

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC-2013-0005; NIOSH-263]

Request for Information About Diethanolamine (CAS No. 111-42-2)

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) intends to evaluate the scientific data on diethanolamine, and develop appropriate communication documents, such as a Criteria Document, which will convey the potential health risks, recommended measures for safe handling, and establish an updated Recommended Exposure Limit (REL). The current NIOSH REL for diethanolamine is 3 parts per million (ppm) as a time-weighted average (TWA) concentration for up to a 10-hr work shift during a 40-hr workweek.

NIOSH is requesting information on the following: (1) Published and unpublished reports and findings from *in vitro* and *in vivo* toxicity studies with diethanolamine; (2) information on possible health effects observed in workers exposed to diethanolamine, including exposure data and the method(s) used for sampling and analyzing exposures; (3) description of work tasks and scenarios with a potential for exposure to diethanolamine; (4) information on control measures (e.g. engineering controls, work practices, personal protective equipment, exposure data before and after implementation of control measures) that are being used in workplaces with potential exposure to diethanolamine; and (5) surveillance findings including protocol, methods, and results.

Public Comment Period: Comments must be received by June 24, 2013.

ADDRESSES: You may submit comments, identified by CDC-2013-0005 and Docket Number NIOSH-263, by either of the two following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments.
- **Mail:** NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676

Columbia Parkway, Cincinnati, OH 45226.

Instructions: All information received in response to this notice must include the agency name and docket number (CDC-2013-0005; NIOSH-263). All relevant comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. All electronic comments should be formatted as Microsoft Word. Please make reference to CDC-2013-0005 and Docket Number NIOSH-263.

FOR FURTHER INFORMATION CONTACT: Jennifer Reynolds, MPH, NIOSH, Robert A Taft Laboratories, MS-C32, 4676 Columbia Parkway, Cincinnati, OH 45226, telephone (513) 533-8531.

SUPPLEMENTARY INFORMATION: Diethanolamine is a highly reactive compound. It decomposes on burning producing toxic fumes. Diethanolamine reacts violently with oxidants and strong acids. Diethanolamine is used to produce surface active agents widely used in soaps, cosmetics and personal care items. It also has other uses including as an absorbent in gas purification, as a dispersing agent in agricultural chemicals, a corrosion inhibitor and wetting agent in metalworking fluids.

The annual production of diethanolamine in the United States was estimated in 1995 to be 106,000 tons (Technology Planning and Management Corp, 2002). NIOSH estimates from the National Occupational Exposure Survey (NIOSH 1989) that the number of workers potentially exposed to diethanolamine is approximately 830,000/year.

Significant occupational exposures to diethanolamine are through the skin (dermal) and via inhalation (lung) during the use of lubricating liquids in various processes in machine building. Chronic exposure to diethanolamine can cause skin sensitization. Diethanolamine is also corrosive to the eyes. The current REL for diethanolamine is 3 ppm as a TWA concentration for up to a 10-hr work shift during a 40-hr workweek. The NIOSH REL was established as a result of testimony submitted to the Occupational Safety and Health Administration (OSHA) on their proposed rulemaking of Air Contaminants in 1988. Currently, concentrations below the REL can be detected and quantified. As part of an effort to identify RELs that may not be adequate to protect workers from adverse health effects due to exposure, NIOSH is reexamining the REL for diethanolamine. There is no OSHA

permissible exposure limit (PEL) for diethanolamine. The American Conference of Governmental Hygienists (ACGIH®) threshold limit value (TLV®)—TWA for diethanolamine is 1 mg/m³ (inhalable fraction and vapor), with a Skin notation (indicating danger of cutaneous absorption), and an A3 carcinogenicity classification (confirmed animal carcinogen with unknown relevance to humans).

NIOSH seeks to obtain materials, including published and unpublished reports and research findings, to evaluate the possible health risks of occupational exposure to diethanolamine. Examples of requested information include, but are not limited to, the following:

- (1) Identification of industries or occupations in which exposures to diethanolamine may occur.
- (2) Trends in the production and use of diethanolamine.
- (3) Description of work tasks and scenarios with a potential for exposure to diethanolamine.
- (4) Workplace exposure measurement data of diethanolamine in various types of industries and jobs.
- (5) Case reports or other health information demonstrating potential health effects in workers exposed to diethanolamine.
- (6) Research findings from *in vitro* and *in vivo* studies.
- (7) Information on control measures (e.g., engineering controls, work practices, PPE) being taken to minimize worker exposure to diethanolamine.
- (8) Educational materials for worker safety and training on the safe handling of diethanolamine.
- (9) Data pertaining to the feasibility of establishing a more protective REL for diethanolamine.
- (10) Names of substitute chemicals or processes being used in place of diethanolamine and type of work tasks.

References

- NIOSH [1989]. National occupational exposure survey analysis of management interview responses. Vol. III. Pedersen DH, Sieber WK, eds. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 89-103.
- Technology Planning and Management Corporation [2002]. *Report on carcinogens background document for diethanolamine*. Prepared for the U.S. Department of Health and Human Services, National Toxicology Program: Research Triangle Park, NC.

Dated: April 18, 2013.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2013-09651 Filed 4-23-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.676]

Announcement of the Award of 12 Single-Source Program Expansion Supplement Grants to Unaccompanied Alien Children's Shelter Care Grantees

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, Department of Health and Human Services.

ACTION: Announcement of the award of 12 single-source program expansion grants to 10 current grantees to expand bed capacity and supportive services to the increasing number of unaccompanied alien children.

SUMMARY: The Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR) announces the award of twelve single-source program expansion supplement grants to the following ten current grantees, for a total of \$33,653,092.

Organization	Location	Amount
Children's Center, Inc	Galveston, TX	\$354,377
BCFS Health and Human Services	San Antonio, TX	11,826,867
Heartland Human Care Services, Inc	Chicago, IL	1,459,119
Southwest Key, Inc	Austin, TX	12,450,000
United States Conference of Catholic Bishops	Washington, DC	300,000
Lutheran Immigration Refugee Services	Baltimore, MD	2,500,000
Lutheran Social Services of the South	Austin, TX	2,171,142
His House	Opa Locka, FL	950,000
Lincoln Hall	Lincolndale, NY	523,520
Youth For Tomorrow	Bristow, VA	1,118,067

These supplement grants will support the expansion of bed capacity and supportive services to meet the number of unaccompanied alien children referrals from the Department of Homeland Security (DHS). The funding program is mandated by section 462 of the Homeland Security Act to ensure appropriate placement of all referrals from the DHS. The program is tied to DHS apprehension strategies and sporadic number of border crossers. Award funds will support services to unaccompanied alien children through September 30, 2013.

DATES: The period of support under these supplements is October 1, 2012 through September 30, 2013.

FOR FURTHER INFORMATION CONTACT:

Jalyn Sualog, Acting Director, Division of Children's Services, Office of Refugee Resettlement, 901 D Street SW., Washington, Telephone (202) 401-4997. Email: jalyn.sualog@acf.hhs.gov.

SUPPLEMENTARY INFORMATION: Since the beginning of FY 13, the Unaccompanied Alien Children (UAC) program has seen a dramatic increase in the number of DHS referrals. The influx of border crossers referred by DHS has grown beyond anticipated rates and has resulted in the program needing a significant increase in the number of shelter beds and supportive services.

The UAC program has specific requirements for the provision of services to unaccompanied alien children. These grantee organizations

are the only entities with the infrastructure, licensing, experience, and appropriate level of trained staff to meet the required service requirements and the urgent need for the expansion of services required to respond to unexpected arrivals of unaccompanied children. The program expansion supplement will support such services and alleviate the buildup of children waiting in border patrol stations for placement in shelter care.

Statutory Authority: Section 462 of the Homeland Security Act, (6 U.S.C. 279) and sections 235(c) and 235(d) of the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008, (8 U.S.C. 1232(c) and 1232(d)).

Eskinder Negash,

Director, Office of Refugee Resettlement.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0403]

Agency Information Collection Activities; Proposed Collection; Comment Request; Protection of Human Subjects; Informed Consent; Institutional Review Boards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the regulations that provide protection for human subjects of clinical investigations conducted in support of applications or submissions to FDA for FDA-regulated products. The regulations provide protection of the rights, safety, and welfare of human subjects involved in research activities within FDA's jurisdiction.

DATES: Submit either electronic or written comments on the collection of information by June 24, 2013.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.