

Toxicological profile	NTIS Order No.	CAS No.
3. Creosote .....	PB2003-100136	008001-58-9
Coal Tars .....	.....	008007-45-2
Coal Tar Pitch .....	.....	065996-93-2
4. DDT .....	PB2003-100137	000050-29-3
DDD .....	.....	000072-54-8
DDE .....	.....	000072-55-9
5. Di (2-ethylhexyl) phthalate .....	PB2003-100138	000117-81-7
6. Hexachlorobenzene .....	PB2003-100139	000118-74-1
7. Methoxychlor .....	PB2003-100140	000072-43-5

Dated: October 18, 2002.

**Georgi Jones,**

Director, Office of Policy and External Affairs,  
Agency for Toxic Substances and Disease  
Registry.

[FR Doc. 02-27085 Filed 10-23-02; 8:45 am]

BILLING CODE 4163-70-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Toxic Substances and Disease Registry

[ATSDR-187]

#### Availability of Draft Toxicological Profiles

**AGENCY:** Agency for Toxic Substances  
and Disease Registry (ATSDR),  
Department of Health and Human  
Services (HHS).

**ACTION:** Notice of availability.

**SUMMARY:** The Comprehensive  
Environmental Response,  
Compensation, and Liability Act of 1980  
(CERCLA), as amended by the  
Superfund Amendments and  
Reauthorization Act of 1986 (SARA),  
section 104(i)(3) (42 U.S.C. 9604(i)(3))  
directs the Administrator of ATSDR to  
prepare toxicological profiles of priority  
hazardous substances and to revise and  
publish each updated toxicological  
profile as necessary. This notice  
announces the availability of the 16th  
set of toxicological profiles, which  
consists of two new drafts and three  
updated drafts, prepared by ATSDR for  
review and comment.

**DATES:** In order to be considered,  
comments on these draft toxicological  
profiles must be received on or before  
February 24, 2003. Comments received  
after the close of the public comment  
period will be considered at the  
discretion of ATSDR based upon what  
is deemed to be in the best interest of  
the general public.

**ADDRESSES:** Requests for printed copies  
or CD-ROMs of the draft toxicological  
profiles should be sent to the attention  
of Ms. Franchetta Stephens, Division of  
Toxicology, Agency for Toxic

Substances and Disease Registry,  
Mailstop E-29, 1600 Clifton Road, NE,  
Atlanta, Georgia 30333. Electronic  
access to these documents is also  
available at the ATSDR website: [http://  
www.atsdr.cdc.gov/toxpro2.html](http://www.atsdr.cdc.gov/toxpro2.html).

Comments regarding the draft  
toxicological profiles should be sent to  
the attention of Ms. Lori Miller, Division  
of Toxicology, Agency for Toxic  
Substances and Disease Registry,  
Mailstop E-29, 1600 Clifton Road, NE,  
Atlanta, Georgia 30333.

Requests for printed copies or CD-  
ROMs of the draft toxicological profiles  
must be in writing, and must  
specifically identify the hazardous  
substance(s) profile(s) that you wish to  
receive. ATSDR reserves the right to  
provide only one copy of each profile  
requested, free of charge. In case of  
extended distribution delays, requestors  
will be notified.

Written comments and other data  
submitted in response to this notice and  
the draft toxicological profiles should  
bear the docket control number ATSDR-  
187. Send one copy of all comments and  
three copies of all supporting  
documents to Ms. Lori Miller at the  
above stated address by the end of the  
comment period. Because all public  
comments regarding ATSDR  
toxicological profiles are available for  
public inspection, no confidential  
business information or other  
confidential information should be  
submitted in response to this notice.

**FOR FURTHER INFORMATION CONTACT:** Ms.  
Franchetta Stephens, Division of  
Toxicology, Agency for Toxic  
Substances and Disease Registry,  
Mailstop E-29, 1600 Clifton Road, NE,  
Atlanta, Georgia 30333, telephone 1-  
888-422-8737 or (404) 498-0720.

**SUPPLEMENTARY INFORMATION:** The  
Superfund Amendments and  
Reauthorization Act (SARA) (Pub. L.  
99-499) amends the Comprehensive  
Environmental Response,  
Compensation, and Liability Act  
(CERCLA or Superfund) (42 U.S.C. 9601  
*et seq.*) by establishing certain  
responsibilities for the ATSDR and the  
U.S. Environmental Protection Agency  
(EPA) with regard to hazardous

substances which are most commonly  
found at facilities on the CERCLA  
National Priorities List (NPL). Among  
these responsibilities is that the  
Administrator of ATSDR prepare  
toxicological profiles for substances  
included on the priority lists of  
hazardous substances. These lists  
identified 275 hazardous substances  
that ATSDR and EPA determined pose  
the most significant potential threat to  
human health. The availability of the  
revised priority list of 275 hazardous  
substances was announced in the  
**Federal Register** on October 25, 2001  
(66 FR 54014). For prior versions of the  
list of substances see **Federal Register**  
notices dated April 17, 1987 (52 FR  
12866); October 20, 1988 (53 FR 41280);  
October 26, 1989 (54 FR 43619); October  
17, 1990 (55 FR 42067); October 17,  
1991 (56 FR 52166); October 28, 1992  
(57 FR 48801); February 28, 1994 (59 FR  
9486); April 29, 1996 (61 FR 18744);  
November 17, 1997 (62 FR 61332) and  
October 21, 1999 (64 FR 56792).  
(CERCLA also requires ATSDR to assure  
the initiation of a research program to  
fill data needs associated with the  
substances.)

Section 104(i)(3) of CERCLA (42  
U.S.C. 9604(i)(3)) outlines the content of  
these profiles. Each profile will include  
an examination, summary and  
interpretation of available toxicological  
information and epidemiologic  
evaluations. This information and these  
data are to be used to identify the levels  
of significant human exposure for the  
substance and the associated health  
effects. The profiles must also include a  
determination of whether adequate  
information on the health effects of each  
substance is available or in the process  
of development. When adequate  
information is not available, ATSDR, in  
cooperation with the National  
Toxicology Program (NTP), is required  
to assure the initiation of research to  
determine these health effects.

Although key studies for each of the  
substances were considered during the  
profile development process, this  
**Federal Register** notice seeks to solicit  
any additional studies, particularly  
unpublished data and ongoing studies,

which will be evaluated for possible addition to the profiles now or in the future.

The following draft toxicological profiles will be made available to the public on or about October 17, 2002.

Document No. and hazardous substance	CAS No.
1. Ammonia and ammonia compounds	007664-41-7 various
2. Chlorine dioxide	10049-04-4
3. Copper cupric sulfate	007440-50-8 007758-98-7
4. Polybrominated biphenyls and polybrominated diphenyl ethers	067774-32-7 various
5. Synthetic vitreous fibers	various

All profiles issued as "Drafts for Public Comment" represent ATSDR's best efforts to provide important toxicological information on priority hazardous substances. We are seeking public comments and additional information which may be used to supplement these profiles. ATSDR remains committed to providing a public comment period for these documents as a means to best serve public health and our clients.

Dated: October 18, 2002.

**Georgi Jones,**

Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.

[FR Doc. 02-27086 Filed 10-23-02; 8:45 am]

BILLING CODE 4163-70-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 84F-0331]

**Quest International; Withdrawal of Food Additive Petition**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 4A3817) proposing that the food additive regulations be amended to provide for the safe use of white mineral oil as a component of defoaming agents for use in the brewing of beer.

**FOR FURTHER INFORMATION CONTACT:** Andrew Zajac, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy, College Park, MD 20740, 202-418-3095.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of October 25, 1984 (49 FR 42985), FDA announced that a food additive petition

(FAP 4A3817) had been filed by J. E. Siebel Sons' Co., 4055 West Peterson Ave., Chicago, IL 60646. The petition proposed to amend the food additive regulations in § 173.340 *Defoaming agents* (21 CFR 173.340) to provide for the safe use of white mineral oil as defined by § 172.878(a) as a component of defoaming agents for use in the brewing of beer. On June 5, 2002, Quest International, 5115 Sedge Blvd., Hoffman Estates, IL 60192, informed FDA in writing that they had acquired J. E. Siebel Sons' Co. and had rights to FAP 4A3817. Quest International has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: October 9, 2002.

**Alan M. Rulis,**

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 02-27047 Filed 10-23-02; 8:45 am]

BILLING CODE 4160-01-S

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 01E-0363]

**Determination of Regulatory Review Period for Purposes of Patent Extension; MIFEPREX; Amendment**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending a previous determination of the regulatory review period for MIFEPREX that appeared in the **Federal Register** of January 25, 2002 (67 FR 3724). The agency is taking this action in response to received comments. FDA is publishing notice of that amendment as required by law.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug

Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Claudia V. Grillo, Office of Regulatory Policy (HFD-007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4565.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 25, 2002 (67 FR 3724), FDA published its determination of the regulatory review period for MIFEPREX. On June 10, 2002, Corcept Therapeutics, Inc., (Corcept) filed a request for revision of the regulatory review period. On July 2, 2002, the applicant filed a comment, disagreeing with Corcept's request and maintaining that FDA's initial determination was correct.

The basis of Corcept's request is that August 4, 1994, is not the correct date an investigational new drug application (IND) covering the approved drug product became effective. Corcept asserts that June 13, 1983, is the appropriate date. FDA has re-examined its records and has determined that Corcept is correct. The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective is June 13, 1983.

The agency, the applicant, and Corcept agree that the relevant IND is IND 22,047. All agree that IND 22,047 became effective in 1983.

The applicant's argument for keeping the initial determination is based on the claim that August 4, 1994, represents the date the IND first covered the "approved human drug product." While acknowledging that IND 22,047 became effective in 1983, the applicant observes that during the next several years the only studies conducted were studies of mifepristone alone, that is, not in conjunction with the administration of other drugs. The 1994 date is when the applicant submitted an amendment to IND 22,047 to initiate studies of mifepristone when followed by the later