9pE12 Hc #35

6970674

1PHARMACIA

Print Date: December 05, 2001
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Agent Id#: 56179

**** MATERIAL SAFETY DATA SHEET ****

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

COMMON NAME: GENOTROPIN(R) MINIQUICK(R)
SYNONYMS: 0013-2649-02 - NDC NUMBER
0013-2650-02 - NDC NUMBER
0013-2651-02 - NDC NUMBER
0013-2652-02 - NDC NUMBER
0013-2653-02 - NDC NUMBER
0013-2654-02 - NDC NUMBER
0013-2655-02 - NDC NUMBER
0013-2656-02 - NDC NUMBER
0013-2657-02 - NDC NUMBER
0013-2658-02 - NDC NUMBER

I-468217 C-00013265002
I-468218 C-00013265102
I-469351 C-00013265202
I-477166 C-00013264902

MOLECULAR FORMULA: Mixture
CHEMICAL FAMILY: Recombinant human growth hormone.
USE: Human drug used for the treatment of human growth hormone deficiency.
MANUFACTURER/SUPPLIER: PHARMACIA & UPJOHN CO., A SUBSIDIARY OF
PHARMACIA CORP.
7171 PORTAGE RD
KALAMAZOO, MI 49001-0199

TELEPHONE NUMBERS: (269) 833-5122 - (24 HOURS)
(800) 821-7000 - (8:00 a.m. - 4:30 p.m.)

2. COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENT 1
COMMON NAME: Water
% BY WEIGHT: 96 % (component of diluent in rear chamber)
CAS NUMBER: 7732-18-5
EXPOSURE LIMIT(S): Not established.

INGREDIENT 2
COMMON NAME: Somatropin
% BY WEIGHT: < 1 % (component of dry powder in front chamber)
CAS NUMBER: 12629-01-5
EXPOSURE LIMIT(S): Not established.

EXPOSURE LIMIT(S) FOR THE MATERIAL: Not established.

3. HAZARDS IDENTIFICATION

PRIMARY ROUTE(S) OF EXPOSURE: Skin contact, eye contact, ingestion and inhalation.
EFFECTS OF OVEREXPOSURE:
ACUTE OVEREXPOSURE: Single subcutaneous doses of recombinant human growth hormone in rats at 8000 times the expected human dose caused no deaths.
CHRONIC OVEREXPOSURE: The few effects (mammary hyperplasia, decidual cell reaction in the uterus, decrease cholesterol) observed in long-term rat and monkey studies with Genotropin were similar to those observed with pituitary human growth hormone.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Not applicable.

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4. FIRST AID MEASURES

EYES: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
SKIN: Wash off with soap and water. Take off all contaminated clothing immediately.
INHALATION: Move to fresh air.
INGESTION: Contact a physician or poison control center.

5. FIRE FIGHTING MEASURES

FLASH POINT: Nonflammable.
LOWER EXPLOSION LIMIT (LEL): Not applicable.
UPPER EXPLOSION LIMIT (UEL): Not applicable.
EXTINGUISHING MEDIA: Water, carbon dioxide, or dry chemical.
FIRE-FIGHTING PROCEDURES: Wear self-contained breathing apparatus and full body protective equipment.
UNUSUAL FIRE OR EXPLOSION HAZARDS: None.
HAZARDOUS COMBUSTION PRODUCTS: Carbon monoxide. Carbon dioxide. Nitrogen oxides Sulfur oxides.

6. ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED: Provide ventilation and respiratory, skin and eye protection to prevent overexposure. Keep product out of drains; prevent entry to surface water, groundwater and soil. Small spills may be absorbed with paper towels or appropriate media. Large spills can be vacuumed or scooped and placed in a suitable container.

7. HANDLING AND STORAGE

PRECAUTIONS FOR HANDLING AND STORING: Avoid contact with skin, eyes and clothing. Wash thoroughly after handling. Launder contaminated clothes before reuse. Store in original package under refrigeration, 2-8 C (36-46 F) and protect from light. After dispensing, may be stored at or below 25 C (77 F) for up to 3 months. After reconstitution, the cartridge may be stored unde refrigeration for up to 24 hours. Do not freeze. Keep out of the reach of children.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

RESPIRATORY PROTECTION: Not required.
VENTILATION: Local exhaust.
PROTECTIVE GLOVES: Rubber.
EYE PROTECTION: Safety glasses with side-shields.

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE/PHYSICAL STATE: Two-chamber cartridge. Front chamber: White powder Rear chamber: Clear colorless liquid.
ODOR: Odorless.
SOLUBILITY IN WATER: Soluble.

10. STABILITY AND REACTIVITY

STABILITY: Stable.
PHYSICAL CONDITIONS TO AVOID: None known.
INCOMPATIBILITY WITH OTHER MATERIALS: None known.
HAZARDOUS DECOMPOSITION PRODUCTS: Not applicable.
HAZARDOUS POLYMERIZATION: Does not occur.

11. TOXICOLOGICAL INFORMATION

OTHER STUDIES:
CARCINOGENICITY: Ingredient(s) are not listed as carcinogenic by IARC, NTP or OSHA.

12. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Dispose of by incineration in accordance with applicable international, national, state, and/or local waste disposal regulations.

13. SHIPPING REGULATIONS

Not regulated for transportation by the United States Department of Transportation (DOT), International Maritime Organization (IMO), or International Air Transport Association (IATA). May be subject to state and/or local transportation requirements.

14. OTHER INFORMATION

REVIEWED BY: Environment and Safety.
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15. LABELING

This drug is subject to FDA labeling requirements; therefore, it is exempt from the labeling requirements of the OSHA Hazard Communication Standard.