

Package Leaflet: Information for the user
Oxaliplatin 5mg/ml Concentrate for Solution for Infusion
oxaliplatin

Read all of this leaflet carefully before you start using this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Oxaliplatin Concentrate for solution for infusion is and what it is used for
2. What you need to know before you use Oxaliplatin Concentrate for solution for infusion
3. How to use Oxaliplatin Concentrate for solution for infusion
4. Possible side effects
5. How to store Oxaliplatin Concentrate for solution for infusion
6. Contents of the pack and other information

1. What Oxaliplatin Concentrate for solution for infusion is and what it is used for

The name of your medicine is 'Oxaliplatin 5mg/ml Concentrate for Solution for Infusion' but in the rest of the leaflet it will be called 'Oxaliplatin concentrate for solution for infusion'.

The active ingredient of Oxaliplatin concentrate for solution for infusion is oxaliplatin.

Oxaliplatin concentrate for solution for infusion is used to treat cancer of the large bowel (treatment of stage III colon cancer after complete resection of primary tumour, metastatic cancer of colon and rectum). Oxaliplatin concentrate for solution for infusion is used in combination with other anticancer medicines called 5 fluorouracil and folinic acid.

Oxaliplatin concentrate for solution for infusion has to be dissolved and made into a solution before it can be injected into a vein. Oxaliplatin concentrate for solution for infusion is an antineoplastic or anticancer drug and contains platinum.

2. What you need to know before you use Oxaliplatin Concentrate for solution for infusion

Do not use Oxaliplatin Concentrate for solution for infusion if:

- You are allergic to oxaliplatin or any of the other ingredients of the Oxaliplatin concentrate for solution for infusion,
- You breast feeding,
- You already have a reduced number of blood cells,
- You already have tingling and numbness in the fingers and/or toes, and have difficulty performing delicate tasks, such as buttoning clothes,
- You have severe kidney problems.

Warnings and precautions

Talk to your doctor or pharmacist before taking Oxaliplatin Concentrate for solution for infusion

- If you have ever suffered an allergic reaction to platinum-containing medicines such as carboplatin or cisplatin. Allergic reactions can occur during any oxaliplatin infusion.
- If you have moderate or mild kidney problems
- If you have any liver problems or abnormal liver function test results during your treatment.
- If you have or had heart disorders such as an abnormal electrical signal called prolongation of the QT interval, an irregular heartbeat, or a family history of heart problems.
- If you have recently received or plan to receive any vaccines. During treatment with oxaliplatin, you should not have a vaccination with "live" or "attenuated" vaccines, such as yellow fever vaccine.

If any of the following applies to you at any time, tell your doctor immediately. Your doctor may need to treat you for these events, and may need to potentially reduce the dose of Oxaliplatin Concentrate for solution for infusion, or delay or stop Oxaliplatin Concentrate for solution for infusion treatment.

If you have an unpleasant sensation in the throat, in particular when swallowing, and have a sensation of shortness of breath, during the treatment, tell your doctor.

If you have nerve problems in your hands or feet, such as numbness or tingling, or decreased sensations in your hands or feet, tell your doctor.

If you have headache, altered mental functioning, seizures and abnormal vision from blurriness to vision loss, tell your doctor.

If you feel or are sick (nausea or vomiting), tell your doctor.

If you have severe diarrhea, tell your doctor.

If you have sore lips or mouth ulcers (mucositis/ stomatitis), tell your doctor.

If you have diarrhea, or a reduction in white blood cells or platelets, tell your doctor. Your doctor may reduce the dose of Oxaliplatin Concentrate for solution for infusion or postpone your treatment with Oxaliplatin Concentrate for solution for infusion.

If you have unexplained respiratory symptoms such as cough, or any difficulties in breathing, tell your doctor. Your doctor may stop your treatment with Oxaliplatin Concentrate for solution for infusion.

If you develop an extreme tiredness, shortness of breath, or kidney disease where you pass little or no urine (symptoms of acute renal failure), tell your doctor.

If you have fever (temperature greater than or equal to 38°C), or chills, which could be signs of infection, tell your doctor immediately. You may be at risk of getting an infection of the blood.

If you have fever > 38°C, tell your doctor. Your doctor may determine you also have a reduction in white blood cells.

If you experience unexpected bleeding or bruising (disseminated intravascular coagulation), tell your doctor as these could be signs of blood clots throughout the small vessels of your body.

If you faint (lose consciousness) or have an irregular heartbeat while taking ELOXATINE, tell your doctor immediately as this may be a sign of a serious heart condition.

If you experience muscle pain and swelling, in combination with weakness, fever, or red-brown urine, tell your doctor.

These could be signs of muscle damage (rhabdomyolysis) and could lead to kidney problems or other complications.

If you have abdominal pain, nausea, bloody vomit or vomit that looks like “coffee-grounds”, or dark-colored/ tarry stools, which may be signs of an ulcer of the bowel (gastrointestinal ulcer, with potential bleeding or perforation), tell your doctor.

If you have abdominal (tummy) pain, bloody diarrhea, and nausea and/or vomiting, which may be caused by a reduction of blood flow to your gut wall (intestinal ischaemia), tell your doctor.

Children and adolescents

Oxaliplatin should not be used in children and adolescents below 18 years of age.

Other medicines and Oxaliplatin Concentrate for solution for infusion

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- 5-fluorouracil (an anti-cancer medicine)
- Erythromycin, (an antibiotic medicine)
- Salicylates, (pain relieving medicine)
- Granisetron, (an antiemetic medicine)
- Paclitaxel, (an anti-cancer medicine)
- Sodium valproate. (antiepileptic medicine)

Pregnancy, breast-feeding and fertility

Pregnancy

- It is not recommended that you become pregnant during treatment with oxaliplatin and must use an effective method of contraception. - Female patients should take appropriate contraceptive measures during and after cessation of therapy continuing for 4 months.
- If you are pregnant or planning a pregnancy it is very important that you discuss this with your doctor **before** you receive any treatment.
- If you get pregnant during your treatment you must immediately inform your doctor.

Breast-feeding

- You must not breast-feed while you are treated with oxaliplatin.

Fertility

- Oxaliplatin may have an anti-fertility effect, which could be irreversible. Male patients should seek advice on conservation of sperm prior to treatment.
- Male patients are advised not to father a child during treatment and until 6 months after treatment, and to take appropriate contraceptive measures during this time.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines:

Oxaliplatin treatment may result in an increased risk of dizziness, nausea and vomiting, and other neurological symptoms that affect walking and balance. If this happens you should not drive or operate machinery. If you have vision problems while taking Oxaliplatin concentrate for solution for infusion, do not drive, operate heavy machines, or engage in dangerous activities.

3. How to use Oxaliplatin Concentrate for solution for infusion

Oxaliplatin concentrate for solution for infusion is intended only for adults.

For single use only.

Dose

The dose of Oxaliplatin concentrate for solution for infusion is based on your body surface area. This is calculated from your height and weight.

The usual dose for adults including the elderly is 85 mg/m² of body surface area. The dose you receive will also depend on results of blood tests and whether you have previously experienced side effects with Oxaliplatin concentrate for solution for infusion.

Method and route of administration

- Oxaliplatin concentrate for solution for infusion will be prescribed for you by a specialist in cancer treatment.
- You will be treated by a healthcare professional, who will have made up the required dose of Oxaliplatin concentrate for solution for infusion.
- Oxaliplatin concentrate for solution for infusion is given by slow injection into one of your veins (an intravenous infusion) over a 2 to 6 hour period.
- Oxaliplatin concentrate for solution for infusion will be given to you at the same time as folinic acid and before the infusion of 5 fluorouracil.

Frequency of administration

You should usually receive your infusion once every 2 weeks.

Duration of treatment

The duration of the treatment will be determined by your doctor.

Your treatment will last a maximum of 6 months when used after complete resection of your tumour.

If you use more Oxaliplatin concentrate for solution for infusion than you should

As this medicine is administered by a healthcare professional it is highly unlikely that you will be given too much or too little.

In case of overdose, you may experience increased side effects. Your doctor may give you appropriate treatment for these side effects.

If you have any questions about your treatment, ask your doctor, nurse or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any side effect it is important that you inform your doctor about it before your next treatment.

You will find described below the side effects that you could experience.

Tell your doctor immediately if you notice any of the following:

- Allergic or anaphylactic reaction with sudden signs such as rash, itching or hives on the skin, difficulties in swallowing, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing, extreme tiredness (you may feel you are going to faint).
- Abnormal bruising, bleeding, or signs of infection such as a sore throat and high temperature,
- Persistent or severe diarrhoea or vomiting,
- Presence of blood or dark brown coffee-coloured particles in your vomit,
- Stomatitis/mucositis (sore lips or mouth ulcers),
- Respiratory symptoms such as dry or wet cough, difficulties in breathing or crackles, shortness of breath and wheezing
- A group of symptoms with or without hypertension,
- Stroke symptoms (including sudden severe headache, confusion, trouble seeing in one or both eyes, numbness or weakness of face, arm or leg usually on one side, face drooping, trouble walking, dizziness, loss of balance and speech difficulty)
- Extreme tiredness with decreased number of red blood cells (haemolytic anaemia), alone or combined with low platelet count, abnormal bruising (thrombocytopenia) and kidney disease where you pass little or no urine (symptoms of Haemolytic-uraemic syndrome)

Other known side effects of Oxaliplatin concentrate for solution for infusion are:

Very common (may affect more than 1 in 10 people)

- Tingling and/or numbness in the fingers, toes, around the mouth or in the throat, which may sometimes occur in association with cramps (peripheral neuropathy).
- Sensation of discomfort close to or at the injection site during the infusion,
- Fever, rigors (tremors), mild or severe tiredness, body pain,
- Weight changes, loss or lack of appetite, taste disorders, constipation,
- Stomach pain,
- Abnormal bleeding including nose bleeds,
- Mild hair loss (alopecia).

Common (may affect up to 1 in 10 people)

- Infection due to a reduction in white blood cells,
- Serious infection of the blood in addition to a reduction in white blood cells (neutropenic sepsis), which may be fatal,
- Reduction in white blood cells accompanied by fever $> 38.3^{\circ}\text{C}$ or a prolonged fever $> 38^{\circ}\text{C}$ for more than one hour (febrile neutropenia),
- Indigestion and heart burn, hiccups, flushing, dizziness,
- Increased sweating and nail disorders, flaking skin,
- Chest pain,
- Lung disorders and runny nose,
- Joint pain and bone pain,
- Pain on passing urine and changes in kidney function, changes of frequency of urination, dehydration,
- Blood in the urine/stools, swelling of the veins, clots in the lung,
- High blood pressure

- Depression and insomnia,
- Conjunctivitis and visual problems,
- Decreased levels of calcium in the blood.
- Fall

Uncommon (may affect up to 1 in 100 people)

- Serious infection of the blood (septicaemia), which may be fatal,
- Blockage or swelling of the bowel,
- Nervousness.

Rare (may affect up to 1 in 1,000 people)

- Loss of hearing,
- Scarring and thickening in the lungs with difficulties in breathing, sometimes fatal (interstitial lung disease),
- Reversible short-term loss of vision,
- Unexpected bleeding or bruising due to widespread blood clots throughout the small blood vessels of the body (disseminated intravascular coagulation), which may be fatal.

Very rare (may affect up to 1 in 10,000 people)

- Vascular disorders of the liver (symptoms include abdominal pain and swelling, weight gain and tissue swelling of the feet, ankles or other parts of the body).

Not known (frequency cannot be estimated from the available data)

- Allergic vasculitis (inflammation of blood vessels),
- Auto-immune reaction leading to reduction of all blood cell lines (autoimmune pancytopenia), pancytopenia,
- Convulsion (uncontrolled shaking of the body),
- Spasm of the throat causing difficulty in breathing,
- Abnormal heart rhythm (QT prolongation), that can be seen on electrocardiogram (ECG), which may be fatal,
- Muscle pain and swelling, in combination with weakness, fever, or red-brown urine (symptoms of muscle damage called rhabdomyolysis), which may be fatal,
- Dark-coloured/tarry stools (symptoms of gastrointestinal ulcer, with potential bleeding or perforation), which may be fatal,
- Decreased blood flow to the intestine/bowel (intestinal ischaemia), which may be fatal,
- Myocardial infarction (Heart attack), angina pectoris (pain or uncomfortable feeling in the chest) Oesophageal inflammation (inflammation of the lining of the esophagus - the tube that connects your mouth with your stomach- resulting in pain and swallowing difficulty)
- Risk of new cancers like leukemia, when taken in combination with certain other medicines.
- Abnormal non-cancerous liver nodules (focal nodular hyperplasia).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Oxaliplatin Concentrate for solution for infusion

Keep this medicine out of the sight and reach of children.

Prior to mixing this medicine must be kept in the outer carton in order to be protected from light and must not be frozen.

Do not use this medicine after the expiry date (EXP) which is stated on the outer pack and vial label. The expiry date refers to the last day of the month.

Chemical and physical in-use stability has been demonstrated for 48 hours at 2°C to 8°C and for 24 hours at +25°C. From a microbiological point of view, this infusion preparation should be used immediately. If not used immediately, in-use

storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2°C to 8°C unless dilution has taken place in controlled and validated aseptic conditions.

Do not use Oxaliplatin concentrate for solution for infusion if you notice that the solution is not clear and free of particles.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Oxaliplatin concentrate for solution for infusion should not come into contact with the eyes or skin. If there is any accidental spillage, tell the doctor or nurse immediately.

When the infusion has finished, Oxaliplatin concentrate for solution for infusion will be disposed of carefully by the doctor or nurse.

6. Contents of the pack and other information

What Oxaliplatin Concentrate for solution for infusion contains:

Oxaliplatin concentrate for solution for infusion contains the active ingredient oxaliplatin.

The other ingredients are water for injections.

What Oxaliplatin Concentrate for solution for infusion looks like and contents of the pack:

1 ml concentrate for solution for infusion contains 5 mg oxaliplatin.

Oxaliplatin concentrate for solution for infusion is a clear colourless solution free from visible particles. Each glass vial is packed in individual carton.

10 ml of concentrate for solution for infusion contains 50 mg of oxaliplatin.

20 ml of concentrate for solution for infusion contains 100 mg of oxaliplatin.

40 ml of concentrate for solution for infusion contains 200 mg of oxaliplatin.

Not all pack size may be marketed.

Marketing Authorisation Holder

Accord Healthcare Ireland Limited,
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomska 50,95-200 Pabianice, Poland

Accord Healthcare B.V.,
Winthontlaan 200,
3526 KV Utrecht,
The Netherlands

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Name of the Member State	Name of the medicine
United Kingdom (Northern Ireland)	Oxaliplatin 5 mg/ml Concentrate for Solution for Infusion
Austria	Oxaliplatin Accord 5 mg/ml Konzentrat zur Herstellung einer Infusionslösung
Belgium	Oxaliplatin Accord Healthcare 5 mg/ml concentré pour solution de perfusion/ concentraat voor oplossing voor infusie / Konzentrat zur

	Herstellung einer Infusionslösung
Bulgaria	Оксалиплатин Акорд 5 mg/ml концентрат за инфузионен разтвор
Czech Republic	Oxaliplatin Accord 5 mg/ml Koncentrát pro Přípravu Infuzního Roztoku
Germany	Oxaliplatin Accord 5 mg/ml Konzentrat zur Herstellung einer Infusionslösung
Denmark	Oxaliplatin Accord 5 mg/ml koncentrat til infusionsvæske, opløsning.
Estonia	Oxaliplatin Accord 5 mg/ml infusioonilahuse kontsentraat
Spain	Oxaliplatino Accord 5 mg/ml Concentrado para Solución para Perfusión EFG
Finland	Oxaliplatin Accord 5 mg/ml Infuusiokonsentraatti, Liuosta Varten/ koncentrat till infusionsvätska, lösning
France	Oxaliplatin Accord 5 mg/ml concentré pour solution de perfusion
Hungary	Oxaliplatin Accord 5 mg/ml koncentrátum oldatos infúzióhoz
Ireland	Oxaliplatin 5 mg/ml Concentrate for Solution for Infusion
Italy	Oxaliplatino Accord 5 mg/ml concentrato per soluzione per infusione
Latvia	Oxaliplatin Accord 5 mg/ml koncentrāts infūziju šķīduma pagatavošanai
Lithuania	Oxaliplatin Accord 5 mg/ml koncentratas infuziniam tirpalui
Malta	Oxaliplatin 5 mg/ml Concentrate for Solution for Infusion
The Netherlands	Oxaliplatine Accord 5 mg/ml concentraat voor oplossing voor infusie
Poland	Oxaliplatinum Accord, 5 mg/ml, koncentrat do sporządzania roztworu do infuzji
Portugal	Oxaliplatina Accord
Romania	Oxaliplatin Accord 5 mg/ml koncentrat pentru solutie perfuzabilă
Sweden	Oxaliplatin Accord 5 mg/ml koncentrat till infusionsvätska, lösning

The leaflet was last revised in 02/2024.

The following information is intended for medical or healthcare professionals only

PREPARATION GUIDE FOR USE WITH OXALIPLATIN CONCENTRATE FOR SOLUTION FOR INFUSION

It is important that you read the entire contents of this procedure prior to the preparation of OXALIPLATIN CONCENTRATE FOR SOLUTION FOR INFUSION

1. FORMULATION

Oxaliplatin concentrate for solution for infusion is a clear colourless solution containing 5 mg/ml oxaliplatin.

2. PRESENTATION

Oxaliplatin concentrate for solution for infusion is supplied as single-dose vials. 1 vial per carton.

For 10 ml,

Concentrate for solution for infusion is filled in 15 mL Type I clear tubular glass vial (Siliconized) with 20 mm V9048 FM259/0 OMNIFLEX PLUS 2500/RF rubber stopper and 20 mm aluminium flip off lavender seal.

For 20 ml,

Concentrate for solution for infusion is filled in 20 mL Type I clear tubular glass vial (Siliconized) with 20 mm V9048 FM259/0 OMNIFLEX PLUS 2500/RF rubber stopper and 20 mm aluminium flips off lavender seal.

For 40 ml,

Concentrate for solution for infusion is filled in 50 mL Type I clear tubular glass vial (Siliconized) with 20 mm V9048 FM259/0 OMNIFLEX PLUS 2500/RF rubber stopper and 20 mm aluminium flips off lavender seal.

Shelf life and storage:

2 years

After dilution of the solution in 5% glucose solution, chemical and physical in-use stability has been demonstrated for up to 48 hours at +2°C to +8°C and for 24 hours at +25°C.

From a microbiological point of view, the infusion preparation should be used immediately.

If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 °C to 8 °C unless dilution has taken place in controlled and validated aseptic conditions.

Keep the vial in the outer carton in order to protect from light. Do not freeze.

Inspect visually prior to use. Only clear solutions without particles should be used.

The medicine is for single use only. Any unused solution should be discarded.

3. RECOMMENDATIONS FOR THE SAFE HANDLING

As with other potentially toxic compounds, caution should be exercised when handling and preparing oxaliplatin solutions.

Instructions for Handling

The handling of this cytotoxic agent by healthcare personnel requires every precaution to guarantee the protection of the handler and his surroundings.

The preparation of injectable solutions of cytotoxic agents must be carried out by trained specialist personnel with knowledge of the medicines used, in conditions that guarantee the integrity of the product, the protection of the environment and in particular the protection of the personnel handling the medicines, in accordance with the hospital policy. It requires a preparation area reserved for this purpose. It is forbidden to smoke, eat or drink in this area.

Personnel must be provided with appropriate handling materials, notably long sleeved gowns, protection masks, caps, protective goggles, sterile single-use gloves, protective covers for the work area, containers and collection bags for waste.

Excreta and vomit must be handled with care.

Pregnant women must be warned to avoid handling cytotoxic agents.

Any broken container must be treated with the same precautions and considered as contaminated waste. Contaminated waste should be incinerated in suitably labelled rigid containers. See below chapter “Disposal”.

If oxaliplatin concentrate for solution for infusion, should come into contact with skin, wash immediately and thoroughly with water.

If oxaliplatin concentrate for solution for infusion, should come into contact with mucous membranes, wash immediately and thoroughly with water.

4. PREPARATION FOR THE INTRAVENOUS ADMINISTRATION

Special precautions for administration

- DO NOT use injection equipment containing aluminium.
- DO NOT administer undiluted.
- Only 5% glucose solution is to be used as a diluent. DO NOT dilute for infusion with sodium chloride or chloride containing solutions.
- DO NOT mix with any other medicines in the same infusion bag or administer simultaneously by the same infusion line.
- DO NOT mix with alkaline medicines or solutions, in particular 5-fluorouracil, folinic acid preparations containing trometamol as an excipient and trometamol salts of others active substances. Alkaline medicines or solutions will adversely affect the stability of oxaliplatin.

Instruction for use with folinic acid (as calcium folinate or disodium folinate)

Oxaliplatin 85mg/m² IV infusion in 250 to 500 ml of 5% glucose solution is given at the same time as folinic acid intravenous infusion in 5% glucose solution, over 2 to 6 hours, using a Y-line placed immediately before the site of infusion.

These two medicines should not be combined in the same infusion bag. Folinic acid must not contain trometamol as an excipient and must only be diluted using isotonic 5% glucose solution, never in alkaline solutions or sodium chloride or chloride containing solutions.

Instruction for use with 5 fluorouracil

Oxaliplatin should always be administered before fluoropyrimidines – i.e. 5-fluorouracil. After oxaliplatin administration, flush the line and then administer 5-fluorouracil.

For additional information on medicines combined with oxaliplatin, see the corresponding manufacturer’s summary of product characteristics.

- USE ONLY the recommended solvents (see below).
- Only clear solutions without particles should be used.

4.1 Preparation of the infusion solution

Withdraw the required amount of concentrate from the vial(s) and then dilute with 250 ml to 500 ml of a 5% glucose solution to give an oxaliplatin concentration between not less than 0.2 mg/ml and 0.7 mg/ml. The concentration range over which the physico-chemical stability of oxaliplatin has been demonstrated is 0.2 mg/ml to 2.0 mg/ml.

Administer by Intravenous infusion.

After dilution in 5% glucose, chemical and physical in-use stability has been demonstrated for 48 hours at +2°C to +8°C and for 24 hours at +25°C.

From a microbiological point of view, this infusion preparation should be used immediately.

If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2°C to 8°C unless dilution has taken place in controlled and validated aseptic conditions.

Inspect visually prior to use. Only clear solutions without particles should be used.

The medicine is for single use only. Any unused infusion solution should be discarded (see chapter “disposal” below).

NEVER use sodium chloride or chloride containing solutions for dilution.

The compatibility of Oxaliplatin solution for infusion has been tested with representative, PVC-based, administration sets.

4.2 Infusion of the solution

The administration of oxaliplatin does not require prehydration.

Oxaliplatin diluted in 250 to 500 ml of a 5% glucose solution to give a concentration not less than 0.2 mg/ml must be infused either by peripheral vein or central venous line over 2 to 6 hours. When oxaliplatin is administered with 5-fluorouracil, the oxaliplatin infusion must precede the administration of 5-fluorouracil.

4.3 Disposal

Remnants of the medicinal product as well as all materials that have been used for dilution and administration must be destroyed according to hospital standard procedures applicable to cytotoxic agents in accordance with local requirements related to the disposal of hazardous waste.