According to EC Regulation 1907/2006 (REACH)



REVISION DATE: 20/07/10

PRODUCT SAFETY DATA SHEET OXYTET 20 INJECTION

1. IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY / UNDERTAKING

Product Name Oxytet 20 Injection

Manufacturer Norbrook Laboratories Ltd,

Station Works, Newry, Co.Down,

N.Ireland, BT35 6JP.

Supplier Norbrook, Inc.

9733 Loiret Blvd Lenexa, KS 66219 Phone: 913 599 5777 Fax: 913 599 5766

2. HAZARDS IDENTIFICATION

Physical and Chemical Hazards : Not classified as dangerous under EEC Directives 67/548/EEC,

88/379/EEC or 99/45/EC.

Environmental Hazards : None known

Adverse Human Health Effects : There are no known adverse effects of exposure to Oxytet 20

Injection.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Substance/Preparation : Preparation

Active Ingredients : Oxytetracycline Hydrochloride

Description : Antibacterial
Chemical Family : Tetracyclines

4. FIRST AID MEASURES

Inhalation : Remove to fresh air. If any signs or symptoms occur or persist seek medical advice.

Skin Contact : Wash thoroughly with soap and water. Remove contaminated clothing and wash before

reuse.

Eyes Contact : Immediately flush eyes with copious amounts of water for at least 15 minutes. If irritation

persists, seek medical attention.

Ingestion : Do not induce vomiting. Seek medical attention.

5. FIRE FIGHTING MEASURES

Extinguishing media: Use carbon dioxide, dry chemical or alcohol-resistant foam spray extinguishers.

Use water spray to cool fire-exposed containers. A fine water mist may be used

to smother or to disperse vapours.

REVISION DATE: 20/07/10

Fire and explosion hazards: None.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions : Provide good ventilation. Prevent skin and eye contact.

Environmental Precautions: Keep away from drains, surface-water, ground-water and soil.

Method for Clean-up : Absorb small spills on spill pillows, sand, sawdust or other suitable absorbing

material.

7. HANDLING AND STORAGE

Handling : Avoid contact with eyes, skin or clothing. Do not breathe vapours or mist. Do not ingest.

Do not smoke or eat while handling the product. Wash thoroughly after handling. The

containers should be stored in their original boxes when not in use.

Storage : Store in closed containers in a cool, dry, well-ventilated area, below 25°C and away from

oxidisers, heat, sparks and open flame. Protect containers from physical damage and

light.

Keep container closed when not in use. Do not transfer contents to unlabelled containers.

Use only with adequate ventilation. Keep out of reach of children.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Component - Occupational Exposure Standard

Oxytetracycline Not Established

For pure oxytetracycline:

LD50 (Oral, mouse) 2240 mg/kg LD50 (Oral, rat) 4800 mg/kg

Protective Equipment : Wear vinyl, nitrile or rubber gloves, a waterproof bib-apron and suitable eye

protection when applying the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form : Sterile aqueous solution

Odour : None.

10. STABILITY AND REACTIVITY

Colour

Stability : Stable under normal temperatures and pressures.

Clear, yellow/brown

Conditions to avoid : None known Materials to avoid : None known

11. TOXICOLOGICAL INFORMATION

Exposure Effects (Acute)

Eye Contact : Direct contact of the solution with eyes can cause irritation.

ANADA (200-452) - OXYTET 20 INJECTION

Skin Contact : Prolonged or repeated contact with Oxytet 20 Injection may cause irritation

and/or drying and cracking of the skin.

Inhalation : None known.

Ingestion : Oral toxicity of the Oxytet 20 Injection solution is low.

Exposure Effects (Chronic)

Unknown for the product mixture. When this product is used according to the

REVISION DATE: 20/07/10

directions, prolonged exposure of man is not expected. Both its mutagenicity

and its teratogenicity are not known.

12. ECOLOGICAL INFORMATION

Data on the ecological implications for Oxytet 20 Injection is not yet available.

13. DISPOSAL CONSIDERATIONS

Product/Residues : Do not discharge the product material into surface or waste water. For

disposal, use an incinerator licensed for chemical waste.

Package : Dispose of waste containers using regular disposal methods in accordance

with local and national environmental regulations.

14. TRANSPORT INFORMATION

Land, Sea & Air Transport

ADR/RID, IMO/IMDG, IATA/ICAO, UN No. : Not applicable

15. REGULATORY INFORMATION

Labelling Information : None

Safety phrases : S2 Keep out of reach of children

S7 Keep container tightly closed

16. OTHER INFORMATION

ML: 2000/01 For Animal Treatment Only

ANADA 200-452, approved by FDA

JINAD 011-068

Revision Date : 20/07/10

Revision No : 02

Printing Date : 20/07/2010

Suppliers data sheets and various chemicals and pharmaceuticals databases were used to compile this sheet.

The information contained in this PSDS is believed to be accurate and represents the best information available at the time of preparation. However Norbrook Laboratories Limited makes no warranty, express or implied, with respect to such information and assumes no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes, and Norbrook Laboratories Limited will not be held liable for any damage resulting from the handling of or contact with the above product.