxidising properties	216.8 ml/100g
· **Vapour pressure at 25 ℃:**	0.0000000001333 Pa
· **Density at 26 ℃:**	0.2 – 0.5 gm/cc (After Tapping)
· **Solubility in / Miscibility with water at 26 ℃:**	Insoluble
· **Partition coefficient (n-octanol/water) at 26 ℃:**	1.25 log POW

(Contd. on page 9)

NEELIKON FOOD DYES & CHEMICALSLTD.
Safety data sheet
COMMISSION REGULATION (EU) No 2015/830 of 1 June 2015 amending Annex II of Regulation (EU) No 453/2010

Issue date 30.04.2018 *Date of Revision: 01.09.2018* *Due Date of Revision: 31.08.2020*

Trade name: Neelicert FD & C Blue 1 Lake.

(Contd. of page 8)

· **9.2 Other information** Granulometry: The particle size distribution (granulometry) of dihydrogen (ethyl)[4-[[4-[ethyl(3-sulphonatobenzyl)amino]phenyl](2-sulphonatophenyl)methylene]cyclohexa-2,5-dien-1-ylidene](3-sulphonatobenzyl) ammonium, aluminum salt (Brilliant Blue FCF Lake)by the sieve analysis method was found to be in the range of 75 micrometer to 500 micrometer. Majority of the particles were found to be in the size more than 250 (40.51%) micrometers in size.

SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.
· **10.2 Chemical stability**
· **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
· **10.3 Possibility of hazardous reactions** No dangerous reactions known.
· **10.4 Conditions to avoid** Open flames and sparks, extreme heat, oxidizing materials.
· **10.5 Incompatible materials:**
Oxidizing materials and strong caustic materials can cause a reaction.
· **10.6 Hazardous decomposition products:**
Incomplete combustion can form CO, CO2, and dense smoke.

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	> 2000 mg/kg bw (rat (Wistar))

· **Primary irritant effect:**
· **Skin corrosion/irritation**
May cause mild skin irritation.
Species: guinea pig
Coverage: semiocclusive and occlusive
Result:
Primary dermal irritation index (PDII): 1 (mean)
Inference:
Slight irritation
· **Serious eye damage/irritation**
Species: rabbit (New Zealand White)
Vehicle: water (3%, w/v in water)

(Contd. on page 10)

NEELIKON FOOD DYES & CHEMICALSLTD.
Safety data sheet
COMMISSION REGULATION (EU) No 2015/830 of 1 June 2015 amending Annex II of Regulation (EU) No 453/2010

Issue date 30.04.2018 *Date of Revision: 01.09.2018* *Due Date of Revision: 31.08.2020*

Trade name: Neelicert FD & C Blue 1 Lake.

(Contd. of page 9)

Method: Test material (3%,wt./vol. in aqueous vehicle) was administered once daily, for a total of 21 days, to the conjunctival sac of the right eye of New Zealand White Rabbits (6 of each sex per group) at a dose volume of 30 µL to evaluate the ocular irritation, staining, and embedding potential.
Result:
Conjunctivae score:
(mean) (Time point: 21 days) (All animals survived and were free of significant clinical signs of toxicity throughout the study. Ophthalmoscopic examinations revealed that all animals were free of abnormalities & free of signs of ocular irritation, staining and particle embedment.)
Inference:
Not irritating

· **Respiratory or skin sensitisation**
mildly sensitising.
OECD Guideline 429 (Skin Sensitisation: Local Lymph Node Assay)
Local lymph node assay
Species:mouse (CBA/J) female
Result:
Stimulation index: The stimulation indices were less than 3 at all tested concentrations
Inference:
Not sensitising

· **Toxicokinetics, metabolism and distribution**
The absorption, metabolism and excretion of 14C-labelled Brilliant Blue FCF was studied in 13 female Sprague Dawley female rats and Wistar rats by oral administration. There was little intestinal absorption, and almost all of the dye was excreted unchanged mostly through the faeces and very little through the urine. This suggests that the chemical shall not exhibit bio-accumulation potential within the living system

· **Repeated dose toxicity**
Repeated dose toxicity: oral
Species: rat (Wistar) male/female
Study type: subchronic
Route of exposure: oral: gavage
Exposure: 90 days (daily)
Result:
NOAEL: 245.33 mg/kg bw/day (male/female) based on: test mat. (Effects: no dose related adversed effects was observed on body weight, food consumption, haematology, histopathology and organ weight.)

Repeated dose toxicity: inhalation
Data waiving
Justification: The test substance Brilliant Blue FCF Lake has very low vapor pressure (0.0000000001333 Pa). Also the particle size distribution indicates that the majority particle size is more than 250 (40.51%) micro meter. so the potential for the generation of inhalable forms is low. Moreover the normal conditions of use of this substance will not result in aerosols, particles or droplets of an inhalable size, so exposure to humans via the inhalatory route will be unlikely to occur, and therefore acute toxicity by inhalation route was considered to be waived.

(Contd. on page 11)

(Contd. of page 10)

Repeated dose toxicity: dermal
Data waiving
Justification: Acute dermal toxicity is unlikely to occur since dermal absorption of Brilliant Blue FCF Lake is limited. Also considering the use of the chemical as a colouring agent in food and cosmetics and considering the volatility absorption by the dermal route is not considered to be significant. Thus, given the above considerations, it is assumed that Brilliant Blue FCF shall not exhibit acute dose toxicity by the dermal route.

· ***CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)***
· ***Germ cell mutagenicity***
Genetic toxicity:
Test Guideline: bacterial reverse mutation assay (e.g. Ames test)
Species/strain: S. typhimurium TA 92. TA 1535, TA 100, TA 1537, TA 94, TA 98, TA 2637
Metabolic activation: with
Metabolic activation system: S-9 mix
Dose: Not reported
Test results:
Negative for S. typhimurium TA 92. TA 1535, TA 100, TA 1537, TA 94, TA 98, TA 2637
Metabolic activation: with

· ***Reproductive toxicity***
Toxicity for reproduction:
Type of study: two-generation study
Species: rat (Crj: CD(SD)) male/female
Route of exposure: oral: gavage
Exposure: 90 days (daily)
Result:
NOAEL (F1): 423 mg/kg bw/day (actual dose received) (male/female) based on: test mat. (Effects: No adverse effects were observed on fertility index, mating index, Clinical signs and Reproductive function.)

Developmental toxicity:
Species: rat (Wistar)
Route of exposure: oral: gavage
Dose: 0 (control), 250, 500 or 1000 mg Green S/kg body weight (nominal in diet)
Vehicle: Spratt's Laboratory Diet No. 5 (Spratt's Patent Ltd, Barking, Essex)
Exposure: 0-19 of pregnancy (daily)
Result:
NOAEL (teratogenicity): 1000 mg/kg bw/day based on: test mat. (effects: does not represent a structural abnormality of the foetus and cannot be considered to be the result of an abnormal development or a teratogenic effect.)

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

(Contd. on page 12)

NEELIKON FOOD DYES & CHEMICALSLTD.
Safety data sheet
COMMISSION REGULATION (EU) No 2015/830 of 1 June 2015 amending Annex II of Regulation (EU) No 453/2010

Issue date 30.04.2018 Date of Revision: 01.09.2018 Due Date of Revision: 31.08.2020

Trade name: Neelicert FD & C Blue 1 Lake.

(Contd. of page 11)

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

SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**	
EC50 (48 h)	31.48925 mg/L (Daphnia magna)
LC50 (48 hrs) (static)	> 100 mg/L (Cyprinus carpio)
LC50 (96 h)	413.0448 mg/L (Fish Onchorhynchus mykiss(Rainbow trout))
NOEC (72 h) (static)	5.9361 mg/L (Pseudokirchneriella subcapitata)

· **12.2 Persistence and degradability**

Biodegradation in water:
The half-life period of dihydrogen (ethyl) [4-[[4-[ethyl(3-sulphonatobenzyl) amino]phenyl](2-sulphonatophenyl) methylene]cyclohexa-2,5-dien-1-ylidene](3-sulphonatobenzyl) ammonium, aluminium salt (Brilliant Blue FCF Lake) in water is 180 days and based on this value it can be concluded that the chemical is persistent in water medium since the half-life is more than the threshold of 60 days (to qualify the chemical as persistent). Also the diffusion percentage of Brilliant Blue FCF Lake in water medium is 1 %. This coupled with the dilution of water shall result in non biodegradability of the chemical.

Biodegradation in water and sediment
Half-life period of dihydrogen (ethyl) [4-[[4-[ethyl(3-sulphonatobenzyl) amino]phenyl](2-sulphonatophenyl) methylene]cyclohexa-2,5-dien-1-ylidene](3-sulphonatobenzyl) ammonium, aluminium salt (Brilliant Blue FCF Lake) in water is observed to be 180 days (4320 hrs) while in sediment it is 1600 days (38400 hrs). Based on these half-life values of Brilliant Blue FCF Lake, it is concluded that the chemical is non biodegradable in water and sediment environment.

Biodegradation in soil
The PBT Profiler & EPI Suite has estimated that dihydrogen (ethyl) [4-[[4-[ethyl(3-sulphonatobenzyl) amino]phenyl](2-sulphonatophenyl) methylene]cyclohexa-2,5-dien-1-ylidene](3-sulphonatobenzyl) ammonium, aluminium salt (Brilliant Blue FCF Lake) is expected to be found predominantly in soil and its persistence estimate is based on its transformation in this medium. Its half-life in soil, 360 days (8640 hrs exceeds the threshold of 120 days as per Annex XIII of REACH. Therefore, Brilliant Blue FCF Lake is estimated to be persistent in the soil environment

· **12.3 Bioaccumulative potential**

The estimated bioconcentration factor (BCF) for dihydrogen (ethyl) [4-[[4-[ethyl(3-sulphonatobenzyl) amino]phenyl](2-sulphonatophenyl) methylene]cyclohexa-2,5-dien-1-ylidene](3-sulphonatobenzyl) ammonium, aluminium salt (Brilliant Blue FCF Lake) is 3.2, which does not exceed the bioconcentration threshold of 2000. Thus, it is concluded that Brilliant Blue FCF Lake is not expected to bioaccumulate in the food chain because it does not exceed the BCF criteria.

(Contd. on page 13)

NEELIKON FOOD DYES & CHEMICALSLTD.
Safety data sheet
COMMISSION REGULATION (EU) No 2015/830 of 1 June 2015 amending Annex II of Regulation (EU) No 453/2010

Issue date 30.04.2018 *Date of Revision: 01.09.2018* *Due Date of Revision: 31.08.2020*

Trade name: Neelicert FD & C Blue 1 Lake.

(Contd. of page 12)

· **12.4 Mobility in soil**
Soil Adsorption Coefficient i. e Koc value of dihydrogen (ethyl) [4-[[4-[ethyl(3-sulphonatobenzyl) amino]phenyl](2-sulphonatophenyl) methylene]cyclohexa-2,5-dien-1-ylidene](3-sulphonatobenzyl) ammonium, aluminium salt (Brilliant Blue FCF Lake) was estimated as 10000000000 L/kg (log Koc=10) by means of MCI method. This indicates that Brilliant Blue FCF Lake will have a Very strong sorption to soil and sediment, negligible migration potential to groundwater.
· **12.5 Results of PBT and vPvB assessment**
TO BE PROVIDED IN THE REGISTRATION DOSSIER
· **PBT:** *Not applicable.*
· **vPvB:** *Not applicable.*
· **12.6 Other adverse effects** *No further relevant information available.*

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**
· **Recommendation**
Dispose of in accordance with all applicable federal, state, and local regulations.
Material may be sent to an approved landfill or licensed treatment, storage, and disposal facility.

· **Uncleaned packaging:**
· **Recommendation:** *Disposal must be made according to official regulations.*

SECTION 14: Transport information

· **14.1 UN-Number**	
· **ADR, ADN, IMDG, IATA**	*Not applicable*
· **14.2 UN proper shipping name**	
· **ADR, ADN, IMDG, IATA**	*Not applicable*
· **14.3 Transport hazard class(es)**	
· **ADR, ADN, IMDG, IATA**	
· **Class**	*Not applicable*
· **14.4 Packing group**	
· **ADR, IMDG, IATA**	*Not applicable*
· **14.5 Environmental hazards:**	
· **Marine pollutant:**	*No*
· **14.6 Special precautions for user**	*Not applicable.*

(Contd. on page 14)

NEELIKON FOOD DYES & CHEMICALSLTD.
Safety data sheet
COMMISSION REGULATION (EU) No 2015/830 of 1 June 2015 amending Annex II of Regulation (EU) No 453/2010

Issue date 30.04.2018 *Date of Revision: 01.09.2018* *Due Date of Revision: 31.08.2020*

Trade name: Neelicert FD & C Blue 1 Lake.

(Contd. of page 13)

· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**	Not applicable.
· **UN "Model Regulation":**	Not applicable

SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **Labelling according to Regulation (EC) No 1272/2008** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations**
· **Substances of very high concern (SVHC) according to REACH, Article 57**
The substance is not listed as SVHC.

· **15.2 Chemical safety assessment:**
A Chemical Safety Assessment is not applicable.

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.

· **Department issuing MSDS:** Product safety department.
· **Contact:**
+91-02194 263527 (Direct Line)
+91-02194 263694 Ext-259
+91 9970004009
rrmore@neelikon.com
· **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 européen sur le transport 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

(Contd. on page 15)

NEELIKON FOOD DYES & CHEMICALSLTD.
Safety data sheet
COMMISSION REGULATION (EU) No 2015/830 of 1 June 2015 amending Annex II of Regulation (EU) No 453/2010

Issue date 30.04.2018 *Date of Revision: 01.09.2018* *Due Date of Revision: 31.08.2020*

Trade name: Neelicert FD & C Blue 1 Lake.

(Contd. of page 14)

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 Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
• CSR for CAS: 68921-42-6
• https://echa.europa.eu/registration-dossier/-/registered-dossier/10136/10

· **** Data compared to the previous version altered.***
• Section 1 Identification of the substance / preparation &of the company/ undertaking.
• 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
• Section 8 - Exposure Controls / Personal Protection
• Section 9 - Physical & Chemical Properties
• Section 10 – Stability and reactivity
• Section 11 - Toxico-logical Information
• Section 12 - Ecological Information
• Section 13 - Disposal Considerations
• Section 15 - Regulatory Information

IN

PREPARED BY	APPROVED BY	ISSUED BY	STATUS
Q.C. HEAD	QA & QC HEAD	Management Representative	