

Safety data sheet

COMMISSION REGULATION (EU) No 2015/830 of 1 June 2015 amending Annex II of Regulation (EU) No 453/2010

Issue date 12.10.2018

Date of Revision: 00

Due Date of Revision: 11.10.2020

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

- **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
 - SU9 Manufacture of fine chemicals
 - SU17 General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment
 - SU5 Manufacture of textiles, leather, fur
 - SU6a Manufacture of wood and wood products
 - 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
 - SU4 Manufacture of food products
 - SU19 Building and construction work
 - SU8 Manufacture of bulk, large scale chemicals (including petroleum products)
 - SU11 Manufacture of rubber products
 - SU18 Manufacture of furniture
 - SU20 Health services
 - SU24 Scientific research and development
 - SU 0: Other: NACE code 2893: Manufacture of machinery for food, beverage and tobacco processing.
 - SU 0: Other: nace code 2341: Manufacture of ceramic household and ornamental articles
 - SU 0: Other: NACE code9602: hairdressing and other beauty treatment
 - SU 0: Other: cosmetics
- **Product category**
 - PC1 Adhesives, sealants
 - PC2 Adsorbents
 - PC3 Air care products
 - PC4 Anti-Freeze and de-icing products
 - PC7 Base metals and alloys
 - PC8 Biocidal products (e.g. Disinfectants, pest control)
 - PC9a Coatings and paints, thinners, paint removers
 - PC9b Fillers, putties, plasters, modelling clay
 - PC9c Finger paints
 - PC11 Explosives
 - PC12 Fertilisers
 - PC13 Fuels
 - PC14 Metal surface treatment products, including galvanic and electroplating products
 - PC15 Non-metal-surface treatment products
 - PC16 Heat transfer fluids
 - PC17 Hydraulic fluids
 - PC18 Ink and toners
 - PC19 Intermediate
 - PC20 Products such as ph-regulators, flocculants, precipitants, neutralisation agents

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PC21 Laboratory chemicals
 PC23 Leather tanning, dye, finishing, impregnation and care products
 PC24 Lubricants, greases, release products
 PC25 Metal working fluids
 PC26 Paper and board dye, finishing and impregnation products: including bleaches and other processing aids
 PC27 Plant protection products
 PC28 Perfumes, fragrances
 PC29 Pharmaceuticals
 PC30 Photo-chemicals
 PC31 Polishes and wax blends
 PC32 Polymer preparations and compounds
 PC33 Semiconductors
 PC34 Textile dyes, finishing and impregnating products; including bleaches and other processing aids
 PC35 Washing and cleaning products (including solvent based products)
 PC36 Water softeners
 PC37 Water treatment chemicals
 PC38 Welding and soldering products (with flux coatings or flux cores.), flux products
 PC39 Cosmetics, personal care products
 PC40 Extraction agents
 PC41: Oil and gas exploration or production products
 PC42: Electrolytes for batteries
 PC 0: Other: Plastic products
 PC 0: Other: Wood products

· **Process category**

PROC28 Manual maintenance (cleaning and repair) of machinery
 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
 PROC6 Calendering operations
 PROC7 Industrial spraying
 PROC9 Transfer of substance or preparation into small containers (dedicated filling line, including weighing)
 PROC15 Use as laboratory reagent
 PROC14 Production of preparations or articles by tableting, compression, extrusion, pelletisation
 PROC10 Roller application or brushing
 PROC11 Non industrial spraying
 PROC13 Treatment of articles by dipping and pouring
 PROC19 Hand-mixing with intimate contact and only PPE available
 PROC21 Low energy manipulation of substances bound in materials and/or articles
 PROC24 High (mechanical) energy work-up of substances bound in materials and/or articles

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PROC22 Potentially closed processing operations with minerals/metals at elevated temperature - Industrial setting

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)

· **Environmental release category**

ERC1 Manufacture of substances

ERC2 Formulation of preparations

ERC3 Formulation in materials

ERC4 Industrial use of processing aids in processes and products, not becoming part of articles

ERC5 Industrial use resulting in inclusion into or onto a matrix

ERC6a Industrial use resulting in manufacture of another substance (use of intermediates)

ERC6b Industrial use of reactive processing aids

ERC6c Industrial use of monomers for manufacture of thermo-plastics

ERC6d Industrial use of process regulators for polymerisation processes in production of resins, rubbers, polymers

ERC7 Industrial use of substances in closed systems

ERC8a Wide dispersive indoor use of processing aids in open systems

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

ERC10a Wide dispersive outdoor use of long-life articles and materials with low release

ERC11a Wide dispersive indoor use of long-life articles and materials with low release

ERC11b Wide dispersive indoor use of long-life articles and materials with high or intended release (including abrasive processing)

· **Article category**

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

AC7 Metal articles

AC13f: Plastic articles: Articles with intense direct dermal contact during normal use

· **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:**

Neelikon Food Dyes & Chemicals Ltd.,

D-8, D-17 Everest, 5th Floor,

Pandit Madan Mohan Malviya Marg,

Tardeo, Mumbai – 400034.

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· **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.· **vPvB:** Not applicable.**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

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· **Additional information:**Molecular Formula: C₁₆H₉N₄O₉S₂Na₃

Molecular Weight: 534.35 g/mol

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. Get medical aid.*· **After skin contact:***In case of contact, flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical aid if irritation develops and persists. Wash clothing before reuse.*· **After eye contact:***In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical aid.*· **After swallowing:***Rinse mouth with water. Never give anything by mouth to an unconscious person. If any symptoms happen, look for medical assistance.*· **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.*· **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:***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 (NO_x)**Carbon monoxide (CO)**Carbon dioxide (CO₂)*

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· **5.3 Advice for firefighters**· **Protective equipment:**

Normal firefighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

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. Contaminated material should be disposed of in compliance with the provisions set forth in Section Disposal Considerations.

· **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 cool place.

· **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)**

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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· **Additional information about design of technical facilities:**

No further data; see item 7.

· **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.

· **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:**

Wear a NIOSH/MSHA or European Standard EN 149 approved full-face piece airline respirator in the positive pressure mode with emergency escape provisions.

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· **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:** Splash proof safety goggles**SECTION 9: Physical and chemical properties**· **9.1 Information on basic physical and chemical properties**· **General Information**· **Appearance:**

· Form:	Powder
· Colour:	Light orange-yellow
· Odour:	Characteristic
· Odour threshold:	Not available

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

· **Change in condition**

· Melting point/Melting range:	347.1 °C
· Boiling point/Boiling range:	909.54 °C

· **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, gaseous):** non flammable

· **Ignition temperature:**

· **Decomposition temperature:** >314 °C

· **Self-igniting:** Product is not self-igniting.

· **Danger of explosion:** The tested substance could be considered as a not-explosive substance

· **Explosion limits:**

· **Oxidising properties** No oxidizing properties.

· **Vapour pressure at 25 °C:** 6.89E-017 Pa (Estimated)

· **Density at 20 °C:** 2.121 g/cm³

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- | | |
|--|--|
| · Solubility in / Miscibility with Water at 25 °C: | 167.05 g/l (Shake flask method) |
| · Partition coefficient (n-octanol/water) at 20 °C: | -1.572 (Shake flask method) |
| · Viscosity: | |
| · Dynamic: | Not applicable. |
| · 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 > 1000 mg/kg bw (Mouse (Swiss Webster)) (oral : gavage) |
- **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

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defined experimental conditions in the two vehicles tested.

- **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** No data available.

- **STOT-repeated exposure** No data available.

- **Aspiration hazard** No data available

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SECTION 12: Ecological information

- **12.1 Toxicity**

- **Aquatic toxicity:**

EC 50 (48 hrs) (static)	125 mg/L (<i>Daphnia Magna</i> (Water Flea))
EC 50 (3 hrs)	>1000 (Microorganisms)
EC50 (72 hrs) (static)	125 mg/L (Algae) (fresh water)
LC 50 (96 hrs) (dynamic)	120 mg/L (<i>Leuciscus idus</i> (Golden Orfe)) (Flow through (fresh water))

- **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.

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· **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:**

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

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:** Not PBT· **vPvB:** Not vPvB· **12.6 Other adverse effects** No further relevant information 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 thermo destructions 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 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.· **14.7 Transport in bulk according to**

Annex II of Marpol and the IBC Code Not applicable.

· **UN "Model Regulation":** Not applicable

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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** Not applicable
- **Signal word** Not applicable
- **Hazard statements** Not applicable
- **Precautionary statements** Not applicable

- **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.

- **Contact:**
+91-02194 263527 (Direct Line)
+91-02194 263694 Ext-259
+91 9970004009
rrmore@neelikon.com
- **Abbreviations and acronyms:**
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
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
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
 - Data from registered dossier
<https://echa.europa.eu/registration-dossier/-/registered-dossier/17292>
- *** 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.
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- Section 9: Physical and Chemical properties.
- Section 10: Stability and Reactivity.
- Section 11: Toxicological Information.
- Section 12: Ecological Information.

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