



Clonidine Transdermal Patch (all dosage and packaging variants)

US - OSHA SAFETY DATA SHEET

Version: 0

SECTION 1 IDENTIFICATION

Product Identifier

Product name	Clonidine Transdermal Patch, all dosage and packaging variants
Synonyms	Not Available
Other means of identification	Not Available

Recommended use of the chemical and restrictions on use

Relevant identified uses	SDS are intended for use in the workplace. For domestic-use products, refer to consumer labels. Pharmaceutical for human use / prescription medication.
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Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party

Registered company name	Dr.Reddy's Laboratories Limited
Address	8-2-337, Road No 3, Banjara Hills, Hyderabad, Telangana 500034 India
Company Phone Number	+91 40 4900 2900
Emergency Response (24/7)	+918000403230
Fax	+91 40 4900 2999
Website	www.drreddys.com

SECTION 2 HAZARD(S) IDENTIFICATION

Classification of the substance or mixture

NFPA 704 diamond



Note: The hazard category numbers found in GHS classification in section 2 of this SDSs are NOT to be used to fill in the NFPA 704 diamond. Blue = Health Red = Fire Yellow = Reactivity White = Special (Oxidizer or water reactive substances)

Classification	Acute Aquatic Hazard Category 3, Chronic Aquatic Hazard Category 3
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Label elements

GHS label elements	Not Applicable
SIGNAL WORD	NOT APPLICABLE

Hazard statement(s)

H412	Harmful to aquatic life with long lasting effects.
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Hazard(s) not otherwise specified.

Not Applicable

Precautionary statement(s) Prevention

P273	Avoid release to the environment.
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Precautionary statement(s) Response

Not Applicable

Precautionary statement(s) Storage

Not Applicable

Precautionary statement(s) Disposal

P501	Dispose of contents/container in accordance with local regulations.
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SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

Substances

See section below for composition of Mixtures.

Mixtures

CAS No	%[weight]	Name
		clonidine, as
4205-91-8	NotSpec.	clonidine hydrochloride
Not Available	NotSpec.	synthetic polymer/ solvent adhesive mixture proprietary
1338-43-8	NotSpec.	sorbitan monooleate
		aluminum foil, as
7429-90-5	NotSpec.	aluminium
Not Available	NotSpec.	paper liner
Not Available	NotSpec.	low density polyethylene backing fild
Not Available	NotSpec.	polyester overlapped release liner

The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

SECTION 4 FIRST-AID MEASURES

Description of first aid measures

Eye Contact	- Generally not applicable. - If this product comes in contact with eyes: - Wash out immediately with water. - If irritation continues, seek medical attention. - Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	Generally not applicable.
Inhalation	- If fumes, aerosols or combustion products are inhaled remove from contaminated area. - Other measures are usually unnecessary.
Ingestion	- Not considered a normal route of entry. - If swallowed do NOT induce vomiting. - If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. - Observe the patient carefully. - Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. - Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. - Seek medical advice.

Most important symptoms and effects, both acute and delayed

See Section 11

Indication of any immediate medical attention and special treatment needed

For clonidine intoxication:

If overdose occurs the stomach should be emptied by aspiration and lavage.

Severe hypotension may respond to placing the patient in the supine position with the feet raised. The effects of gross overdosage may respond to the infusion of plasma.

Absorbed from the gastrointestinal tract with peak plasma concentrations between 1.5 and 3 hours and a reported half-life of about 12 hours. About 50% of the dose is excreted in the urine unchanged.

[Martindale]

Treatment of overdose of oral sympathomimetics should be symptomatic and supportive and may include the following:

- Consider gastric lavage within one hour of ingestion. Induced vomiting may not be advisable because of the potential for seizures and worsening hypertension.
- Administer activated charcoal slurry.
- Monitor EKG, ECG, serum electrolytes, blood sugar, blood pressure, urinary output, and renal function. Pharmacological action is required only in severely symptomatic patients.
- For pulmonary edema (noncardiogenic) - Maintain ventilation and oxygenation with close arterial blood gas monitoring.
- For seizures or severe agitation - Administer benzodiazepines.
- For dystonic reactions - Administer benzotropine or diphenhydramine.
- For ventricular tachycardia - Administer lidocaine.
- For severe hypertension - Nitroprusside, labetalol, or phentolamine may be necessary.
- For hypotension - Infuse patient with isotonic solution; if condition persists, administer dopamine or norepinephrine.
- For rhabdomyolysis - Administer sufficient 0.9% saline to maintain urine output of 2 to 3 l/kg/hour. Diuretics may be necessary; urinary alkalization is NOT routinely recommended.
- For hyperthermia - Manage with external cooling; avoid phenothiazines. [Meditext 2006]

SECTION 5 FIRE-FIGHTING MEASURES

Extinguishing media

- Foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.

Special hazards arising from the substrate or mixture

Fire Incompatibility	▶ Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result
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Special protective equipment and precautions for fire-fighters

Fire Fighting	▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Wear breathing apparatus plus protective gloves. ▶ Prevent, by any means available, spillage from entering drains or water courses. ▶ Use water delivered as a fine spray to control fire and cool adjacent area.
Fire/Explosion Hazard	Combustible products include,; carbon monoxide (CO), carbon dioxide (CO2), nitrogen oxides (NOx), chlorides, fluorides, other pyrolysis products typical of burning organic material

SECTION 6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

Minor Spills	▶ Clean up all spills immediately. ▶ Secure load if safe to do so. ▶ Bundle/collect recoverable product. ▶ Collect remaining material in containers with covers for disposal.
Major Spills	▶ Clean up all spills immediately. ▶ Secure load if safe to do so. ▶ Bundle/collect recoverable product. ▶ Collect remaining material in containers with covers for disposal.

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling

Safe handling	▶ Limit all unnecessary personal contact. ▶ Wear protective clothing when risk of exposure occurs. ▶ Use in a well-ventilated area. ▶ When handling DO NOT eat, drink or smoke.
Other information	▶ Store in original containers. ▶ Keep containers securely sealed. ▶ Store in a cool, dry, well-ventilated area. ▶ Store away from incompatible materials and foodstuff containers. ▶ [Store at 20-25 degC.]

Conditions for safe storage, including any incompatibilities

Suitable container	Store in original containers.
Storage incompatibility	▶ Avoid reaction with oxidizing agents



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- Must not be stored together

— May be stored together with specific precautions

— May be stored together

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
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US OSHA Permissible Exposure Levels (PELs) - Table Z1	aluminium	Aluminum, metal / Aluminum, metal-Respirable fraction	15 mg/m3 / 5 mg/m3	Not Available	Not Available	Total dust; (as Al) / (as Al)
US OSHA Permissible Exposure Levels (PELs) - Table Z3	aluminium	Inert or Nuisance Dust	5 mg/m3 / 15 mg/m3 / 15 mppcf / 50 mppcf	Not Available	Not Available	Respirable fraction; All inert or nuisance dusts, whether mineral, inorganic, or organic, not listed specifically by substance name are covered by this limit, which is the same as the Particulates Not Otherwise Regulated (PNOR) limit in Table Z-1. / Total dust; All inert or nuisance dusts, whether mineral, inorganic, or organic, not listed specifically by substance name are covered by this limit, which is the same as the Particulates Not Otherwise Regulated (PNOR) limit in Table Z-1.
US ACGIH Threshold Limit Values (TLV)	aluminium	Aluminum metal and insoluble compounds	1 mg/m3	Not Available	Not Available	TLV® Basis: Pneumoconiosis; LRT irr; neurotoxicity
US NIOSH Recommended Exposure Limits (RELs)	aluminium	Aluminium, Aluminum metal, Aluminum powder, Elemental aluminum	10 (total), 5 (resp) mg/m3	Not Available	Not Available	Not Available

EMERGENCY LIMITS

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
sorbitan monooleate	Sorbitan, monooleate	45 mg/m3	490 mg/m3	3000 mg/m3
aluminium	Aluminum	3 mg/m3	33 mg/m3	200 mg/m3

Ingredient	Original IDLH	Revised IDLH
clonidine hydrochloride	Not Available	Not Available
synthetic polymer/ solvent adhesive mixture proprietary	Not Available	Not Available
sorbitan monooleate	Not Available	Not Available
aluminium	Not Available	Not Available
paper liner	Not Available	Not Available
low density polyethylene backing fild	Not Available	Not Available
polyester overlapped release liner	Not Available	Not Available

Exposure controls

Appropriate engineering controls	General exhaust is adequate under normal operating conditions.
Personal protection	
Eye and face protection	No special equipment for minor exposure i.e. when handling small quantities. OTHERWISE: ▶ Safety glasses with side shields. ▶ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task.
Skin protection	See Hand protection below
Hands/feet protection	▶ Wear chemical protective gloves, e.g. PVC. ▶ Wear safety footwear or safety gumboots, e.g. Rubber The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application. The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice. Personal hygiene is a key element of effective hand care.
Body protection	See Other protection below
Other protection	No special equipment needed when handling small quantities. OTHERWISE: ▶ Overalls. ▶ Barrier cream. ▶ Eyewash unit.
Thermal hazards	Not Available

Respiratory protection

Type A-P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Where the concentration of gas/particulates in the breathing zone, approaches or exceeds the "Exposure Standard" (or ES), respiratory protection is required. Degree of protection varies with both face-piece and Class of filter; the nature of protection varies with Type of filter.

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	A-AUS P2	-	A-PAPR-AUS / Class 1 P2
up to 50 x ES	-	A-AUS / Class 1 P2	-
up to 100 x ES	-	A-2 P2	A-PAPR-2 P2 ^

^ - Full-face
A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G = Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Three layered transdermal adhesive patch. The active ingredient is a clear colorless gel with a faint odor.		
Physical state	Manufactured	Relative density (Water = 1)	Not Applicable
Odor	Not Available	Partition coefficient n-octanol / water	Not Available
Odor threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Applicable	Decomposition temperature	Not Available
Melting point / freezing point (°C)	Not Applicable	Viscosity (cSt)	Not Applicable
Initial boiling point and boiling range (°C)	Not Applicable	Molecular weight (g/mol)	Not Applicable
Flash point (°C)	Not Applicable	Taste	Not Available
Evaporation rate	Not Applicable	Explosive properties	Not Available
Flammability	Not Applicable	Oxidizing properties	Not Available
Upper Explosive Limit (%)	Not Applicable	Surface Tension (dyn/cm or mN/m)	Not Applicable
Lower Explosive Limit (%)	Not Applicable	Volatile Component (%vol)	Not Applicable
Vapor pressure (kPa)	Not Applicable	Gas group	Not Available
Solubility in water (g/L)	Not Applicable	pH as a solution (1%)	Not Applicable
Vapor density (Air = 1)	Not Applicable	VOC g/L	Not Available

SECTION 10 STABILITY AND REACTIVITY

Reactivity	See section 7		
Chemical stability	▶ Unstable in the presence of incompatible materials. ▶ Product is considered stable. ▶ Hazardous polymerization will not occur.		
Possibility of hazardous reactions	See section 7		
Conditions to avoid	See section 7		
Incompatible materials	See section 7		
Hazardous decomposition products	See section 5		

SECTION 11 TOXICOLOGICAL INFORMATION

Information on toxicological effects

Clonidine Transdermal Patch (all dosage and packaging variants)

Issue Date: 17-JAN-2024

Inhaled	Not normally a hazard due to physical form of product.
Ingestion	Not normally a hazard due to physical form of product. Side effects of treatment with clonidine, an agent used to reduce blood pressure, include drowsiness, dryness of the mouth (common during initial stages of treatment), anxiety, swelling of the blood vessels, pain in the cheek, coldness of the fingers, discoloration of the fingertips when cold, generalised itch, depression, dizziness, swelling, constipation, nausea, weight gain as well as poor appetite, slow heart rate, abnormalities on ECG, euphoria, headache, eye irritation, low blood pressure on standing, enlarged breasts in the male, impotence, difficulty passing urine, pins and needles, restlessness at night, skin rash, weakness and temporary high blood sugar. Overdose has resulted in high blood pressure, temporary high blood pressure, muscle weakness, vomiting, irritability, reduced or absent reflexes, lethargy, sleepiness, sedation or coma, pallor, low body temperature, slow heart rate, conduction deficits, heart rhythm disturbances, pinpoint pupils, stoppage of breathing, and seizure. Injection may produce pallor in the face.
Skin Contact	Not normally a hazard due to physical form of product. The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.
Eye	Not normally a hazard due to physical form of product.
Chronic	Animal testing showed that long-term oral administration of p-aminoclonidine did not cause an increase in tumors. There was no evidence of p-aminoclonidine causing mutations, genetic damage, or affecting fertility. However it caused death of embryos at very high doses. In therapeutic use, lightheadedness, dry mouth, hypotension, dizziness and constipation. Limited evidence of harm to fetus during pregnancy, based on animal data.

Dr.Reddy's Clonidine Transdermal Patch, all dosage and packaging variants	TOXICITY	IRRITATION
	Not available	Not available
Clonidine Hydrochloride	TOXICITY	IRRITATION
	Inhalation (rat) LC50:0.0197 mg/L/4hr ^[2]	Nil reported
	Oral (rat) LD50:126 mg/kg ^[2]	
Sorbitan Monooleate	TOXICITY	IRRITATION
	Oral (rat) LD50:39800 mg/kg ^[2]	Skin (rabbit):0.25 mg mild
Aluminium	TOXICITY	IRRITATION
	Oral (rat) LD50:>2000 mg/kg ^[1]	Not available

Legend:	1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.* Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances
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CLONIDINE HYDROCHLORIDE	The following information refers to contact allergens as a group and may not be specific to this product. Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. Somnolence, hallucinations, tremor, convulsions, excitement, ataxia, coma, decreased pulse rate, lowered blood pressure, elevated blood pressure, pulse pressure increase, respiratory tract changes, gastrointestinal changes, maternal effects, effects of embryo/ fetus, specific developmental effects (cardiovascular system), effects on newborn recorded.
SORBITAN MONOOLEATE	The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin. The sorbitan esters are agents that typically find use as emulsifiers, stabilizers, and thickeners in foods, cosmetics and medical products. They do not represent a toxicological concern since they are derived from naturally occurring materials and are ultimately metabolized back to these same natural constituents.
SORBITAN MONOOLEATE & ALUMINIUM	No significant acute toxicological data identified in literature search.

Acute Toxicity	☹	Carcinogenicity	☹
Skin Irritation/Corrosion	☹	Reproductivity	☹
Serious Eye Damage/Irritation	☹	STOT - Single Exposure	☹
Respiratory or Skin sensitisation	☹	STOT - Repeated Exposure	☹
Mutagenicity	☹	Aspiration Hazard	☹

Legend: ✗ – Data available but does not fill the criteria for classification
✔ – Data required to make classification available
☹ – Data Not Available to make classification

SECTION 12 ECOLOGICAL INFORMATION

Toxicity

Ingredient	Endpoint	Test Duration (hr)	Species	Value	Source
Sorbitan Monooleate	LC50	96	Fish	0.538mg/L	3
Sorbitan Monooleate	EC50	96	Algae or other aquatic plants	0.049mg/L	3
Aluminium	LC50	96	Fish	0.078-0.108mg/L	2
Aluminium	EC50	48	Crustacea	0.7364mg/L	2
Aluminium	EC50	96	Algae or other aquatic plants	0.0054mg/L	2
Aluminium	BCF	360	Algae or other aquatic plants	9 mg/L	4

Aluminium	EC50	120	Fish	0.000051mg/L	5
Aluminium	NOEC	72	Algae or other aquatic plants	>=0.004mg/L	2
Legend	Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data				

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
DO NOT discharge into sewer or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
sorbitan monooleate	LOW	LOW

Bioaccumulative potential

Ingredient	Bioaccumulation
Sorbitan	HIGH (LogKOW = 5.8851)

Mobility in soil

Ingredient	Mobility
sorbitan monooleate	LOW (KOC = 565.1)

SECTION 13 DISPOSAL CONSIDERATIONS

Waste treatment methods

Product / Packaging disposal	Waste disposal must be in accordance with appropriate Federal, State, and local regulations.
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SECTION 14 TRANSPORT INFORMATION

Labels Required

Marine Pollutant	NO
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Land transport (DOT): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

SECTION 15 REGULATORY INFORMATION

Safety, health and environmental regulations / legislation specific for the substance or mixture

CLONIDINE HYDROCHLORIDE(4205-91-8) IS FOUND ON THE FOLLOWING REGULATORY LISTS	
Not Applicable	
SORBITAN MONOOLEATE(1338-43-8) IS FOUND ON THE FOLLOWING REGULATORY LISTS	
US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory	
ALUMINIUM(7429-90-5) IS FOUND ON THE FOLLOWING REGULATORY LISTS	
International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs	US - Washington Permissible exposure limits of air contaminants US - Wyoming Toxic and Hazardous Substances Table Z1 Limits for Air Contaminants US ACGIH
US - Alaska Limits for Air Contaminants	US ACGIH Threshold Limit Values (TLV) Threshold Limit Values (TLV) - Carcinogens
US - California OEHHA/ARB - Chronic Reference Exposure Levels and Target Organs (CRELs)	US ATSDR Minimal Risk Levels for Hazardous Substances (MRLs)
US - California Permissible Exposure Limits for Chemical Contaminants	US EPCRA Section 313 Chemical List
US - Hawaii Air Contaminant Limits	US NIOSH Recommended Exposure Limits (RELs)
US - Michigan Exposure Limits for Air Contaminants	US OSHA Permissible Exposure Levels (PELs) - Table Z1
US - Minnesota Permissible Exposure Limits (PELs)	US OSHA Permissible Exposure Levels (PELs) - Table Z3
US - Oregon Permissible Exposure Limits (Z-1)	US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory
US - Tennessee Occupational Exposure Limits - Limits For Air Contaminants	

US - Vermont Permissible Exposure Limits Table Z-1-A Final Rule Limits for Air Contaminants
US - Vermont Permissible Exposure Limits Table Z-1-A Transitional Limits for Air Contaminants

Federal Regulations

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SECTION 311/312 HAZARD CATEGORIES

Immediate (acute) health hazard	No
Delayed (chronic) health hazard	No
Fire hazard	No
Pressure hazard	No
Reactivity hazard	No

US. EPA CERCLA HAZARDOUS SUBSTANCES AND REPORTABLE QUANTITIES (40 CFR 302.4)

None Reported

State Regulations

US. CALIFORNIA PROPOSITION 65

None Reported

National Inventory	Status
Australia - AICS	Y
Canada - DSL	Y
Canada - NDSL	N (clonidine hydrochloride; sorbitan monooleate; aluminium)
China - IECSC	N (clonidine hydrochloride)
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N (clonidine hydrochloride; aluminium)
Korea - KECI	N (clonidine hydrochloride)
New Zealand - NZIoC	Y
Philippines - PICCS	N (clonidine hydrochloride)
USA - TSCA	N (clonidine hydrochloride)
Legend:	Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)

SECTION 16 OTHER INFORMATION

Other information

Ingredients with multiple cas numbers

Name	CAS No
aluminium	7429-90-5, 91728-14-2

Issue Date: 17-JAN-2024
Revision Note: Not available.

Disclaimer
DRL considers that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. The information contained herein is designated only as guidance for safe handling, storage and use of the substance and is not a specification nor does it guarantee any specific properties. Only competent personnel, within a controlled environment should handle all chemicals. DRL shall not be held liable for any loss, injury or damage from contact with the product.

End of Safety Data Sheet