HOT PINK #28 D & C WATER SOLUBLE COLOUR POWDER SAFETY DATA SHEET

SECTION 1: MATERIAL & SUPPLY COMPANY IDENTIFICATION

1.1 Product Identifiers

Product Name: D & C Red No. 28 Water Soluble

Chemical Name: Spiro[isobenzofuran-1(3H),9'-[9H]xanthen]-3-one, 2',4',5',7'-tetrabromo-

4,5,6,7-tetrachloro-3',6'-dihydroxy-, disodium salt

Colour Index: 45410 – Acid Red 92

CAS Number: 18472-87-2 EINECS Number: 242-355-6 Country of Origin India

1.2 Relevant identified uses of the substance or mixture

		Field of Appl	ication			
Common Name colour index no	Japanese Reference	EC/1223/2009 & IS 4707	USA 21 CFR	рН	Light	Heat °C (Maximum)
D & C Red 28 45410	Red # 104-1	1	C	4-10	4	250

- 1 Colouring agents allowed to be used in all cosmetic products
- C Permitted for colouring cosmetics generally in amounts consistent with good manufacturing practice

1.3 Supplier Details

Supplier: Heirloom Body Care Pty Ltd

Address: Unit 9, 28 Coombes Drive Penrith NSW 2750 Australia

Telephone: 02 4722 2123 Fax 02 4722 2904

1.4 Information in case of emergency

Poisons Information 13 11 26

Centre

SECTION 2: HAZARDS IDENTIFICATION

HAZARDOUS NATURE

Not classified as Hazardous according to the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) and Safe Work Australia criteria.

Not classified as Dangerous Goods according to the Australian Code for the Transport of Dangerous Goods by Road and Rail. (7th edition)

The substance is not classified according to the Globally Harmonised System (GHS).

SIGNAL WORD

None – Not Hazardous

HAZARD STATEMENT



None - Not Hazardous

CLASSIFICATION ACCORDING TO REGULATION (EC) NO

1272/2008 Not Applicable Not Applicable

Classification according to Directive 67/548/EEC or Directive 1999/45/EC: Information concerning particular hazards for human and environment:

SECTION 3: COMPOSITION AND INFORMATION ON INGREDIENTS

CHEMICAL CHARACTERISATION: Substance CAS NO. DESCRIPTION, SYNONYMS CAS# 18472-87-2

C.I. 45410

Trisodium salt of 8-hydroxy-1,3,6-pyrenetrisulfonic acid

EC NUMBER 247-368-0

 INGREDIENTS
 CAS #
 Concentration %

 D&C Red 28
 18472-87-2
 100% - Pure (*)

(*) COMMERCIALLY PURE. MAY INCLUDE SMALL QUANTITIES OF MATERIAL DUE TO MANUFACTURING OR REACTION PROCESSES.

This is a commercial product whose extract ratio of components may vary slightly. Minor quantities of other non-hazardous ingredients are also possible

ADDITIONAL INFORMATION: IMPURITIES:

Lead (as Pb) Not more than 20 ppm (Parts per million)

Arsenic (as As)
Mercury (as Hg)
Cadmium (as Cd)
Not more than 1 ppm
Not more than 1 ppm

SECTION 4: FIRST AID MEASURES

General Information

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

Inhalation:

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention if breathing problems develop.

Skin Contact:

In case of skin contact, immediately remove contaminated clothing and shoes wash affected area with water and soap. Seek medical attention if symptoms occur

Eye Contact:

In case of eye contact, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention if any irritation occurs

Ingestion:

If swallowed, do not induce vomiting. Immediately rinse mouth with water. Give 2-4 glass of milk or water. Never give anything by mouth to an unconscious person. Seek immediate medical attention if large quantities have been swallowed.

SYMPTOMS CAUSED BY EXPOSURE:

Inhalation: May cause respiratory irritation

Skin Contact: May cause skin irritation. May cause allergic skin reaction

Eye Contact: May cause eye irritation

Ingestion: May cause skin irritation. May cause gastrointestinal irritation

SECTION 5: FIRE FIGHTING MEASURES

FIRE AND EXPLOSION HAZARD:

There is no risk of an explosion from this product under normal circumstances if it is involved in a fire EXTINGUISHING MEDIA:

Not combustible. Use extinguishing media suited to burning materials



For small fires use dry chemical powder, this product is a water soluble food colour For large fires use water spray, fog or foam, Do Not Use full water jet.

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL:

Hazardous combustion products include oxides, nitrogen, sulphur and sodium.

Product may be combustible at high temperatures. Use water spray to cool fire exposed containers and if safe to do so remove from the area.

SPECIAL PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIRE FIGHTERS

When fighting a major fire wear self-contained breathing apparatus and protective equipment. MSHA/NIOSH (approved or equivalent)

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES	Wear approved dust/particulate filter respirator and full protective clothing. Evacuate all non-essential personnel from the affected area. Do not breathe dust. Ensure adequate ventilation. Avoid generating dust
ENVIRONMENTAL PRECAUTIONS	In the event of major spills, prevent spillage from entering drains or water courses/surface ground water
METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP	In case of dry powder spills use vacuum equipment with HEPA filters. Contain spilled material immediately with an inert substance such as sand or earth if sweeping is required. Collect in suitable, closed container for subsequent disposal, according to local State or Federal guidelines. Avoid generating dust. Wash spill areas with water.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING	Use of Safe Work practices are recommended to avoid eye or skin contact and inhalation of dust. Food, beverages and tobacco products should not be stored or consumed where this material is in use. Always wash hands before smoking, eating, drinking or using the toilet. Wash contaminated clothing and other protective equipment before storage or re-use. Provide eyewash fountains and safety showers in close proximity to points of potential exposure.
ENVIRONMENTAL PRECAUTIONS	Store in a cool. Dry and well ventilated area. Keep in original container tightly closed when not in use. Protect from extreme temperatures. Keep away from strong oxidizing agents.

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

EXPOSURE STANDARDS	Nuisance dust: TWA - 10 mg/m3 (inspirable dust)		
ENGINEERING CONTROLS	Provide sufficient mechanical (general and/or local exhaust) ventilation to maintain exposure below the limits		
RESPIRATORY PROTECTION	Where an inhalation risk exists, wear a Class P1		

	(particulate) respirator. At high dust levels, wear a powered air purifying respirator (PAPR) with Class P3 (Particulate) filter or an air-line respirator or a full-face Class P3 (particulate) respirator. See Australian/New Zealand Standards AS/NZS 1715 and 1716 for more information.
SKIN PROTECTION	PVC, PVA, nitrile, neoprene, rubber or vinyl gloves. See Australian/New Zealand Standard AS/NZS 2161 for more information. When selecting gloves for use against certain chemicals, the degradation resistance, permeation rate and permeation breakthrough time should be considered. Occupational protective clothing (depending on conditions in which it has to be used, in particular as regards the period for which it is worn, which shall be determined on the basis of the seriousness of the risk, the frequency of exposure to the risk, the characteristics of the workstation of each worker and the performance of the protective clothing). See Australian/New Zealand Standard AS/NZS 4501 for more information.
EYE AND FACE PROTECTION	Eye and face protectors for protection against splashing materials or liquids. See Australian/New Zealand Standard AS/NZS 1337 for more information

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE FORM: COLOUR: ODOUR:	Dry powder or granules Red Odourless (Characteristic)
ODOUR THRESHOLD	No Information Available
PH-VALUE	Not Applicable
MELTING POINT/MELTING RANGE	No Information Available
INITIAL BOILING POINT/BOILING RANGE	No Information Available
FLASH POINT	Not Applicable
FLAMMABILITY	May be combustible at high temperatures
AUTO-IGNITION TEMPERATURE	No Information Available
DECOMPOSITION TEMPERATURE	No Information Available
EXPLOSION LIMITS LOWER: UPPER:	Not Applicable Not Applicable
RELATIVE DENSITY AT 20°C	No Information Available
SOLUBILITY IN WATER AT 20 °C	95 grams oer litre

SECTION 10: STABILITY AND REACTIVITY



CHEMICAL STABILITY

Stable at ambient temperature and under normal conditions of use

CONDITIONS TO AVOID

Extreme temperatures and dust generation

INCOMPATIBLE MATERIALS

Strong oxidizing agents, temperatures above 151°C (304°F).

HAZARDOUS DECOMPOSITION PRODUCTS

Nitrogen oxides, carbon monoxide, oxides of nitrogen, oxides of sulfur, carbon dioxide, sodium oxide

SECTION 11: TOXICOLOGICAL INFORMATION

TOXICITY: LD50/LC50 VALUES RELEVANT FOR CLASSIFICATION

CAS # 18472-87-2

SUBSTANCE Spiro[isobenzofuran-1(3H),9'-[9H]xanthen]-3-one, 2',4',5',7'-tetrabromo-4,5,6,7-tetrachloro-

3',6'-dihydroxy-, disodium salt

(Literature data)

ORAL LD-50 LD50 (rat) > 3 160 mg/kg bw [DFG, Kosmetische Färbemittel]

LD50 (dog) > 1 000 mg/kg bw [DFG, Kosmetische Färbemittel]

Comment

Even though details on study design and purity of the test material are not available, Acid Red 33 shows no acute lethality in rats even when tested at much higher concentration than requested by current guideline. Repetition of an animal test is not justified due to the low toxicity reported.

ACUTE HEALTH EFFECTS:

INHALATION May cause respiratory irritation

SKIN May cause skin irritation. May cause allergic skin reaction

EYE May cause eye irritation

INGESTION May be harmful if swallowed. May cause gastrointestinal irritation

SKIN CORROSION / IRRITATION

Based on classification principles, the classification criteria are not met

SERIOUS EYE DAMAGE / IRRITATION

Based on classification principles, the classification criteria are not met

RESPIRATORY OR SKIN SENSITISATION

Based on classification principles, the classification criteria are not met

GERM CELL MUTAGENICITY

Based on classification principles, the classification criteria are not met

CARCINOGENICITY This product does NOT contain any IARC listed chemicals

REPRODUCTIVE TOXICITY

Based on classification principles, the classification criteria are not met

SPECIFIC TARGET ORGAN TOXICITY (STOT) - SINGLE EXPOSURE

Based on classification principles, the classification criteria are not met

SPECIFIC TARGET ORGAN TOXICITY (STOT) - REPEATED EXPOSURE

Based on classification principles, the classification criteria are not met

ASPIRATION HAZARD Based on classification principles, the classification criteria are not met CHRONIC HEALTH EFFECTS

This Product is known to provoke asthma attacks and urticaria (nettle rash) in children EXISTING CONDITIONS AGGRAVATED BY EXPOSURE

Respiratory conditions

ADDITIONAL TOXICOLOGICAL INFORMATION

- > The substance is not subject to classification according to the latest version of the EU lists
- > When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY
AQUATIC TOXICITY
PERSISTENCE AND DEGRADABILITY
BIOACCUMULATIVE POTENTIAL
MOBILITY IN SOIL
No information available
No information available
No information available

GENERAL NOTES > Do not allow undiluted product or large quantities of it to reach ground

water, water course or sewage system.

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL METHODS AND CONTAINERS

Dispose according to applicable local and state government regulations

SPECIAL PRECAUTIONS FOR LANDFILL OR INCINERATION

Please consult your state Land Waste Management Authority for more information

SECTION 14: TRANSPORTATION INFORMATION

UN NUMBER Not regulated
PROPER SHIPPING NAME Not regulated
DANGEROUS GOODS CLASS Not regulated
PACKING GROUP Not regulated

MARINE POLLUTANT No

SECTION 15: REGULATORY INFORMATION

AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES:

CAS # 18472-87-2

SUBSTANCE Spiro[isobenzofuran-1(3H),9'-[9H]xanthen]-3-one, 2',4',5',7'-tetrabromo-4,5,6,7-tetrachloro-

3',6'-dihydroxy-, disodium salt

STANDARD FOR THE UNIFORM SCHEDULING OF DRUGS AND POISONS (SUSMP) - POISON SCHEDULE:

Not a scheduled poison

SECTION 16: OTHER INFORMATION

DATE OF PREPARATION OR LAST REVISION

PREPARED BY

5th November 2020 Heirloom Body Care Telephone 02 4722 2123 www.heirloombodycare.com.au

BATCH DETAILS



Batch (lot) Number	FG/17-18/1275
FDA Lot No	AY0394
Manufacture Date	11th July, 2017
Expiry Date: Shelf Life:	10th July, 2025 8 Years (Re-Test)

ANALYSIS DETAILS

No.	Test		Specification		Analytical
			Min	Max	Results
1	Pure Dye Content (Spectrophotometric)	% w/w	85	100	96.61
2	Sum of Volatile matter at 135°C and Chlorides & Sulphates (as Sodium salt)	% w/w		15	5.31
3	Volatile matter at 135°C	% w/w			2.42
4	Chlorides (As Sodium Salt)	% w/w			1.89
5	Sulphates (As Sodium Salt)	% w/w			< 1
6	Water Insoluble Matter	% w/w		0.5	0.09
7	Ethyl Ester of colour	% w/w		2	< 0.50
8	Brominated Resorcinol	% w/w		0.4	Not Detected
9	Tetrachlorophthalic Acid	% w/w		1.2	Not Detected
10	Tetra CI(Dibr-DiOH-Benzoyl)Bine	% w/w		0.7	<0.7
11	Lower Halogenated	% w/w		4	<1.00
12	Lead	mg/kg		20	1.00
13	Arsenic	mg/kg		3	0.012
14	Mercury	mg/kg		1	0.025

USA FDA INFORMATION

§74.1328 D&C Red No. 28.

- (a) Identity. (1) The color additive D&C Red No. 28 is principally the disodium salt of 2',4',5',7'-tetrabromo-4,5,6,7-tetrachlorofluorescein (CAS Reg. No. 18472-87-2) formed by alkaline hydrolysis of the parent tetrabromotetrachlorofluorescein.
- (2) Color additive mixtures for drug use made with D&C Red No. 28 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.
- (b) Specifications. D&C Red No. 28 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Sum of volatile matter (at 135 °C) and halides and sulfates (calculated as sodium salts), not more than 15 percent.

Insoluble matter (alkaline solution), not more than 0.5 percent.

Tetrachlorophthalic acid, not more than 1.2 percent.

Brominated resorcinol, not more than 0.4 percent.

2,3,4,5-Tetrachloro-6-(3,5-dibromo-2,4-dihydroxybenzoyl)benzoic acid, not more than 0.7 percent.

2',4',5',7'-Tetrabromo-4,5,6,7-tetrachlorofluorescein, ethyl ester, not more than 2 percent.

Lower halogenated subsidiary colors, not more than 4 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.



Mercury (as Hg), not more than 1 part per million.

Total color, not less than 85 percent.

- (c) Uses and restrictions. D&C Red No. 28 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.
- (d) Labeling. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of §70.25 of this chapter.
- (e) Certification. All batches of D&C Red No. 28 shall be certified in accordance with regulations in part 80 of this chapter.

DECLARATION ON GENETIC MODIFICATION

This is to certify that, regarding cosmetic grade colours the scope relating to the subject of genetically modified foods and how it relates to our products is extensive and beyond the capabilities of our organisation, to categorically state that none of the large number of chemicals used in our processes, have not been in contact with other materials which may have been modified in some way.

However, as we are not directly involved in the food chain and the processing of foods, or in the direct use of crops (modified plants) for food use, we are confident that none of the chemicals, either organic or inorganic are directly associated with any modifications or are derived from biotechnology industries. We can further qualify that the organic dyes, as manufactured, do not come under the scope of containing gluten, so are gluten free. We also state that we are not directly involved in the genetic modification of any of our products.

DECLARATION ON ANIMAL TESTING

This is to certify that, regarding cosmetic grade colours the scope relating to the subject of animal testing and how it relates to our above mentioned products is extensive and beyond the capabilities of our organization, to categorically state that none of the large number of chemicals used in our processes, have not been involved in animal testing as required by the laws or particular countries.

However, we can confirm that no animal testing is carried out within our organisation in any of the technical laboratories and we have not been involved nor have requested animal testing to be carried out by third parties

DECLARATION ON IRRADIATION

This is to certify that cosmetic grade colours are neither treated for any radiation nor exposed to radiation. Food colours products are declared as irradiation free.

DECLARATION ON PETROLEUM COMPOUNDS

This is to certify that cosmetic grade colours are Synthetic dyestuffs and there is no possibility of the presence of Petroleum Compounds in detectable quantities from our best of chemical knowledge of these products and the manufacturing process involved.

DECLARATION FOR VEGETARIANS AND VEGANS

This is to certify that all the products are suitable for Vegetarians and Vegans from our best knowledge of these products and the manufacturing processes involved.

DECLARATION ON ALLERGENS

This is to certify that cosmetic grade colours are synthetic dyestuffs and do not contain or consist of any Allergens like Milk or Milk derivatives, Egg or Egg derivatives, Soybean or Soybean derivatives, Peanuts or Peanut derivatives, Tree nuts or Tree nut derivatives, Grains or Grain derivatives, Fish or Seafood and their derivatives, Seed or Seed derivatives and any Sensitisers and have not been in contact with other materials which have been modified in some way. We also declare that the intermediates used for manufacturing of colours do not contain or consist of any allergens as above.

DECLARATION FOR MAJOR ALLERGENS

Allergen	Yes	No
Milk and products thereof		٧
Eggs and products thereof		٧
Fish and products thereof		٧
Shellfish Mollusc / Crustacean and products thereof		٧
Peanuts and products thereof		٧
Soybeans and products thereof		٧
Tree Nuts and products thereof		٧
Almond		٧
Brazil		V
Cashew		٧
Coconut		٧
Hazelnut (filbert)		V
Pine nuts (Pinyon, Pinon)		V
Pistachio		V
Pecan		V
Macadamia		V
Walnut		٧
Gluten (wheat, Rye, Oat or Barley and products thereof		٧
Seed Products (Excluding refined Oils)		٧
Canary Seed		٧
Sesame Seeds		V
Poppy Seed		٧
Sunflower Seed		٧
Celery (Stalks, Leafs or roots excluding seeds)		٧
Sulfites (more than 10 PPM)		٧
Mustard and products thereof		٧
Lupin and products thereof		٧
Molluscs and products thereof		٧

DECLARATION ON METAL DETECTOR

This is to certify that cosmetic grade colours after getting product in the final stage (powder form), it passes through a Magnet with Gauss power 8000 – 10000 to remove any iron particles.

Also, a metal detection (free iron) test is carried out by a QC Chemist on all batches at the finished goods stage by using a hand magnet with Gauss power 8000 – 10000.

NON COMEDOGENIC DECLARATION

This is to certify that cosmetic grade colours are synthetic dyestuffs.

The quality of our products comply as per CFR and EC regulation for use in Food, Drugs & Cosmetics applications.

From the best of our chemical knowledge our product is Non Comedogenic for humans.

DECLARATION ON PARTICLE SIZE

This is to certify that cosmetic grade colours, in the manufacturing process nanomaterial producing technology has not been used, consequently there are not intentionally produced nanoparticles.

Therefore there is no possibility of the presence of Nanoparticles in our range produced from the best of our knowledge of our product and manufacturing process involved for it.

From the best of our knowledge of products and the manufacturing process the average particle size for the range is < 5 micron.

SECTION 17: ABBREVIATIONS AND ACRONYMS

CAS Chemical Abstracts Service (division of the American Chemical Society)

CI Colour index number.

D&C Drug and Cosmetic

EINECS European Inventory of Existing Commercial Chemical Substances

FAO Food and Agriculture Organisation of the United States

FD & C Food, Drug and Cosmetic

GHS Globally Harmonised System of Classification and Labelling of Chemicals

IARC International Agency for Research on Cancer

INS Refer to CI

JECFA The Joint FAO/WHO Expert Committee on Food Additives

LC₅₀ Lethal concentration, 50 percent

LD₅₀ Lethal dose, 50 percent

NES National Exposure Standard(Safe Work Australia-Workplace Exposure Standards For Airborne

Contaminants)

PPM Parts Per Million

SDS Safety Data Sheet. Formally known as Material Safety Data Sheet (MSDS)

STEL Short Term Exposure Limit

SUSMP Standard for the Uniform Scheduling of Drugs and Poisons

TWA Time Weighted Average
WHO World Health Organisation

WS Water Soluble