Schering-Plough HealthCare Products, Inc.
3030 Jackson Avenue
Memphis, TN 38151

MATERIAL SAFETY DATA SHEET

Schering-Plough urges each user or recipient of this MSDS to read the entire data sheet to become aware of the hazards associated with this material.

SECTION 1. IDENTIFICATION OF SUBSTANCE AND CONTACT INFORMATION

MSDS NAME: **Loratadine and Pseudoephedrine Sulfate Repetabs Tablets [Bulk Product Formulation]**

SYNONYM(S): CLARITIN-D Tablets (12 Hour)

CHLOR-TRIPOLON Nasal Decongestant; CLARATYNE Cold Repetabs; CLARATYNE Cold Tablets; CLARATYNE Decongestant Repetabs; CLARIDEX Grageas A.P.; CLARIDEX Repetabs; CLARIDON Drageias; CLARINASE Confetti; CLARINASE Dragees; CLARINASE Manteldragees; CLARINASE Repetabs Tablets; CLARINASE Tablets; CLARINASE-12; CLARITIN Extra; CLARITIN-D Drageas; CLARITINE-D; CLARITYNE D 12 Horas Repetabs; CLARITYNE D Repetabs; CLARITYNE D Tabletas; CLARITYNE-D Repetabs; DEMAZIN Non-Drowsy Repetabs; DEMAZIN NS Repetabs; LERTAMINE D Repetabs; LERTAMINE Repetabs; LORATYNE Tablets; NARINE Repetabs; POLARATYNE D Repetabs; PROACTIN D 12 Horas Repetabs; RHINASE Tablets; RINASE Grageas; SINEASE Tablets

MSDS NUMBER: SP001823

EMERGENCY NUMBER(S): Schering-Plough Security Control Center (908) 820-6921 (24 hours)

Transportation Emergencies - CHEMTREC:
(800) 424-9300 (Inside Continental USA)
(703) 527-3887 (Outside Continental USA)

Safety/Environmental Affairs (901) 320-2384

INFORMATION: Safety/Environmental Affairs (901) 320-2384

SCHERING-PLOUGH MSDS HELPLINE: (800) 770-8878 (US and Canada)
(908) 629-3657 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time) .

SECTION 2. HAZARDS IDENTIFICATION

SECTION 2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Powder
White to off-white
Odor unknown

May be harmful if swallowed.
May cause allergic reactions in susceptible individuals.
May be irritating to eyes and respiratory system.

May cause effects to:
central nervous system
cardiovascular system
respiratory system
bladder
kidney

Harmful to aquatic organisms.

POTENTIAL HEALTH EFFECTS:

This product is presented as a final, solid dosage form (tablet).

The following summary is based upon available information about the individual ingredients of the mixture, or of the expected properties of the mixture. Only information about the ingredients that are expected to contribute significantly to the potential health hazard profile of the formulation(s) are presented.

Pseudoephedrine and its salts are primarily given orally for the relief of nasal congestion. Common adverse clinical effects from psuedoephedrine include rapid or irregular heart beat, increased blood pressure, headaches, agitation, muscle tremors, increased sweating, nausea or vomiting, anxiety, restlessness, and insomnia. Skin rashes and urinary retention have also been reported. Exposure to high concentrations may cause hallucinations or seizures. Pseudoephedrine is excreted in human breast milk; however, the drug used during lactation has not been associated with adverse effects in exposed newborns.

Loratadine is an antihistamine with low toxicity. The most frequently reported adverse events include headache, drowsiness, fatigue and dry mouth. Loratadine has been reported to be present in breast milk but is unlikely to cause harm.

Calcium sulfate (gypsum) dust may be irritating to eyes, mucous membranes, and respiratory tract. Reports of conjunctivitis, chronic rhinitis, laryngitis, pharyngitis, impaired sense of smell and taste, bleeding from the nose, and reactions of the tracheal and bronchial membranes have been reported in exposed workers.

LISTED CARCINOGENS

CHEMICAL NAME	CAS NUMBER	OSHA	IARC	NTP	ACGIH
Sucrose.	57-50-1				Group A4 Not classifiable as a human carcinogen.
Talc (non-asbestos form).	14807-96-6	Not classifiable.	3 Classification not possible from current data.		Not classifiable.
Povidone.	9003-39-8		3 Classification not possible from current data.		
Titanium Dioxide.	13463-67-7		2B Possible carcinogen.		Group A4 Not classifiable as a human carcinogen.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

PRODUCT USE: Drug product

CHEMICAL FORMULA: Mixture.

This product is presented as a final, solid dosage form (tablet).

The formulation for this product is proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the Chemical Composition table. Active ingredients in any concentration are listed. For additional information about carcinogenic ingredients see Section 2.

CHEMICAL COMPOSITION

CHEMICAL NAME	CAS NUMBER	PERCENT
Pseudoephedrine Sulfate.	7460-12-0	13
Loratadine.	79794-75-5	0.55
Calcium Sulfate Anhydrous.	7778-18-9	20-30
Calcium Sulfate Dihydrate.	10101-41-4	20-30
Lactose Monohydrate.	64044-51-5	10-20
Sucrose.	57-50-1	10-20
Corn Starch.	65996-62-5	<10
Talc (non-asbestos form).	14807-96-6	<10
Acacia.	9000-01-5	<10
Povidone.	9003-39-8	<10
Titanium Dioxide.	13463-67-7	<1

ADDITIONAL INFORMATION: This MSDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

SECTION 4. FIRST AID MEASURES

INHALATION: Remove to fresh air. If any trouble breathing, get immediate medical attention. Administer artificial respiration if breathing has ceased. If irritation or symptoms occur or persist, consult a physician.

SKIN CONTACT: In case of skin contact, while wearing protective gloves, carefully remove any contaminated clothing, including shoes, and wash skin thoroughly with soap and water. If irritation or symptoms occur or persist, consult a physician.

EYE CONTACT: In case of eye contact, immediately rinse eyes thoroughly with plenty of water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. If irritation occurs or persists, consult a physician.

INGESTION: Rinse mouth and drink a glass of water. Do not induce vomiting unless under the direction of a qualified medical professional or Poison Control Center. If symptoms persist, consult a physician.

SECTION 5. FIRE FIGHTING MEASURES

FLAMMABILITY DATA:

Flash Point: Not determined (liquids) or not applicable (solids).

OTHER EXPLOSION HAZARDS:
Under normal conditions of use, this material does not present a significant fire or explosion hazard. However, like most organic compounds, this material may present a dust deflagration hazard if sufficient quantities are suspended in air. This hazard may exist where sufficient quantities of finely divided material are (or may become) suspended in air during typical process operations. An assessment of each operation should be conducted and suitable deflagration prevention and protection techniques employed. The sensitivity of this material to ignition by electrostatic discharges has not been determined. In the absence of testing data, all conductive plant items and operations personnel handling this material should be suitably grounded.

SPECIAL FIRE FIGHTING PROCEDURES:
Wear full protective clothing and self-contained breathing apparatus (SCBA).

SUITABLE EXTINGUISHING MEDIA:
Carbon dioxide (CO2), extinguishing powder or water spray.

See Section 9 for Physical and Chemical Properties.

SECTION 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:
Avoid generation of dust during clean-up. Wear appropriate personal protective equipment as specified in Section 8. Keep personnel away from the clean-up area.

SPILL RESPONSE / CLEANUP:
All spills should be handled according to site requirements and based on precautions cited in the MSDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, HEPA vacuuming prior to wet mopping or cleaning is required.

ENVIRONMENTAL PRECAUTIONS:
This product is harmful to aquatic organisms. Do not allow product to reach ground water, water course, sewage or drainage systems.

See Sections 9 and 10 for additional physical, chemical, and hazard information.

SECTION 7. HANDLING AND STORAGE

HANDLING:
Keep containers adequately sealed during material transfer, transport, or when not in use.

Appropriate handling of this material is dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. See Section 8 (Exposure Controls) for additional guidance.

STORAGE:
Store out of direct light. Store in a cool, dry, well ventilated area. Store between 20 and 25 deg C.

See Section 8 for exposure controls and additional safe handling information.

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

The following guidance applies to the handling of the active ingredient(s) in this formulation.

S-P HEALTH HAZARD CATEGORY (HHC):
The Schering-Plough Health Hazard Category (HHC) for this material is HHC2. Materials in this category are considered moderate health hazards. Health Hazard Categories are intended to be a component of workplace risk assessment. Consult your site safety and industrial hygiene staff for guidance on handling and control strategies.

S-P OCCUPATIONAL EXPOSURE GUIDELINE (OEG):
Schering-Plough Corporation has established an Occupational Exposure Guideline (OEG) of 250 mcg/m^3 (8-hr TWA) for loratadine. Consult your site safety and industrial hygiene professional(s) for additional guidance.

EXPOSURE CONTROLS:
The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.

RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT (PPE):

Respiratory Protection:	Respiratory protective equipment (RPE) may be required for certain laboratory and large-scale manufacturing tasks if potential airborne breathing zone concentrations of substances exceed the relevant exposure limit(s). Workplace risk assessment should be completed before specifying and implementing RPE usage. Potential exposure points and pathways, task duration and frequency, potential employee contact with the substance, and the ability of the substance to be rendered airborne during specific tasks should be evaluated. Initial and ongoing strategies of quantitative exposure measurement should be obtained as required by the workplace risk assessment. All RPE must conform to local and regional specifications for efficacy and performance. Consult your site or corporate health and safety professional for additional guidance.
Skin Protection:	Gloves that provide an appropriate barrier to the skin are recommended if there is potential for contact with this material. Consult your site safety staff for guidance.

Eye Protection: Safety glasses with side shields. Use of goggles or full face protection may be required based on hazard, potential for contact, or level of exposure. Consult your site safety staff for guidance.

Body Protection: In small-scale or laboratory operations, lab coats or equivalent protection is required. Disposable Tyvek or other dust impermeable suit should be considered based on procedure or level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

In large-scale or manufacturing operations, disposable Tyvek or other dust impermeable suit is recommended and based on level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

EXPOSURE LIMIT VALUES

CHEMICAL NAME	CAS NUMBER	ACGIH TLV (TWA)	OSHA PEL (TWA)
Calcium Sulfate Anhydrous.	7778-18-9	10 mg/m^3 Inhalable fraction.	5 mg/m^3 Respirable fraction. 15 mg/m^3 Total dust.
Calcium Sulfate Dihydrate.	10101-41-4	10 mg/m^3 Inhalable fraction.	5 mg/m^3 Respirable fraction. 15 mg/m^3 Total dust.
Sucrose.	57-50-1	10 mg/m^3	5 mg/m^3 Respirable fraction. 15 mg/m^3 Total dust.
Talc (non-asbestos form).	14807-96-6	2 mg/m^3 Respirable fraction. The value is for particulate matter containing no asbestos and <1% crystalline silica.	20 mppcf (containing <1% quartz)
Titanium Dioxide.	13463-67-7	10 mg/m^3	15 mg/m^3 Total dust.

CHEMICAL NAME	CAS NUMBER	ACGIH TLV (STEL / SKIN)	ACGIH TLV (CEIL)	OSHA PEL (STEL / SKIN)	OSHA PEL (CEIL)
Talc (non-asbestos form).	14807-96-6			20 mppcf (containing <1% quartz)	

Fields in the above table(s) that do not contain data indicate that exposure limits are not available for those endpoints.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM: Powder
COLOR: White to off-white
ODOR: Odor unknown
SOLUBILITY:
Water: Not determined

See Section 5 for flammability/explosivity information.

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
Stable under normal conditions.

INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:
None known.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
No dangerous decomposition is expected if used according to manufacturer's specifications.

SECTION 11. TOXICOLOGICAL INFORMATION

The information presented below pertains to the following individual ingredients, and not to the mixture(s). Only information about the ingredients that are expected to contribute significantly to the potential health hazard profile of the formulation(s) is presented.

ACUTE TOXICITY DATA

INHALATION:
Pseudoephedrine Sulfate: Inhalation LC50 (4hr): >2.37 mg/L (rat)

Loratadine: No mortality occurred in rats exposed to 0.05 mg/L (maximum attainable concentration) for 1 hour. Treatment related clinical signs included secretory responses and wet ano-genital area. Lung discoloration was seen in 7/10 animals. The toxicological significance of this finding, if any, is not known.

SKIN:
Pseudoephedrine sulfate was not irritating to the skin of rabbits in a primary skin irritation study.

Loratadine was not irritating to the skin of rabbits.

EYE:
Loratadine did not produce ocular irritation in rabbits.

Calcium sulfate (gypsum) was not irritating to the eyes of rabbits.

ORAL:
Pseudoephedrine Sulfate: 1170 mg/kg (rat)

Loratadine: Oral LD50: >5000 mg/kg (rat); >1280 mg/kg (monkey)

SENSITIZATION:
Loratadine has not been reported as a sensitizer during production.

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:
Loratadine was given to rats in oral dosages of 4-240 mg/kg/day and to monkeys at dosages ranging from 0.4-90 mg/kg/day in six-month studies. Anticholinergic effects, reduced fecal excretion, and/or mydriasis were observed in rats at dosages of 128 mg/kg/day and greater. Monkeys given 16 mg/kg/day or more in a 12-month study also showed evidence of anticholinergic effects. Rats began to show evidence of phospholipidosis (lipid accumulation in cells) at 8 mg/kg/day and higher. Monkeys were observed to have phospholipidosis at 4 mg/kg/day and greater. Phospholipidosis has not been observed in man at these dosages of loratadine. CNS studies in the mouse indicated weak or no activity, as evidenced by a lack of CNS effect versus acetic acid writhing and electro-convulsive shock seizures at doses as high as 320 mg/kg of loratadine.

Animals exposed to calcium sulfate (gypsum) dust developed pneumonia and interstitial pneumonsclerosis, and blood and lymph circulation disorders of the lungs.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:
There was no evidence of teratogenicity in studies of loratadine performed in rats and rabbits using oral doses as high as 96 mg/kg (~ 75x and 150x the maximum recommended human daily oral dose on a mg/m2 basis, respectively). When given to pregnant rats, loratadine crossed the placental barrier; the concentration in the fetuses was lower than the concentration in the dams. Loratadine takes the same time to metabolize and has the same products of metabolism in the fetuses as observed in the dams. A reversible decrease in male rat fertility was reported at 64 mg/kg/day [NOEL 24 mg/kg/day]. No fertility effects reported in female rats.

MUTAGENICITY / GENOTOXICITY:
Loratadine was negative in bacterial mutagenicity study (Ames), chromosome aberration study in human lymphocytes in the presence and absence of metabolic activation, rat bone marrow micronucleus assay, mouse bone marrow micronucleus assay, chromosomal aberration (HPBL) assay.

CARCINOGENICITY:
There was no evidence of carcinogenicity when loratadine was given to mice, rats, and monkeys.

SECTION 12. ECOLOGICAL INFORMATION

There are no data for the final product or its formulation(s). The information presented below pertains to the following ingredient(s).

ECOTOXICITY DATA

INGREDIENT ECOTOXICITY

Loratadine:
96-hr LC50 (bluegill) 0.82 mg/L, NOEC = 0.093 mg/L
48-hr EC50 (daphnid) 3.1 mg/L, NOEC = 0.098 mg/L
72-hr IC50 (algae) 40 mg/L

ENVIRONMENTAL DATA

OTHER INGREDIENT ENVIRONMENTAL DATA:

Loratadine is not readily biodegradable.
Loratadine: log Pow: 2.3

ENVIRONMENTAL FATE AND EFFECTS:
Loratadine photodegraded in an aqueous photolysis rate study. The calculated half-life was 10.8 days at pH 7. Total degradation was measured at 87.1% at pH 5 in 25 days, 79.3% at pH 7 in 27 days and 78.3% at pH 9 in 27 days.

SECTION 13. DISPOSAL CONSIDERATIONS

MATERIAL WASTE:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incineration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

PACKAGING AND CONTAINERS:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations.

SPECIAL ENVIRONMENTAL HANDLING PROCEDURES:
This product contains materials that are harmful to the environment. Do not allow product to reach ground water, water courses, sewage or drainage systems.

SECTION 14. TRANSPORT INFORMATION

This material is not subject to the transportation regulations of DOT, IATA, IMO, and the ADR.

SECTION 15. REGULATORY INFORMATION

TSCA LISTING

CHEMICAL NAME	TSCA
Pseudoephedrine Sulfate.	Listed.
Calcium Sulfate Anhydrous.	Listed.
Calcium Sulfate Dihydrate.	Listed.
Sucrose.	Listed
Corn Starch.	Listed.
Talc (non-asbestos form).	Listed
Acacia.	Listed.
Povidone.	Listed
Titanium Dioxide.	Listed.

U.S. STATE REGULATIONS

CHEMICAL NAME	California Proposition 65	CARTK	NJRTK	CTRTK	MARTK
Calcium Sulfate Anhydrous.					Listed.
Calcium Sulfate Dihydrate.					Listed.
Sucrose.					Listed.
Talc (non-asbestos form).	Not applicable.	Listed.	Substance no. 1773 Listed.		Listed.
Acacia.			Substance no. 0965 Listed.		
Povidone.		Listed.			
Titanium Dioxide.			Substance no. 1861 Listed.		Listed.

CHEMICAL NAME	PARTK	MNRTK	MIRTK	ILRTK	LARTK	RIRTK
Calcium Sulfate Anhydrous.	Listed.	Listed.		Listed.		
Calcium Sulfate Dihydrate.	Listed.	Listed.		Listed.		Listed.
Sucrose.	Listed.	Listed.		Listed.		Listed.
Talc (non-asbestos form).	Listed.	Listed.		Listed.		Listed.
Titanium Dioxide.	Listed.	Listed.		Listed.		Listed.

Fields in the above tables that do not contain data indicate that those materials have not been listed by local regulations.

SECTION 16. OTHER INFORMATION

SECTION 16. OTHER INFORMATION

Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

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