September, 14 2012

Response to the public consultation launched by ECHA
Formaldehyde, oligomeric reaction products with aniline (technical MDA)
CAS N° 25214-70-4

1. Synthesis

EDF has a specific use for Formaldehyde, oligomeric reaction with aniline (technical MDA) (CAS N° 25214-70-4), which it considers to be of the utmost importance. Ion exchange resins are indispensable for nuclear power plants to operate. At present, they may only be conditioned by means of the MERCURE process which employs the hardening agent that contains technical MDA.

Measures to eliminate chemical risks are being implemented at every work sites. They are based on the protection of the health of operators involved (risk of cutaneous absorption and inhalation), and the environment (both within and outside the conditioning area).

The results of all the assessments carried out (urine analysis for staff and swab samples for equipments) confirm that the measures in place are efficient.

Research into alternative products, which is actively conducted by the various stakeholders involved, is encouraging and should be concluded in the near future. Taking into account all of the technical and administrative requirements to be met by the replacement solution, the new substance could only be implemented by late 2015 at the earliest, subject to positive results from all technical tests needed for approval.

According to the regulatory schedule, this would therefore potentially make it necessary to file an application for authorisation for a very limited period of use of the technical MDA.

2. Detail of the process and risk assessment

2.1 Process Description

Context

Ion exchange resins are used in the purification process of the primary coolant at the nuclear power plants (NPP) of the EDF fleet. This purification process performs a vital role in reducing the radiological activity of the primary coolant and, consequently, in protecting the parties involved from radiation. Moreover, the ion exchange resins retain corrosion products and are therefore able to protect the systems.

Once saturated, these spent resins are transferred to storage tanks at the nuclear power plants. These resins are then conditioned in concrete containers, in preparation for removal and long term disposal at the CSFMA (Disposal Centre for Low and Intermediate Level Waste) which is operated by ANDRA (French national radioactive waste management agency).

The conditioning process is made possible by two mobile machines called “MERCURE” (Machines for Encapsulating Resins in Containers Using Epoxide Resins), which are taken from site to site with a suitable schedule which allows that the storage tanks can be processed.

Principle of the MERCURE process

The requirements set forth by ANDRA for disposing waste packages at CSFMA specify that conditioning must guarantee the containment of ion exchange resins radioactivity, a good resistance to compression and a low leaching of the matrix, among other things. These requirements are also constraints for the resin conditioning process. The MERCURE process is the only currently available process which satisfies all of these requirements and which is approved by ANDRA for ion exchange resin conditioning.

The MERCURE process is based on a polymerisation reaction between the waste (the spent ion exchange resins) and two chemical products: an epoxide resin and a hardening agent. These two products are supplied by the company CCP Composites (formerly Cray Valley), which makes preparations using substances supplied by the company Air Products.

The hardening agent contains the substance covered in this document, i.e., the "technical MDA" (see the appended Safety Data Sheet). The matrix which results from this reaction fulfils the particular requirements set forth by ANDRA in relation to the quality of the waste (resistance to compression, radioactivity containment, etc.)

The MERCURE process is the only process currently approved by ANDRA for ion exchange resins conditioning and is therefore the only existing solution for the removal of ion exchange resins of the power plants.

Process implementation

The mobile conditioning facility includes two fundamental components: the tank containing the products required for the process, including the technical MDA which is located outside the resin storage area, and the machine itself, which is located inside this area. Hoses are used to connect the tank containing the necessary chemical products to the machine.

The three components of the die (spent resins, epoxide resin and hardening agent) are placed in a concrete container which includes Internal Radiation Protection, in which a mixing cycle is carried out by a rotor located within the container.

As soon as the container is conditioned, a steel lid is welded on to the internal radiation protection and a concrete cap is then cast onto the upper section of the container. At the end of this process, the final waste package is transported to the ANDRA disposal centre.

2.2 Quantities

Approximately 500 waste packages of this kind are produced in a year at the EDF fleet of nuclear power plants, which represents a yearly consumption of about 45 tons of hardening agent. According to the Safety Data Sheet, the hardening agent comprises less than 26% of Formaldehyde, oligomeric reaction products with aniline (technical MDA) and **the annual consumption of this substance is approximately 12 tons.**

Each of the concrete packages includes between 79 and 98kg of the hardening agent, (therefore between 20 and 26kg of Formaldehyde, oligomeric reaction products with aniline (technical MDA)).

A conditioning "campaign" at a nuclear power plant may give rise to a production of between 50 and 200 waste packages. There is an average of 6 campaigns a year.

Chemical products, including Formaldehyde, oligomeric reaction products with aniline (technical MDA), are taken to the various sites inside a double compartment tank with a capacity of 15m^3 of epoxide resin and 9m^3 of hardening agent (the average density of which totals 1.08). This amount is therefore the maximum amount which may be found on a site at any given time.

2.3 Replacement of CMR products

After demonstration of the chemical hazard related to the substances used by the process, studies were conducted at the request of the EDF operator by the EDF research and development division, in collaboration with SOCODEI, operator of the MERCURE machine, and its supplier, CCP Composites. This research has already led to the substitution of two hazardous chemical substances initially used by the process.

The research conducted at present is aiming to substitute the hardener containing Formaldehyde, oligomeric reaction products with aniline (technical MDA) (CAS No. 25214-70-4), the last CMR product used by the process. The technical MDA constitutes the "skeleton" of the matrix and, as a result, its substitution has a great impact on the quality of the waste package.

The specifications for research into this new substance meet a series of technical and administrative requirements. The matrix produced by the polymerisation reaction should in fact meet the requirements set by ANDRA and comply with the specifications required: mechanical characteristics, resistance to thermal cycles, resistance to exudation, resistance to leaching, etc. In fact, the quality of the matrix is important for the safety of the waste disposal centre in which it will be stored. Furthermore, the Process Description, a document subject to approval by ANDRA, specifies a series of parameters to be verified, such as time and temperature for the polymerisation reaction to guarantee compliance of the waste package.

Research in progress has recently led to identification of a hardener that appears to be able to meet all of these requirements.

To approve the compliance of this substance with the technical specifications set by the constraints discussed above, a series of technical characterisation tests should be performed, according to specific procedures defined by ANDRA. Some of these tests may require the use of specialist laboratories whose completion times depend on availability.

An initial waste package has been produced with the replacement substance in order to approve its compliance with the process specifications. Tests have already been performed on samples taken from this container, with conclusive results.

A full programme of characterisation tests has been sent to ANDRA for approval, which is expected by late 2012, and it is planned to have all results available by late 2014 at the earliest.

Subject to positive results from all technical tests mentioned above, ANDRA approval for implementation of this new process takes approximately at least six months. Any new formulation should also be approved by the Nuclear Safety Authority before operating on site.

Thus, taking into account all of the technical and administrative requirements to be met by the replacement solution, the new substance could only be implemented by late 2015 at the earliest.

According to the regulatory schedule, this would therefore potentially make it necessary to file an application for authorisation for a very limited period of use of the technical MDA.

2.4 Risk management

The work site risk management is in keeping with regulations in force.

Design

For the production stages, the entire process is automated; thus the operator does not come into contact with the chemical products during normal operation.

For the other stages (installation, fall back, maintenance, etc.), various improvements have been made to the work site so as to minimise the chemical risk. For example, concerning the hoses cleaning stage, a scraping system has been set up to clean the products which are left in the hoses at the end of the process in the best possible manner.

Area designation

Two CMR (chemicals classified as Carcinogenic, Mutagenic or toxic to Reproduction) risk areas are designated on the work site:

- The first corresponds to the tank storage location. This tank is located inside the conditioning building. Wire mesh is used to outline the area. The tank may only be accessed through a cabin where all safety equipment required for the work in that area is kept.

- The second corresponds to the area within the immediate vicinity of the conditioning machine. This machine is located inside the building in which the connections with the spent resin storage tanks are made.

An updated information sheet in relation to these areas is available at the entrance, and the following details are included at the very least: the Safety Data Sheet and instructions about how products are to be used, safety guidelines and a list of the staff members with authorisation to access the area. The industrial doctor issues a medical certificate of no contraindication to those working in these areas.

There is a register for signing in and out of each area. It is kept up to date and displays arrival and departure times as well as the reason for being present.

Protection of operators involved in the process

The necessary Personal Protective Equipment is available at the entrance to each area. This includes compatible gloves, antacid overalls, protective visors and outer boots as well as pre-impregnated cleaning wipes.

Further, showers and eye wash stations can be found at the entrance of each area for quick rinsing in the event of an accident.

Cutaneous contamination prevention

At the beginning of the campaign, a briefing takes place in the presence of staff to discuss any risks related to the use of these chemical products. The medical protocol is presented at these briefings.

The medical protocol is drafted taking into account that the main risk to consider is cutaneous contamination. In case of contamination, it may be detected via urine analysis.

The protocol is outlined by the industrial doctor of the site where the campaign is being carried out. It generally involves at least a weekly sample, as well as samples targeted during high-risk stages (hose connection and disconnection, any possible maintenance related activity, etc.)

These urine samples are subsequently sent to a laboratory for analysis to identify any possible contamination.

Records show that no urinalysis has produced positive results since 2009.

Prevention of contamination by inhalation

Atmospheric measurements are recorded at least once a year in order to detect if any individuals are at risk of contamination by inhalation. Records show that no significant Formaldehyde, oligomeric reaction products with aniline (technical MDA) atmospheric contamination readings have been made.

Despite these results, measures have been taken to ensure the safety of those involved.

- As for the machine, a ventilated anti-contamination tenting has been secured by an air exhaust with a minimal flow of 100 Nm^3/h.

- The tank temperature control system means that products with a temperature measuring between 20 and 25°C, and with a maximum threshold of 30°C, can be controlled. The products and the tank are maintained at atmospheric pressure, and the tank has a device which protects against overpressure and negative pressure.

Prevention of environmental pollution (outside of buildings at nuclear power plants)

The tank is located in an airtight retention. The hoses used to ensure that products are transferred to the machine are confined by heated cladding and kevlar blankets, which are, in turn, protected by a vinyl enclosure thereby preventing leakages into the environment.

An anti-pollution kit is in close proximity to the tank containing the products so that swift action may be taken in the event of an accidental spillage.

Any waste arising from the implementation of the process (gloves, overalls, etc.) are to be treated as CMR risk waste. The waste is deposited in PEHD drums which are subsequently sent to an adapted subsidiary along with a file detailing the CMR nature of the products.

Pollution prevention in the buildings at the nuclear power plants

The level of cleanliness of the machine reception area and of the various pieces of equipment is assessed as swab samples are regularly taken. The wipes are sent to be analysed. In the event that contamination is detected, a cleaning process is undertaken until acceptable levels of cleanliness are achieved.

Prevention of environmental pollution (outside nuclear power plants)

The whole set of equipment (machine, tank and other containers) is cleaned and then a swab sample is taken before it leaves the nuclear power plant.

Note: Companies involved in the supply of chemical products and quoted herein have given their consent for this document to be circulated at the public consultation of ECHA.