

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
US OSHA Hazard Communication Standard 2024 (29 CFR 1910.1200) and Canada Hazardous Products Act (HPA) and the
Hazardous Products Regulation (HPR), as amended

Issuing Date 25-Jan-2018

Revision date 25-Jan-2018

Revision Number 1

1. Identification

Product identifier

Product Name up & up

Other means of identification

Product Code(s) 1358040_TG

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use Allergy Relief (Antihistamine)

Restrictions on use No information available

Details of the supplier of the safety data sheet

Supplier Name DR.REDDY'S LABORATORIES INC

Supplier Address

600 COLLEGE ROAD EAST
Suite 4000
PRINCETON
NJ
08540
US

Emergency telephone number

Supplier Phone Number Phone:640-867-4971
Fax:6092286090

24 Hour Emergency Phone Number 6093759900

Emergency Telephone No information available

2. Hazard(s) identification

Classification of the substance or mixture

This product is not considered hazardous by either the US OSHA Hazard Communication Standard 2024, or Canada Hazardous Products Act (HPA) and Hazardous Products Regulation (HPR), as amended.

Label elements

Hazard statements

No hazard statements required.

Hazards classified under paragraph (d)(1)(ii) of 1910.1200

No information available.

Other information

Causes mild skin irritation.

3. Composition/information on ingredients**Substance**

Not applicable.

Mixture

Chemical name	CAS No.	Weight-%	Hazardous Material Information Review Act registry number (HMIRA registry #)	Date HMIRA filed and date exemption granted (if applicable)
Titanium dioxide	13463-67-7	1	-	-
Magnesium stearate	557-04-0	1	-	-

4. First-aid measures**Description of first aid measures**

Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash skin with soap and water.
Ingestion	Rinse mouth.

Most important symptoms and effects, both acute and delayed

Symptoms Prolonged contact may cause redness and irritation.

Effects of Exposure No information available.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. Fire-fighting measures

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media Do not scatter spilled material with high pressure water streams.

Specific hazards arising from the chemical No information available.

Hazardous combustion products Carbon oxides.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

Special protective equipment and precautions for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions Avoid contact with eyes.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Pick up and transfer to properly labeled containers.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

7. Handling and storage

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place.

8. Exposure controls/personal protection

Control Parameters

Exposure Limits

Chemical name	ACGIH TLV	OSHA PEL	NIOSH
Titanium dioxide 13463-67-7	TWA: 10 mg/m ³	TWA: 15 mg/m ³ total dust (vacated) TWA: 10 mg/m ³ total dust	IDLH: 5000 mg/m ³
Magnesium stearate 557-04-0	TWA: 10 mg/m ³	-	-

Chemical name	Alberta	British Columbia	Ontario	Quebec
Titanium dioxide 13463-67-7	TWA: 10 mg/m ³ ;	TWA: 10 mg/m ³ ; total dust TWA: 3 mg/m ³ ; respirable fraction	TWA: 10 mg/m ³ ;	TWAEV: 10 mg/m ³ ; total dust
Magnesium stearate	TWA: 10 mg/m ³ ;	TWA: 10 mg/m ³ ;	TWA: 10 mg/m ³ ;	TWAEV: 10 mg/m ³ ;

557-04-0		inhalable TWA: 3 mg/m ³ ; respirable	inhalable particulate matter TWA: 3 mg/m ³ ; respirable particulate matter	inhalable aerosol fraction TWA _{EV} : 3 mg/m ³ ; respirable aerosol fraction
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Chemical name	Manitoba	New Brunswick	Newfoundland and Labrador	Nova Scotia
Titanium dioxide	TWA: 0.2 mg/m ³ ; nanoscale respirable particulate matter TWA: 2.5 mg/m ³ ; finescale respirable particulate matter	TWA: 10 mg/m ³ ;	TWA: 0.2 mg/m ³ ; nanoscale respirable particulate matter TWA: 2.5 mg/m ³ ; finescale respirable particulate matter	TWA: 0.2 mg/m ³ ; nanoscale respirable particulate matter TWA: 2.5 mg/m ³ ; finescale respirable particulate matter
Magnesium stearate	TWA: 10 mg/m ³ ; inhalable particulate matter TWA: 3 mg/m ³ ; respirable particulate matter	TWA: 10 mg/m ³ ;	TWA: 10 mg/m ³ ; inhalable particulate matter TWA: 3 mg/m ³ ; respirable particulate matter	TWA: 10 mg/m ³ ; inhalable particulate matter TWA: 3 mg/m ³ ; respirable particulate matter

Chemical name	Nunavut	Prince Edward Island	Saskatchewan	Yukon
Titanium dioxide	TWA: 10 mg/m ³ ; STEL: 20 mg/m ³ ;	TWA: 0.2 mg/m ³ ; nanoscale respirable particulate matter TWA: 2.5 mg/m ³ ; finescale respirable particulate matter	TWA: 10 mg/m ³ ; STEL: 20 mg/m ³ ;	TWA: 30 mppcf; TWA: 10 mg/m ³ ; STEL: 20 mg/m ³ ;
Magnesium stearate	TWA: 10 mg/m ³ ; STEL: 20 mg/m ³ ;	TWA: 10 mg/m ³ ; inhalable particulate matter TWA: 3 mg/m ³ ; respirable particulate matter	TWA: 10 mg/m ³ ; STEL: 20 mg/m ³ ;	-

Note See section 16 for terms and abbreviations.

Other information on limit values Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

Biological occupational exposure limits This product, as supplied, contains materials that do not have reportable biological exposure limits or are not subject to the reporting requirements of the local jurisdiction.

Appropriate engineering controls

Engineering controls Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection Appropriate eye/face protection should be selected and used according to the chemical nature, hazards and use of this product and safety requirements of the local jurisdiction.

Hand protection Appropriate hand protection should be selected and used according to the chemical nature, hazards and use of this product and safety requirements of the local jurisdiction.

Skin and body protection	Appropriate skin and body protection should be selected and used according to the chemical nature, hazards and use of this product and safety requirements of the local jurisdiction.
Respiratory protection	Appropriate respiratory protection should be selected and used according to the chemical nature, hazards and use of this product and safety requirements of the local jurisdiction. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Solid
Color	No information available
Odor (includes odor threshold)	Odorless
Odor threshold	No data available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
Melting point / freezing point	No data available	None known
Boiling point (or initial boiling point or boiling range)	No data available	None known
Flammability	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
SADT (°C)	No data available	None known
pH	No data available	None known
pH (as aqueous solution)	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Solubility	No data available	None known
Water solubility	No data available	
Partition coefficient n-octanol/water (log value)	N/A	
Vapor pressure (includes evaporation rate)	No data available	None known
Evaporation rate	No data available	None known
Density and/or relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Relative vapor density	No data available	None known
Particle characteristics		None known
Particle Size	No data available	
Particle Size Distribution	No data available	

Other information

Miscible	No
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10. Stability and reactivity

Reactivity	No information available.
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Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Hazardous polymerization	Hazardous polymerization does not occur.
Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.
Hazardous decomposition products	Carbon oxides.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available. Causes mild skin irritation.
Ingestion	Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	Prolonged contact may cause redness and irritation.
Acute toxicity	No information available.

Numerical measures of toxicity

The following ATE values have been calculated for the mixture

ATEmix (oral)	99,999.00 mg/kg
ATEmix (dermal)	99,999.00 mg/kg
ATEmix (inhalation-gas)	99,999.00 ppm
ATEmix (inhalation-vapor)	99,999.00 mg/l
ATEmix (inhalation-dust/mist)	99,999.00 mg/l

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Titanium dioxide	> 2000 mg/kg (Rat)	-	> 5.09 mg/L (Rat) 4 h
Magnesium stearate	> 10000 mg/kg (Rat)	-	-

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	Classification based on data available for ingredients. Causes mild skin irritation.
Serious eye damage/eye irritation	No information available.
Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	Based on available data, the classification criteria are not met. Classification based on data available for ingredients. This product contains titanium dioxide in a non-respirable form. Inhalation of titanium dioxide is unlikely to occur from exposure to this product.

The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical name	ACGIH	IARC	NTP	OSHA
Titanium dioxide	A3 - Confirmed animal carcinogen (with unknown relevance to humans)	Group 2B - Possibly carcinogenic to humans	-	X
Magnesium stearate	A4 - Not classifiable as a human carcinogen	-	-	-

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

12. Ecological information

Ecotoxicity Based on available data, the classification criteria are not met.

Persistence and degradability No information available.

Bioaccumulative potential No information available.

Mobility in soil No information available.

Other adverse effects No information available.

13. Disposal considerations

Disposal methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

14. Transport information

DOT NOT REGULATED
Transport hazard class(es) N/A

TDG Not applicable

<u>MEX</u>	Not applicable
<u>ICAO (air)</u>	Not applicable
<u>IATA</u> Transport hazard class(es)	Not applicable N/A
<u>IMDG</u> Transport hazard class(es)	Not applicable N/A

15. Regulatory information

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

International Regulations

The Montreal Protocol on Substances that Deplete the Ozone Layer Not applicable

The Stockholm Convention on Persistent Organic Pollutants Not applicable

The Rotterdam Convention Not applicable

International Inventories

TSCA Contact supplier for inventory compliance status.

DSL/NDSL Contact supplier for inventory compliance status.
EINECS/ELINCS Contact supplier for inventory compliance status.
ENCS Contact supplier for inventory compliance status.
IECSC Contact supplier for inventory compliance status.
KECL Contact supplier for inventory compliance status.
PICCS Contact supplier for inventory compliance status.
AIIC Contact supplier for inventory compliance status.
NZIoC Contact supplier for inventory compliance status.
TCSI Contact supplier for inventory compliance status.

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing Chemicals Inventory

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AIIC - Australian Inventory of Industrial Chemicals

NZIoC - New Zealand Inventory of Chemicals

TCSI - Taiwan Chemical Substance Inventory

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CAA (Clean Air Act)

This product does not contain any substances regulated as pollutants pursuant to Clean Air Act (CAA).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations**California Proposition 65**

This product contains the following Proposition 65 chemicals:

Chemical name	California Proposition 65
Titanium dioxide	Carcinogen

U.S. State Right-to-Know Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
Titanium dioxide	X	X	X

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA	Health hazards 1	Flammability 0	Instability 0	Special hazards -
HMIS	Health hazards 1	Flammability 0	Physical hazards 0	Personal protection X

Key or legend to abbreviations and acronyms used in the safety data sheet

List may include phrases which are not applicable to this product

ACGIH	American Conference of Governmental Industrial Hygienists
ADN	Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Europe)
ADR	Agreement concerning the International Carriage of Dangerous Goods by Road (Europe)
AIIC	Australian Inventory of Industrial Chemicals
ATE	Acute Toxicity Estimate
ASTM	American Society for the Testing of Materials
bar	Biological Reference Values for Chemical Compounds in the Work Area
BAT	Biological tolerance values for occupational exposure
BEL	Biological exposure limits
bw	Body weight
Ceiling	Maximum limit value
CMR	Carcinogen, Mutagen or Reproductive Toxicant
DOT	Department of Transportation (United States)
DSL	Domestic Substances List (Canada)
EmS	Emergency Schedule
ENCS	Existing and New Chemical Substances (Japan)
EPA	Environmental Protection Agency
GHS	Globally Harmonized System
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer

IATA	International Air Transport Association
IBC	International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
ICAO	International Civil Aviation Organization
IECSC	Inventory of Existing Chemical Substances in China
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
ISO	International Organization for Standardization
KECI	Korean Existing Chemicals Inventory
LC50	Lethal Concentration to 50% of a test population
LD50	Lethal Dose to 50% of a test population (Median Lethal Dose)
MARPOL	International Convention for the Prevention of Pollution from Ships
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
n.o.s.	Not Otherwise Specified
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NOELR	No Observable Effect Loading Rate
NTP	National Toxicology Program (United States)
NZIoC	New Zealand Inventory of Chemicals
OECD	Organization for Economic Cooperation and Development
OEL	Occupational exposure limits
OSHA	Occupational Safety and Health Administration of the US Department of Labor
PBT	Persistent, Bioaccumulative and Toxic substance
PICCS	Philippines Inventory of Chemicals and Chemical Substances
PMT	Persistent, Mobile and Toxic
PPE	Personal protective equipment
QSAR	Quantitative Structure Activity Relationship
RID	Agreement concerning the International Carriage of Dangerous Goods by Rail (Europe)
SADT	Self-Accelerating Decomposition Temperature
SAR	Structure-activity relationship
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
SL	Surface Limit
STEL	Short Term Exposure Limit
STOT RE	Specific target organ toxicity - Repeated exposure
STOT SE	Specific target organ toxicity - Single exposure
TCSI	Taiwan Chemical Substance Inventory
TDG	Transport of Dangerous Goods (Canada)
TSCA	Toxic Substances Control Act (United States)
TWA	Time-Weighted Average
UN	United Nations
VOC	Volatile organic compounds
vPvB	Very Persistent and Very Bioaccumulative
vPvM	Very Persistent and Very Mobile
As	Allergenic substance
DS	Dermal Sensitizer
Ot	Ototoxicant
pOt	Ototoxicant - potential to cause hearing disorders
PS	Photosensitizer
RS	Respiratory Sensitizer
S	Sensitizer
poS	Sensitizer - capable of causing occupational asthma
Sa	Simple asphyxiant
Sd	Skin designation
pSd	Skin designation - potential for cutaneous absorption
Sdv	Skin designation - vacated
Sk	Skin notation

dSk	Skin notation - danger of cutaneous absorption
pSk	Skin notation - potential for cutaneous absorption

Key literature references and sources for data used to compile the SDS

U.S. Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
U.S. Environmental Protection Agency
Acute Exposure Guideline Level(s) (AEGL(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
Japan National Institute of Technology and Evaluation (NITE)
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine's PubMed database (NLM PUBMED)
U.S. National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
International Organization for Economic Co-operation and Development (OECD) Environment, Health, and Safety Publications
International Organization for Economic Co-operation and Development (OECD) High Production Volume Chemicals Program
International Organization for Economic Co-operation and Development (OECD) Screening Information Data Set
United Nations World Health Organization (WHO)

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Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet