CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-521

ADMINISTRATIVE DOCUMENTS

PROJECT MANAGER LABELING REVIEW

NDA:	20-521
DATE:	06/17/98
SPONSOR:	ONY, Inc.
DRUG:	Infasurf (calfactant) Intratracheal Suspension
PROJECT MANAGER:	Denise P. Toyer
SUBMISSION DATE:	June 17, 1998

Background

The Division faxed comments pertaining to the physician insert to ONY on June 3, 1998. ONY submitted a revised physician package insert on June 17, 1998.

Review

The applicant accepted all of the Division's recommendations, for the physician package insert, except for the following.

1. A comma should be added after the word "right" which can be found on page three, in the Infasurf versus Survanta, Treatment Trial, section. Line ten of this section should read . . . four different positions (prone, supine, right, and left lateral). . .

2. A comma should be added after the word "right" which can be found on page four, in the Infasurf versus Survanta, Prophylaxis Trial, section. Line five of this section should read . . . four different positions (prone, supine, right, and left lateral) . . .

3. The word "treated" was omitted in the Infasurf versus Survanta, Prophylaxis Trial section. Line nine of the second paragraph should read . . . Infasurf and Survanta when analyzed for all treated patients and for evaluable patients.

4. The word "a" was omitted in the WARNINGS section. Line one of the third paragraph should read . . . Infasurf therapy is not a substitute for neonatal intensive . . .

The modifications listed above should be included in the action letter issued to the sponsor.

/S/

Denise P. Toyer, Pharm.D.
Project Manager

/S/ 6-19-98

cc:
Original NDA
HFD-570/Division File
HFD-570/Pina
HFD-570/Nashed
HFD-570/Sun

APPEARS THIS WAY
ON ORIGINAL

ONY INC
BAIRD RESEARCH PARK
1576 SWEET HOME ROAD • AMHERST, NEW YORK 14228
(716) 636-9096 (800) 274-4669

NEW DRUG APPLICATION
NDA # 20-521

INFASURF®

Patent Information

We certify that the Drug Product, Infasurf® /Drug Substance, Calf Lung Surfactant Extract (CLSE) Suspension and the method of preparing the Drug Product/Drug Substance are not covered by a U.S. Patent.

Edmund A. Egan, M.D.
President
Ony, Inc.

3/10/95
Date

APPEARS THIS WAY
ON ORIGINAL

EXCLUSIVITY SUMMARY FOR NDA # 20-521 SUPPL #_____

Trade Name__ Infasurf_____ Generic Name _(calfactant)___
Applicant Name __ONY, Inc_____ HFD # __570_____

Approval Date If Known _____

PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?

1. An exclusivity determination will be made for all original applications, but only for certain supplements. Complete PARTS II and III of this Exclusivity Summary only if you answer "yes" to one or more of the following question about the submission.

a) Is it an original NDA?

YES /_X_/ NO /___/

b) Is it an effectiveness supplement?

YES /___/ NO /_X_/

If yes, what type? (SE1, SE2, etc.) _____

c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "no.")

YES /_X_/ NO /___/

If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

_____

_____

If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

_____

_____

d) Did the applicant request exclusivity?

YES /___/ NO /_X_/

If the answer to (d) is "yes," how many years of exclusivity did the applicant request? _____

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. Has a product with the same active ingredient(s), dosage form, strength, route of administration, and dosing schedule, previously been approved by FDA for the same use?

YES /___/ NO /_X_/

If yes, NDA #_____. Drug Name _____.

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

3. Is this drug product or indication a DESI upgrade?

YES /___/ NO /_X_/

IF THE ANSWER TO QUESTION 3 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8 (even if a study was required for the upgrade).

PART II FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES

(Answer either #1 or #2 as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES /___/ NO /_X_/

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA# _____ _____

NDA# _____ _____

NDA# _____ _____

2. Combination product.

If the product contains more than one active moiety (as defined in Part II, #1), has FDA previously approved an application under section 505 containing any one of the active moieties in the drug product? If, for example, the combination contains one never-before-approved active moiety and one previously approved active moiety, answer "yes." (An active moiety that is marketed under an OTC monograph, but that was never approved under an NDA, is considered not previously approved.)

YES /___/ NO /_X_/

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA# _____ _____

NDA# _____ _____

NDA# _____ _____

IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8. IF "YES" GO TO PART III.

PART III THREE-YEAR EXCLUSIVITY FOR NDA'S AND SUPPLEMENTS

To qualify for three years of exclusivity, an application or supplement must contain "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." This section should be completed only if the answer to PART II, Question 1 or 2 was "yes."

1. Does the application contain reports of clinical investigations? (The Agency interprets "clinical investigations" to mean investigations conducted on humans other than bioavailability studies.) If the application contains clinical investigations only by virtue of a right of reference to clinical investigations in another application, answer "yes," then skip to question 3(a). If the answer to 3(a) is "yes" for any investigation referred to in another application, do not complete remainder of summary for that investigation.

YES /___/ NO /___/

IF "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. A clinical investigation is "essential to the approval" if the Agency could not have approved the application or supplement without relying on that investigation. Thus, the investigation is not essential to the approval if 1) no clinical investigation is necessary to support the supplement or application in light of previously approved applications (i.e., information other than clinical trials, such as bioavailability data, would be sufficient to provide a basis for approval as an ANDA or 505(b)(2) application because of what is already known about a previously approved product), or 2) there are published reports of studies (other than those conducted or sponsored by the applicant) or other publicly available data that independently would have been sufficient to support approval of the application, without reference to the clinical investigation submitted in the application.

(a) In light of previously approved applications, is a clinical investigation (either conducted by the applicant or available from some other source, including the published literature) necessary to support approval of the application or supplement?

YES /___/ NO /___/

If "no," state the basis for your conclusion that a clinical trial is not necessary for approval AND GO DIRECTLY TO SIGNATURE BLOCK ON PAGE 8:

_____

_____

(b) Did the applicant submit a list of published studies relevant to the safety and effectiveness of this drug product and a statement that the publicly available data would not independently support approval of the application?

YES /___/ NO /___/

(1) If the answer to 2(b) is "yes," do you personally know of any reason to disagree with the applicant's conclusion? If not applicable, answer NO.

YES /___/ NO /___/

If yes, explain: _____

_____

(2) If the answer to 2(b) is "no," are you aware of published studies not conducted or sponsored by the applicant or other publicly available data that could independently demonstrate the safety and effectiveness of this drug product?

YES /___/ NO /___/

If yes, explain: _____

_____

(c) If the answers to (b)(1) and (b)(2) were both "no," identify the clinical investigations submitted in the application that are essential to the approval:

_____

_____

Studies comparing two products with the same ingredient(s) are considered to be bioavailability studies for the purpose of this section.

3. In addition to being essential, investigations must be "new" to support exclusivity. The agency interprets "new clinical investigation" to mean an investigation that 1) has not been relied on by the agency to demonstrate the effectiveness of a previously approved drug for any indication and 2) does not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness of a previously approved drug product, i.e., does not redemonstrate something the agency considers to have been demonstrated in an already approved application.

a) For each investigation identified as "essential to the approval," has the investigation been relied on by the agency to demonstrate the effectiveness of a previously approved drug product? (If the investigation was relied on only to support the safety of a previously approved drug, answer "no.")

Investigation #1 YES /___/ NO /___/

Investigation #2 YES /___/ NO /___/

If you have answered "yes" for one or more investigations, identify each such investigation and the NDA in which each was relied upon:

_____ _____

_____ _____

b) For each investigation identified as "essential to the approval", does the investigation duplicate the results of another investigation that was relied on by the agency to support the effectiveness of a previously approved drug product?

Investigation #1 YES /___/ NO /___/

Investigation #2 YES /___/ NO /___/

If you have answered "yes" for one or more investigation, identify the NDA in which a similar investigation was relied on:

_____ _____

_____ _____

c) If the answers to 3(a) and 3(b) are no, identify each "new" investigation in the application or supplement that is essential to the approval (i.e., the investigations listed in #2(c), less any that are not "new"):

_____ _____

_____ _____

4. To be eligible for exclusivity, a new investigation that is essential to approval must also have been conducted or sponsored by the applicant. An investigation was "conducted or sponsored by" the applicant if, before or during the conduct of the investigation, 1) the applicant was the sponsor of the IND named in the form FDA 1571 filed with the Agency, or 2) the applicant (or its predecessor in interest) provided substantial support for the study. Ordinarily, substantial support will mean providing 50 percent or more of the cost of the study.

a) For each investigation identified in response to question 3(c): if the investigation was carried out under an IND, was the applicant identified on the FDA 1571 as the sponsor?

Investigation #1

IND # _____ YES /___/ ! NO /___/ Explain: _____

! _____

Investigation #2

IND # _____ YES /___/ ! NO /___/ Explain: _____

_____

(b) For each investigation not carried out under an IND or for which the applicant was not identified as the sponsor, did the applicant certify that it or the applicant's predecessor in interest provided substantial support for the study?

Investigation #1

YES /___/ Explain _____ ! NO /___/ Explain _____

_____ ! _____

_____ ! _____

Investigation #2

YES /___/ Explain _____ ! NO /___/ Explain _____

_____ ! _____

_____ ! _____

(c) Notwithstanding an answer of "yes" to (a) or (b), are there other reasons to believe that the applicant should not be credited with having "conducted or sponsored" the study? (Purchased studies may not be used as the basis for exclusivity. However, if all rights to the drug are purchased (not just studies on the drug), the applicant may be considered to have sponsored or conducted the studies sponsored or conducted by its predecessor in interest.)

YES /___/ NO /___/

If yes, explain: _____

_____

/S/

Signature
Title: Project Manager

4/9/97

Date

/S/

Signature of [redacted]
Division Director

6/19/98

Date

cc: Original NDA Division File HFD-85 Mary Ann Holovac

APPEARS THIS WAY
ON ORIGINAL

DRUG STUDIES IN PEDIATRIC PATIENTS
(To be completed for all NME's recommended for approval)

NDA # 20-521 Trade (generic) names INFASURF (calfactant)

Check any of the following that apply and explain, as necessary, on the next page:

✓ 1. A proposed claim in the draft labeling is directed toward a specific pediatric illness. The application contains adequate and well-controlled studies in pediatric patients to support that claim.

___ 2. The draft labeling includes pediatric dosing information that is not based on adequate and well-controlled studies in children. The application contains a request under 21 CFR 210.58 or 314.126(c) for waiver of the requirement at 21 CFR 201.57(f) for A&WC studies in children.

___ a. The application contains data showing that the course of the disease and the effects of the drug are sufficiently similar in adults and children to permit extrapolation of the data from adults to children. The waiver request should be granted and a statement to that effect is included in the action letter.

___ b. The information included in the application does not adequately support the waiver request. The request should not be granted and a statement to that effect is included in the action letter. (Complete #3 or #4 below as appropriate.)

___ 3. Pediatric studies (e.g., dose-finding, pharmacokinetic, adverse reaction, adequate and well-controlled for safety and efficacy) should be done after approval. The drug product has some potential for use in children, but there is no reason to expect early widespread pediatric use (because, for example, alternative drugs are available or the condition is uncommon in children).

___ a. The applicant has committed to doing such studies as will be required.

___ (1) Studies are ongoing.
___ (2) Protocols have been submitted and approved.
___ (3) Protocols have been submitted and are under review.
___ (4) If no protocol has been submitted, on the next page explain the status of discussions.

___ b. If the sponsor is not willing to do pediatric studies, attach copies of FDA's written request that such studies be done and of the sponsor's written response to that request.

___ 4. Pediatric studies do not need to be encouraged because the drug product has little potential for use in children.

____ 5. If none of the above apply, explain.

Explain, as necessary, the foregoing items: INFASURF is only indicated for infants with Respiratory Distress Syndrome (RDS).

APPEARS THIS WAY
ON ORIGINAL

/S/
Signature of Preparer

7/1/96
Date

cc: Orig NDA
HFD-___/Div File
NDA Action Package

FAX: (212) 750-9152
DIRECT LINE:

DEBARMENT CERTIFICATION

In compliance with Section 306(k) of the Federal Food, Drug and Cosmetic Act, we hereby certify that Forest Laboratories, Inc. did not and will not use in any capacity the services of any person debarred under sub section 306(a) or (b) of the Act in connection with this application (NDA #20-521) for Infasurf® (Calf Lung Surfactant Extract) Intratracheal Suspension.

FOREST LABORATORIES, INC.

Michael M. Rosen, Ph.D.
Director of Regulatory Affairs

ONY INC
BAIRD RESEARCH PARK
1576 SWEET HOME ROAD • AMHERST, NEW YORK 14228
(716) 636-9096 (800) 274-4669

DEBARMENT CERTIFICATION

In compliance with Section 306(k) of the Federal Food, Drug and Cosmetic Act, we hereby certify that Ony, Inc. did not and will not use in any capacity the services of any person debarred under sub section 306(a) or (b) of the Act in connection with this application (NDA #20-521) for Infasurf® (Calf Lung Surfactant Extract) Intratracheal Suspension.

Edmund A. Egan, M.D.
President

USAN

UNITED STATES ADOPTED NAMES COUNCIL

RUTA FREIMANIS, PharmD., R.Ph., Secretary
(312) 464-4045

American Medical Association
515 North State Street
Chicago, Illinois 60610

Telefax: 312-464-4184

April 21, 1997

JJ-18

ONY, Inc.
Baird Research Park
1576 Sweet Home Road
Amherst, NY 14228

Attn.: Edmund A. Egan, MD
President/Chief Medical Officer

Dear Dr. Egan:

The USAN Council has completed its evaluation of your September 3, 1996, request for a nonproprietary name for Ony's calf lung lavage extract trademarked Infasurf and being developed for the prevention and treatment of neonatal respiratory distress syndrome (RDS).

Your suggested names, (1) calf lung surfactant extract and (2) CLSE were rejected by the Council because they are not constructed in accordance with the USAN Nomenclature rules as published in the USP Dictionary of USAN and International Drug Names. In place of your suggested terms, the USAN Council selected and recommends adoption of **calfactant.** Please evaluate this counterproposal. If it is acceptable to Ony, we shall forward the name and pertinent background information to the WHO International Name Committee for nonproprietary name and trademark clearance. Please note that the WHO Committee currently is not assigning names to natural mixtures of this type and will not be formally selecting an International Nonproprietary Name for Infasurf.

The WHO review process will require approximately eight to twelve weeks. At the end of this time and in the absence of any reported nomenclature problems, calfactant will be adopted as the USAN for your substance.

I look forward to acceptance of the name by Ony. Do not hesitate to contact me if you have any questions.

Sincerely yours,

Ruta Freimanis

Ruta Freimanis, PharmD
Secretary, USAN Council

RF/dmk

ONY INC
BAIRD RESEARCH PARK
1576 SWEET HOME ROAD • AMHERST, NEW YORK 14228
(716) 636-9096 (800) 274-4669

April 25, 1997

Ruth Freimanis, PharmD
Secretary, USAN Council
United States Adopted Names Council
American Medical Association
515 North State Street
Chicago, Ill 60610

Dear Secretary Freimanis,

ONY, Inc accepts the non-proprietary name of calfactant for its calf lung extract trademarked as Infasurf you recommended in your April 21, 1997 letter.

Thank you for your assistance.

Sincerely,

Edmund A. Egan, MD
President

APPEARS THIS WAY
ON ORIGINAL

SUB/USAN1.047

REQUEST FOR TRADEMARK REVIEW

To: Labeling and Nomenclature Committee

Attention: Dan Boring, Chair (HFD-530), 9201 Corporate Blvd, Room N461

From: Division of Pulmonary Drug Products	**HFD-** 570
Attention: Mr. Dan Boring	**Phone:** 827-2333
Date: May 9, 1996	
Subject: Request for Assessment of a Trademark for a Proposed New Drug Product	
Proposed Trademark: Infasurf	**NDA#** 20-521
Established name, including dosage form: None available, suspension	
Other trademarks by the same firm for companion products: NA	
Indications for Use (may be a summary if proposed statement is lengthy): Prevention and Treatment of respiratory distress syndrome (RDS) in premature infants and treatment ("rescue") of newborn infants who develop RDS.	
Initial Comments from the submitter (concerns, observations, etc.): A similar bovine-derived surfactant product, trade name Survanta, has an established name of beractant.	

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG FOR HUMAN USE OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314)

Form Approved: OMB No. 0910-0001.
Expiration Date: December 31, 1995.
See OMB Statement on Page 3.

FOR FDA USE ONLY	
DATE RECEIVED	DATE FILED
DIVISION ASSIGNED	NDA/ANDA NO. ASS.

NOTE: No application may be filed unless a completed application form has been received *(21 CFR Part 314)*.

NAME OF APPLICANT ONY, Inc.	DATE OF SUBMISSION July 21, 1997
	TELEPHONE NO. *(Include Area Code)* 716-636-9096
ADDRESS *(Number, Street, City, State and ZIP Code)* Baird Research Park 1576 Sweet Home Road Amherst, New York 14228	NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER *(If previously issued)* 20-521 -

DRUG PRODUCT

ESTABLISHED NAME *(e.g., USP/USAN)*	PROPRIETARY NAME *(If any)*
calfactant	Infasurf

CODE NAME *(If any)*	CHEMICAL NAME
	N/A

DOSAGE FORM	ROUTE OF ADMINISTRATION	STRENGTHS (S)
Suspension	Intratracheal	35mg/ml

PROPOSED INDICATIONS FOR USE

Prevention of Respiratory Distress Syndrome in premature infants and treatment ("rescue") of newborn infants who develop RDS.

LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS *(21 CFR Part 312)*, NEW DRUG OR ANTIBIOTIC APPLICATIONS *(21 CFR Part 314)*, AND DRUG MASTER FILES *(21 CFR 314.420)* REFERRED TO IN THIS APPLICATION:

INFORMATION ON APPLICATION

TYPE OF APPLICATION *(Check one)*

☐ THIS SUBMISSION IS A FULL APPLICATION *(21 CFR 314.50)* ☐ THIS SUBMISSION IS AN ABBREVIATED APPLICATION (ANDA) *(21 CFR 314.55)*

IF AN ANDA, IDENTIFY THE APPROVED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

NAME OF DRUG	HOLDER OF APPROVED APPLICATION

TYPE SUBMISSION *(Check one)*

☐ PRESUBMISSION ☐ AN AMENDMENT TO A PENDING APPLICATION ☐ SUPPLEMENTAL APPLICATION
☐ ORIGINAL APPLICATION ☐ RESUBMISSION X other (see page 2)

SPECIFIC REGULATION(S) TO SUPPORT CHANGE OF APPLICATION *(e.g., Part 314.70(b)(2)(iv))* _____

PROPOSED MARKETING STATUS *(Check one)*

☒ APPLICATION FOR A PRESCRIPTION DRUG PRODUCT *(Rx)* ☐ APPLICATION FOR AN OVER-THE-COUNTER PRODUCT *(OTC)*

APPENDIX B:

Material Safety Data Sheet

Material Safety Data Sheet ONY, Inc.

Infasurf®
Effective Date: 10/21/96 Supersedes 09/07/93

ONY, Inc.•Baird Research Park•1576 Sweet Home Road•Amherst, New York 14228•Telephone: (716)636-9096•Fax: (716)636-3942

PRODUCT IDENTIFICATION:

Synonyms: calf lung surfactant extract, CLSE, pulmonary surfactant
CAS No.: None
Molecular Weight: Unknown
Chemical Formula: Unknown
Hazardous Ingredients: None

PRODUCT COMPOSITION:

Infasurf® contains natural phospholipids, neutral lipids and hydrophobic surfactant associated proteins suspended in 0.9% sodium chloride.

PRODUCT DESCRIPTION:

Infasurf® (calf lung surfactant extract) Intratracheal Suspension is a sterile, non-pyrogenic lung surfactant intended for intratracheal instillation only. It is an extract of natural surfactant from calf lungs.

Infasurf is an off-white suspension of calf lung surfactant extract (CLSE) in 0.9% sodium chloride solution. Each mL of Infasurf contains: 35 mg total phospholipids (including 19-28 mg/mL phosphatidylcholine & 12-18 mg/mL of dissaturated phosphatidylcholine) and 0.55-0.80 mg/mL surfactant proteins. It is supplied as a 6 mL (210 mg phospholipids) single use vial.

PRECAUTIONARY MEASURES:

- Avoid contact with eyes.

EMERGENCY FIRST AID:

In case of eye contact, immediately flush eyes with plenty of water. Call a physician if irritation occurs. SEE SECTION 5.

Infasurf®
Effective Date: 10/21/96 Supersedes 09/07/93

ONY, Inc.•Baird Research Park•1576 Sweet Home Road•Amherst, New York 14228•Telephone: (716)636-9096•Fax: (716)636-3942

SECTION 1 - Physical Data

Appearance: off-white, unstable aqueous suspension
Odor: no specific odor
Solubility: insoluble in water, very soluble in chloroform and other organic solvents
Boiling Point: ≃ 100°C (approximately that of water)
Melting Point: ≃ 0°C (approximately that of water)
Specific Gravity: 1.08
Vapor Pressure (mm Hg): No information found
Vapor Density (Air=1): No information found
Evaporation Rate: No information found

SECTION 2 - Fire and Explosion Information

Fire:

Not a fire hazard.

Explosion:

Not an explosion hazard.

Fire Extinguishing Media:

Use any means suitable for extinguishing surrounding fire.

SECTION 3 - Reactivity Data

Stability:

Stable under ordinary conditions of use and storage.

Hazardous Decomposition Products:

None. Oxidation products are CO_2 and H_2O

Hazardous Polymerization:

Will not occur.

Incompatibilities:

No information found.

SECTION 4 - Leak/Spill Disposal Information

Spills: Wipe or mop up and container for disposal. Disposal: Contains no hazardous materials. May be disposed of as normal, non-hazardous solid or liquid waste.

Dispose of container and unused contents in accordance with federal, state and local requirements.

ONY, Inc.•Baird Research Park•1576 Sweet Home Road•Amherst, New York 14228•Telephone: (716)636-9096•Fax: (716)636-3942

SECTION 5 - Health Hazard Information

A. Exposure/Health Effects

Inhalation:
None known.

Ingestion:
None known.

Skin Contact:
Not expected to be a health hazard.

Eye Contact:
May cause irritation.

Chronic Exposure:
No information found.

Aggravation of Pre-existing Conditions:
No information found.

B. First Aid

Inhalation:
Get medical attention for any breathing difficulty.

Ingestion:
If large amounts were swallowed, get medical advice.

Skin Exposure:
Wash exposed area with soap and water. Get medical advice if irritation develops.

Eye Exposure:
Wash thoroughly with running water. Get medical advice if irritation develops.

C. Toxicity

None known.

SECTION 6 - Occupational Control Measures

None established.

SECTION 7 - Storage and Special Information

Keep in the container/closure supplied until use, refrigerate at 2-8°C. Protect against light and physical damage.

General Healthcare Division

Baxter Healthcare Corporation
One Parkway North, Suite 100
Post Office Box 851
Deerfield, Illinois 60015-0851

708 940 1[illegible]
Fax: 708 940 [illegible]35

Baxter

June, 1992

Dear Valued Customer:

This letter is in response to your recent request for Material Safety Data Sheets (MSDS) on one or more of the following Baxter Products:

0.9% Sodium Chloride Irrigation, USP
0.9% Sodium Chloride Injection, USP
0.9% Sodium Chloride Inhalation, USP
0.45% Sodium Chloride Injection, USP
0.45% Sodium Chloride Inhalation, USP
Sterile Water for Irrigation, USP
Sterile Water for Injection, USP
Sterile Water for Inhalation, USP
5% Dextrose Injection, USP
Plasmalyte® R, A, 56, and 148, Injection
10 % Osmitrol in Water (Mannitol Injection, USP)
Lactated Ringer's Injection, USP
Lactated Ringer's and 5% Dextrose Injection, USP
5% Dextrose and Ringer's Injection
5% Dextrose 0.9% Sodium Chloride Injection, USP
5% Dextrose 0.45% Sodium Chloride Injection, USP
5% Dextrose 0.2% Sodium Chloride Injection, USP
20 mEq/L Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection
10 mEq/L Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection
0.25% Acetic Acid Irrigation, USP
3% Sorbitol Urologic Irrigating Solution
1.5% Glycine Irrigation, USP (Aminoacetic Acid Irrigation)
Bacteriostatic Water for Injection, USP, with Benzyl Alcohol
Bacteriostatic Water for Injection, USP, with Parabens

These solution products are exempt from OSHA Hazard Communication Standards because they contain no hazardous ingredients. The information sent with the product in the form of Package Inserts and/or Product Labeling provides data on ingredients, hazards associated with use, and handling precautions. In most cases, this information is more detailed than required on a Standard Material Safety Data Sheet.

If we may be of further assistance, do not hesitate to contact customer service at (800) 635-6021 or (800) 423-2311.

Sincerely,

Glenn Balasky
Quality Assurance Manager
Baxter General Healthcare Division

MATERIAL SAFETY DATA SHEET

SODIUM CHLORIDE

MALLINCKRODT

Effective Date: 08-08-86 Supersedes 08-07-85

A Division of Mallinckrodt Baker, Inc. • 222 Red School Lane • Phillipsburg, NJ 08865 • Telephone: (908) 859-2151 • Fax: (908) 859-9318
Emergency Phone: 908-859-2151 • CHEMTREC: 202-483-7616 • CANUTEC: 613-996-6666

PRODUCT IDENTFICATION:

Synonyms: Salt
CAS No.: 7647-14-5
Molecular Weight: 58.44
Chemical Formula: NaCl
Hazardous Ingredients: Sodium chloride

PRECAUTIONARY MEASURES:

WARNING! CAUSES EYE IRRITATION.

- Avoid contact with eyes.
- Wash thoroughly after handling.

EMERGENCY FIRST AID:

In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician. SEE SECTION 5.

SECTION 1 - Physical Data

Appearance: White crystalline.
Odor: Odorless.
Solubility: 36g/100cc water @ 20 C (68 F)
Boiling Point: 1413 C (2575 F)
Melting Point: 801 C (1474 F)
Specific Gravity: 2.16
Vapor Pressure (mm Hg): 1.0 @ 865 C (1589 F)
Vapor Density (Air=1): No information found.
Evaporation Rate: No information found.

SECTION 2 - Fire and Explosion Information

Fire:

Not considered to be a fire hazard.

Explosion:

Not considered to be an explosion hazard.

Fire Extinguishing Media:

Use any means suitable for extinguishing surrounding fire.

Special Information:

In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

SECTION 3 - Reactivity Data

Stability:

Stable under ordinary conditions of use and storage.

Hazardous Decomposition Products:

When heated to above 801 C (1474 F) it emits toxic fumes of chloride and sodium oxide.

Hazardous Polymerization:

Will not occur.

Incompatibilities:

Lithium, bromide trifluoride.

SECTION 4 - Leak/Spill Disposal Information

Spills: Sweep up and containerize for reclamation or disposal. Vacuuming or wet sweeping may be used to avoid dust dispersal. Disposal: Whatever cannot be saved for reclamation may be delivered to an approved waste disposal facility, or if local ordinances allow, can be dissolved in sufficient amounts of water to meet water quality standards, and flushed down a sewer drain.

Dispose of container and unused contents in accordance with federal, state, and local requirements.

SECTION 5 - Health Hazard Information

A. Exposure/Health Effects

Inhalation:

Inhalation of dust may cause mild irritation to mucous membranes, nose and throat. Symptoms may include coughing, dryness, and sore throat.

Ingestion:

Very large doses can cause vomiting, diarrhea, and prostration. Dehydration and congestion occur in most internal organs. Hypertonic salt solutions can produce violent inflammatory reactions in the gastrointestinal tract.

Skin Contact:

Not expected to be a health hazard.

Eye Contact:

May cause irritation.

Chronic Exposure:

No information found.

Aggravation of Pre-existing Conditions:
No information found.

B. FIRST AID

Inhalation:
Remove to fresh air. Get medical attention for any breathing difficulty.

Ingestion:
If large amounts were swallowed, get medical advice.

Skin Exposure:
Wash exposed area with soap and water. Get medical advice if irritation develops.

Eye Exposure:
Wash thoroughly with running water. Get medical advice if irritation develops.

C. TOXICITY (RTECS, 1986)

Oral rat LD50: 3000 mg/kg. Reproductive effects cited.

SECTION 6 - Occupational Control Measures

Airborne Exposure Limits:
None established.

Ventilation System:
In general, dilution ventilation is a satisfactory health hazard control for this substance. However, if conditions of use create discomfort to the worker, a local exhaust system should be considered.

Personal Respirators: (NIOSH Approved)
For conditions of use where exposure to the dust is apparent, a dust/mist respirator may be worn For emergencies or instances where the exposure levels are not known, use a positive-pressure, air-supplied respirator. WARNING: Air-purifying respirators do not protect workers in oxygen-deficient atmospheres.

Skin Protection:
Wear protective gloves and clean body-covering clothing.

Eye Protection:
Use chemical safety goggles. Maintain eye wash fountain and quick-drench facilities in work area.

SECTION 7 - Storage and Special Information

Keep in a tightly closed container, stored in a cool, dry, ventilated area. Protect against physical damage.

SODIUM CHLORIDE

Effective Date: 08-08-86 Supersedes 08-07-85

MALLINCKRODT

A Division of Mallinckrodt Baker, Inc. • 222 Red School Lane • Phillipsburg NJ 08865 • Telephone: (908) 859-2151 • Fax: (908) 859-9318

Emergency Phone: 908-859-2151 • CHEMTREC: 202-483-7616 • CANUTEC: 613-996-6666

Addendum to Material Safety Data Sheet

REGULATORY STATUS

Hazard Categories for SARA Section 311/312 Reporting

Acute	Chronic	Fire	Pressure	Reactive
X				

Product or Components of Product:	SARA EHS Sec. 302 RQ	SARA EHS Sec. 302 TPQ	SARA Sec. 313 Chemicals Name List	SARA Sec. 313 Chemicals Chemical Category	CERCLA Sec.103 RQ lbs	RCRA Sec. 261.3
SODIUM CHLORIDE (7647-14-5)	No	No	No	No	No	No

SARA Section 302 EHS RQ:
Reportable Quantity of Extremely Hazardous Substance, listed at 40 CFR 355.

SARA Section 302 EHS TPQ:
Threshold Planning Quantity of Extremely Hazardous Substance. An asterisk (*) following a Threshold Planning Quantity signifies that if the material is a solid and has a particle size equal to or larger than 100 micrometers, the Threshold Planning Quantity = 10,000 LBS.

SARA Section 313 Chemicals:
Toxic Substances subject to annual release reporting requirements listed at 40 CFR 372.65.

CERLCA Sec. 103:
Comprehensive Environmental Response, Compensation and Liability Act (Superfund) Releases to air, land or water of these hazardous substances which exceed the Reportable Quantity (RQ) must be reported to the National Response Center, (800-424-8802); Listed at 40 CFR 302.4

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RCRA:

Resource Conservation and Recovery Act. Commercial chemical product wastes designated as acute hazards or toxic under 40 CFR 261.33.

APPENDIX C:

Emission Permit Table

EMISSION PERMIT TABLE

	Permits for ONY, New York Facility		
Emission	Authorizing Agency	Permit #	Expiration Date
Air	New York State Department of Environmental Conservation	1422 001066 00001 WI 1422 001066 00002 WI 1422 001066 00003 WI	3/18/99 3/18/99 3/18/99
Waste Water	Town of Amherst Sewer Department	Not Required	N/A
Regulated Waste	Environmental Protection Agency	EPA ID # NY0000075754	N/A