

THE UNIVERSITY OF TEXAS
MD ANDERSON
CANCER CENTER

1302 '98 MAY 27 A9:40

Division of Pharmacy - 90

May 26, 1998

Docket Management Branch (HFA-305)
Food and Drugs Administration
12420 Parklawn Drive, Room 1-23
Rockville, MD 20855

RE: Docket No. 98N-0182

Dear Sirs:

Please find enclosed information to nominate three candidate bulk drug substances for consideration for inclusion in the list for pharmacy compounding of materials that do not have USP or NF monographs and are not components of approved drugs. This is a new list that is being assembled in accordance with the Food and Drug Administration Modernization Act of 1997 (FDAMA).

The three candidate bulk drug substances at this time are:

1. Dinitrochlorobenzene (DNCB)
2. Sodium butyrate
3. Ferric subsulfate

I have also forwarded this material to USP for their use in participating in this process.

If there is anything further I need to do, please let me know. (713-792-2870).

Sincerely yours,



Lawrence A. Trissel, FASHP
Director, Clinical Pharmaceutics Research Program

98N-0182

NOM2

Bulk Drug Substance to be Used in Pharmacy Compounding

Docket No. 98N-0182

Bulk Drug Substance 1303 '98 MAY 27 A9:40

Ingredient Name: Chlorodinitrobenzene; CDNB; Dinitrochlorobenzene; DNCB

Chemical Name: 1-Chloro-2,4-Dinitrobenzene CAS: 97-00-7

Chemical Grade or Strength: Minimum 98%

How Supplied: Loose powder and/or chunks

International Pharmacopeial Recognition: Martindale The Extra Pharmacopoeia p.1698

Bibliography: 1) MSDS attached
2) Medline search identified 856 articles since 1966. A bibliography of 175 articles appearing since 1990 is attached.

Compounded Product

Formulations: Topical liquid. DNCB dissolved in acetone.

Strength(s): Bulk stock solution compounded at 2 mg/0.1 mL.

Dilutions in acetone prepared at concentrations of:

100 µg/0.1 mL

50 µg/0.1 mL

25 µg/0.1 mL

12.5 µg/0.1 mL

6.25 µg/0.1 mL

Route of Administration: Topically on skin.

Past/Proposed Use: DNCB is used as a skin sensitizer to estimate immune system competency. See attached articles. No commercial product of DNCB exists.

Stability Data: None available

Additional Information: None

Nominated by: University of Texas M. D. Anderson Cancer Center
Division of Pharmacy (Box 90)
1515 Holcombe Blvd.
Houston, Texas 77030

tel: (713) 792-2870



THE WORLD'S FOREMOST MANUFACTURER OF RESEARCH
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OUTSIDE USA/CANADA call COLLECT 314-771-5750
FAX: USA/CANADA 1-800-325-5052
OUTSIDE USA/CANADA 314-771-5757
INTERNET EMAIL: sigma@stal.com

ATTN: SAFETY DIRECTOR
PAULENE THOMAS-PARKS
UNIVERSITY OF TEXAS
MD ANDERSON CANCER CTR
PO BOX 301101
HOUSTON TX 77230

EMERGENCY PHONE 1-314-771-5765
PO BOX 14508 ST LOUIS MO 63178
DATE 05/22/98
CUST#: 1-085-83857
PO#:

M A T E R I A L S A F E T Y D A T A S H E E T PAGE 1

SECTION 1. - - - - - CHEMICAL IDENTIFICATION- - - - -

CATALOG #: C6396
NAME: 1-CHLORO-2,4-DINITROBENZENE

SECTION 2. COMPOSITION/INFORMATION ON INGREDIENTS

CAS #: 97-00-7
MF: C6H3CLN2O4
EC NO: 202-551-4

SYNONYMS

CONR * 1-CHLOR-2,4-DINITROBENZENE (DUTCH) * 1-CHLOR-2,4-DINITROBENZENE * 1-CHLORO-2,4-DINITROBENZENE * 4-CHLORO-1,3-DINITROBENZENE * 6-CHLORO-1,3-DINITROBENZENE * 1-CHLORO-2,4-DINITROBENZOL (GERMAN) * 1-CHLORO-2,4-DINITROBENZOL (ITALIAN) * 1,5-DINITRO-4-CHLOROBENZENE * 2,4-DINITROCHLOROBENZENE * 2,4-DINITRO-1-CHLOROBENZENE * DINITROCHLOROBENZOL * DNCB *

SECTION 3. - - - - - HAZARDS IDENTIFICATION - - - - -

LABEL PRECAUTIONARY STATEMENTS

HIGHLY TOXIC (USA)
TOXIC (EU)
TOXIC BY INHALATION, IN CONTACT WITH SKIN AND IF SWALLOWED.
MAY CAUSE SENSITIZATION BY INHALATION AND SKIN CONTACT.
DANGER OF CUMULATIVE EFFECTS.
CAUSES SEVERE IRRITATION.
TARGET ORGAN(S):
NERVES
BLOOD
IN CASE OF ACCIDENT OR IF YOU FEEL UNWELL, SEEK MEDICAL ADVICE IMMEDIATELY (SHOW THE LABEL WHERE POSSIBLE).
IN CASE OF CONTACT WITH EYES, RINSE IMMEDIATELY WITH PLENTY OF WATER AND SEEK MEDICAL ADVICE.
WEAR SUITABLE PROTECTIVE CLOTHING, GLOVES AND EYE/FACE PROTECTION.
DO NOT BREATHE DUST.

SECTION 4. - - - - - FIRST-AID MEASURES- - - - -

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M A T E R I A L S A F E T Y D A T A S H E E T PAGE 2

CATALOG #: C6396
 NAME: 1-CHLORO-2,4-DINITROBENZENE
 IN CASE OF CONTACT, IMMEDIATELY FLUSH EYES OR SKIN WITH COPIOUS AMOUNTS OF WATER FOR AT LEAST 15 MINUTES WHILE REMOVING CONTAMINATED CLOTHING AND SHOES.
 IF INHALED, REMOVE TO FRESH AIR. IF NOT BREATHING GIVE ARTIFICIAL RESPIRATION. IF BREATHING IS DIFFICULT, GIVE OXYGEN.
 IF SWALLOWED, WASH OUT MOUTH WITH WATER PROVIDED PERSON IS CONSCIOUS. CALL A PHYSICIAN IMMEDIATELY.
 DISCARD CONTAMINATED CLOTHING AND SHOES.

SECTION 5. - - - - - FIRE FIGHTING MEASURES - - - - -

EXTINGUISHING MEDIA

WATER SPRAY.
CARBON DIOXIDE, DRY CHEMICAL POWDER OR APPROPRIATE FOAM.

SPECIAL FIREFIGHTING PROCEDURES

WEAR SELF-CONTAINED BREATHING APPARATUS AND PROTECTIVE CLOTHING TO PREVENT CONTACT WITH SKIN AND EYES.

UNUSUAL FIRE AND EXPLOSIONS HAZARDS

EMITS TOXIC FUMES UNDER FIRE CONDITIONS.
CONTAINER EXPLOSION CAN OCCUR UNDER FIRE CONDITIONS. IN ADVANCED OR MASSIVE FIRES THE AREA SHOULD BE EVACUATED AND THE FIRE SHOULD BE FOUGHT FROM A REMOTE EXPLOSION-RESISTANT LOCATION.

SECTION 6. - - - - - ACCIDENTAL RELEASE MEASURES - - - - -

EVACUATE AREA.
WEAR SELF-CONTAINED BREATHING APPARATUS, RUBBER BOOTS AND HEAVY RUBBER GLOVES.
SWEEP UP, PLACE IN A BAG AND HOLD FOR WASTE DISPOSAL.
VENTILATE AREA AND WASH SPILL SITE AFTER MATERIAL PICKUP IS COMPLETE.

SECTION 7. - - - - - HANDLING AND STORAGE - - - - -

REFER TO SECTION 8.

SECTION 8. - - - - - EXPOSURE CONTROLS/PERSONAL PROTECTION - - - - -

WEAR APPROPRIATE NIOSH/MSHA-APPROVED RESPIRATOR, CHEMICAL-RESISTANT GLOVES, SAFETY GUGGLES, OTHER PROTECTIVE CLOTHING.
SAFETY SHOWER AND EYE BATH.

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CUST#: 1-085-83857

M A T E R I A L S A F E T Y D A T A S H E E T PAGE 3

CATALOG #: C6396
 NAME: 1-CHLORO-2,4-DINITROBENZENE
 USE ONLY IN A CHEMICAL FUME HOOD.
 DO NOT BREATHE DUST.
 DO NOT GET IN EYES, ON SKIN, ON CLOTHING.
 AVOID PROLONGED OR REPEATED EXPOSURE.
 READILY ABSORBED THROUGH SKIN.
 WASH THOROUGHLY AFTER HANDLING.
 HIGHLY TOXIC.
 SEVERE IRRITANT.
 STRONG SENSITIZER.
 KEEP TIGHTLY CLOSED.
 STORE IN A COOL DRY PLACE.

SECTION 9. - - - - - PHYSICAL AND CHEMICAL PROPERTIES - - - - -

APPEARANCE AND ODOR
LIGHT-YELLOW TO BROWN CRYSTALS

PHYSICAL PROPERTIES

BOILING POINT:	316 C
MELTING POINT:	49 C TO 52 C
FLASHPOINT	56/F
	186.11C

EXPLOSION LIMITS IN AIR:

UPPER	22%
LOWER	2%

SECTION 10. - - - - - STABILITY AND REACTIVITY - - - - -

INCOMPATIBILITIES
STRONG BASES
STRONG OXIDIZING AGENTS

HAZARDOUS COMBUSTION OR DECOMPOSITION PRODUCTS
 TOXIC FUMES OF:
 CARBON MONOXIDE, CARBON DIOXIDE
 NITROGEN OXIDES
 HYDROGEN CHLORIDE GAS

SECTION 11. - - - - - TOXICOLOGICAL INFORMATION - - - - -

ACUTE EFFECTS
MAY BE FATAL IF INHALED, SWALLOWED, OR ABSORBED THROUGH SKIN.
CAUSES SEVERE IRRITATION.

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M A T E R I A L S A F E T Y D A T A S H E E T PAGE 4

CATALOG #: C6396
 NAME: 1-CHLORO-2,4-DINITROBENZENE
 HIGH CONCENTRATIONS ARE EXTREMELY DESTRUCTIVE TO TISSUES OF THE MUCOUS
 MEMBRANES AND UPPER RESPIRATORY TRACT, EYES AND SKIN.
 SYMPTOMS OF EXPOSURE MAY INCLUDE BURNING SENSATION, COUGHING,
 WHEEZING, LARYNGITIS, SHORTNESS OF BREATH, HEADACHE, NAUSEA AND
 VOMITING.
 ABSORPTION INTO THE BODY LEADS TO THE FORMATION OF METHEMOGLOBIN
 WHICH IN SUFFICIENT CONCENTRATION CAUSES CYANOSIS. ONSET MAY BE
 DELAYED 2 TO 4 HOURS OR LONGER.
 MAY CAUSE ALLERGIC RESPIRATORY AND SKIN REACTIONS.
 TARGET ORGAN(S):
 PERIPHERAL NERVOUS SYSTEM
 CENTRAL NERVOUS SYSTEM
 BLOOD
 LIVER, KIDNEYS

RTECS #: CZ0525000
BENZENE, 1-CHLORO-2,4-DINITRO-

IRRITATION DATA

SKN-HMN 30 UG	CODEDG 2,247,1976
SKN-RBI 100 UG/24H OPEN	AIHAAP 23,95,1962
SKN-RBT 2 MG/24H SEV	85JCAE -,600,1986
EYE-RBT 50 UG/24H SEV	85JCAE -,600,1986

TOXICITY DATA

ORL-RAT LD50:780 MG/KG	GTPZAB 32(2),48,1988
IPR-RAT LD50:280 MG/KG	AGGHAR 17,217,1959
SKN RBT LD50:130 MG/KG	AIHAAP 23,95,1962

TARGET ORGAN DATA

BEHAVIORAL (CONVULSIONS OR EFFECT ON SEIZURE THRESHOLD)
 GASTROINTESTINAL (PERITONITIS)
 BLOOD (METHEMOGLOBINEMIA-CARBOXHEMOGLOBINEMIA)
 SKIN AND APPENDAGES (PRIMARY IRRITATION)
 ONLY SELECTED REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES
 (RTECS) DATA IS PRESENTED HERE. SEE ACTUAL ENTRY IN RTECS FOR
 COMPLETE INFORMATION.

SECTION 12. - - - - - ECOLOGICAL INFORMATION - - - - -

DATA NOT YET AVAILABLE.

SECTION 13. - - - - - DISPOSAL CONSIDERATIONS - - - - -

CONTINUED ON NEXT PAGE

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M A T E R I A L S A F E T Y D A T A S H E E T PAGE 5

CATALOG #: C6396
NAME: 1-CHLORO-2,4-DINITROBENZENE
DISSOLVE OR MIX THE MATERIAL WITH A COMBUSTIBLE SOLVENT AND BURN IN A
CHEMICAL INCINERATOR EQUIPPED WITH AN AFTERBURNER AND SCRUBBER.
OBSERVE ALL FEDERAL, STATE AND LOCAL ENVIRONMENTAL REGULATIONS.

SECTION 14. - - - - - TRANSPORT INFORMATION - - - - -

CONTACT SIGMA CHEMICAL COMPANY FOR TRANSPORTATION INFORMATION.

SECTION 15. - - - - - REGULATORY INFORMATION - - - - -

EUROPEAN INFORMATION

TOXIC
R 23/24/25
TOXIC BY INHALATION, IN CONTACT WITH SKIN AND IF SWALLOWED.
R 42/43
MAY CAUSE SENSITIZATION BY INHALATION AND SKIN CONTACT.
R 33
DANGER OF CUMULATIVE EFFECTS.
S 45
IN CASE OF ACCIDENT OR IF YOU FEEL UNWELL, SEEK MEDICAL ADVICE
IMMEDIATELY (SHOW THE LABEL WHERE POSSIBLE).
S 26
IN CASE OF CONTACT WITH EYES, RINSE IMMEDIATELY WITH PLENTY OF
WATER AND SEEK MEDICAL ADVICE.
S 36/37/39
WEAR SUITABLE PROTECTIVE CLOTHING, GLOVES AND EYE/FACE
PROTECTION.
S 22
DO NOT BREATHE DUST.

REVIEWS, STANDARDS, AND REGULATIONS

OEL=MAK
NOHS 1974: HZD 83616; NIS 1; TNF 174; NOS 1; TNE 1221
NOHS 1983: H7D 83616; NTS 2; TNF 82; NOS 2; TNF 170; TFF 14
EPA TSCA SECTION 8(B) CHEMICAL INVENTORY
EPA TSCA SECTION 8(D) UNPUBLISHED HEALTH/SAFETY STUDIES
EPA TSCA TEST SUBMISSION (TSCATS) DATA BASE, SEPTEMBER 1997

SECTION 16. - - - - - OTHER INFORMATION - - - - -

THE ABOVE INFORMATION IS BELIEVED TO BE CORRECT BUT DOES NOT PURPORT TO

CONTINUED ON NEXT PAGE

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M A T E R I A L S A F E T Y D A T A S H E E T PAGE 6

CATALOG #: C6396
NAME: 1-CHLORO-2,4-DINITROBENZENE
BE ALL INCLUSIVE AND SHALL BE USED ONLY AS A GUIDE. SIGMA SHALL NOT BE
HELD LIABLE FOR ANY DAMAGE RESULTING FROM HANDLING OR FROM CONTACT WITH
THE ABOVE PRODUCT. SEE REVERSE SIDE OF INVOICE OR PACKING SLIP FOR
ADDITIONAL TERMS AND CONDITIONS OF SALE.

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Database: Medline <1966 to present>

Set	Search	Results
1	benzene.tw.	4702
2	<u>dinitrochlorobenzene.tw.</u>	817
3	<u>chlorodinitrobenzene.tw.</u>	39
4	<u>2 or 3</u>	856
5	<u>limit 4 to (yr=1988 or yr=1989 or yr=1990 o</u>	224
6	<u>limit 5 to (yr=1990 or yr=1991 or yr=1992 o</u>	175

+ 1998

<1>

Unique Identifier

98124271

Authors

Strobbe LJ. Hart AA. Rumke P. Israels SP. Nieweg OE.
Kroon BB.

Institution

Department of Surgery, The Netherlands Cancer
Institute(Antoni van Leeuwenhoek ziekenhuis), Amsterdam.

Title

Topical dinitrochlorobenzene combined with systemic
dacarbazine in the treatment of recurrent melanoma.

Source

Melanoma Research. 7(6):507-12, 1997 Dec.

<2>

Unique Identifier

98101888

Authors

Hayag MV. Chartier T. DeVoursney J. Tie C. Machler B.
Taylor JR.

Institution

Dermatology Service, V.A. Medical Center, Miami, FL 33125,
USA.

Title

A high SPF sunscreen's effects on UVB-induced
immunosuppression of DNCB contact hypersensitivity.

Source

Journal of Dermatological Science. 16(1):31-7, 1997 Nov.

<3>

Unique Identifier

97468486

□

Authors

Ness LS. Ferguson GP. Nikolaev Y. Booth IR.

Institution

Department of Molecular and Cell Biology, University of

Aberdeen, Foresterhill, United Kingdom.

Title

Survival of Escherichia coli cells exposed to iodoacetate and chlorodinitrobenzene is independent of the glutathione-gated K⁺ efflux systems KefB and KefC.

Source

Applied & Environmental Microbiology. 63(10):4083-6, 1997 Oct.

<4>

Unique Identifier

98131685

Authors

Mallon E. Powell S. Mortimer P. Ryan TJ.

Institution

Department of Dermatology, Churchill Hospital, Oxford, U.K.

Title

Evidence for altered cell-mediated immunity in postmastectomy lymphoedema.

Source

British Journal of Dermatology. 137(6):928-33, 1997 Dec.

<5>

Unique Identifier

98078830

Authors

Stricker RB. Goldberg B. Epstein WL.

Institution

Department of Medicine, California Pacific Medical Center, San Francisco 94108, USA. rstricker:barron-centers.com

Title

Topical immune modulation (TIM): a novel approach to the immunotherapy of systemic disease. [Review] [39 refs]

Source

Immunology Letters. 59(3):145-50, 1997 Dec.

<6>

Unique Identifier

98067711

Authors

Stricker RB. Goldberg B. Mills LB. Epstein WL.

Institution

Department of Medicine, California Pacific Medical Center, San Francisco 94108, USA.

Title

Decrease in viral load associated with topical dinitrochlorobenzene therapy in HIV disease.

Source

Research in Virology. 148(5):343-8, 1997 Sep-Oct.

<7>

Unique Identifier

98072629

Authors

Lukacs L. Istvan M. Toth P.
Institution
First Department of Surgery, University Medical School of
Pecs, Hungary.
Title
Lymphonodal response to sensitization with
2,4-dinitrochlorobenzene (DNCB) in laboratory rats.
Source
Acta Chirurgica Hungarica. 36(1-4):210-2, 1997.

<8>

Unique Identifier
98084699
Authors
Dai R. Streilein JW.
Institution
The Schepens Eye Research Institute and Department of
Dermatology, Harvard Medical School, Boston, Massachusetts
02114, USA.
Title
Naive, hapten-specific human T lymphocytes are primed in
vitro with derivatized blood mononuclear cells.
Source
Journal of Investigative Dermatology. 110(1):29-33, 1998
Jan.

<9>

Unique Identifier
98056816
Authors
Aiba S. Terunuma A. Manome H. Tagami H.
Institution
Department of Dermatology, Tohoku University School of
Medicine, Aobaku, Japan. aiba@mail.cc.tohoku.ac.jp

Page Number : 4

Title
Dendritic cells differently respond to haptens and
irritants by their production of cytokines and expression
of co-stimulatory molecules.
Source
European Journal of Immunology. 27(11):3031-8, 1997 Nov.

<10>

Unique Identifier
98051714
Authors
Holliday MR. Corsini E. Smith S. Basketter DA. Dearman
RJ. Kimber I.
Institution
Zeneca Central Toxicology Laboratory, Macclesfield,
Cheshire, UK.
Title
Differential induction of cutaneous TNF-alpha and IL-6 by
topically applied chemicals.
Source
American Journal of Contact Dermatitis. 8(3):158-64, 1997

Sep.

<11>

Unique Identifier

98072216

Authors

Das KC. Lewis-Molock Y. White CW.

Institution

Department of Pediatrics, National Jewish Medical and Research Center, Denver, Colorado 80206, USA.

Title

Elevation of manganese superoxide dismutase gene expression by thioredoxin.

Source

American Journal of Respiratory Cell & Molecular Biology. 17(6):713-26, 1997 Dec.

<12>

Unique Identifier

97275305

Authors

Burnett R. Guichard Y. Barale E.

Institution

Pathology Department, Chrysalis, L'Arbresle, France.

Title

Page Number : 5

Immunohistochemistry for light microscopy in safety evaluation of therapeutic agents: an overview. [Review] [38 refs]

Source

Toxicology. 119(1):83-93, 1997 Apr 11.

<13>

Unique Identifier

97269823

Authors

LeVee GJ. Oberhelman L. Anderson T. Koren H. Cooper KD.

Institution

Department of Dermatology, University of Michigan, Ann Arbor, USA.

Title

UVA II exposure of human skin results in decreased immunization capacity, increased induction of tolerance and a unique pattern of epidermal antigen-presenting cell alteration.

Source

Photochemistry & Photobiology. 65(4):622-9, 1997 Apr.

<14>

Unique Identifier

97210838

Authors

Arts JH. Droge SC. Spanhaak S. Bloksma N. Penninks AH. Kuper CF.

Institution

TNO Nutrition and Food Research Institute, Toxicology
Division, Zeist, The Netherlands.

Title

Local lymph node activation and IgE responses in brown
Norway and Wistar rats after dermal application of
sensitizing and non-sensitizing chemicals.

Source

Toxicology. 117(2-3):229-34, 1997 Feb 28.

<15>

Unique Identifier

97186538

Authors

Bunce C. Bell EB.

Institution

Immunology Research Group, Biological Sciences, University
of Manchester, United Kingdom.

Page Number : 6

Title

CD45RC isoforms define two types of CD4 memory T cells, one
of which depends on persisting antigen.

Source

Journal of Experimental Medicine. 185(4):767-76, 1997 Feb
17.

<16>

Unique Identifier

97424785

Authors

el Walily AF. Blaih SM. Barary MH. el Sayed MA. Abdine
HH. el Kersh AM.

Institution

Pharmaceutical Analytical Chemistry Department, College of
Pharmacy, University of Alexandria, Egypt.

Title

Simultaneous determination of tenoxicam and 2-aminopyridine
using derivative spectrophotometry and high-performance
liquid chromatography.

Source

Journal of Pharmaceutical & Biomedical Analysis.
15(12):1923-8, 1997 Aug.

<17>

Unique Identifier

97427909

Authors

Hirai A. Minamiyama Y. Hamada T. Ishii M. Inoue M.

Institution

Department of Dermatology, Osaka City University Medical
School, Osaka, Japan.

Title

Glutathione metabolism in mice is enhanced more with
hapten-induced allergic contact dermatitis than with
irritant contact dermatitis.

Source

Journal of Investigative Dermatology. 109(3):314-8, 1997

Sep.

<18>

Unique Identifier

97416552

Authors

Serre I. Cano JP. Picot MC. Meynadier J. Meunier L.

Institution

Page Number : 7

Laboratory of Drug Toxicology, University of Montpellier,
France.

Title

Immunosuppression induced by acute solar-simulated
ultraviolet exposure in humans: prevention by a sunscreen
with a sun protection factor of 15 and high UVA protection.

Source

Journal of the American Academy of Dermatology. 37(2 Pt
1):187-94, 1997 Aug.

<19>

Unique Identifier

97311258

Authors

Ziem G. McTamney J.

Institution

Occupational and Environmental Medicine, Baltimore,
Maryland, USA.

Title

Profile of patients with chemical injury and sensitivity.

Source

Environmental Health Perspectives. 105 Suppl 2:417-36,
1997 Mar.

<20>

Unique Identifier

97319198

Authors

Kobayashi Y.

Institution

R & D Headquarters, Sunstar Inc., Osaka, Japan.

Title

Langerhans' cells produce type IV collagenase (MMP-9)
following epicutaneous stimulation with haptens.

Source

Immunology. 90(4):496-501, 1997 Apr.

<21>

Unique Identifier

97200293

Authors

Dearman RJ. Smith S. Basketter DA. Kimber I.

Institution

Zeneca Central Toxicology Laboratory, Macclesfield,
Cheshire, UK.

Title

Classification of chemical allergens according to cytokine secretion profiles of murine lymph node cells.

Source

Journal of Applied Toxicology. 17(1):53-62, 1997 Jan-Feb.

<22>

Unique Identifier

97225176

Authors

Gonzalez-Lopez A. Esquivias JI. Miranda-Romero A. Massa CF. Tejerina JA. Blasco MJ.

Institution

Department of Dermatology, University Hospital of Valladolid, Spain.

Title

Buschke-Lowenstein tumor and immunity.

Source

Cutis. 59(3):119-22, 1997 Mar.

<23>

Unique Identifier

97292199

Authors

Dearman RJ. Cumberbatch M. Hilton J. Fielding I. Basketter DA. Kimber I.

Institution

Zeneca Central Toxicology Laboratory, Macclesfield, Cheshire, UK.

Title

A re-appraisal of the skin-sensitizing activity of 2,4-dinitrothiocyanobenzene.

Source

Food & Chemical Toxicology. 35(2):261-9, 1997 Feb.

<24>

Unique Identifier

97216545

Authors

Basketter DA. Dearman RJ. Hilton J. Kimber I.

Institution

Unilever Environmental Safety Laboratory, Sharnbrook, Bedfordshire, UK.

Title

Dinitrohalobenzenes: evaluation of relative skin sensitization potential using the local lymph node assay.

Source

Contact Dermatitis. 36(2):97-100, 1997 Feb.

<25>

Unique Identifier

96328090

Authors

Nuwaysir EF. Daggett DA. Jordan VC. Pitot HC.

Institution

Environmental Toxicology Center, McArdle Laboratory for
Cancer Research, University of Wisconsin, Madison 53706,
USA.

Title

Phase II enzyme expression in rat liver in response to the
antiestrogen tamoxifen.

Source

Cancer Research. 56(16):3704-10, 1996 Aug 15.

<26>

Unique Identifier

96204899

Authors

Heylings JR. Clowes HM. Cumberbatch M. Dearman RJ.
Fielding I. Hilton J. Kimber I.

Institution

Zeneca Central Toxicology Laboratory, Macclesfield,
Cheshire, UK.

Title

Sensitization to 2,4-dinitrochlorobenzene: influence of
vehicle on absorption and lymph node activation.

Source

Toxicology. 109(1):57-65, 1996 May 3.

<27>

Unique Identifier

97167124

Authors

Dearman RJ. Moussavi A. Kemeny DM. Kimber I.

Institution

Zeneca Central Toxicology Laboratory, Macclesfield,
Cheshire, UK.

Title

Contribution of CD4+ and CD8+ T lymphocyte subsets to the
cytokine secretion patterns induced in mice during
sensitization to contact and respiratory chemical
allergens.

Source

Immunology. 89(4):502-10, 1996 Dec.

Page Number : 10

<28>

Unique Identifier

96381214

Authors

Basketter DA. Scholes EW. Fielding I. Dearman RJ.
Hilton J. Kimber I.

Institution

Unilever Environmental Safety Laboratory, Sharnbrook,
Beds., UK.

Title

□

Dichloronitrobenzene: a reappraisal of its skin sensitization potential.

Source

Contact Dermatitis. 34(1):55-8, 1996 Jan.

<29>

Unique Identifier

97089885

Authors

Hilton J. Dearman RJ. Boylett MS. Fielding I. Basketter DA. Kimber I.

Institution

Zeneca Central Toxicology Laboratory, Alderley Park, Cheshire, UK.

Title

The mouse IgE test for the identification of potential chemical respiratory allergens: considerations of stability and controls.

Source

Journal of Applied Toxicology. 16(2):165-70, 1996 Mar-Apr.

<30>

Unique Identifier

97072093

Authors

Hauptmann N. Grimsby J. Shih JC. Cadenas E.

Institution

Department of Molecular Pharmacology and Toxicology, School of Pharmacy, University of Southern California, Los Angeles 90033, USA.

Title

The metabolism of tyramine by monoamine oxidase A/B causes oxidative damage to mitochondrial DNA.

Source

Page Number : 11

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Source
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Authors
Swedmark S. Romert L. Morgenstern R. Jenssen D.
Institution
Department of Genetic and Cellular Toxicology, Wallenberg
Laboratory, Stockholm University, Sweden.
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Yaari A. Sikuler E. Keynan A. Ben-Zvi Z.
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Department of Medicine B, Soroka Medical Center, Beer
Sheva, Israel.
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Source
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Database: Medline <1966 to present>

Set	Search	Results
1	benzene.tw.	4702
2	dinitrochlorobenzene.tw.	817
3	chlorodinitrobenzene.tw.	39
4	2 or 3	856
5	limit 4 to (yr=1988 or yr=1989 or yr=1990 o	224
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Department of Pharmacology and Molecular Sciences, Johns Hopkins School of Medicine, Baltimore, MD 21205.

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Department of Medical Oncology, Fox Chase Cancer Center, Philadelphia, PA 19111.

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Krancer Center for Inflammatory Bowel Disease Research,
Hahnemann University, Philadelphia, Pennsylvania.

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Institution

Department of Dermatology, University of Michigan, Ann
Arbor 48109.

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Langerhans cell depletion.

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Authors

Cumberbatch M. Gould SJ. Peters SW. Basketter DA.
Dearman RJ. Kimber I.

Institution

Immunology Group, Zeneca Central Toxicology Laboratory,
Macclesfield, Cheshire, UK.

Title

Influence of topical exposure to chemical allergens on
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Authors

Mack DR. Gaginella TS. Sherman PM.

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Department of Pediatrics, Hospital for Sick Children,
University of Toronto, Ontario, Canada.

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Effect of colonic inflammation on mucin inhibition of
Escherichia coli RDEC-1 binding in vitro.

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Katsutani N. Shionoya H.

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Department of Drug Safety Research, Eisai Co., Ltd., Gifu,
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ICI Central Toxicology Laboratory, Alderley Park,
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CIRD Galderma, Valbonne, France.

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Department of Radiation Oncology, School of Medicine,
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Department of Parasitology, Faculty of Medicine, University of Ain Shams, Egypt.

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Tochigi Research Laboratories, Kao Corporation, Tochigi, Japan.

Title

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Department of Dermatology, University of Newcastle upon Tyne, Royal Victoria Infirmary, England, UK.

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University Department of Dermatology, University of Newcastle upon Tyne, UK.

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Department of Dermatology, Kansai Medical University, Osaka, Japan.

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Department of Microbiology and Immunology, University of Miami School of Medicine, Florida 33101.

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Department of Environmental Health Sciences, School of
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Department of Animal and Poultry Science, University of
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Hunan Medical University, Changsha, People's Republic of
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Department of Entomology, University of California, Davis
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Department of Pharmacology, Duke University Medical Center,
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Dai Y. Hang B. Huang Z. Li P.

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China Pharmaceutical University, Nanjing.

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Department of Internal Medicine (Section of Neurology),
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Photobiology Laboratory, Veterans Affairs Medical Center,
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Department of Preventive Medicine and Environmental Health,
College of Medicine, University of Iowa, Iowa City 52242.
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Children's Hospital of San Francisco, CA 94118.
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Stringer CP. Hicks R. Botham PA.
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ICI Central Toxicology Laboratory, Macclesfield, UK.

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Department of Pathology, Ontario Veterinary College,

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Department of Medicine (Skin and Venereal Diseases), JN Medical College, Aligarh Muslim University.

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ICI Central Toxicology Laboratory, Macclesfield, UK.

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Antigen-restricted antigenic competition induced by

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W. Bloksma N.
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The Netherlands.
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Department of Gastroenterology, G. B. Pant Hospital, New
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Division of Veterinary Medical Research, Food and Drug
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Authors

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Gajewska A. Booth IR.

Institution

Department of Genetics and Microbiology, University of
Aberdeen, Marischal College, UK.

Title

Activation of potassium efflux from Escherichia coli by
glutathione metabolites.

Source

Molecular Microbiology. 4(3):405-12, 1990 Mar.

<166>

Unique Identifier

90374555

Authors

Friedmann PS. Rees J. White SI. Matthews JN.

Institution

Dermatology Department, University of Newcastle upon Tyne,
England.

Title

Low-dose exposure to antigen induces sub-clinical
sensitization.

Source

Clinical & Experimental Immunology. 81(3):507-9, 1990 Sep.

<167>

Unique Identifier

90372673

Authors

Rees J. Friedmann PS. Matthews JN.

Institution

Department of Dermatology, University of
Newcastle-upon-Tyne, England.

Title

Contact sensitivity to dinitrochlorobenzene is impaired in
atopic subjects. Controversy revisited.

Source

Archives of Dermatology. 126(9):1173-5, 1990 Sep.

<168>

Unique Identifier

90347130

Authors

Sehgal VN. Joginder. Sharma VK. Prakash SK.

Institution

Department of Dermatology & Venereology and Maulana Azad

Medical College, New Delhi, India.
Title
Cell-mediated and humoral immunity in leprosy in children.
Source
Journal of Dermatology. 17(6):356-61, 1990 Jun.

<169>
Unique Identifier
90331247
Authors
Kawano S. Kohmura H. Ohta S. Takahashi N.
Institution
Drug Safety Research Department, Bristol-Myers Research
Institute, Ltd., Aichi, Japan.
Title
[Antigenicity study of buspirone hydrochloride in guinea
pigs and mice]. [Japanese]
Source
Journal of Toxicological Sciences. 15 Suppl 1:15-30, 1990
Apr.

<170>
Unique Identifier
90321067
Authors
Tachibana T. Toda KI. Furukawa F. Taniguchi S. Imamura
S.
Institution
Department of Dermatology, Faculty of Medicine, Kyoto
University, Japan.
Title
Histamine metabolism in delayed type
hypersensitivity--comparative analysis with cellular
infiltrates.
Source
Archives of Dermatological Research. 282(4):217-22, 1990.

<171>
Unique Identifier
90265973

Page Number : 24

Authors
Stokar LM. Burckart GJ. D'Souza M. Cohen B.
Venkataramanan R.
Institution
Department of Dermatology, University of Pittsburgh, PA
15261.
Title
Topical cyclosporine administration in rabbits.
Source
Research Communications in Chemical Pathology &
Pharmacology. 68(1):117-20, 1990 Apr.

<172>
Unique Identifier

90256308

Authors

Tingle MD. Clarke JB. Kitteringham NR. Park BK.

Institution

Department of Pharmacology and Therapeutics, University of Liverpool, UK.

Title

Influence of glutathione conjugation on the immunogenicity of dinitrophenyl derivatives in the rat.

Source

International Archives of Allergy & Applied Immunology. 91(2):160-5, 1990.

<173>

Unique Identifier

90248297

Authors

Thivolet J. Nicolas JF.

Institution

Clinique Dermatologique, Hopital Edouard Herriot, Lyon, France.

Title

Skin ageing and immune competence.

Source

British Journal of Dermatology. 122 Suppl 35:77-81, 1990 Apr.

<174>

Unique Identifier

90178636

Authors

Bean MF. Pallante-Morell SL. Dulik DM. Fenselau C.

Page Number : 25

Institution

Department of Pharmacology and Molecular Sciences, Johns Hopkins University School of Medicine, Baltimore, Maryland 21205.

Title

Protocol for liquid chromatography/mass spectrometry of glutathione conjugates using postcolumn solvent modification.

Source

Analytical Chemistry. 62(2):121-4, 1990 Jan 15.

<175>

Unique Identifier

90122623

Authors

Rees JL. Friedmann PS. Matthews JN.

Institution

University Department of Dermatology, Royal Victoria Infirmary, Newcastle upon Tyne, U.K.

Title

The influence of area of application on sensitization by dinitrochlorobenzene.

Source

□

Bulk Drug Substance to be Used in Pharmacy Compounding

Docket No. 98N-0182

Bulk Drug Substance

Ingredient Name: Sodium Butyrate
Chemical Name: Butyric acid, sodium salt CAS 156-54-7
Chemical Grade or Strength: Minimum 98%
How Supplied: White powder
International Pharmacopeial Recognition: Unknown.
Bibliography: 1) MSDS attached
2) Medline search bibliography attached

Compounded Product

Formulations: Short Chain Fatty Acid Enema. Aqueous solution for use as an enema.
Enema Formulation: Sodium acetate 8.166 g
Sodium propionate 2.882 g
Sodium butyrate 4.404 g
Sodium chloride 2.5 g
Sterile water for irrigation qs 1000 mL

Strength(s): See above.
Route of Administration: Rectally 60 mL as an enema.
Past/Proposed Use: Treatment of colitis. No commercial formulation is available.
Stability Data: None
Additional Information: None

Nominated by: University of Texas M. D. Anderson Cancer Center
Division of Pharmacy (Box 90)
1515 Holcombe Blvd.
Houston, Texas 77030

tel: (713) 792-2870

PRODUCT #: 303410 NAME: SODIUM BUTYRATE, 98%
MATERIAL SAFETY DATA SHEET, Valid 5/1998 - 7/1998
Printed 05/26/1998 8:57

Aldrich Chemical Co., Inc.
1001 West St. Paul
Milwaukee, WI 53233 USA
Phone: 414-273-3850

SECTION 1. - - - - - CHEMICAL IDENTIFICATION- - - - -

CATALOG #: 303410
NAME: SODIUM BUTYRATE, 98%

SECTION 2. - - - - - COMPOSITION/INFORMATION ON INGREDIENTS - - - - -

CAS #: 156-54-7
MF: C4H8O2
EC NO: 205-857-6

SYNONYMS

BUTANOIC ACID, SODIUM SALT (9CI) * BUTYRATE SODIUM * SODIUM BUTANOATE
* SODIUM BUTYRATE * SODIUM N-BUTYRATE *

SECTION 3. - - - - - HAZARDS IDENTIFICATION - - - - -

LABEL PRECAUTIONARY STATEMENTS

HARMFUL
HARMFUL BY INHALATION, IN CONTACT WITH SKIN AND IF SWALLOWED.
IRRITATING TO EYES, RESPIRATORY SYSTEM AND SKIN.
IN CASE OF CONTACT WITH EYES, RINSE IMMEDIATELY WITH PLENTY OF
WATER AND SEEK MEDICAL ADVICE.
WEAR SUITABLE GLOVES AND EYE FACE PROTECTION.
HYGROSCOPIC
KEEP TIGHTLY CLOSED.

SECTION 4. - - - - - FIRST-AID MEASURES- - - - -

IN CASE OF CONTACT, IMMEDIATELY FLUSH EYES WITH COPIOUS AMOUNTS OF
WATER FOR AT LEAST 15 MINUTES.
IN CASE OF CONTACT, IMMEDIATELY WASH SKIN WITH SOAP AND COPIOUS
AMOUNTS OF WATER.
IF INHALED, REMOVE TO FRESH AIR. IF NOT BREATHING GIVE ARTIFICIAL
RESPIRATION. IF BREATHING IS DIFFICULT, GIVE OXYGEN.
IF SWALLOWED, WASH OUT MOUTH WITH WATER PROVIDED PERSON IS CONSCIOUS.
CALL A PHYSICIAN.
WASH CONTAMINATED CLOTHING BEFORE REUSE.

SECTION 5. - - - - - FIRE FIGHTING MEASURES - - - - -

EXTINGUISHING MEDIA

WATER SPRAY.
CARBON DIOXIDE, DRY CHEMICAL POWDER OR APPROPRIATE FOAM.

SPECIAL FIREFIGHTING PROCEDURES

WEAR SELF-CONTAINED BREATHING APPARATUS AND PROTECTIVE CLOTHING TO
PREVENT CONTACT WITH SKIN AND EYES.

UNUSUAL FIRE AND EXPLOSIONS HAZARDS

EMITS TOXIC FUMES UNDER FIRE CONDITIONS.

SECTION 6. - - - - - ACCIDENTAL RELEASE MEASURES- - - - -

WEAR SELF-CONTAINED BREATHING APPARATUS, RUBBER BOOTS AND HEAVY
RUBBER GLOVES.

SWEEP UP, PLACE IN A BAG AND HOLD FOR WASTE DISPOSAL.
AVOID RAISING DUST.

VENTILATE AREA AND WASH SPILL SITE AFTER MATERIAL PICKUP IS COMPLETE.

SECTION 7. - - - - - HANDLING AND STORAGE- - - - -

REFER TO SECTION 8.

SECTION 8. - - - - - EXPOSURE CONTROLS/PERSONAL PROTECTION- - - - -

CHEMICAL SAFETY GOGGLES.

PRODUCT #: 303410 NAME: SODIUM BUTYRATE, 98%
MATERIAL SAFETY DATA SHEET, Valid 5/1998 - 7/1998
Printed 05/26/1998 8:57

RUBBER GLOVES.
NIOSH/MSHA-APPROVED RESPIRATOR.
SAFETY SHOWER AND EYE BATH.
MECHANICAL EXHAUST REQUIRED.
AVOID CONTACT AND INHALATION.
DO NOT GET IN EYES, ON SKIN, ON CLOTHING.
WASH THOROUGHLY AFTER HANDLING.
IRRITANT.
HARMFUL SOLID.
KEEP TIGHTLY CLOSED.
HYGROSCOPIC
STORE IN A COOL DRY PLACE.

SECTION 9. - - - - - PHYSICAL AND CHEMICAL PROPERTIES - - - - -

APPEARANCE AND ODOR

WHITE POWDER

PHYSICAL PROPERTIES

MELTING POINT: 250 C TO 253 C

SECTION 10. - - - - - STABILITY AND REACTIVITY - - - - -

INCOMPATIBILITIES

STRONG OXIDIZING AGENTS

HAZARDOUS COMBUSTION OR DECOMPOSITION PRODUCTS

TOXIC FUMES OF:

CARBON MONOXIDE, CARBON DICHIDE

SECTION 11. - - - - - TOXICOLOGICAL INFORMATION - - - - -

ACUTE EFFECTS

MAY BE HARMFUL BY INHALATION, INGESTION, OR SKIN ABSORPTION.

CAUSES EYE AND SKIN IRRITATION.

MATERIAL IS IRRITATING TO MUCOUS MEMBRANES AND UPPER
RESPIRATORY TRACT.

TO THE BEST OF OUR KNOWLEDGE, THE CHEMICAL, PHYSICAL, AND
TOXICOLOGICAL PROPERTIES HAVE NOT BEEN THOROUGHLY INVESTIGATED.

RTECS #: E18400000

BUTYRIC ACID, SODIUM SALT

ONLY SELECTED REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES
(RTECS) DATA IS PRESENTED HERE. SEE ACTUAL ENTRY IN RTECS FOR
COMPLETE INFORMATION.

SECTION 12. - - - - - ECOLOGICAL INFORMATION - - - - -

DATA NOT YET AVAILABLE.

SECTION 13. - - - - - DISPOSAL CONSIDERATIONS - - - - -

DISSOLVE OR MIX THE MATERIAL WITH A COMBUSTIBLE SOLVENT AND BURN IN A
CHEMICAL INCINERATOR EQUIPPED WITH AN AFTERBURNER AND SCRUBBER.

OBSERVE ALL FEDERAL, STATE AND LOCAL ENVIRONMENTAL REGULATIONS.

SECTION 14. - - - - - TRANSPORT INFORMATION - - - - -

CONTACT ALDRICH CHEMICAL COMPANY FOR TRANSPORTATION INFORMATION.

SECTION 15. - - - - - REGULATORY INFORMATION - - - - -

EUROPEAN INFORMATION

HARMFUL

R 20/21/22

HARMFUL BY INHALATION, IN CONTACT WITH SKIN AND IF SWALLOWED.

R 36/37/38

IRRITATING TO EYES, RESPIRATORY SYSTEM AND SKIN.

S 26

IN CASE OF CONTACT WITH EYES, RINSE IMMEDIATELY WITH PLENTY OF
WATER AND SEEK MEDICAL ADVICE.

S 37/39

WEAR SUITABLE GLOVES AND EYE/FACE PROTECTION.

PRODUCT #: 303410 NAME: SODIUM BUTYRATE, 99%
MATERIAL SAFETY DATA SHEET, Valid 5/1998 - 7/1999
Printed 05/26/1998 8:57

REVIEWS, STANDARDS, AND REGULATIONS

CEL=MAK

NOES 1983: HZD 82158; NIS 1; TNF 22; NCS 2; TNE 194; TFE 101

EPA TSCA SECTION 8(B) CHEMICAL INVENTORY

SECTION 16. - - - - - OTHER INFORMATION- - - - -

THE ABOVE INFORMATION IS BELIEVED TO BE CORRECT BUT DOES NOT PURPORT TO BE ALL INCLUSIVE AND SHALL BE USED ONLY AS A GUIDE. SIGMA, ALDRICH, FLUKA SHALL NOT BE HELD LIABLE FOR ANY DAMAGE RESULTING FROM HANDLING OR FROM CONTACT WITH THE ABOVE PRODUCT. SEE REVERSE SIDE OF INVOICE OR PACKING SLIP FOR ADDITIONAL TERMS AND CONDITIONS OF SALE.

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□

Database: Medline <1966 to present>

Set	Search	Results
1	fatty acid enemas.tw.	8
2	short chain fatty acid enemas.tw.	7
3	1 or 2	8

<1>

Unique Identifier

98089837

Authors

Sandborn WJ.

Title

Are short-chain fatty acid enemas effective for left-sided ulcerative colitis?.

Source

Gastroenterology. 114(1):218-9, 1998 Jan.

<2>

Unique Identifier

97211658

Authors

Cummings JH.

Institution

Addenbrooke's Hospital, MRC Dunn Clinical Nutrition Centre, Cambridge, UK.

Title

Short-chain fatty acid enemas in the treatment of distal ulcerative colitis [comment]. [Review] [27 refs]

Comments

Comment on: Eur J Gastroenterol Hepatol 1997 Feb;9(2):163-8

Source

European Journal of Gastroenterology & Hepatology. 9(2):149-53, 1997 Feb.

<3>

Unique Identifier

97099404

Authors

Scheppach W.

Institution

Department of Medicine, University of Wurzburg, Germany.

Title

Treatment of distal ulcerative colitis with short-chain fatty acid enemas. A placebo-controlled trial.
German-Austrian SCFA Study Group.

Source

Abstract

Rectal enemas containing a short-chain fatty acid mixture, butyrate alone, or saline placebo were administered to 47 patients with active distal ulcerative colitis. Enemas were instilled twice daily and the patients' condition was evaluated at entry and after four and eight weeks of local therapy. A disease activity index, chosen as the major end point, decreased significantly after all three modes of treatment with no difference among groups. The endoscopic appearance of the mucosa and the histologic degree of inflammation was not different among groups. After eight weeks, fewer colonic segments were affected endoscopically following butyrate than placebo treatment. This study showed trends towards a beneficial effect of topical short-chain fatty acids in active ulcerative colitis, but more patients are needed to demonstrate this effect with sufficient statistical power.

<4>

Unique Identifier

96186649

Authors

Patz J. Jacobsohn WZ. Gottschalk-Sabag S. Zeides S. Braverman DZ.

Institution

Department of Gastroenterology and Pathology, Shaare Zedek Medical Center, Jerusalem, Israel.

Title

Treatment of refractory distal ulcerative colitis with short chain fatty acid enemas.

Source

American Journal of Gastroenterology. 91(4):731-4, 1996 Apr.

Abstract

OBJECTIVES: To determine the efficacy and safety of short chain fatty acids (SCFA) in the treatment of refractory distal ulcerative colitis (UC). METHODS: Ten patients with distal UC who had failed to respond to rectal and oral therapy with 5-ASA and corticosteroids were treated with twice daily enemas containing sodium acetate 60 mM, sodium propionate 30 mM, and sodium butyrate 40 mM titrated to a pH of 7. Patients were assessed clinically (rectal bleeding, tenesmus, bowel motions), endoscopically, and

Page Number : 3

histologically before and after 6 wk of therapy. In addition, patients gave a self-assessment of the efficacy of treatment. RESULTS: Five of the 10 patients responded clinically, and four of these had a clinical remission as reflected by a decrease in degree of bleeding (2.2 vs. 1.2, $p < 0.05$) and tenesmus (1.6 vs. 0.3, $p < 0.05$) and by global self-assessment. Endoscopic improvement occurred in five (6.78 +/- 0.83 vs. 4.44 +/- 2.7, $p < 0.05$). Histologically, no improvement was noted. No side effects were noted, and no patient's condition deteriorated. CONCLUSIONS: In this open-labeled study in patients with highly refractory distal UC, 50% had an overall clinical and endoscopic response. Forty percent of the patients

assessed the treatment to be superior to previous treatments and expressed a desire to continue. This trial confirms other studies as to the efficacy of this treatment and further confirms the need for controlled trials of this promising therapy.

<5>

Unique Identifier

96384844

Authors

al-Sabbagh R. Sinicrope FA. Sellin JH. Shen Y. Rouben L.

Institution

Division of Gastroenterology, University of Texas Medical School, Houston, USA.

Title

Evaluation of short-chain fatty acid enemas: treatment of radiation proctitis.

Source

American Journal of Gastroenterology. 91(9):1814-6, 1996 Sep.

Abstract

BACKGROUND: Radiation proctitis is a common complication of abdominal and pelvic radiotherapy; unfortunately, there is no established effective therapy for radiation proctitis. Short-chain fatty acids (SCFA) have been effectively used to treat a variety of colitides. We sought to determine whether SCFA enemas have a role in the treatment of radiation proctitis. METHODS: Seven patients completed an open-labeled, pilot study to evaluate the effect of SCFA on clinical, endoscopic, and pathological parameters of radiation proctitis. RESULTS: Four weeks of treatment with SCFA enemas resulted in clinical improvement in all patients. There were modest, but not significant, changes in endoscopic and pathological parameters. CONCLUSION: SCFA

Page Number : 4

are a promising therapeutic option in radiation proctitis.

<6>

Unique Identifier

93010164

Authors

Senagore AJ. MacKeigan JM. Scheider M. Ebrum JS.

Institution

Department of Surgical Research, Ferguson Clinic, Grand Rapids, Michigan.

Title

Short-chain fatty acid enemas: a cost-effective alternative in the treatment of nonspecific proctosigmoiditis [see comments].

Comments

Comment in: Dis Colon Rectum 1993 May;36(5):518

Source

Diseases of the Colon & Rectum. 35(10):923-7, 1992 Oct.

Abstract

The purpose of this study was to perform a randomized, prospective comparison of corticosteroid enemas (CS--100 mg

of hydrocortisone/60 cc P.R. q.h.s.; n = 12), mesalamine enemas (5-ASA--4 g/60 cc P.R. q.h.s.; n = 19), and short-chain fatty acid enemas (SCFA--60 cc P.R. b.i.d.; n = 14) for the treatment of proctosigmoiditis. Patients presenting to the Ferguson Clinic with the diagnosis of idiopathic proctosigmoiditis were evaluated for age, sex, prior history of proctitis, duration of symptoms prior to presentation, endoscopic scoring, and mucosal biopsies. Clinical evaluation was performed at two-week intervals for six weeks, with repeat biopsies taken at six weeks. There was no significant difference with respect to age, male/female ratio, past history of proctosigmoiditis, length of colorectum involved at the time of initial presentation, symptom resolution, and endoscopic and histologic improvement among the three treatment groups. Recovery occurred in a similar proportion in each of the three groups: CS, 10/12; 5-ASA, 17/19; and SCFA, 12/14. The cost of six weeks of treatment was: CS, \$71.82; 5-ASA, \$347.28; and SCFA, \$31.50. This study indicates that SCFA enemas are equally efficacious to CS or 5-ASA enemas for the treatment of proctosigmoiditis at a significant cost savings.

<7>

Unique Identifier
92266017

Page Number : 5

Authors

Silk DB.

Title

Medical management of severe inflammatory disease of the rectum: nutritional aspects. [Review] [101 refs]

Source

Baillieres Clinical Gastroenterology. 6(1):27-41, 1992
Mar.

Abstract

It is clear that the nutritional state of patients with inflammatory bowel disease is often impaired and can be improved by the provision of nutritional support. Improvement in nutritional status can be achieved as effectively with enteral as with parenteral nutrition. Nutritional support appears to have no primary therapeutic effect in patients with ulcerative colitis. With regard to nutritional support in Crohn's disease, parenteral nutrition should be restricted to use as supportive rather than primary therapy. Available information now seems to suggest that most of the benefits of parenteral nutrition in Crohn's disease are related to an improvement in nutritional state rather than as primary therapy, and its use should be restricted to the treatment of specific complications of Crohn's disease, such as intestinal obstruction related to stricture formation or short bowel syndrome following repeated resection. Although some doubt exists over the efficacy of oligopeptide-containing elemental and polymeric enteral diets, the present evidence indicates that chemically defined free amino acid-containing elemental diets have primary therapeutic efficacy in the management of acute exacerbations of

Crohn's disease. As such, these diets are worthy of therapeutic trial in patients with severe Crohn's disease involving the distal colon and rectum, particularly in those patients who are malnourished and who prove to be resistant to treatment with a combination of topical corticosteroids and 5-aminosalicylic acid-containing compounds. Clinicians should be aware, though, that the beneficial effects are likely to be restricted to the short term, with high relapse rates by 1 year, this being particularly so in patients with distal Crohn's proctocolitis (Teahon et al, 1988). Volatile fatty acid enemas clearly have potential in the management of patients with severe steroid-resistant proctitis. Finally, one of the most important observations made in recent years is the one concerning the large losses of nitrogen that will occur in patients with inflammatory bowel disease treated with corticosteroids in the absence of adequate protein intake (O'Keefe et al, 1989). Hopefully the days of treating

Page Number : 6

patients with severe inflammatory bowel disease with high dose corticosteroids and a peripheral dextrose or dextrose-saline drip have passed into history. [References: 101]

<8>

Unique Identifier

93195263

Authors

Haque S. West AB.

Title

Diversion colitis--20 years a-growing [editorial].

Source

Journal of Clinical Gastroenterology. 15(4):281-3, 1992
Dec.

Abstract

During the last decade, clinical and pathologic studies of diversion colitis have led to a better understanding of its nature. The clinical features are well described, and the endoscopic appearances, and gross and microscopic pathology are now defined. Thus, firm diagnosis and distinction from other colitides, notably ulcerative colitis and Crohn's disease, are possible in most cases. Restoration of the fecal stream cures diversion colitis, which in some cases may be successfully treated with short-chain fatty acid enemas, although the efficacy of this method remains to be substantiated. An understanding of the pathogenesis of diversion colitis (currently unknown) may lead to better methods of prevention and treatment.

Bulk Drug Substance to be Used in Pharmacy Compounding

Docket No. 98N-0182

Bulk Drug Substance

Ingredient Name: Ferric subsulfate; Monsel's salt NDC 0395-0910-94
Chemical Name: Ferric subsulfate $\text{Fe}_4(\text{OH})_2(\text{SO}_4)_5$
Chemical Grade or Strength: Ferric iron 22 to 24%
How Supplied: Yellow powder
International Pharmacopeial Recognition: Martindale The Extra Pharmacopoeia p.1361
Bibliography: 1) MSDS attached
2) Medline search bibliography attached

Compounded Product

Formulations: Ferric Subsulfate Hemostat (as gel)
Formulation: Ferric subsulfate 50 g
Propylene glycol 10% 36 mL
Strength(s): See above
Route of Administration: Vaginally
Past/Proposed Use: Hemastatic gel. Monsel's solution is available, but is too fluid and runny for this application. The gel formulation is preferred.
Stability Data: None available
Additional Information: None
Nominated by: University of Texas M. D. Anderson Cancer Center
Division of Pharmacy (Box 90)
1515 Holcombe Blvd.
Houston, Texas 77030
tel: (713) 792-2870

Ferric Subsulfate
(Powder)

Material Safety Data Sheet

1998

Medisca Inc.
Plattsburgh, New York

661 Route 3, Unit C, Plattsburgh, New York, 12901

CALL TOLL FREE: 1-800-932-1039 - In Plattsburgh call: 1-518-561-0109 - FAX: 1-518-561-0078

SECTION I - PRODUCT INFORMATION
--

RTECS:	N/A
CAS:	1310-45-8
PRODUCT NAME:	Ferric Subsulfate
CHEMICAL NAME:	Feric Sulfate Basic.
SYNONYMS:	N/A
EMPERICAL FORMULA:	approx.: $Fe_2(OH)_2(SO_4)_3$
USES:	Used mainly as a hemostatic in minor surgical procedures. The chemical coagulates tissue and blood proteins at the site of application, the coagulum closing the bleeding vessels. Electrocautery at the same site may cause the precipitation of elemental iron and insoluble iron compounds with a resulting cosmetic disfigurement ("tattoo").
STATUS:	N/A

SECTION II - TOXICOLOGICAL INFORMATION

ROUTE OF ENTRY:	Topical, Inhalation, Ingestion.
IRRITANCY:	Causes skin, eye, mucous membranes, and upper respiratory tract irritation.

CLINICAL FINDINGS:

Toxic effects of iron are due to unbound iron in the serum. Soluble ferrous iron salts also cause corrosive damage to the stomach and small intestine. The pathologic findings in fatal cases include pulmonary edema and hemorrhages, dilatation of the heart, and hemorrhagic and necrotic gastroenteritis. Iron pigment may be found in the stomach, liver, lungs, and kidneys. Degenerative changes may be found in the lymph nodes, liver, and kidneys. Venous thromboses are found in the mucosa of the small intestine. The principal manifestations of poisoning are vomiting, diarrhea, and circulatory collapse. The dangerous dose of iron can be as small as 30 mg/kg.

ACUTE POISONING:

(From Ingestion) Lethargy nausea and vomiting, upper abdominal pain, tarry stools, diarrhea, fast and weak pulse, hypotension, dehydration, acidosis, and coma occur within one half to one hour following ingestion of iron salts. All symptoms may clear in a few hours and the patient may be asymptomatic for 24 hours, after which symptoms return, with cyanosis, pulmonary edema, shock, convulsions, acidosis, anuria, hyperthermia, and death in coma within 24-48 hours. Liver necrosis may occur 2 days after ingestion. Injection of iron-dextran has

caused fever, tachycardia, enlargement of lymph nodes, skin rash, back pain, and in some cases, anaphylactoid reactions.

CHRONIC POISONING:

Administration of parenteral iron preparations in excess dosage causes exogenous hemosiderosis with damage to the liver and pancreas. Injection of large amounts of iron-dextran complex (Imferon) intramuscularly in experimental animals has caused sarcoma. However, injection of 953 mL of iron-dextran in one patient did not result in sarcoma

LABORATORY FINDINGS :

- 1) Increased red blood cell count and hemoglobin indicate hemoconcentration
- 2) Stools may contain gross or occult blood.
- 3) Serum iron levels above 400-500 ug/dL are a cause for concern; iron levels over 500 ug/dL in a symptomatic patient are an indication for chelation therapy with deferoxamine.
- 4) Measurements of iron-binding capacity are not usually helpful.
- 5) Iron medications are opaque in x-rays of the abdomen, but an absence of opaque material on x-ray does not exclude the possibility of iron ingestion.

MUTATION DATA:

Not been studied yet.

REPRODUCTIVE EFFECTS DATA:

Not been studied yet.

TUMORIGENIC DATA:

Not been studied yet.

TOXICITY DATA:

INTRAPERITONEAL:

MOUSE: LD50: 601 mg/kg;

INTRAVENOUS:

RABBIT: LD50 : 7.2 mg/kg.

SECTION III - PHYSICAL DATA

STATE: LIQUID _____ SOLID X _____ GAS _____

DESCRIPTION: Brown to reddish brown, crystalline powder; almost odourless.

SOLUBILITY: Freely soluble in Water; very soluble in boiling water; practically insoluble in ethanol (96%)

USP 23 SPECIFICATIONS : NOT LISTED.

BP 93 SPECIFICATIONS : NOT LISTED.

SECTION IV - FIRE AND EXPLOSION HAZARDS

FLAMMABILITY: Non-Flammable.

MEANS OF EXTINCTION: Water, foam, carbon dioxide.

SECTION V - REACTIVITY DATA

STABILITY: Stable.

INCOMPATIBLE PRODUCTS:

Potentially explosive reaction with methylisocyno acetate at 25°. May ignite on contact with arsenic trioxide and sodium nitrate.

HAZARDOUS DECOMPOSITION PRODUCTS:

When heated to decomposition emits toxic fumes of Sulfur oxides.

HAZARDOUS POLYMERIZATION:

Will not occur.

SECTION VI - PREVENTIVE MEASURES

PREVENTIVE MEASURES:

Avoid raising dust. Do not ingest. Wear protective clothing.

PERSONAL PROTECTIVE EQUIPMENT:

Respirator, gloves, goggles.

SPECIFIC ENGINEERING CONTROLS:

Adequate mechanical ventilation with a chemical fumehood.

SPILL AND LEAK PROCEDURES:

Evacuate area. Wear self contained breathing apparatus, rubber boots and gloves. Sweep and hold for disposal. Avoid raising dust. Avoid getting dust into your mouth. Ventilate area and wash spill site.

WASTE DISPOSAL:

Dissolve or mix with a combustible solvent. Incinerate.

STORAGE REQUIREMENT:

Preserve in airtight containers. Protect from light. Hygroscopic.

WHMIS:

Class D: 1B.

LABELLING REQUIREMENTS:

Harmful if swallowed, inhaled, or absorbed through skin. Causes skin, eye, mucous membranes, and upper respiratory tract irritation. Avoid ingestion, inhalation, and contact with skin, eye, and mucous membranes. Preserve in airtight containers. Protect from light. Hygroscopic.

SECTION VII - FIRST AID MEASURES

EYES:

Flush with copious amounts of water for 15 minutes.

SKIN:

Wash with soap and water for 15 minutes.

INGESTION:

Call a physician. Wash out mouth with water.

INHALATION:

Remove to fresh air. If not breathing, give A.R. If breathing is difficult, give oxygen.

TREATMENT:**A. EMERGENCY PROCEDURES**

- 1) Establish airway and maintain respiration.
- 2) If the serum iron determination will be delayed and the patient has a history of excessive iron ingestion and symptoms more serious than nausea and vomiting, consider giving deferoxamine, 40 mg/kg intravenously.
- 3) Draw blood for determination of hemoglobin level, white blood cell count, serum iron level, electrolyte concentrations, and blood typing.
- 4) In patients not in shock or coma, induce emesis with syrup of ipecac if the patient has not vomited. If gastric lavage is performed as well, add sodium bicarbonate, 20 g/L, and leave sodium bicarbonate solution in the stomach.
- 5) Start infusion of isotonic saline or dextrose solution to correct electrolyte disturbances and dehydration. Maintain blood pressure by blood or plasma transfusion.
- 6) Order abdominal x-ray only if large numbers of ferrous sulfate tablets were ingested.

ANTIDOTE:

If there are iron tablets visible on x-ray, symptoms or signs of iron poisoning, or pink urine with good urine output, give chelation therapy with deferoxamine, 15mg/kg/h by continuous intravenous infusion to a maximum of 30 mg/kg in each 12 hour period. Monitor blood pressure during administration of deferoxamine, and reduce the rate of administration if deferoxamine if the blood pressure falls. Single doses should not exceed 1g and the maximum in 24 hours should not exceed 6g. Deferoxamine is hazardous in patients with severe renal disease or anuria, and dialysis is necessary in such cases. Injected deferoxamine is associated with a high risk and should be reserved for serious poisoning. Continue deferoxamine therapy until the patient is free of symptoms and signs for 24 hours.

GENERAL MEASURES:

Treat shock and acidosis. Maintain adequate intravascular volume and tissue perfusion by blood transfusion or other intravenous therapy. Exchange transfusion has also been used in small infants. Maintain urine output at 1 mL/kg/h. Gastrotomy may be necessary to remove a bolus of iron tablets.

PROGNOSIS:

If the patient is asymptomatic at the end of 48 hours, recovery is likely.

SECTION VIII - ECOLOGICAL DATA

TO THE BEST OF OUR KNOWLEDGE THERE ARE NO ECOLOGICAL STUDIES AVAILABLE AT THE PRESENT TIME IN REGARDS TO THIS PRODUCT.

SECTION X - HAZARDOUS INGREDIENTS

Not applicable.

SECTION X - FINAL NOTES

The above information is intended to describe our product in respect to safety and handling requirements only. We have attempted to be complete and correct, however liability for and damage or injury is hereby declined since conditions of use and utilization of the product are beyond our control. Observance of all legal requirements is the responsibility of the user.

SECTION XI - BIBLIOGRAPHY

REFERENCES:

Available upon request only.

UPDATED: Mar. / 1998

Database: Medline <1966 to present>

Set	Search	Results
1	ferric subsulfate.tw.	3
2	monsel's salt.tw.	1
3	hemastatic.tw.	1
4	1 or 2 or 3	5

<1>

Unique Identifier

80169477

Authors

Bascom J.

Title

Pilonidal disease: origin from follicles of hairs and results of follicle removal as treatment.

Source

Surgery. 87(5):567-72, 1980 May.

Abstract

Contrary to current concepts, shafts of hairs apparently are not the source of most pilonidal disease. Instead, follicles of hairs seem to be the source. Pilonidal disease progresses through five stages. Accumulation of hair within a chronic pilonidal abscess is a late and secondary phenomenon. The acute abscess is drained only. Over the chronic abscess the distended hair follicles are removed individually from the gluteal cleft. In addition, the cavity of the chronic abscess is cleaned out through incisions placed parallel to, but to one side of, the cleft. Acute abscesses are similiary treated 5 days after drainage. Cavity walls are not excised. They are allowed to fall closed and to heal. An epithelial tube, when found, is dissected out through incisions beside the cleft.

Nonhealing wounds are effectively treated with Monsel's Salt. Fifty patients were treated in the author's office under local anesthesia. Disability averaged 1 day. Healing time, without disability, averaged 3 weeks. Recurrences in four patients were healed in an average of 2 weeks.

<2>

Unique Identifier

81253501

Authors

Wood C. Severin GL.

Page Number : 2

Title

Unusual histiocytic reaction to Monsel's solution.

Source

American Journal of Dermatopathology. 2(3):261-4, 1980

Fall.

Abstract

Monsel's solution for hemostasis was applied to a wound produced at the site of a punch excision biopsy from the wrist of a 51-year-old white man. The biopsy specimen showed an incompletely excised basal cell carcinoma. Thirty days later, the residual carcinoma was excised. Adjacent to a basal cell carcinoma in the second biopsy specimen was an intradermal nodule composed of large polygonal cells and multinucleated histiocytic giant cells containing granules and clumps of dark brown and black pigment. This pigment was strongly positive for iron when stained by Perl's method. This unusual histiocytic reaction to topically applied ferric subsulfate must be differentiated from malignant melanomas and from histiocytic neoplasms with siderosis.

<3>

Unique Identifier

81253487

Authors

Amazon K. Robinson MJ. Rywlin AM.

Title

Ferrugination caused by Monsel's solution. Clinical observations and experimentations.

Source

American Journal of Dermatopathology. 2(3):197-205, 1980 Fall.

Abstract

Ferrugination of fibrin, dermal collagen, and striated muscle fibers may result from the application of Monsel's solution (20% ferric subsulfate) for hemostasis to wounds caused by excisions of skin. The collagen fibers in the dermis are coated with a slightly refractile, gray-brown substance which is strongly positive with Perl's reaction for iron. Ferruginated collagen fibers are eliminated through the epidermis as the epidermis regenerates. Some of the ferruginated fibers become calcified. Siderophages are present in these and adjacent areas. Seepage of Monsel's solution into deeper tissues at the site of biopsy may result in ferrugination of skeletal muscle, perichondrium, and even cartilage. We applied Monsel's solution to biopsy sites caused experimentally in a rabbit and confirmed the capacity of the solution to produce ferrugination of

Page Number : 3

collagen fibers and skeletal muscle. Ferrugination of collagen fibers becomes less pronounced as the wounds heal and as iron pigment is taken up by macrophages. Ferruginated fibers of skeletal muscle act as foreign bodies to elicit a granulomatous reaction. Comparison of biopsy sites to which Monsel's solution had been applied with biopsy sites to which the solution had not been applied indicates that the substance does not seem to interfere with the rate of epidermal regeneration. However, when there is injury to skeletal muscle and other deep tissues by Monsel's solution, an inflammatory reaction persists at these sites for weeks.

<4>

Unique Identifier

90042966

Authors

Hallock GG. Rice DC.

Institution

Department of Surgery, Dorothy Rider Pool Laser and
Microsurgery Laboratory, Allentown, Pennsylvania 18103.

Title

In utero fetal surgery using a milliwatt carbon dioxide
laser.

Source

Lasers in Surgery & Medicine. 9(5):482-4, 1989.

Abstract

In utero surgery represents a future new frontier with
unknown possibilities for medical intervention. Since the
presently available microsurgery instruments are too
cumbersome or indelicate, low-energy carbon dioxide lasers
have been investigated as a tool that holds promise as a
fetal scalpel and hemostatic device. Preliminary results
demonstrate that continued investigation is necessary to
limit the zone of tissue destruction in these most
diminutive patients.

<5>

Unique Identifier

87058271

Authors

Sawchuk WS. Friedman KJ. Manning T. Pinnell SR.

Title

Delayed healing in full-thickness wounds treated with
aluminum chloride solution. A histologic study with
evaporimetry correlation.

Source

Page Number : 4

Journal of the American Academy of Dermatology. 15(5 Pt
1):982-9, 1986 Nov.

Abstract

Optimizing wound healing parameters seems to be the utmost
importance in the present age of sophisticated wound care
and dressings. We studied the effect of two hemostatics:
30% aluminum chloride and ferric subsulfate (Monsel's
solution) on the rate of wound healing in Yucatan miniature
hairless pigs. Wound healing was examined in occluded and
nonoccluded full-thickness 3-mm punch biopsy wounds. Wounds
were treated either with 30% aluminum chloride solution or
ferric subsulfate solution or were allowed to clot with
minimal pressure from a gauze pad. The course of wound
healing was followed utilizing evaporimetry readings from
the wound sites in addition to periodic histologic
examination in an attempt to correlate the evaporimetry
readings with corresponding histology. Delay in
reepithelialization was noted histologically both in wounds
treated with aluminum chloride and in those treated with
ferric subsulfate compared to controls. Presumably this
delay was the result of tissue necrosis caused by these
hemostatic agents, resulting in slightly larger and less

cosmetically acceptable scars. Plots of evaporimetry data revealed a biphasic pattern of water loss during healing, with an initial rapid decline in water loss followed by a much slower decline. Histologic reepithelialization seemed to correlate best with the point on the evaporimetry curve where the slope changed from the phase of rapid water loss to a slower rate.

□